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October 30, 2020

VIA E-MAIL: 340B@help.senate.gov and 340B@mail.house.gov

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20460

The Honorable Greg Walden
Ranking Member
U.S. House Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, DC 20515

Re: Request for Input on Modernizing 340B Drug Pricing Program

Dear Senator Alexander and Representative Walden:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the invitation by Senator Lamar Alexander and Congressman Greg Walden to comment on your *Request for Input on Modernizing 340B Drug Pricing Program* (RFI). PhRMA represents the country's leading innovative biopharmaceutical research companies devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

America's biopharmaceutical companies are committed to developing solutions to help diagnose and treat those with COVID-19, a disease caused by a novel strain of coronavirus. In addition to applying their scientific expertise to find ways to diagnose, treat, and prevent infections from the virus, the biopharmaceutical industry is providing financial support and in-kind donations to organizations and collaborating with U.S. and global health authorities to combat this global public health emergency. Most PhRMA members have research and development efforts underway and are providing donations of medicines and critical medical supplies to support patients and first responders in addressing this evolving crisis.

PhRMA is pleased to provide input on how the 340B Drug Pricing Program (340B) can be strengthened to better support our nation's most vulnerable patients. We look forward to continuing our conversations on meaningful improvements that can be made to ensure the 340B program is overseen and operated in a way that sustains the program for the long-term so that patients more directly benefit from the discounts provided by biopharmaceutical manufacturers.

PhRMA and our member companies have long supported the 340B program and the critical safety-net role it was intended to play in our nation's health care system. The program was enacted to help make prescription medicines more accessible to uninsured or vulnerable patients, but the 340B program has veered off course, and as noted in the RFI, "changes are long overdue." Today, it is no longer accurate to characterize the 340B program as a *safety-net* program primarily focused on *vulnerable patient care.* Increasingly, the 340B program has become a *revenue stream* for certain stakeholders decoupled from the medical and pharmaceutical access needs of vulnerable patients.

The lack of meaningful program transparency, integrity, eligibility, and sustainability standards have contributed to a program that has strayed far from focusing on vulnerable, needy patients as originally intended. A mounting body of evidence from independent watchdogs—Congressional oversight hearings, audits by the Health Resources and Services Administration (HRSA), government reports, and academic research—reinforces the need for changes.[1]

Program realignment must more directly benefit vulnerable patients. The program's intent has always been to support patients; therefore, any program realignment emerging from your efforts must advantage vulnerable patients and not serve as a revenue-maximizing enterprise for hospitals, contract pharmacies, or for-profit vendors. To ensure the 340B program fulfills its purpose of providing discounts on covered outpatient drugs to true safety-net providers that serve low-income, uninsured, and other vulnerable patients, policymakers should address several critical shortcomings in the current program by:

- **Providing broader program accountability and transparency.** Requiring fundamental transparency in the 340B program is the first essential step in ensuring the program delivers for patients. Program standards should include clear rules for how all covered entities must use savings from 340B drug discounts to benefit eligible patients. Improvements to the reporting standards will enable policymakers to ensure that all 340B covered entities are consistently and systematically serving the needs of low-income, uninsured, and other vulnerable patients. Transparency standards in previously introduced legislation—the *Helping Ensure Low-income Patients have Access to Care and Treatment* (HELP Act) S.2312 and *Protecting Access for the Underserved and Safety-Net Entities Act* (340B PAUSE Act) H.R. 4710— are a sound starting point for aligning the program to meet its intended purpose and serve more vulnerable patients, and should be expanded to account for all 340B covered entities.

- **Ensuring clarity for all stakeholders on which patients are eligible for the program.** Without a clear definition of which individuals are deemed "patients" of 340B covered entities, it remains difficult to ensure the program is serving the patients for whom it was designed and is not being used in ways that divert funds from these patients. Many stakeholders have expressed concern over the lack of clarity for this fundamental element of the program, which also poses significant program integrity risks. HRSA has yet to address this, and changes are long overdue. Meaningful patient eligibility criteria should ensure that the program is focused on ensuring vulnerable patients with demonstrated need can benefit from the program.

[1] Government Accountability Office, "*340 Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*," GAO-20-212, January 2020; Government Accountability Office. *Increased Oversight Needed to Ensure. Nongovernmental Hospitals Meet Eligibility Requirements*, December 11, 2019; Government Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480: Jun 28, 2018; Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.* GAO-15-442. June 2015; Government Accountability Office. *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. September 23, 2011.

- **Addressing the asymmetry between contract pharmacies' growth and patient benefit.** While the 340B program has grown exponentially over the past decade, there is limited evidence that there has been a commensurate improvement in patient benefits. The current unlimited use of contract pharmacy arrangements is unsustainable and diverts savings meant for 340B patients to for-profit pharmacies and other middlemen. Program realignment must address the misuse of the 340B program by for-profit contract pharmacies and create consistent processes to prevent prohibited behavior.

- **Establishing more meaningful linkages between care for vulnerable patients and program eligibility standards.** Policymakers should reconsider and revise flawed hospital and child-site eligibility standards. Current standards are not correlated with the level of care delivered to vulnerable patients or the level of charity care at 340B hospitals. This misalignment calls into question whether the program is focused on fully benefiting low-income patients and other vulnerable patient groups. Updating eligibility metrics should account for the degree to which 340B covered entities continue to serve a meaningful and measurable safety-net function relative to typical non-340B providers. The Government Accountability Office (GAO) has cited inadequate oversight of covered entity and child site eligibility, including providers whose eligibility is based on a "contract with a state or local government." Furthermore, the proliferation of child sites under the 340B program should not be permitted to continue without better oversight. Instead, specific criteria should be established to set clear requirements for such sites to demonstrate their ability to address unmet medical needs in rural, medically underserved, and shortage areas, thereby bringing them in line with broader public health priorities.

- **Improving audits and program violation enforcement to prevent diversion and duplicate discount violations.** A growing body of evidence from HRSA audits, government reports, and academic research demonstrates repeated examples of diversion and duplicate discount abuses that exist among covered entities. There are persistent problems with diversion and duplicate discounts that have gone unaddressed due to HRSA's insufficient and inconsistent guidance. Failure to ensure compliance with basic program requirements, which are intended to direct program resources and benefits to eligible patients at safety-net facilities, further erodes confidence that the program is serving those patients most in need of support.

Policymakers should examine problems that have been identified by GAO, HHS Office of Inspector General (OIG), and others related to hospital eligibility criteria, transparency, and requirements for patient benefit, all of which provide opportunities to ensure the 340B program is serving its intended purpose for patients. Program improvements should adopt an integrity architecture that creates sustainability and certainty for patients, prevents program abuses, and assures covered entity compliance.

The 340B program has strayed far from its focus of serving low-income, vulnerable patients and safety-net providers as originally intended.

Congress created the 340B program in 1992 to restore the voluntary drug discounts for uninsured or vulnerable patients that manufacturers provided before the passage of the Medicaid drug rebate statute. A lot has changed in the healthcare landscape since the 340B program was enacted, including new legislative mandates requiring manufacturers to pay Part D coverage gap discounts and statutory rebates on Medicaid managed care claims. As part of the 340B program, manufacturers provide steep discounts averaging about 60 percent[2] on most outpatient medicines to certain types of clinics

[2] Berkeley Research Group, Measuring the Relative Size of the 340B Program, 2018 Update. May 2020.

(known as "grantees") and qualifying hospitals as a condition of their medicines being covered in Medicaid. Some safety-net clinics have federal grant requirements that ensure they reinvest profits into care for the uninsured or vulnerable patients they treat. In contrast, the current 340B program rules lack standards for how covered entities, including DSH hospitals, should use these discounts. For sales through Apexus, hospitals comprise 87 percent of all 340B sales,[3] with the use of the 340B program most concentrated in the disproportionate share (DSH) hospitals.[4]

Today, it is no longer accurate to characterize the program as primarily focused on vulnerable patient care by safety-net providers. Instead, much of the 340B program is increasingly dominated by a complex web of financial transactions and proprietary, contractual relationships that have evolved to benefit hospitals and middlemen, leaving vulnerable patients to fend for themselves. Even as hospitals' 340B drug purchases have grown dramatically, hospitals' uncompensated care has dropped.[5] Based on evidence from GAO, OIG, analysis in the *New England Journal of Medicine*, *JAMA*, and others,[6] *immediate* changes are needed in each of the following areas to help refocus the program to its intended purpose.

Broader program accountability and transparency are needed to put the program back on track for the patients it was intended to serve.

An essential step in ensuring that the 340B program provides measurable patient benefit is adopting fundamental improvements in transparency. Currently, standards are highly variable, and in some instances woefully inadequate, across the range of providers participating in the 340B program. As a result, policymakers and stakeholders are unable to evaluate the program, quantify its benefit to patients, or objectively confirm that patients fully benefit from the program discounts. Current 340B program rules do not provide adequate standards for how covered entities should use 340B discounts, how much covered entities can keep in 340B profits, how much 340B profit can be made by marking up prices charged to vulnerable and uninsured patients, or how the program has helped improve patient affordability. In this way, the 340B program creates incentives that can increase costs for patients, insurers, and the government[7, 8, 9] without any evidence to support claims that eligible patients are benefiting from program discounts.

At a minimum, all covered entities should have similar reporting requirements to ensure that vulnerable patients benefit from the program. Specific data are needed to quantify patient benefit in terms of the number of vulnerable patients who benefit from the 340B program and covered entities use the discounts they receive to help patients. Commonsense reporting requirements should be focused on basic information hospitals are likely already collecting for other purposes. For example, the data on the insurance status of patients is already needed for payment purposes.

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[3] Government Accountability Office. Increased Oversight Needed to Ensure. Nongovernmental Hospitals Meet Eligibility Requirements, December 11, 2019.

[4] Apexus, 340B Health Summer Conference, July 2016; Apexus, 340B Health Summer Conference, July 2016

[5] Fein A. Exclusive: The 340B Program Reached $19.3 Billion in 2017 – As Hospitals' Charity Care Has Dropped

[6] HHS Office of Inspector General. Contract Pharmacy Arrangements in the 340B Program. February 2014; Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015; Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med*. 2018; Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA*. 2013;309(19):1995-1996; Hirsch BR, Balu S, Schulman KA. The Impact Of Specialty Pharmaceuticals As Drivers Of Health Care Costs. *Health Affairs*. 2014;33(10):1714-1720.

[7] 8 S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," N Engl J Med 2018.

[8] R. Conti, P. Bach, "Cost Consequences of the 340B Drug Discount Program," JAMA: The Journal of the American Medical Association, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.

[9] Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015.

There are several examples of how these policies might be developed.[10] Two prior legislative proposals offer a sound starting point: S. 2312, the *Helping Ensure Low-income Patients have Access to Care and Treatment* (HELP Act),[11] introduced by Senator Cassidy and H.R. 4570, the *Protecting Access for the Underserved and Safety-Net Entities Act* (340B PAUSE Act), introduced by Representatives Larry Bucshon and Scott Peters. The HELP Act included many essential and commonsense reporting and accountability measures that could help all stakeholders better understand how DSH hospitals are using the 340B program and which patients have access to 340B discounts. This legislation also included much-needed standards for how DSH hospitals and their child sites qualify for the 340B program. The 340B PAUSE Act would have required similar steps to increase understanding of how 340B hospitals qualify for the program and which patients receive 340B prescriptions.

Whether Congress adopts these policy options or seeks another legislative route, essential transparency and reporting requirements should be applied consistently across the 340B program, so the public and policymakers have the assurance that eligible patients are fully benefiting from 340B drug discounts. These data are essential to guaranteeing low-income, uninsured patients benefit more directly from discounts on 340B medicines and helping to ensure program sustainability. Importantly, in its January 2018 report on the 340B program, the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations questioned numerous HRSA grantees about their additional reporting requirements under their HRSA grants. Grantees told the Committee, "they found the additional program requirements manageable."[12]

To ensure the 340B program delivers fully on its promise for patients, policymakers must clearly define the population of "patients" to whom benefits must be delivered.

The 340B program was created to provide manufacturer discounts on covered outpatient drugs to safety-net facilities that serve low-income, uninsured, and other vulnerable patients. Under the 340B law, a covered entity has access to a 340B discount if the medicine is used for the covered entity's own "patient."[13] The 340B law prohibits covered entities from reselling or otherwise transferring medicines purchased under the 340B program to anyone but a "patient" of the covered entity (a practice known as "diversion").[14]

Despite this centrality of "patient" to defining the program's scope and assuring that statutory program integrity requirements are met, it has been a quarter of a century since the 340B program was created, and the patient definition has yet to be more clearly defined.[15] As a result, there is broad consensus that the lack of specificity in the current (1996) patient definition invites abuse. For example:

- "[S]ome 340B covered entities may have interpreted the [patient] definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program…. This [never finalized] clarification provides covered

[10] 8 S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," N Engl J Med 2018.
[10] R. Conti, P. Bach, "Cost Consequences of the 340B Drug Discount Program," JAMA: The Journal of the American Medical Association, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.".
[11] Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015
[12] House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf
[13] 42 U.S.C. § 256b(a)(5)(b).
[14] 42 U.S.C. § 256b(a)(5)(B).
[15] We support the general approach to defining a 340B "patient" reflected in HRSA's proposed (now withdrawn) omnibus guidance, taking into account considerations for HRSA grantees in the 340B program. 80 Fed. Reg. 52300 (Aug. 28, 2015).

entities with more explicit guidance regarding the relationship between a covered entity and an individual that makes that individual a 'patient' of the covered entity." (HRSA, 2007.)[16]

- "HRSA officials told us that the [patient] definition currently includes individuals receiving health care services from providers affiliated with covered entities through 'other arrangements' as long as the responsibility for care provided remains with the entity. However, HRSA does not define 'other arrangements,' and officials told us what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, HRSA has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus … for whom the entity does not actually have the responsibility for care." (GAO, 2011)[17]

- "[C]overed entities … use different methods to identify 340B-eligible [patients and] prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility…. [T]wo covered entities may categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) …. [T]here is inconsistency within the 340B program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible." (HHS OIG, 2014)[18]

- "HRSA has outlined three criteria for who is an eligible patient, but some of these criteria are not clearly defined." (MedPAC, 2015)[19]

- "HRSA's guidance addresses patient eligibility but leaves room for interpretation as to which of the patient's prescriptions might be eligible in a retail pharmacy setting. In these retail settings, we found that providers, in fact, are making different determinations of what prescriptions are eligible for the 340B discounts." (Oral Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate Health, Education, Labor & Pensions (HELP) Committee, May 15, 2018.)

- "HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements...In its 2014 report, OIG found wide variation in these [340B] eligibility determinations. Different determinations of 340B eligibility appear to stem from the application of the patient definition by 340B providers and their contract pharmacies to a wide variety of prescription-level scenarios. Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not." (Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate HELP Committee, May 15, 2018)[20]

As highlighted by HRSA, GAO, OIG, and others, the 1996 patient definition is vague and lacks the specificity needed to provide clear direction to covered entities and manufacturers about who qualifies as a patient for 340B discount purposes.[21] This has encouraged covered entities to take broad interpretations of the patient definition guidance and use 340B medicines for many individuals Congress never intended the program to serve. This behavior is even more aggressive with DSH

[16] 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).
[17] Government Accountability Office. Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. September 23, 2011.
[18] HHS Office of Inspector General. Contract Pharmacy Arrangements in the 340B Program. February 5, 2014.
[19] MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.
[20] Ann Maxwell, HHS OIG, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Examining Oversight Reports on the 340B Drug Pricing Program, May 15, 2018.
[21] Debra Draper, GAO, Testimony Before the Committee on Health, Education, Labor & Pensions, U.S. Senate, May 15, 2018.; Testimony of Ann Maxwell, OIG, Testimony Before the Committee on Health, Education, Labor & Pensions, U.S. Senate, May 15, 2018.

hospitals that often develop a web of complex arrangements that appear to have the goal of growing revenue by capturing as many "patients" as possible, rather than more fully serving uninsured, low-income patients.

The lapse in guidance defining 340B eligible patients is glaring given the 340B statute creates an absolute prohibition on covered entities transferring or selling 340B drugs to individuals *who are not patients* of the covered entity. Therefore, a clear definition of "patient" is a crucial element of the program and critical to the integrity and long-term sustainability of the 340B program. We believe a new definition of 340B patients could make significant strides in resolving many of the inconsistencies in the way stakeholders have interpreted this key term.

A sound patient definition in the 340B program should address several key issues, including, at a minimum: clarifying the relationship between the 340B provider seeing the patient (including the need for in-person visits to maintain the provider-patient relationship); specifying child site criteria for patient receipt of outpatient care at a covered entities' facilities, and delineating hospital eligibility standards for the 340B program as a result of a state government contract (defining criteria for patients receiving care within the scope of the contract). This clarification is an essential building block in putting the 340B program on a firm footing – a clear definition of "340B patient" is needed urgently to ensure that the program is fully serving the vulnerable, low-income patients for whom it was designed.

Improve hospital eligibility standards to provide a stronger linkage between 340B eligibility and the extra help provided to uninsured, low-income, and other vulnerable patients.

Current hospital eligibility standards for the 340B program are woefully outdated and not serving safety-net patients well. As a result, one of the program's primary failings over the past several decades has been explosive program growth driven by hospitals (including many large health systems) that appears largely focused on expanding revenue and is disconnected increasingly from benefitting patients. Consequently, the program's significant growth in recent years has not been matched by a commensurate, demonstrable increase in benefits to the uninsured and other vulnerable patients for whom the program was designed.

For example, the DSH metric – one of the requirements for 340B hospital eligibility does not target the 340B program's intended patient population or even represent outpatient care, raising questions about whether the program is helping those in medically underserved areas who disproportionately lack access to primary care. According to a *Health Affairs* study on the 340B program, the program has evolved "from [a program] that serves vulnerable communities to one that enriches hospitals,"[22] with the majority of DSH hospitals participating in the 340B program providing below national average levels of free and reduced cost treatment to uninsured or vulnerable patients, when compared to all hospitals.[23]

In 2004, more than a decade after enactment, federal grantees accounted for 55 percent of 340B sales, and hospitals accounted for 45 percent. By 2016, grantees' share of sales had dropped to just 13 percent while hospitals' share of 340B sales increased to 87 percent.[24] Based on Apexus sales data, the clear majority of 340B sales to hospitals are to DSH hospitals, accounting for about 80 percent of 340B hospital sales.[25] With 45 percent of acute care hospitals participating in a

[22] R. Conti, P. Bach. "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities," Health Affairs 33, no. 10 (2014): 1786-1792.
[23] Ibid
[24] Mathematica, The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities, August 2004. Apexus, 340B Health Summer Conference, July 2016; Apexus, 340B Health Summer Conference, July 2016.
[25] Chris Hatwig, Apexus Update, 340B Health Summer Conference, 2016

program intended for true safety-net facilities,[26] the eligibility criteria for DSH hospitals must be reexamined. DSH hospitals qualify for the 340B program based, in part, on their DSH adjustment percentage,[27] which relates to the number of Medicaid and low-income Medicare patients treated in a hospital's *inpatient* unit. MedPAC reported that it had found little correlation between hospitals' DSH adjustment percentages and whether they had high percentages of uninsured patients.[28]

Another important issue is ensuring that 340B-eligible hospitals are true safety-net facilities. The statute requires that for private nonprofit hospitals to participate in the 340B program they must either have been formally granted governmental powers by a state or local government or have entered into a contract with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. Meaningful eligibility standards are needed for both types of eligibility, and significantly more oversight is needed to ensure discounts are going to hospitals serving a truly indigent or vulnerable population

Unfortunately, there is little guidance, transparency, or oversight to enforce these requirements. A recent GAO report on private hospitals' participation in the 340B program concluded, "Given the weaknesses in HRSA's oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B program and receiving discounted prices for drugs for which they may not be eligible. Although HRSA has initiated some efforts to strengthen its processes for assessing hospitals' eligibility, continued growth in the number of participating hospitals and 340B-purchased drugs highlights the need for HRSA to improve its oversight processes. Assessing hospitals' eligibility is critical to safeguarding the integrity of the 340B Program."[29]

This lack of oversight makes it difficult to ensure that these hospital contracts meet Congressional intent to serve a low-income and vulnerable patient population. The legislative history states that a private nonprofit hospital that had "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues" could not qualify for the 340B program under the state and local government contract test.[30] Yet this requirement is not currently being enforced, an issue highlighted by GAO[31] when it found "weaknesses in the Health Resources and Services Administration's (HRSA) oversight that may result in some hospitals receiving discounts for which they are not eligible." [32]

The current eligibility criteria for hospitals' satellite facilities (so-called "child sites") further weaken the link between 340B drug discounts and delivery of benefits to needy patients.

The current 340B hospital "child site" policy is outdated, increases costs, and drives consolidation that can negatively impact patient access to care. At a minimum, 340B hospitals should be required to report how discounts are used at each of these child sites. In addition, as policymakers consider broader restructuring of hospital 340B eligibility standards to deliver more benefit to patients, the appropriate role of child sites must be addressed.

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[26] MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.
[27] See 42 U.S.C. § 256b(a)(4)(L)-(O).
[28] MedPAC. Report to the Congress: Medicare Payment Policy. March 2007.
[29] Government Accountability Office, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, 23 (Dec. 2019).
[30] U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).
[31] Government Accountability Office. *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. September 23, 2011.
[32] Government Accountability Office. *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. September 23, 2011.

The 340B law defines the types of hospitals that can participate in the program with particular specificity[33] but never mentions the participation of off-campus outpatient facilities associated with these hospitals. Although there is no basis in the statute for including these sites, in 1994, HRSA unilaterally issued guidance dramatically expanding 340B by permitting child sites to participate—even if they are only loosely connected to the parent hospital and without regard for whether they serve a disadvantaged population.[34] Child sites have become a significant source of program growth and inducement for that growth. In 1994, there were 34 child sites. By 2016, this had increased to over 15,000.[35]

In addition to accounting for much of the 340B program's explosive growth, the policy on hospital child sites has shifted the program away from its original goal of helping make discounted medicines more accessible for uninsured and vulnerable patients.[36] The authors of a 2018 *New England Journal of Medicine* Perspective on the 340B program state, "hospitals have purchased community practices in part … to expand their footprint into wealthier neighborhoods to 'profit' from the 340B program."[37]

Evidence suggests that growth and abuse of the 340B program are creating distorted market incentives that result in shifts in care to more expensive and less convenient settings (as 340B hospitals buy up smaller facilities to generate more revenue), increases costs to commercial payers and patients (as hospitals leverage market power to demand higher prices), and ultimately raises premiums. Government reports reinforce this concern, indicating that hospitals frequently exploit the guidance on child site eligibility that has not been revisited since 1994, allowing hospitals to obtain more 340B discounts by buying community-based physician practices so that prescriptions written by those physicians then qualify for 340B discounts.[38]

The rampant growth in the number of 340B hospital child sites, the lack of any meaningful requirement that these clinics are a part of the parent hospital, and lack of HRSA oversight in this area are a major reason why the 340B program has become increasingly disconnected from a mission focused on serving vulnerable patients. Eligibility standards must be strengthened to focus the 340B program on this mission and should include: tightening the eligibility criteria to assess when these outpatient facilities are considered a part of a covered entity for 340B program purposes. Child sites should also be subject to the same requirements applied to the parent hospital, such as serving low-income and vulnerable patients, providing a broad range of services (not just dispensing of a drug), and if applicable, offering the same parent hospital sliding fee scale that shares 340B discounts with low-income patients. In addition, any newly considered reporting and transparency requirements should apply to both the parent hospital and individual child sites.

Rampant growth of contract pharmacy arrangements not aligned with patient benefit.

PhRMA appreciates the call for stakeholder feedback on improvements that can strengthen the 340B program, including how "contract pharmacies are an important part of the continued discussion around 340B modernization." While contract pharmacies can help provide improved access to medicines, their role and unchecked growth in the 340B program continues to raise troubling concerns about the unfettered expansion of the 340B program. Researchers, economists, thought leaders, and Members of Congress have documented how contract pharmacy arrangements' growth contributes to the

[33] 42 U.S.C. § 256b(a)(4)(L)-(O).
[34] 59 Fed. Reg. 47884, 47885 (September 19, 1994).
[35] HRSA OPA Database, October 2016.
[36] Vandervelde A, Blalock E. *340B Program Sales Forecast: 2016 – 2021*. 2016. Available at: http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf.
[37] Gellad, WF, James AE. Discounted drugs for needy patients and hospitals—understanding the 340B Debate. *New England Journal of Medicine*. 2018;378(6):501-503.
[38] Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442, June 2015; 59 Federal Register 47884, 47885 (September 19, 1994).

program's ballooning size without any accompanying guarantee of patient benefit.[39,40] As respected health economist and 340B expert Rena Conti of Boston University has noted, "*Here's a policy that is maximizing revenue for hospitals and contract pharmacies and perversely going against the intent of the program, which is to provide accessible and affordable health care for vulnerable people.*"[41]

Most alarming is that repeatedly, these reports show that 340B covered entities and their contract pharmacies share in 340B profits but, in most cases, do not share 340B discounts with uninsured patients at contract pharmacies.[42] These same reports have also raised significant concerns about program integrity. Independent agencies such as the OIG and GAO have found that this vast expansion increases the risk of 340B law violations, noting that contract pharmacy arrangements create complications in preventing diversion and duplicate discounts, two practices prohibited by the 340B law. In fact, two-thirds of the diversion findings in HRSA audits for non-compliance involved drugs distributed at contract pharmacies.[43,44]

Without providing a clear benefit to needy patients, as the 340B program was intended to do, the dramatic expansion of contract pharmacy arrangements into the for-profit, retail pharmacy sector represents an unreasonable and unnecessary risk to program compliance. Any potential policy discussions must seriously examine the role contract pharmacies should play in a program that has grown significantly over the past ten years without any accountability for helping patients access the medicines they need.

Promulgated under HRSA guidance, contract pharmacy arrangements lack the force and effect of law.

Under the 340B law, manufacturers must offer each qualifying covered entity "covered outpatient drugs" for purchase at or below a deeply discounted price (statutorily defined as the "340B ceiling price"). When the program began, covered entity providers were able to access the discounts for medicines used to treat their patients. However, certain entities may have lacked the operational capacity to provide retail medicines through an on-site pharmacy – such as not having adequate inventory space to store the medicines or the staff and pharmacy license to dispense the 340B purchased medications to the vulnerable patients they served.

To accommodate those entities that could not house an on-site pharmacy HRSA issued guidance in 1996 allowing a covered entity *without* their own in-house pharmacy to enter into an agreement with *one* contract pharmacy ("contract pharmacy arrangement") to dispense covered outpatient drugs to the 340B patient on behalf of the covered entity.[45] This is referred to as a 'ship-to-bill-to' model, whereby the covered entity is invoiced for the 340B medicine, but the manufacturer is directed by the covered entity to ship the drug to a designated contract pharmacy for dispensing to an eligible patient.

In 2010, through updated guidance, HRSA dramatically expanded the use of contract pharmacies by allowing any covered entity (including covered entities *with* an in-house pharmacy) to contract with an *unlimited* number of contract

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[39] Hayes, Tara. Market Distortions Caused by the 340B Program. American Action Forum. November 2017.
[40] Energy and Commerce Committee. Report of the 340B Drug Pricing Program. January 2018. https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf
[41] Karlin-Smith, Sarah. Perverse Incentives? Why some 340B pharmacies are opting for branded drugs. July 2018. https://www.politico.com/newsletters/prescription-pulse/2018/07/02/perverse-incentives-why-some-340b-pharmacies-are-opting-for-branded-drugs-268802
[42] Government Accountability Office. "*Drug Pricing: Manufacturing Discounts In The 340B Program Offer Benefits, But Federal Oversight Needs Improvements*", GAO-11-836, September 2011.
[43] HHS Office of Inspector General, "*Contract Pharmacy Arrangements in the 340B Program,*" February 2014.
[44] Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO-18-480: Jun 28, 2018.
[45] 61 FR 43549, August 23, 1996

pharmacies,[46] regardless of whether the "covered entity had an in-house pharmacy. Today, there are well over 100,000 contract pharmacy arrangements[47], but this change did nothing to ensure that 340B patients benefit from this expansion. A 2014 OIG report found that most covered entities in their study *did not* ensure that they passed 340B discounts back to uninsured patients who filled their prescriptions at a contract pharmacy.[48] That same report noted it is not uncommon that "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." This means such uninsured or vulnerable patients did not benefit from manufacturer discounts on 340B drugs dispensed at contract pharmacies.

Instead, the 2010 guidance has raised significant concerns from multiple stakeholders that the exponential growth of contract pharmacies without appropriate safeguards creates complications in preventing diversion and duplicate discounts, in which manufacturers pay twice on the same prescription claim (a 340B discount and a rebate).[49, 50] It is important to note that the term "contract pharmacy" is not mentioned in the 340B law or in any regulations. Agency guidance such as the 2010 contract pharmacy guidance cannot impose any binding requirements on the public and lacks the force and effect of law.

Growth of contract pharmacy arrangements without appropriate safeguards has contributed to a lack of clear patient benefit.

Since HRSA updated its guidance in 2010, contract pharmacy participation has skyrocketed, growing by more than 4,000%.[51] This growth rate may not necessarily cause concern if the growth correlated with an expansion in discounted medicines for vulnerable and indigent patients. However, despite the explosion in contract pharmacy arrangements, there is little evidence to suggest patients have benefited from contract pharmacy growth—in fact, contract pharmacies may often charge patients a drug's full retail price.[52] There are no HRSA requirements that covered entities reinvest any portion of their 340B-generated revenue into patient care or report how these profits are used to benefit uninsured or vulnerable patients. As a result, there is little to no insight into whether those profits are invested in caring for underserved patients or whether 340B patients are actually receiving the benefit of the 340B discount at contract pharmacies today.

Without standardized requirements for a specific designation of a 340B-eligible prescription or some clear patient identifier, contract pharmacies generally do not know which individuals are 340B patients when they fill their prescriptions. Unlike at a covered entity's on-site pharmacy, a prescription filled at a contract pharmacy oftentimes is not identified as being eligible for 340B discounts until after the prescription is filled.[53] In such cases, it is difficult, if not impossible, for uninsured or vulnerable patients to benefit directly from the discounts. In addition, this lack of identifier creates a large risk of diversion and duplicate discounts. The OIG has confirmed that contract pharmacies are typically unable to determine who is eligible for 340B discounts at the time a prescription is filled.[54]

Current unlimited use of contract pharmacies diverts savings from the 340B program to for-profit pharmacies and other middlemen, threatening the safety-net.

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[46] 75 FR 10272, March 5, 2010
[47] BRG Analysis of HRSA OPA Database, August 2020.
[48] HHS Office of Inspector General, "Contract Pharmacy Arrangements in the 340B Program," Feb. 2014.
[49] Government Accountability Office. "*Drug Pricing: Manufacturing Discounts In The 340B Program Offer Benefits, But Federal Oversight Needs Improvements*", GAO-11-836, September 2011.
[50] Government Accountability Office. "*340 Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*," GAO-20-212, January 2020.
[51] Berkeley Research Group: For-Profit Pharmacy Participation in the 340B Program. October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[52] Conti, Rena M., and Peter B. Bach. "Cost consequences of the 340B drug discount program." *JAMA* 309.19 (2013): 1995-1996.
[53] Ibid.
[54] HHS Office of Inspector General, "*State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*", June 2016.

Contract pharmacies are dominated mainly by for-profit, retail pharmacies with whom covered entities partner to dispense 340B medicines. The contract pharmacy and the covered entity may share the profit generated from the "spread" between a drug's third-party reimbursement and the covered entity's 340B acquisition cost[55,56] with no guarantee that patients benefit from the 340B discount. Depending on their agreements with covered entities, contract pharmacies can also generate higher returns by dispensing more 340B prescriptions compared to non-340B prescriptions. The average profit margin on 340B medicines commonly dispensed through contract pharmacies (i.e., reimbursement rate for the drug minus its acquisition cost to the covered entity) is an estimated 72% compared with a margin of 22% for non-340B medicines dispensed through independent pharmacies.[57]

Although there are more than 27,000 distinct pharmacy locations that participate in the 340B program, over half of the 340B profits retained by contract pharmacies are estimated to be concentrated in just three pharmacy chains – Walgreens, Walmart, and CVS Health -- and Cigna's Accredo specialty pharmacy.[58] An entire cottage industry of 340B supply chain "middlemen" consisting of for-profit pharmacies, covered entities' third-party administrators (TPAs), and consultants that seek to maximize 340B dispensing has also come into existence since 2010.[59] They financially benefit from 340B drug utilization and the 340B "spread," with no obligation to report what they do with the revenue. For example, one vendor that provides 340B software states in its education materials for pharmacies that "the covered entities are allowed to use the benefit of these substantial [340B] savings in any way they choose. There is no requirement to pass the savings on to patients directly."[60] The fact that large chain pharmacies (which may be owned by health plans or PBMs) often serve as contract pharmacies raises questions about whether these "middlemen" are diverting resources from the 340B program's intended purpose of assisting low-income or vulnerable patients.

Policymakers are correct to be concerned about the rampant growth of contract pharmacies. We strongly encourage a deep and thorough examination by an independent agency that could inform future policy discussions. Any new policy must consider what role contract pharmacies should play in a program that has grown significantly over the past ten years and with little to no guaranteed benefit to patients.

Current mechanisms to identify and prevent duplicate discounts and diversion are ineffective.

The 340B law creates an absolute prohibition on duplicate discounts, which prohibits covered entities from purchasing a drug at a 340B discount that also generates a Medicaid rebate.[61] Despite this straightforward statutory imperative, current prevention methods are insufficient to address the duplicate discounts that persist throughout the 340B program. HRSA covered entity audit data from FY2017 show that two-thirds of all DSH hospitals audited were non-compliant

[55] MedPAC Report to Congress. Overview of the 340B Drug Pricing Program. May 2015.
[56] Fein, A. How Hospitals and PBMs Profit – and Patients Lose – from 340B Contract Pharmacies. July 2020. Available at: https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html
[57] Berkeley Research Group: For-Profit Pharmacy Participation in the 340B Program. October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[58] Berkeley Research Group: For-Profit Pharmacy Participation in the 340B Program. October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[59] The link has been taken down, but it was previously at http://www.linkedin.com/pub/timothy-hong/28/651/511; Senator Charles Grassley, Letter to Walgreens CEO Gregory Watson, July 21, 2013. Available at: http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf; http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf
[60] Talyst, "Benefits to Becoming a Contract Pharmacy: Answering the pharmacist's questions regarding 340B Contract Pharmacy," available at: http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf (accessed August 2020).
[61] Sec. 340B PHSA(a)(5)(i).

in at least one area, and many were non-compliant in multiple areas, including duplicate discounts and diversion.[62] However, it does not appear that HRSA uses audit violations as the basis for enforcement actions against covered entities. At least one Congressional committee found little evidence of strong agency oversight, citing that "HRSA rarely terminates covered entities from 340B through the audit process."[63]

Although 340B/Medicaid duplicate discounts are statutorily prohibited, a drug with a negotiated commercial or Medicare Part D rebate can also be subject to a 340B discount due to the lack of appropriate mechanisms to identify 340B-eligible claims. As a result, manufacturers could end up paying a 340B discount and a plan/PBM rebate on the same claim. While some manufacturers may include provisions in their contracts with commercial plans that drugs purchased through the 340B program are not eligible for rebates to the health plan, in practice, these contract terms are difficult to operationalize and enforce without a 340B claims identifier required to be tagged consistently throughout claims processing and rebate invoicing. The 340B program is already growing; if manufacturers are forced to pay a rebate on a medicine that was already purchased at a large discount, this likely compounds the distortive impact that economists say that 340B discounts already have on prescription medicine prices.[64]

There are no program requirements on PBMs or contract pharmacies to identify 340B claims properly, and some of the profit-driven motives previously mentioned could have unintended affordability consequences for patients.[65] Complications with duplicate discounts are magnified by a convergence of lax agency oversight and marketplace dynamics related to the expansion of Medicaid rebates for medicines used by Medicaid Managed Care Organization (MCO) enrollees since 2010. Today, Medicaid rebates cover an even larger population due to Medicaid expansion and the extension of rebates to Medicaid MCO enrollees. However, to date, the only mechanism HRSA has developed to prevent duplicate discounts (the Medicaid Exclusion File) expressly excludes Medicaid managed care utilization. HRSA has stated that it "recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid Managed Care and is working with CMS to develop policy in this regard."[66] However, neither HRSA nor CMS has developed mechanisms to address this issue despite what the statute requires.[67]

A 2018 GAO report found that because HRSA only assesses the potential for duplicate discounts in fee-for-service and not MCOs, "*[u]ntil HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have an assurance that covered entities' efforts are effectively preventing non-compliance*). This lack of guidance leaves a critical gap in enforcing the law's duplicate discount ban as about 56 million Americans are covered by Medicaid managed care plans. Half of all Medicaid spending on prescription medicines was through MCOs in 2014,[68] and that share has likely increased in recent years.

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[62] HRSA OPA Database Program Integrity FY17 Audit Results. March 6, 2018.
[63] Energy & Commerce Committee's "Review of the 340B Drug Pricing Program."
[64] Conti R, Rosenthal M. Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation. N Engl J Med. 2016;374:703-706.; Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. JAMA. 2013;309(19):1995-1996.
[65] Drug Channels. How Hospitals and PBMs profit – and Patients lose - from 340B Contract Pharmacies. July 23, 2020. https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html
[66] HRSA, 340B Drug Pricing Program Release No. 2014-1 (Dec. 12, 2014). The Medicaid Exclusion File mechanism requires that 340B covered entities either "carve in" (provide 340B drugs to Medicaid patients and report this practice to HRSA, so that these entities are listed on the Exclusion File and State Medicaid programs do not bill manufacturers for rebates on drugs furnished by these entities) or "carve out" (do not provide 340B drugs to Medicaid beneficiaries, so that drugs supplied by a 340B entity to a Medicaid patient triggers a Medicaid rebate, but not a 340B discount). Under the 2014 guidance, this mechanism no longer applies to prevent double discounts on 340B drugs provided to MCO beneficiaries.
[67] 42 USC 256b(a)(5)(A0(ii) and 256b(d)(2)(B)(iii).
[68] KFF, "Total Medicaid Managed Care Enrollment, 2014" available at: https://www.kff.org/medicaid/state-indicator/total-medicaid-mc-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (accessed March 11,

In January 2020, the Centers for Medicare & Medicaid Services (CMS) issued an information bulletin to states to encourage them to consider best practices to avoid duplicate discount violations in state Medicaid programs. In that informational bulletin, CMS notes, "340B duplicate discounts can often best be identified from a review of claims level data by manufacturers."[69] While this is an encouraging development, neither HRSA nor CMS has developed effective policies nor required covered entities to adopt practices to prevent these statutory violations in the 340B program. The result can be lengthy and costly audits and disputes for both manufacturers, state Medicaid agencies, and covered entities.

In identifying the top unimplemented recommendations to reduce fraud and abuse in HHS programs, OIG has stated, "CMS and HRSA should ensure that States can pay correctly for 340B-purchased drugs billed to Medicaid, by requiring claim-level methods to identify 340B drugs and sharing the official 340B ceiling prices".[70] The sharing of basic claims level data can help ensure 340B discounts are being properly applied, ensuring all stakeholders are operating in a compliant manner, and patients are able to benefit in the way the program is intended. PhRMA appreciates that the Energy and Commerce Committee has identified the prevention of duplicate discounts, particularly in Medicaid Managed Care, as a priority area that HRSA and CMS need to address.[71] We look forward to working with stakeholders on identifying solutions to prevent duplicate discounts, strengthen the 340B program, and reduce market distortions exacerbated by manufacturer rebates paid on commercial or Part D drugs that also received 340B discounts.

340B program improvements in several key areas are needed to ensure the program fully benefits vulnerable patients.

PhRMA appreciates your leadership in advancing a broad assessment of the 340B program and the degree to which it could achieve the goal of delivering clinical and affordability benefits to vulnerable patients. Better oversight and administration of the program are foundational for ensuring that it can serve the patients for whom it was created. Failures in program transparency, integrity, eligibility, and sustainability standards have contributed to the lack of focus on the vulnerable, needy patients the program was created to serve. Insufficient guidance, historically weak program oversight, and other areas of insufficient program administration have led to dramatic program growth without a commensurate delivery of benefits to low-income and vulnerable patients.

PhRMA believes that the significant discounts biopharmaceutical manufacturers provide under the 340B program should serve a targeted purpose—helping low-income uninsured and other vulnerable patients obtain the outpatient medicines they need—and all covered entities qualifying for the program should be accountable for using its benefits properly. However, changes in critical areas of the program would help provide the integrity, oversight, and transparency that are urgently needed to put it on a sustainable footing for the long-term and, most importantly, ensure it is doing all it can to support patients most in need. For these reasons, we agree that "changes are long overdue," and meaningful program realignment must be pursued to increase transparency and accountability in the 340B program.

2018); MACPAC, "Medicaid Spending for Prescription Drugs," January 2016. Available at: https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf.

[69] CMCS Informational Bulletin. "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid." January 2020. Available at: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf

[70] HHS Office of Inspector General. OIG's Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste and Abuse in HHS Programs. August 2020. https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf

[71] Energy and Commerce Committee. Review of the 340B Drug Pricing Program. January 2018. https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

PhRMA reiterates our support for the 340B program. We are committed to working with Congress, the Administration, and other program stakeholders to develop patient-focused policy solutions for the sustainability and success of this essential safety-net program. Thank you for the opportunity to comment.

Sincerely,

Stephen J. Ubl
President & Chief Executive Officer

COMMENTS OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

SUBMITTED TO THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES

CONCERNING HHS BLUEPRINT TO LOWER DRUG
PRICES AND REDUCE OUT-OF-POCKET COSTS

July 16, 2018

TABLE OF CONTENTS

Attention: CMS-2018-0075-0001
July 16, 2018

VIA ELECTRONIC FILING – via regulations.gov

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Department of Health & Human Services (HHS) request for information (RFI), *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $65.5 billion in 2016 alone.

Antitrust Statement

At the outset of our comments, it is important to note that numerous questions in the RFI raise competitively sensitive topics for members and that PhRMA's advocacy activities on behalf of its members in responding to the RFI are limited by the antitrust laws and PhRMA's antitrust compliance policy. In particular, PhRMA as a trade association does not permit any discussion about members' current and future drug pricing strategies, relationships with customers or anticipated responses in the marketplace to any proposed changes to law or regulation. PhRMA's comments have been prepared with these guidelines in mind and in compliance with the antitrust laws and thus set forth PhRMA's advocacy views regarding potential government reforms identified in the RFI that HHS could initiate.

The RFI comes at a time when we are in a new era of medicine in which breakthrough science is transforming patient care and enabling us to more effectively treat chronic disease, the biggest cost driver in our health care system. In this new era of medicine, many diseases previously

regarded as deadly are now manageable and even curable. Today, more than 7,000 medicines are in development worldwide, of which 80 percent have the potential to be first in class and 42 percent are personalized medicines.[1] At the same time we are experiencing these scientific breakthroughs, changes in the supply chain and in health insurance benefits have left some patients facing increased out-of-pocket costs due to rising list prices, and high deductibles and coinsurance.

The RFI creates a unique opportunity for policymakers to take a wide view and address all the factors that are influencing the cost of medicines. It recognizes that the powerful entities making up the biopharmaceutical supply chain, such as pharmacy benefit managers (PBMs) and insurers, play a large role in influencing the cost of medicines because they design prescription drug formularies and cost-sharing structures and retain a sizable share of spending on medicines.[2] This broad perspective expands the opportunity for HHS to solve the problems patients face. PhRMA is committed to helping solve these problems and supports efforts to make the fundamental policy changes needed to achieve solutions.

The RFI also recognizes the importance of lowering the amount that patients are charged for medicines at the pharmacy counter. This would reduce financial burdens on patients and help achieve the health benefits and cost savings available through improved adherence to needed treatments and reduced abandonment of prescriptions at the pharmacy counter.[3] Patients' out-of-pocket cost for medicines is determined by payers' choices, including how they decide to allocate the large, rapidly growing discounts[4] they obtain from manufacturers. At present, payers' choices have meant that patients rarely benefit from these discounts at the pharmacy counter.[5] Here, too, PhRMA supports fundamental policy changes to achieve solutions that will help patients and produce better, more efficient health care.

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[1] Long G. The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development. Analysis Group. 2017; Tufts Center for the Study of Drug Development (CSDD). Personalized Medicine Gains Traction But Still Faces Multiple Challenges. *Tufts CSDD Impact Report*. 2015;17(3).

[2] Berkley Research Group, The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders. January 2017. Available at: http://www.thinkbrg.com/newsroom-publications-vandervelde-blalock-phrma.html

[3] Goldman DP, Joyce GF, Escarce JJ, et al. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA*. 2004;291(19):2344-2350.; Doshi JA, Li P, Ladage VP, Pettit AR, Taylor EA. Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. *Am J Managed Care.* 2016;22(3):188-197.

[4] Fein AJ. The gross-to-net bubble topped $150 billion in 2017. Drug Channels Institute. April 24, 2018. Available at: https://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html

[5] PhRMA. Commercially-insured patients pay undiscounted list prices for one in five brand prescriptions, accounting for half of out-of-pocket spending on brand medicines. May 2017. Available at: http://www.phrma.org/report/commercially-insured-patients-pay-undiscounted-list-prices-for-one-in-five-brand-prescriptions-accounting-for-half-of-out-of-pocket-spending-brand-medicines. Notably, less is spent on medicines than other categories of care but payers' choices mean insurance often covers a smaller share of medicines' cost, leaving patients with a higher share.; Avalere Health analysis of the U.S. HHS, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey. 2014. Analysis includes individuals with any source of health care coverage, public or private; this includes individuals who had health coverage without coverage for prescription drugs, which can be expected to account for less than 2 percent of those with health coverage.

The RFI identifies potential policy changes that would remake key aspects of the market for prescription medicines. The reforms would have far-reaching impact on the cost of and access to medicines in the United States (U.S.), significantly affecting manufacturers, the supply chain and patients. They also would make large-scale changes to Medicare Parts B and D and address price differences for medicines between the U.S. and other countries caused by foreign governments' free riding on American biopharmaceutical innovation.

In some cases, the ideas raised in the RFI identify ways to remove obstacles to better functioning of private markets. This market orientation, which preserves the real successes of today's system while addressing its problems, is vital to achieving cost savings, continued medical advances and good patient access to needed treatment. Market-oriented policies identified in the RFI would build on important steps the Trump Administration and Congress have already taken to increase competition, including policies to accelerate U.S. Food and Drug Administration (FDA) review of generics; adoption and implementation of the prescription drug, generic drug, and biosimilar user fee legislation; FDA's recent finalization of two manufacturer communications guidance documents intended to facilitate broader opportunities for value-based contracting; Centers for Medicare & Medicaid Services' (CMS) policy providing appropriate reimbursement of biosimilars in Medicare Part B; and changes to address Medicare overpayments to 340B entities.

PhRMA and its member companies support improving the status quo for Americans who rely on medicines. Addressing market distortions created by current law and regulation and enacting reforms to change the supply chain incentives that favor high list prices and high out-of-pocket costs, even as overall spending on medicines is held down,[6] would have positive consequences for patients and payers. Change also can create broader opportunities for value-based agreements between private payers and manufacturers. Antiquated public policies have constrained these agreements, preventing the biopharma sector from fully participating in the broader movement to promote value-based payment in health care. Addressing foreign governments' systematic free riding on American-supported biopharmaceutical innovation would be another ground-breaking change that would benefit patients and payers.

While some of the policies suggested in the RFI would improve the current system, other policies would restrict patient care and impede innovation. PhRMA opposes changes that would harm access or increase out-of-pocket costs for beneficiaries. We urge caution particularly when making changes that would impact the vulnerable patients who depend on Medicare and Medicaid. The wrong changes to these programs could hurt seniors, children and people with disabilities.

PhRMA is committed to working with the Administration, Congress, patients and payers to advance solutions that will improve affordability of medicines and health care, improve patients' access to needed treatments, and sustain the medical advances Americans expect and need.

[6] IQVIA. 2017 Medicine Use and Spending. April 2018.

An overview of our comments is set out below, followed by detailed comments in each section.

Innovation and Spending on Medicines: Continued advances in medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization.[7] While medicines' role in effective health care has grown sharply and hundreds of new medicines have been brought to patients over the last decade, spending on medicines has grown more slowly than spending for other types of care, and medicines' share of national health spending has remained stable.[8] However, during recent years, publicly reported list prices for medicines have increased more rapidly than the actual prices paid, resulting in a growing gap between list and net prices.[9] This gap has had important consequences for federal programs and has adversely impacted patients who often pay cost sharing based on list price. Policy changes discussed below could help address these trends and improve the current system for both patients and payers.

Rebates: While the current drug distribution and payment system has successfully constrained overall spending on medicines, it could work better for patients, payers, and manufacturers. Today's system is characterized by a complex web of financial transactions and proprietary contracts and has evolved over time with changes in drug benefits as well as changes in the size, role, and structure of PBMs. As the RFI correctly observes, many entities in the system earn revenue based on a percent of the list price. This hurts patients and increases costs and we believe it must change. We also recognize that government reforms to this system will require careful consideration and input from all stakeholders to ensure an orderly transition to a system that focuses on net prices of medicines and their value to patients. As a first step, we support reforms to ensure that patients benefit from rebates at the point of sale and to discourage supply chain entities from being paid based on list price.

Drug Pricing Demonstrations: As HHS considers potential tests of innovative ways to encourage value-based care and lower medicines prices, it will be important to establish in rulemaking the appropriate role for the CMS Innovation Center (CMMI) and to prioritize holistic approaches that recognize the role that appropriate use of medicines plays in improving patient outcomes and reducing spending in other parts of the health care system. We encourage HHS to establish regulations that define small scale, voluntary, and limited duration testing; clearly

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[7] PhRMA. A decade of innovation in rare diseases: 2005-2015. 2015. Available at: http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMA-Decade-of-Innovation-Rare-Diseases.pdf; Lacey MJ, Hanna GJ, Miller JD, Foster TS, Russell MW; Truven Health Analytics. Impact of pharmaceutical innovation in HIV/AIDS treatment during the highly active antiretroviral therapy (HAART) era in the US, 1987-2010: an epidemiologic and cost-impact modeling case study. December 2014. Available at: http://truvenhealth.com/Portals/0/Assets/Life-Sciences/White-Papers/pharma-innovation-hiv-aids-treatment.pdf; Roebuck MC. Medical cost offsets from prescription drug utilization among Medicare beneficiaries [commentary]. *J Managed Care Pharm.* 2014;20(10):994-995; Afendulis CC, Chernew ME. State-level impacts of Medicare Part D. *Am J Managed Care.* 2011;17 Suppl 12:S.

[8] PhRMA analysis of CMS, NHE 2016. December 2017.; Altarum Institute. Projections of the prescription drug share of national health expenditures including non-retail. May 2018. Available at: https://altarum.org/sites/all/libraries/documents/Projections_of_the_Prescription_Drug_Share_of_National_Health_Expenditures_June_2018.pdf

[9] IQVIA. 2017 Medicine Use and Spending. April 2018.

articulate that CMMI may not unilaterally make permanent, structural changes to Medicare and Medicaid; and lay out a transparent model design and evaluation process.

Medicare Part D: PhRMA shares the Administration's goals of strengthening the Part D benefit and lowering out-of-pocket costs for patients. Preserving the success of the program will require targeted and measured reforms that uphold Part D's competitive, market-based structure and improve affordability without compromising beneficiaries' access to medicines. Some reform proposals advanced by the Administration—including passing through to beneficiaries a share of negotiated rebates at the point of sale and establishing an annual maximum out-of-pocket (MOOP) spending limit—would provide immediate and visible financial relief to patients facing high pharmacy costs. Other proposals—specifically, changes to the protected classes, eliminating the two drugs per class requirement, and removing coverage gap discounts from the calculation of true out-of-pocket (TrOOP) spending—would harm access, increase costs for beneficiaries, and jeopardize the health of seniors and persons with disabilities.

Medicare Part B: The Medicare Part B benefit provides access to medicines for vulnerable patients who suffer from a range of serious illnesses and who often have few available treatment options through a structure that provides much needed flexibility for physicians to tailor treatment plans to optimize care for these patients. As HHS considers changes to this program, it will be critical to preserve beneficiary access to a range of treatment options and timely delivery of complex care at the site of service that is best for the patient. Increasing hospital consolidation is driving up the cost of care, for both Medicare and commercial patients, and we encourage CMS to consider approaches that would address this dynamic. At the same time, HHS should avoid increasing patient costs and reducing access by moving Part B covered drugs into the Part D benefit, or by relaunching the competitive acquisition program (CAP) in ways that impose formulary or utilization management tools that would block patients from getting the care they need and place administrative burden on physicians.

Medicaid and Affordable Care Act Taxes: Prescription medicines represent a small share of Medicaid spending and provide substantial value to the program.[10] However, manufacturers' Medicaid rebate liability and tax obligations have increased dramatically with implementation of the Affordable Care Act (ACA). Numerous government analysts and economists have documented the negative consequences of the Medicaid drug rebate program in shifting costs and increasing prices for other customers.[11] The Administration's proposal to repeal the cap on Medicaid rebates at 100 percent of Average Manufacturer Price (AMP) is essentially a new tax on the industry and would not achieve the Administration's goal to lower list prices; instead it would deepen the price distortions caused by the rebate program.

340B Drug Discount Program: PhRMA and our member companies strongly support the 340B program and the important role it plays in our health care safety net. The 340B program is particularly crucial to supporting the care provided by qualifying federally-funded clinics (known

[10] Menges Group analysis of 2016 CMS 64 and state drug utilization files.
[11] The Council of Economic Advisers. Reforming Biopharmaceutical Pricing at Home and Abroad. February 2018.

as "grantees"), who are typically required to reinvest revenue derived from the 340B program into helping the communities they serve. In contrast, hospitals, which now account for the clear majority of 340B sales, have no such requirements. Hospitals' use of 340B has led to growth in the program that economists have found is increasing costs for patients and the overall health care system. The program now needs to be updated to keep it on a sustainable footing. The Administration has authority to make reforms and should update its guidance on important aspects of the program: a clearer patient definition in line with the statute, meaningful limits on hospital child sites, reforms to the contract pharmacy policy, and eligibility standards for private hospitals. Additionally, we urge Health Resources and Services Administration (HRSA) and CMS to develop more comprehensive and effective duplicate discount prevention guidance.

Cost-Sharing Assistance Cards: Cost-sharing assistance cards have become a crucial lifeline for patients with commercial insurance who are increasingly facing high cost sharing for their medicines due to high deductibles or coinsurance. Manufacturers provide these cards as a response to an insurance benefit design system that would otherwise leave many patients abandoning their medicines at the pharmacy counter. Maintaining availability of cost-sharing assistance cards for patients should be a key part of the administration's efforts to promote access to affordable medicines for patients. Thus, the Administration should not seek to change the current exclusion of cost-sharing assistance cards from the determination of the AMP and Best Price, as is contemplated in the RFI.

Value-Based Arrangements: PhRMA appreciates HHS's recognition of the regulatory barriers that can inhibit value-based arrangements, and the recent action by FDA which made a significant advance towards removing one of these obstacles for manufacturer. We encourage HHS to address the remaining barriers by issuing an Anti-Kickback Statute safe harbor for value-based arrangements and clarifying the rules for reporting of Medicaid Best Price. We urge continued reliance on the market as the best mechanism for determining a medicine's value, as many payers assess their own needs in light of available evidence, and avoidance of centralized government approaches that would harm patient access and lead to suboptimal outcomes. We also urge caution as HHS considers long-term financing approaches and indication-based coverage and pricing to ensure any of these approaches support continued innovation and patient access, as well as market-based competition.

National Spending Estimates: Estimates of national health care spending should accurately reflect spending on medicines net of aggregate discounts and rebates to inform policymakers as they make decisions regarding health care spending controls and other payment and reimbursement issues. Although projections of prescription medicine spending included in the National Health Expenditure (NHE) data attempt to capture spending on medicines net of discounts and rebates, they systematically overestimate prescription medicine spending.[12] The actuaries at CMS should reassess their methodology for projecting drug spending, consider

[12] CMS. Accuracy Analysis of The Short-Term (10-Year) National Health Expenditure Projections. February 2018.; PhRMA analysis of CMS. NHE 2016. December 2017.

reporting total drug spending instead of retail drug spending, and break out spending by ingredient costs versus distribution and supply chain costs.

Direct-to-Consumer Advertising: FDA should not pursue any required disclosure of list prices in direct-to-consumer (DTC) pharmaceutical advertising. Such a requirement could confuse patients since the list price often does not represent what they would actually be required to pay, and the requirement could also have the unintended and harmful consequence of deterring patients from seeking care. Moreover, any such requirement would raise significant legal issues including serious First Amendment concerns.

Biosimilar Development, Approval, Education, and Access: PhRMA members support the development and delivery of safe and effective biologics, including biosimilars. The approval pathway outlined in the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and the implementation of the Biosimilar User Fee Act (BsUFA II) goals are helping to provide more predictable and timely access to biosimilar products that will result in increased biopharmaceutical competition in the marketplace. PhRMA urges targeted revisions to the Purple Book to provide more certainty and transparency for stakeholders, supports FDA's continued efforts to increase the public's understanding of both biologics and biosimilars, and encourages FDA to address PhRMA's comments on the draft guidance on interchangeability as it finalizes that guidance.

Availability of Reference Product Samples: Reference product sponsors should not deny access to product samples to delay generic or biosimilar entry. FDA could exercise its existing statutory authority to evaluate whether Risk Evaluation and Mitigation Strategies (REMS) have impacted the availability of generics or biosimilars and whether there are steps the agency might take to address any such issues without undermining the safety issues that resulted in the REMS. Although FDA should take appropriate measures within its current statutory authority, legislation may be useful to fully address product sample access issues.

Fixing Global Freeloading: Foreign governments mandate price controls and other harmful trade practices to artificially depress the market value of U.S innovative medicines, resulting in U.S. patients bearing a disproportionate share of the cost to develop medical advances. Recognizing the global benefits of addressing free riding by other wealthy countries, PhRMA proposes four actions that this Administration could take to end the most unfair and discriminatory trade practices faced by the U.S. innovative biopharmaceutical industry: (1) Securing strong commitments in global, regional and bilateral negotiations (including the ongoing North American Free Trade Agreement (NAFTA) renegotiations) to drive and sustain 21st century biopharmaceutical innovation; (2) Enforcing and defending existing trade commitments (such as those negotiated with South Korea and Australia); (3) Ensuring that foreign government pricing and reimbursement policies are transparent, provide due process and appropriately value U.S. innovation; and (4) Leveraging all available trade tools to combat abuse of compulsory licensing.

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SECTION I: INNOVATION AND SPENDING ON MEDICINES

Medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization.[13] The U. S. is by far the global leader in the development of new medicines.[14] American patients benefit from earlier and wider access to new medicines compared to patients in other countries, where governments restrict access.[15] For example, nearly 90 percent of newly launched medicines from 2011 to 2017 were available in the U.S., compared to just two-thirds in the United Kingdom (U.K.), half in Canada and France, and one third in Australia.[16]

Continued advances in medicines are indispensable to addressing some of our society's biggest health and economic challenges.[17] Likewise, better use of medicines, such as improved adherence to needed treatments, offers the opportunity for better results for patients and an estimated $213 billion per year in health savings.[18] Several policies identified in the RFI could help achieve these important results.

As medicines' role in effective health care has grown sharply and many new medicines have been brought to patients, retail and physician-administered medicines combined have remained 14 percent of total U.S. health spending.[19] Biopharmaceutical innovator companies, which develop the safe and effective new medicines that improve patients' lives, accounted for less than half of all spending on prescription medicines—or about 7 percent of total health care spending in

[13] PhRMA. A decade of innovation in rare diseases: 2005-2015. 2015. Available at: http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMA-Decade-of-Innovation-Rare-Diseases.pdf ; Lacey MJ, Hanna GJ, Miller JD, Foster TS, Russell MW; Truven Health Analytics. Impact of pharmaceutical innovation in HIV/AIDS treatment during the highly active antiretroviral therapy (HAART) era in the US, 1987-2010: an epidemiologic and cost-impact modeling case study. December 2014.; Roebuck MC. Medical cost offsets from prescription drug utilization among Medicare beneficiaries [commentary]. *J Managed Care Pharm.* 2014;20(10):994-995; Afendulis CC, Chernew ME. State-level impacts of Medicare Part D. *Am J Managed Care.* 2011;17 Suppl 12:S.

[14] National Science Foundation, National Science Board, 2018. Available at: https://www.nsf.gov/statistics/2018/nsb20181/data/appendix; TEConomy for PhRMA, analysis of Pitchbook data. April 2018. Companies and Deals. PitchBook Data Inc.; European Commission. The 2016 EU industrial R&D Investment Scoreboard, 2016. Available at: http://iri.jrc.ec.europa.eu/scoreboard16.html

[15] See, e.g., Zhang Y, Hana CH, Hernandez I. Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries. *J Manag Care Spec Pharm.* 2017;23(2):247-254.

[16] PhRMA analysis of IQVIA data.

[17] Alzheimer's Association. Changing the trajectory of Alzheimer's disease: how a treatment by 2025 saves lives and dollars. 2015. Available at: https://www.alz.org/help-support/resources/publications/trajectory_report

[18] IMS Institute for Healthcare Informatics. Avoidable costs in U.S. healthcare: the $200 billion opportunity from using medicines more responsibly. June 2013.

[19] Altarum Institute. Projections of the prescription drug share of national health expenditures including non-retail. May 2018.

2015.[20] Generic manufacturers and intermediaries in the pharmaceutical supply chain retain the other half of spending on medicines.[21]

The ability to bring important medical advances to patients while holding medicines' share of health spending nearly constant is made possible by the highly competitive structure of the U.S. market. Fierce market competition among medicines achieves sizable discounts from brand manufacturers and shifts utilization from brand drugs to generics and biosimilars.[22] As a result of these forces:

- In 2017, total net drug spending grew just 0.6 percent, and prices for brand-name medicines increased 1.9 percent after discounts and rebates, even as many new treatments reached patients.[23]

- In 7 of the last 10 years, net retail prescription drug costs grew more slowly than total health care costs—and, on average, spending for retail prescription drugs has grown more slowly than growth for other major types of care, and more slowly than total health expenditures.[24]

- In 2017, 90 percent of all prescriptions filled were generics, up from 80 percent in 2011.[25] IQVIA projects U.S. brand sales will be reduced by $105 billion due to competition from generics and biosimilars between 2018 and 2022.[26] There is no similar type of cost containment for other health care services.

While growth of net spending on acquiring medicines from manufacturers has been lower than other health care costs, and was lower than inflation in 2017,[27] multiple data sources show that (1) growth in manufacturer rebates and discounts that lower payers' cost of acquiring medicines has

[20] Berkley Research Group, The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders. January 2017. Available at: http://www.thinkbrg.com/newsroom-publications-vandervelde-blalock-phrma.html

[21] In some instances, middlemen who played no role in a medicine's development and took no risk in purchasing it are paid more than the company that developed a medicine through years of research and clinical trials. A recent study reports that for 20 medicines administered in hospital outpatient departments commercial insurers pay hospitals up to three and a half times the medicines' acquisition cost. The Moran Company. Hospital Charges and Reimbursement for Drugs: Analysis of Markups Relative to Acquisition Cost. October 2017. While these markups are recorded as spending on drugs that typically is attributed to manufacturers in policy debates, in fact this is spending that is determined by and goes to middlemen, not spending that either goes to or is determined by biopharmaceutical companies.

[22] Generics and biosimilars are a form of cost containment that applies only to the biopharma sector. For instance, the price of one widely used statin dropped by about 92 percent from 2005 to 2013 when generic versions came to market. Over the same period, the average charge for percutaneous transluminal coronary angioplasty, a surgical procedure to treat cardiovascular disease, increased by almost 66 percent.

[23] IQVIA. 2017 Medicine Use and Spending. April 2018.

[24] PhRMA analysis of CMS. NHE 2016. December 2017.

[25] IQVIA. 2017 Medicine Use and Spending. April 2018.

[26] Id.

[27] PhRMA analysis of CMS. NHE 2016. December 2017.; IQVIA. 2017 Medicine Use and Spending. April 2018.

been substantial and (2) an increasing share of these discounts and rebates are retained by intermediaries involved in distributing and paying for prescription medicines:

- Compared to list price growth, rebates and other discounts reduced average net price growth for brand medicines by nearly three-quarters in 2017.[28]

- The distribution chain accounts for a significant share of prescription drug spending, retaining more than one third of spending on brand medicines in 2015.[29]

- Additionally, manufacturers' gross-to-net reductions[30] have more than doubled since 2012, totaling more than $150 billion in 2017.[31]

This ongoing growth in the difference between the list and the actual net prices paid, combined with a shift of funds to the supply chain, can adversely affect patients using medicines. Health plans typically base patients cost sharing at the pharmacy counter on a medicine's list price rather than the lower discounted price paid by the plan when patients face deductibles or coinsurance. This contrasts with out-of-pocket spending for doctors and hospitals, which is based on negotiated rates. Notably, more than half of commercially insured patients' out-of-pocket spending for brand medicines is based on list price.[32] We are encouraged that some payers recognize that sharing savings with patients at the pharmacy counter is a "best practice"[33] and have undertaken initiatives to do so, although to date they affect only a small share of patients. These changes should not, however, be paired with changes that increase the reliance on coinsurance, thereby reducing the potential for patient savings.

[28] IQVIA. 2017 Medicine Use and Spending. April 2018.
[29] Vandervelde A, Blalock E; Berkeley Research Group. The pharmaceutical supply chain: gross drug expenditures realized by stakeholders. 2017. Available at: http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf
[30] Defined as "rebates, off-invoice discounts, copay assistance, price concessions, and other reductions like distribution fees, product returns, the 340B Drug Pricing Program, and more." (Drug Channels Institute)
[31] Fein AJ; Drug Channels Institute. The gross-to-net bubble topped $150 billion in 2017. April 2018.
[32] PhRMA. Commercially-insured patients pay undiscounted list prices for one in five brand prescriptions, accounting for half of out-of-pocket spending on brand medicines. Available at: http://www.phrma.org/report/commercially-insured-patients-pay-undiscounted-list-prices-for-one-in-five-brand-prescriptions-accounting-for-half-of-out-of-pocket-spending-brand-medicines
[33] Seeking Alpha. Express Scripts Holding (ESRX) Q4 2016 Results – Earnings Call Transcript. February 15, 2017. Available at: http://seekingalpha.com/article/4046365-express-scripts-holding-esrx-q4-2016-results-earnings-call-transcript; Seeking Alpha. CVS Health (CVS) Q4 2016 Results – Earnings Call Transcript. February 9, 2017. Available at: http://seekingalpha.com/article/4044425-cvs-health-cvs-q4-2016-results-earnings-call-transcript?part=single

SECTION II: REBATES (RFI p. 22698)

The RFI correctly identifies a clear problem: while the current system of rebates, list prices, and net prices has constrained overall drug spending, it could work better for patients, payers, and manufacturers. Reforming this system will not be easy and we commend the Trump Administration for taking on this challenge. The drug channel, which is characterized by a complex system of money flows and proprietary contracts, has evolved over time with changes in drug benefits as well as changes in the role and structure of PBMs. Government reforms to this system should be made only after careful consideration of incentives the current system has created, which now appear to favor brand medicines with high list prices and large rebates over lower cost brand medicines. We recommend developing government policies that move to a system that either prohibits or discourages entities in the supply chain from retaining compensation based on a percentage of the list price of the drug. Given the complexity of the current system, transformational change is unlikely to occur immediately and major reforms will need to be phased in over time. A transition period will be necessary given the current complex set of contractual relationships between private entities in the supply chain.[34] Even so, moving to a system where the supply chain does not retain compensation based on a percentage of the list price may be simpler to operationalize than government policies aimed at a wholesale move away from rebates.

REBATES: Role of Rebates in the Current System (RFI p. 22698)

Rebates are the primary lever currently used to enable differential and competitive pricing for pharmaceuticals in the commercial market and in government programs.[35] Market observers note that with differential pricing, manufacturers may (in accordance with applicable laws) adjust the cost of a medicine to a payer based on a wide range of factors, such as formulary access, number of covered lives, patient adherence, and the value delivered by the medicine to patients and payers alike.[36] According to economic theory, a firm's ability to offer different prices to different purchasers typically enhances consumer wellbeing, particularly when it facilitates the expansion of service or increases the output of a good or service.[37] As an example, passengers sitting near each other on an airplane typically pay different prices for their flight, depending on the conditions under which they made the purchase, and on the value they derive from the flight. A business traveler that needs to be in a given location at a specific time will typically be charged more than a leisure traveler with more flexibility in his or her schedule. The airline's ability to

[34] For an overview of these complex relationships see Fein A. Follow the Dollar: The U.S. Pharmacy Distribution and Reimbursement System. *Drug Channels*. Feb. 3, 2016. Available at: https://www.drugchannels.net/2016/02/follow-dollar-us-pharmacy-distribution.html
[35] Vandervelde A, Blalock E; Berkeley Research Group. The pharmaceutical supply chain: gross drug expenditures realized by stakeholders. 2017.
[36] Greenwalt L. Declining Value of Rebate Efficiency. Amundsen Consulting. Available at: https://www.marketingweb.iqvia.com/rebate-efficiency-payer-access/
[37] Varian HR. (2007). Handbook of Industrial Organization, Chapter 8: Price Discrimination. Armstrong M, Porter R (Ed.). North Holland: Elsevier B.V.; Carlton D, Perloff J. (2000). Modern Industrial Organizations (3rd ed.). Reading, MA: Addison-Wesley.

charge different fares depending on the conditions of purchase facilitates the expansion of travel opportunities.

Differential pricing for medicines facilitates the expansion of sales to customers beyond those that might be willing (or able) to purchase them if payers were prevented from negotiating discounts based on the conditions of consumer demand for access to a wide range of medicines. In many cases, differential pricing is the result of robust negotiation between PBMs and manufacturers, who may negotiate favorable formulary placement and other coverage terms in exchange for steeper discounts.[38] Robust negotiation can thus expand access for patients, and as discussed earlier in this letter, has also helped constrain overall spending on medicines in the U.S. In fact, total drug spending grew just 0.6 percent in 2017 and prices for brand-name medicines increased 1.9 percent after discounts and rebates, even as many new treatments reached patients.[39] In contrast, in 2017 the consumer price index for medical care overall increased by 2.5 percent.[40]

Current structure allows PBMs to retain significant share of rebates and other price concessions

While the current system has helped to control overall spending and allows for differential pricing, the growth in rebates may have created incentives for payers to favor medicines that carry higher rebates,[41] thus leading to an environment in which list prices are rising rapidly even as net prices have held steady.[42] This may be the result of the types of arrangements PBMs commonly negotiate with their health plan and employer clients, which allow PBMs to retain a portion of negotiated rebates and other price concessions as compensation for their services.[43] Because the portion of the rebate retained by the PBM, as well as the administrative fees they charge their clients, may be based on a percentage of a medicine's list price, PBMs may have incentives to establish formularies that favor medicines with high list prices and large rebates over lower cost medicines.[44] Under the current system, if a manufacturer were to independently lower the list price of a medicine and abandon the trend towards higher and higher rebates, the revenues PBMs earn on that medicine would likely decline.[45] Since PBMs can influence medicine affordability and availability through their decisions about formulary coverage,

[38] Roehrig, C. The Impact of Prescription Drug Rebates on Health Plans and Consumers. April 2018. Available at: https://altarum.org/publications/the-impact-of-prescription-drug-rebates-on-health-plans-and-consumers
[39] IQVIA. 2017 Medicine Use and Spending. April 2018.
[40] Bureau of Labor Statistics. Consumer price index—all urban consumers, history table. Available at: https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201801.pdf
[41] Hoey DB. Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. November 2016. Available at: https://www.statnews.com/2016/11/28/rebates-pharmacy-benefit-managers-contribute-high-drug-prices/
[42] IQVIA. Understanding the Drivers of Drug Expenditure in the U.S. September 2017.
[43] Roehrig C. The Impact of Prescription Drug Rebates on Health Plans and Consumers. April 2018.
[44] Hoey DB. Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. November 2016.
[45] Johnson CY. In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *The Washington Post.* June 26, 2018. Available at: https://www.washingtonpost.com/news/wonk/wp/2018/06/25/in-may-trump-predicted-the-pharmaceutical-industry-would-start-cutting-prices-in-two-weeks-its-been-three/?noredirect=on&utm_term=.82a4ec23bbb9

utilization management, and formulary tier placement (which establishes cost sharing), a hypothetical manufacturer's unilateral decision to lower list price could result in a significant reduction in formulary access for that manufacturer and significantly impact affordability and access for patients.[46] This threat has been identified by Secretary Azar as an impediment to the Administration's goal of bringing list prices down.[47]

The complex set of rebates and fees can make it difficult for payers to assess whether they are fully benefiting from all price concessions that PBMs negotiate. While a share of rebates is generally passed on to plan sponsors, smaller employers and health plans may not benefit from the price concessions negotiated by the PBM, particularly if the PBM decides not to classify certain fees or other concessions as 'rebates.' For example, one benefits consultant has observed that PBMs are increasingly changing the contractual definition of rebates to exclude certain administrative fees, allowing the PBM to retain these payments rather than passing them back to the plan sponsor. These administrative fees can be as high as 25 to 30 percent of the total amount paid in rebates and fees by the manufacturer to the PBM and in some cases may not be reported to the plan sponsor by the PBM.[48] Lack of transparency over PBM-retained fees in contracts between employers and PBMs has led many plan sponsors to question the share of rebate savings being passed through, how much the PBM is retaining for administrative fees, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates.[49]

Many patients do not directly benefit from significant price negotiations in the market today

Currently, savings generated from confidential price negotiations between manufacturers and payers do not always make their way directly to patients facing high cost sharing for their medicines. Unlike care received at an in-network hospital or physician's office, health plans typically base cost sharing for prescriptions filled in the deductible or with coinsurance on undiscounted list prices, rather than on prices that reflect negotiated rebates and discounts. Enrollment in high-deductible health plans and use of coinsurance for prescription medicines has grown sharply in recent years, increasingly exposing patients to high out-of-pocket costs based on undiscounted prices, creating scenarios in which medicines appear to be more costly than other

[46] Nisen M. Pharma's Quieter Price War Continues. *Bloomberg Businessweek*. August 3, 2017. Available at: https://www.bloomberg.com/news/articles/2017-08-03/pbm-formularies-quieter-drug-price-war-continues

[47] Alex Azar, HHS, Testimony Before the United States Senate Committee on Finance: Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market, June 26, 2018.; Alex Azar, HHS, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Full Committee Hearing: The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices, June 12, 2018.

[48] Dross D. Will Point-of-Sale Rebates Disrupt the PBM Business? *Mercer*. July 31, 2017. Available at: https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html

[49] Midwestern Business Group on Health. Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies. September 2017. Available at: https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf

health care services. High cost sharing is a cause for concern, as a substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.[50]

Over the past 10 years, patient cost sharing has risen substantially faster than health plan costs. For workers with employer-sponsored health insurance, out-of-pocket spending for deductible and coinsurance payments increased by 230 percent and 89 percent, respectively, compared to a 56 percent increase in payments by health plans.[51] Whereas cost sharing for prescription medicines once consisted almost entirely of copays, use of deductibles and coinsurance has increased rapidly, particularly for new medicines that represent the most innovative therapies and treat the sickest patients. The share of patient out-of-pocket drug spending represented by coinsurance more than doubled over the past ten years in the commercial market, while the share accounted for by deductibles tripled.[52]

The increased share of total medication costs that patients are paying through deductibles and coinsurance exposes patients to undiscounted list prices and creates affordability challenges for many patients.[53] Patients enrolled in high-deductible health plans may be asked to pay thousands of dollars out of pocket before any of their prescriptions are covered, while patients with coinsurance are responsible for as much as 30 to 40 percent of the total cost of their medicines, reducing adherence to needed therapy.[54] Again, in sharp contrast, patients typically get access to payer-negotiated discounts on in-network hospital and physician office visits when they are in the deductible or required to pay coinsurance.

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[50] IMS Institute for Healthcare Informatics. Emergency and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans. September 2015; Doshi JA, Li P, Huo H, et al. High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. *American Journal of Managed Care*. 2016;22(4 Suppl):S78-S86; Brot-Goldberg ZC, Chandra A, Handel BR, et al. What Does A Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics. NBER Working Paper 21632, October 2015; Eaddy MT, Cook CL, O'Day K, et al. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *Pharmacy & Therapeutics*. 2012;37(1):45-55.

[51] Claxton G, Levitt L, Long M, et al. Increases in Cost-Sharing Payments Have Far Outpaced Wage Growth. Peterson-Kaiser Health System Tracker. October 4, 2017. Available at: https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start

[52] Claxton G, Levitt L, Long M; Kaiser Family Foundation. Payments for Cost Sharing Increasing Rapidly Over Time. Peterson-Kaiser Health System Tracker. April 2016. Available at: http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/

[53] Claxton G, Levitt L, Long M; Kaiser Family Foundation. Increases in cost-sharing payments continue to outpace wage growth. Peterson-Kaiser Health System Tracker. July 2018. Available at: https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/

[54] Sky-High Deductibles Broke the U.S. Health Insurance System. *Bloomberg.* June 2018. Available at: https://www.bloomberg.com/news/features/2018-06-26/sky-high-deductibles-broke-the-u-s-health-insurance-system; 2017 Employer Health Benefits Survey. Kaiser Family Foundation. September 2017. Available at: https://www.kff.org/report-section/ehbs-2017-section-9-prescription-drug-benefits/

Payers themselves have begun to recognize that using the undiscounted price of a medicine to set cost sharing is problematic for patients: recent statements from the two largest PBMs note that high deductibles for medicines put patients in a "very difficult position" and indicate that sharing rebate savings directly with patients should be considered as a "best practice."[55] In addition, several private health plans and PBMs have already announced that they plan to offer point-of-sale rebate sharing to their commercial clients, indicating that the technical capacity exists to share these savings and the operational challenges are not insurmountable.[56] These changes should not, however, be paired with changes that increase the reliance on coinsurance, thereby reducing the potential for patient savings.

Current structure results in patients subsidizing plan costs

Due to the growing gap between list and net prices, patients' cost sharing for medicines is increasingly based on prices that do not reflect plan sponsors' actual costs. For example, market analysts report that negotiated discounts and rebates can lower the net price of insulin by up to 50 to 70 percent,[57] yet health plans require patients with deductibles to pay the full undiscounted price. As a result, a patient in a high-deductible health plan who pays the list price each month for insulin may be paying hundreds—or even thousands—more annually than their insurer.

As a hypothetical example, imagine a patient enrolled in a high-deductible health plan who takes an insulin with a list price of $400. The patient's insurer has negotiated a 65 percent rebate, which substantially reduces the cost to the plan. However, because the patient has not yet met his deductible, his insurer does not provide any coverage for his prescription, and the patient's bill reflects the insulin's full cost of $400. Despite paying nothing for this patient's insulin, the insurer still collects the rebate, earning over $200.[58]

Unfortunately, as the number of patients with deductibles and coinsurance rises, this situation is becoming more common. Analysis by Amundsen Consulting shows that more than 55 percent of patients' out-of-pocket spending for brand medicines is based on the list price of the medicine, even though their health insurer may be receiving a steep discount.[59]

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[55] Seeking Alpha. Express Scripts Holding (ESRX) Q4 2016 Results – Earnings Call Transcript. February 15, 2017.; Seeking Alpha. CVS Health (CVS) Q4 2016 Results – Earnings Call Transcript. February 9, 2017.

[56] Aetna to Offer Point-of-Sale Pharmacy Rebates to Three Million Customers. *Managed Care*, March 27, 2018; Johnson CY. UnitedHealthcare Will Provide Drug Rebates Directly to Members in Some Plans. *The Washington Post*, March 6, 2018.

[57] Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*. June 29, 2017. Available at: https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices; Langreth R, Keller M, Cannon C. Decoding Big Pharma's Secret Drug Pricing Practices. *Bloomberg.* June 29, 2016. Available at: https://www.bloomberg.com/graphics/2016-drug-prices.; SSR Health. US Brand Net Pricing Growth 0.2% in 3Q17. December 18, 2017.

[58] PhRMA. Follow the Dollar. November 2017. Available at: http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf

[59] IQVIA. Patient Affordability Part One: The Implications of Changing Benefit Designs and High Cost-Sharing. May 2018. Available at: https://www.iqvia.com/locations/united-states/patient-affordability-part-one

Health plans typically use some portion of negotiated rebates to reduce premiums for all enrollees, rather than to directly lower costs for patients facing high cost sharing due to deductibles and coinsurance. According to one actuarial firm, this results in a system of "reverse insurance," whereby payers require patients with high drug expenditures to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.[60] Asking sicker patients with high drug costs to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work.

Certain innovative contracting arrangements tied to clinical outcomes may require rebates

We support HHS' efforts to encourage more innovative contracting arrangements, such as voluntary value-based arrangements between payers and manufacturers.[61] It is important that efforts to reform government rules to address misaligned incentives be pursued in tandem with efforts to promote new approaches to value-based arrangements. In particular, arrangements in which price negotiations are tied to clinical outcomes would require the ability to provide a price concession after a drug is purchased. For example, a hypothetical manufacturer may independently agree to vary the final price of a medicine, so that a payer pays less if patients taking the medicine do not achieve certain health outcomes. In such a case, the manufacturer would adjust the final price paid by the payer using a rebate. As another example, a manufacturer might independently agree to provide an unlimited amount of a medicine to a payer for no more than a certain annual payment limit. This might also be most easily implemented through a rebate. In this case, the payer would continue to pay the pharmacy the usual price for the medicine, but once the agreed upon maximum payment amount is reached, the manufacturer would rebate back the full price of the medicine. Given the potential of such arrangements to drive improved efficiency for the health care system, reforms should allow for continued use of rebates or similar mechanisms in these circumstances.

REBATES: Principles for Government Reform of the Drug Distribution and Payment System (RFI p. 22694)

For the reasons described above, we share the concerns raised in the RFI that the current system's incentives appear to favor high list prices with rebates instead of focusing on the net price.[62] Changes are needed to ensure that the system works better for patients and does not leave them with artificially high out-of-pocket costs.

[60] Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017. Available at: http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf
[61] FDA. Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to advance medical product communications to support drug competition and value-based health care. June 12, 2018.
[62] RFI p. 22694.

Below we suggest several goals that should guide any future government reform.

1. **Patients should benefit directly at the point of sale from negotiated rebates and other price concessions.** Patients in the deductible or facing coinsurance should pay cost sharing that reflects the steep discounts that many manufacturers provide to PBMs and payers. Their cost sharing should not be calculated based off the list price of the drug. Policy changes made to move towards providing this benefit to patients should be executed in a way that is cognizant of the benefits of keeping proprietary pricing information confidential, which the Federal Trade Commission has identified as important to the effective functioning of competitive markets.[63] The confidentiality of those agreements allows for vigorous negotiations that has helped hold net prices steady.[64]

2. **Rebates should not be allocated solely to premiums.** In both Medicare Part D and most commercial coverage, rebate dollars are typically directed to lowering premiums instead of reducing cost sharing for patients who use prescription medicines. This means that patients taking medicines with large rebates are subsidizing coverage for other beneficiaries—which is effectively a tax on the sick.[65] Government policies should encourage rebate dollars to flow back to patients taking prescription drugs, either directly through rebate pass through (as discussed directly above) or through other means of enhancing the level of coverage provided by the prescription drug benefit.

3. **Payers should have sufficient tools and information to ensure PBM incentives are well aligned with plan interests.** Some PBM contracts with employers and group health plans offer little opportunity for assessing whether the PBMs incentives are well aligned with payer priorities and responsibilities to plan enrollees. For example, despite regulatory requirements, employers may not know the share of savings being retained by PBMs as administrative fees, or whether the PBM is sharing the benefit of other types of price concessions with employers, such as savings from price protection rebates.[66] Some contracts provide limited audit rights for payers. In other cases, payers simply may not know the specific questions to ask. Additional education for employers, such as sharing of best practices for engaging with PBMs, could help put payers on stronger footing when negotiating with PBMs. This could promote greater supply chain efficiency and help reduce overall spending on prescription drugs.

4. **Underlying incentives for compensation arrangements should discourage payment tied to list price.** Currently, PBMs, wholesalers, and pharmacies are often compensated as a percentage of list price, or in the case of PBMs, as a percent of rebates that are

[63] Koslov T, Jex E. Price Transparency or TMI? Federal Trade Commission, July 2, 2015.
[64] IQVIA. 2017 Medicine Use and Spending. April 2018.
[65] Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017. Available at: http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf
[66] Midwestern Business Group on Health. Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies. September 2017.

themselves a percentage of the list price. Reforms to the current system should be made with an aim to move toward a compensation structure that is not linked to list price. As policymakers attempt to inject payment for value into all parts of our health care system, all participants in the drug supply chain can and should be paid based on the value they provide. As each of these participants—wholesalers, pharmacies, and providers of PBM services—deliver substantial value, they should be entitled to compensation based on that value. However, it does not make sense that their compensation is always, or even in most cases, proportional to the list price of a drug.

5. **Medicare Part D reforms must be consistent with the noninterference clause.** Changes to the Part D program must not violate the noninterference clause in the Part D statute (Section 1860D-11 (i)(1) of the Social Security Act), which states that the Secretary may not "interfere with the negotiations between drug manufacturers and pharmacies and [stand-alone prescription drug plans (PDP)] sponsors."

REBATES: Public Policy Changes to Improve the Current System (RFI p. 22698)

PhRMA recognizes that the current system needs to evolve and has advocated for several policy changes that would put the current system on a more sustainable path that would be better aligned with the needs of patients and payers.

We note that the current system is complex and care must be taken to avoid unintended consequences from government reform. It is important to recognize that transformational change of the type the Administration is proposing will take time and that reforms need to occur in a step-wise manner to avoid system disruption that would jeopardize patient care. Given the significance of the impact of these transformational changes to the system and to patients, it is critical that specific policy proposals be developed with engagement and feedback from all stakeholders. We also recognize that there may be other approaches that would be consistent with the principles outlined above, and we welcome other ideas and look forward to working with the Administration to improve the drug payment and distribution system.

Passing through rebates at the point of sale

The Administration could immediately lower out-of-pocket costs for millions of beneficiaries by requiring Part D plans to apply a substantial portion of negotiated rebates to reduce cost sharing at the point of sale. This government policy change is discussed in more detail in the Medicare Part D section of our comments. Several private insurers and PBMs have announced plans to offer point-of-sale rebate sharing to their commercial clients, signifying that the infrastructure and the capacity to implement this policy already exist.[67] Analysis that accounts for the potential anticipated behavioral changes from adoption of this policy shows that passing through of rebates

[67] Aetna to Offer Point-of-Sale Pharmacy Rebates to Three Million Customers. *Managed Care*. March 27, 2018; Johnson CY. UnitedHealthcare Will Provide Drug Rebates Directly to Members in Some Plans. *The Washington Post*, March 6, 2018.

could save the federal government money.[68] It could also improve adherence for conditions like diabetes, thereby generating savings in other parts of Medicare.[69] Separately, we also urge the Trump Administration to consider government reforms to encourage further take-up of rebate pass through in the commercial market. Actuarial research of the impact of rebate pass through in the commercial market has found that sharing negotiated savings could save certain commercially insured patients enrolled in plans with high deductibles and coinsurance between $145 and $800 annually, while increasing premiums by 1 percent or less.[70]

Increasing PBM transparency and accountability

The RFI notes the Administration's focus on incentives for intermediaries in the drug payment channel, such as PBMs. Specifically, the RFI asks whether PBMs should be obligated to act solely in the interest of the entity for which they manage pharmaceutical benefits, and what effect this "fiduciary duty" would have on PBM's ability to negotiate drug prices. Fiduciary duty is a concept under Employee Retirement Income Security Act of 1974 (ERISA)—as regulated by the Department of Labor (DOL)—that is linked to the functions an entity performs with respect to a group health plan. For example, an employer plan sponsor is often a fiduciary of its group health plan because it exercises discretion or control over administering the plan.[71] Fiduciary duty may be one potential option to address PBM incentives, depending on implementation. However, the Administration should consider a range of federal policy options that could help drive market-based approaches to greater efficiency and better alignment of PBM incentives with payer interests. We recommend that HHS work with DOL to explore opportunities to increase PBM accountability to their plan sponsors in the commercial market, and that HHS consider additional opportunities to increase accountability in Medicare Part D. For instance, in the employer market, the Administration could consider increasing PBM reporting requirements to include certain information about their compensation structure to group health plan sponsors.[72] Similarly, in Medicare Part D, CMS can use its authority to expound upon what types of arrangements between Part D plan sponsors and first-tier entities (such as PBMs) are "acceptable to CMS."[73] We support the Administration's efforts to ensure that the drug payment system is efficient and effective for plan sponsors and patients across markets. We recommend that the agency engage

[68] Milliman. Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates. January 2018. Available at: http://www.phrma.org/report/reducing-part-d-beneficiary-costs-through-point-of-sale-rebates
[69] IHS Markit. Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare. May 14, 2018.
[70] Bunger A, Gomberg J, Petroske J. Sharing Rebates May Lower Patient Costs and Likely Has Minimal Impact on Premiums. October 12, 2017. Available at: http://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market
[71] Service providers, such as PBMs, have typically not been viewed as fiduciaries, but instead as parties in interest subject to certain arrangements with plans.
[72] The 2014 ERISA Advisory Council recommended that DOL consider extending regulations to health and welfare plan arrangements with PBMs, and thereby deem such arrangements "reasonable" only where PBMs disclose direct and indirect compensation. PBM Compensation and Fee Disclosure. *Advisory Council on Employee Welfare and Pension Benefit Plans Report*. November 2014.
[73] Part D regulations define "first-tier entity" as "any party that enters into a written arrangement, *acceptable to CMS*, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D." 42 CFR § 423.501 (emphasis added).

with all relevant stakeholders as specific proposals are developed to more fully assess the full implications of any particular approach.

Delinking supply chain payment from list price

The questions in the RFI suggest that HHS is considering how rebates may be contributing to the rise in list prices. As discussed above, currently all intermediaries in the pharmaceutical supply chain profit from higher list prices, while patients are often left paying cost sharing based on the higher list price.[74] HHS has asserted that these incentives have contributed to the rise in list prices even as net prices have remained stable.[75] PhRMA shares HHS' concerns about incentives created by the current system and believes reforms focused on delinking payment for intermediaries from the list price may be simpler to operationalize than government policies aimed at a wholesale move away from rebates.

Instead of enacting policies that would eliminate rebates altogether, HHS could focus on reforms to either prohibit or discourage entities in the supply chain from receiving fees for services based on a percentage of the list price of a drug. For example, regulatory reforms could require PBMs, wholesalers and pharmacies be paid a flat fee. This shift could have several advantages. It could help make supply chain intermediaries less sensitive to changes in list prices and thus could help realize HHS' goal of lowering list prices.[76] PhRMA, as a trade association, is not involved in and cannot comment on the individual pricing decision of our members. HHS has, however, noted its concerns that the current system—in which robustly negotiated rebates are tied to a percentage of list price—deters decreases in list price.[77] In a recent article, Adam Fein, an expert on the pharmaceutical supply chain, stated that it would be "difficult, perhaps impossible," to lower list prices because "cutting the list price means wholesalers make less money, pharmacies make less money, PBMs make less money and payers get fewer rebate dollars."[78] Government reforms that support a move away from supply chain payment based on a percentage of list price could also push more of the rebate through to the plan sponsors. Plan sponsors should then use that savings to pass through a share of the rebate and devote some of the remaining money towards lower prescription drug cost sharing more generally.

[74] PhRMA. Commercially-insured patients pay undiscounted list prices for one in five brand prescriptions, accounting for half of out-of-pocket spending on brand medicines. 2017. Available at: https://www.phrma.org/report/commercially-insured-patients-pay-undiscounted-list-prices-for-one-in-five-brand-prescriptions-accounting-for-half-of-out-of-pocket-spending-brand-medicines
[75] RFI p. 22698.; IQVIA Institute for Human Data Science. Understanding the Drivers of Drug Expenditure in the U.S. September 2017.
[76] RFI p. 22698.
[77] Alex Azar, HHS, Testimony Before the United States Senate Committee on Finance: Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market, June 26, 2018.; Alex Azar, HHS, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Full Committee Hearing: The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices, June 12, 2018.
[78] Johnson C. In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *Washington Post.* June 25, 2018.

REBATES: The Role of the Anti-Kickback Statute Safe Harbors (RFI p. 22698)

Any changes to the Anti-Kickback Statute safe harbors would have to be approached with caution

The RFI raises the possibility of revising the discount safe harbor to "restrict the use of rebates and reduce the effect of rebates on list prices."[79] However, the discount safe harbor is limited as a tool to address the misaligned incentives in the drug channel.

First, and most importantly, the Anti-Kickback Statute applies only to Federal health care programs.[80] Changes to the discount safe harbor would not directly impact the commercial market. As noted above, the need for government action to reform the privately-negotiated rebate system spans both the commercial market and Medicare Part D.

Second, the discount safe harbor is just one part of a complex statutory and regulatory framework. The Federal Anti-Kickback Statute is a criminal law that broadly prohibits the knowing and willful offer, solicitation, payment, or receipt of anything of value to induce the purchase of an item or service paid for by a federal health care program.[81] Recognizing that, by its terms, the statute was overly broad, Congress enacted ten statutory exceptions (including a broad exception for discounts) and authorized the promulgation of additional regulatory safe harbors. Currently, there are 28 such safe harbors, including separate safe harbors for discounts and rebates, administrative fees, service fees, and discounts to certain managed care organizations (MCOs), among others. Thus, the discount safe harbor is just one of many available safe harbors that may apply to the complex set of arrangements within the drug channel.[82]

As noted above, we encourage the Administration to think holistically about the complicated system of money flows and contracts within the system, not simply about rebates. Moreover, the administration must recognize that changes to that complicated system cannot be accomplished effectively by immediately disrupting that system. To that end, any changes to the Anti-Kickback Statute safe harbors should be undertaken with caution, and only after careful consideration of the following principles. Consider whether such changes:

1. **Provide clarity on all drug channel payments**. Because PBMs negotiate rebates, administrative fees, and other service fee arrangements, they may rely on a variety of safe harbors or statutory exceptions for protection. If safe harbor protection in one category were removed, they could conceivably shift arrangements from one category to another in order to continue to extract payment and attempt to maintain safe harbor protection.[83]

[79] RFI p. 22698.
[80] 42 U.S.C. § 1320a-7b(b).
[81] 42 U.S.C. § 1320a-7b(b).
[82] Moreover, failure to satisfy the requirements of a safe harbor does not render an arrangement illegal; rather, these arrangements are subject to a case-by-case evaluation. 64 FR 63518, 63546 (Nov. 19, 1999).
[83] In a parallel example of the shifting between rebates and administrative fees, one benefits consultant has observed that PBMs are increasingly changing the contractual definition of rebates to exclude certain administrative fees, allowing the PBM to retain these payments rather than passing them back to the plan sponsor. Dross D. Will Point-of-Sale Rebates Disrupt the PBM Business? *Mercer*. July 31, 2017.

Stakeholders therefore need clear guidance regarding all channel arrangements including administrative fees and service fees, not rebates alone. Moreover, as described above, we suggest that any reforms of the safe harbors be undertaken with the goal of delinking compensation based on list price (including both fees and rebates) throughout the supply chain, and not focus solely on rebates.

2. **Sufficiently encourage PBM compliance**. Because lack of safe harbor protection does not necessarily render an arrangement illegal, and large PBMs both have incredible market power and may not have been subject to the same level of enforcement scrutiny historically as other stakeholders, it is critical that the Administration take steps to ensure PBM compliance, such as enhanced oversight of PBMs, penalties for PBM non-compliance, and a clear articulation of the Administration's expectation that PBMs comply with the terms of any new guidance.

3. **Provide ample time for implementation**. Finally, meaningful change will require renegotiation of contracts throughout the drug channel. Because the Anti-Kickback Statute is a criminal law, with criminal penalties, any policy attempting to use the safe harbors as a lever should recognize the magnitude of this change and provide ample time for contract renegotiation and implementation—for example, two plan years or such longer period as may be required for expiration of existing contracts.

SECTION III: DRUG PRICING DEMONSTRATIONS (RFI p. 22694)

PhRMA recognizes HHS's interest in developing "demonstration projects to test innovative ways to encourage value-based care and lower drug prices." As HHS works to develop directions for CMS, it will be important to consider that drugs are a small, stable share of overall health care spending, which lead to savings in other parts of the health care system, and to focus on holistic approaches to improving cost and value of care. Total retail and non-retail drug spending is expected to remain constant at about 14 percent of total health care expenditures from 2015 through 2025, even as many new treatments reach patients.[84]

It will also be important to establish in rulemaking the appropriate role for CMMI, and to recognize which demonstrations can be successfully and appropriately implemented by CMMI, given its authority. CMMI should not be used to undermine key patient protections and important structural elements of public programs. In addition, CMMI is not the ideal place for tests of value-based arrangements, as CMMI does not have the necessary authority to address key barriers that can impede these arrangements. Instead, as discussed below, CMS should provide regulatory relief from the barriers to value-based arrangements—including lack of clarity in Federal price

Available at: https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html

[84] CMS. NHE Data.; Altarum Institute, A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail. October 2014, addendum update May 2017.

reporting metrics, and lack of clear protection for value-based arrangements under the Anti-Kickback Statute.[85]

Prioritize holistic models that address broader cost drivers and quality of care deficits

The goal of payment and delivery reforms should be to improve care for patients, first and foremost. This includes ensuring that patients are well-informed about their health care options, have access to the full range of treatment options, and are engaged in their treatment choices. It is also important to recognize that medicines are a small share of overall health care spending. Total retail and non-retail drug spending grew just 0.6 percent in 2017[86] and is expected to remain constant at about 14 percent of total health care expenditures from 2015 through 2025,[87] even as many new treatments reach patients. Because holistic models can focus on overall health care spending, including administrative costs, they offer a greater opportunity for meaningful savings.

Holistic models allow medicines to demonstrate their value through offsets in other parts of the health care system, which are generally a result of better patient outcomes. For example, patients who were adherent to prescribed medicines for four chronic conditions (heart failure, hypertension, diabetes and dyslipidemia) exhibited savings of $3 to $10 in non-drug spending for each additional dollar spent on medicines, due to fewer emergency department visits and inpatient hospital days.[88] Similarly, patients with rheumatoid arthritis (RA) who responded to tumor necrosis factor inhibitors had lower all-cause medical, pharmacy, and total costs (excluding biologics) up to 3 years from initiation of therapy.[89] As CMS considers new models, it is important to recognize and include the role that prescription drugs can play in improving quality of life for beneficiaries and reducing system-wide costs.

It is also important to ensure that reforms do not inadvertently drive provider consolidation. As the CMS Administrator herself and other leaders within the Department have noted, "The complexity of many of the current [CMMI] models might have encouraged consolidation within the health-care system, leading to fewer choices for patients."[90] The impact assessment from the Merit-Based Incentive Payment System (MIPS) proposed rule also shows how value-based payment, if not properly constructed, can have a disproportionately negatively impact on smaller practices. CMS estimated that 87.0 percent of solo practitioners and 69.9 percent of 2-9 clinician groups would have a negative MIPS adjustment, compared to 18.3 percent of groups

[85] Detail about how to address the barriers to value-based arrangements is available in the following section: VALUE-BASED ARRANGEMENTS: Value-Based Arrangements and Price Reporting.
[86] IQVIA. 2017 Medicine Use and Spending. April 2018.
[87] CMS. NHE Data.; Altarum Institute. Projections of the prescription drug share of national health expenditures including non-retail. May 2018.
[88] Roebuck MC, et al. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health Affairs.* 2011;30(1):91-9
[89] Grabner M, Boytsov NN, et al. Costs associated with failure to respond to treatment among patients with rheumatoid arthritis initiating TNFi therapy: a retrospective claims analysis. *Arthritis Research & Therapy.* 2017;19(1): 92.
[90] Verma S. Medicare and Medicaid Need Innovation. *W.S.J*. September 19, 2017. Available at: https://www.wsj.com/articles/medicare-and-medicaid-need-innovation-1505862017

with 100 or more eligible clinicians.[91] Concerns over this expected impact ultimately led to a less stringent MIPS final rule.

Provider consolidation increases costs for the health care system at large. Generally, a one percentage point increase in the proportion of medical providers affiliated with hospitals and/or health systems was associated with a 34 percent increase in average annual costs per person and a 23 percent increase in average per person price of treatment.[92] Physician-administered chemotherapy medicines are an example of how the shift from the community to hospitals contributes to higher spending. From 2004 to 2014, chemotherapy infusions in hospital outpatient departments increased dramatically—from 6 to 46 percent for commercial patients and from 16 to 46 percent for Medicare patients. Drug spending was more than twice as high in the hospital setting. Had this consolidation not occurred, spending would have been 5.8 and 7.5 percent lower for commercial and Medicare infused chemotherapy patients, respectively.[93] Market-driven reforms that improve coordination at the provider level can help to address these challenges.

We offer several recommendations for holistic models that CMS might pursue in our comments on the CMMI New Direction RFI (New Direction RFI).[94]

Codify CMMI "Guiding Principles" in Rulemaking

PhRMA supports the establishment of Guiding Principles for CMMI in the Innovation Center New Direction RFI,[95] and encourages CMMI to codify its guiding principles through formal notice and comment rulemaking prior to issuing any new demonstrations to improve the predictability and transparency of the model testing process. CMMI model tests must maintain protections for beneficiaries and achieve scientific rigor. To achieve this, CMMI should strengthen the processes and standards it uses to test new payment and delivery models. Establishing principles in regulation will facilitate more effective collaboration with stakeholders across the health care industry by clearly communicating requirements for CMMI model tests. It would also reduce regulatory burdens by proving greater predictability in future payment policy. Most importantly, these guidelines will help to minimize potential unintended consequences for beneficiaries.

[91] CMS. Medicare Program; MIPS and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models. Proposed Rule. May 9, 2016. 81 FR 28372. Table 64.
[92] Health Care Cost Institute & National Academy for State Health Policy. The Impact of Provider Consolidation on Outpatient Prescription Drug-Based Cancer Care Spending. April 2016.
[93] Kathryn F, et al. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman. 2016.
[94] PhRMA. Comment Letter responding to CMS, Innovation Center New Direction. November 20, 2017. Available at: https://www.phrma.org/policy-paper/request-for-information-center-for-medicare-and-medicaid-services-innovation-center-new-direction.
[95] CMS. Innovation Center New Direction. September 2017.

Regulation should be used appropriately to implement the statute and to provide clarity on how agencies will apply the law. Many aspects of CMMI's authorizing statute have yet to be clearly defined, such as the parameters of a Phase I test. To effectively implement the CMMI guiding principles outlined in the New Direction RFI, like small scale, voluntary testing, CMMI could issue regulations that explain how it will define model populations and provide much-needed clarity and predictability. Regulations should also clearly articulate how CMMI will work with Congress to establish proof of concept for models and make recommendations for changes to the Medicare and Medicaid programs, and to clarify that CMMI may not unilaterally make permanent, structural changes to Medicare and Medicaid.

CMMI is also required by law to collect input from interested parties through open door forums or other mechanisms, and has engaged stakeholders at various points through meetings, RFI's, and technical expert panels. However, CMMI has never publicly described a process that it will consistently follow for engaging stakeholders in model development, implementation and evaluation. As a result, the level of interaction between CMMI and stakeholders has been inconsistent across models. Some models, like the Oncology Care Model (OCM), were developed over a period of years with multiple opportunities for public comment. Others, like the Comprehensive Care for Joint Replacement (CJR) model, were rapidly deployed with limited opportunities for input. CMMI should publish regulations outlining the process for model development and stakeholder engagement to help to address this concern.

PhRMA encourages CMMI to establish regulations that define small scale, voluntary, and limited duration testing; clearly articulate that CMMI may not unilaterally make permanent, structural changes to Medicare and Medicaid; and lay out a transparent model design and evaluation process. We also encourage CMMI to consider principles for use of waivers, facilitating access to medical innovation, and protecting commercially sensitive information. Our specific recommendations for the guiding principles are outlined in our comments on the CMMI New Direction RFI.[96]

Address barriers to innovative value-based arrangements through regulatory changes

We note that HHS may be considering a test of value-based purchasing arrangements among "demonstration projects to test innovative ways to encourage value-based care and lower drug prices."[97] As the health care market shifts to demand that providers and other stakeholders share greater risk for the cost of care, insurers are increasingly pursuing value-based arrangements with biopharmaceutical manufacturers. Value-based arrangements have potential to benefit patients and the health care system by improving health outcomes and other endpoints that matter to patients, reducing medical costs, and reducing the cost of medicines.

[96] PhRMA. Comment Letter responding to CMS, Innovation Center New Direction. November 20, 2017. Available at: https://www.phrma.org/policy-paper/request-for-information-center-for-medicare-and-medicaid-services-innovation-center-new-direction.
[97] RFI p. 22694.

As we describe below, permanent changes are needed to enable an expansion of value-based arrangements both inside and outside of federal health care programs, and CMMI is limited in its ability to address the barriers to value based arrangements. Medicaid Best Price is outside of CMMI's authority. While CMMI can waive the Anti-Kickback Statute, such a waiver could discourage beneficial VBCs outside of CMMI, which would not have the benefit of an Anti-Kickback Statute waiver. We recommend creation of a new safe harbor to the federal Anti-Kickback Statute. If the Administration believes that these regulatory changes must be evaluated, the U.S. Government Accountability Office (GAO) could conduct a study after such regulatory changes are in place, to evaluate the impact, including the impact on manufacturer outcomes.

We also discuss below other key considerations in Medicare Parts B and D that may be relevant to demonstrations that HHS is considering.

SECTION IV: MEDICARE PART D (RFI p. 22694)

For more than a decade, Medicare Part D has successfully provided seniors comprehensive prescription drug coverage with low and stable premiums, and its unique market-based structure has kept overall program costs far below initial projections. With the multitude of changes that have taken place in the insurance and pharmaceutical markets over the past 10 years, it makes sense to now consider whether Part D is due for a "tune up." PhRMA is pleased that the Administration has expressed interest in modernizing Part D and we share the Administration's goal of updating and improving the Part D benefit. We believe that any reforms of Part D should be developed with a focus on ensuring that Medicare beneficiaries have access to and can afford the medicines they need, no matter what health conditions they are facing. Today, exposure to high cost sharing—often tied to an undiscounted "list price" for the medicine—presents affordability challenges that jeopardize patient adherence to needed medicines, which in turn increases costs in other parts of the Medicare program. PhRMA believes that reforms are needed both to improve affordability for beneficiaries facing high out-of-pocket costs at the pharmacy counter, and to realign and strengthen incentives to ensure long-term program sustainability.

It is critical that improvements to Medicare Part D be undertaken in the right way, with targeted and measured reforms that protect beneficiaries' access to medicines they need. Some reform proposals advanced by the Administration—including passing through to beneficiaries a share of negotiated rebates at the point of sale and establishing an annual MOOP spending limit—would provide immediate financial relief to patients facing high pharmacy costs. Other proposals—specifically changes to the protected classes, eliminating the two drugs per class requirement, and removing coverage gap discounts from the calculation of TrOOP spending—would harm access, increase costs for beneficiaries, and jeopardize the health of seniors and persons with disabilities.

MEDICARE PART D: Growing Affordability Challenges Threaten Patients' Access to Medicines (RFI p. 22695)

Despite consistently low and stable premiums in Medicare Part D, many beneficiaries experience high out-of-pocket expenses for prescription medicines. Increasingly, Part D beneficiaries are exposed to high and unpredictable cost sharing, with no limit on the amount they are required to pay out of pocket each year. For beneficiaries with a serious illness or multiple chronic conditions, out-of-pocket expenses for prescription medicines can easily add up to many thousands of dollars annually, resulting in seniors with chronic or life-threatening illnesses such as diabetes, schizophrenia, multiple sclerosis, and cancer ***walking away from the pharmacy counter without filling vital prescriptions***.[98] High cost sharing for medicines puts patients at risk of delayed treatment initiation, gaps in therapy, and premature discontinuation, which research has consistently shown leads to poor health outcomes, increased use of hospital services and other costly medical care, and higher overall Medicare spending.

1. High Cost Sharing, Not Premiums, Drives Affordability Challenges in Part D

The average Part D premium has been growing at a low rate since the program's inception and is substantially lower than initial projections. Part D premiums average just $33.50 a month in 2018, slightly less than the average premium in 2017. Low and stable Part D premiums are one key reason why the program has been so popular, with several surveys showing that about 90 percent or more of Part D beneficiaries are satisfied with their coverage.[99] However, if current cost-sharing trends continue, and the affordability challenges many patients are facing are not addressed, the popularity of the program could soon begin to erode.

Given Part D plan sponsors' strong incentive to keep premiums low, they use the rebates they negotiate with pharmaceutical manufacturers to reduce overall plan costs, rather than to directly reduce beneficiary cost sharing at the pharmacy counter. At the time Part D was implemented, CMS believed plan sponsors would apply a portion of the rebate savings negotiated for a medicine directly at the point of sale, thereby lowering the cost sharing for beneficiaries taking that medicine. However, the agency has observed that plans seldom share rebate savings directly with patients, choosing instead to apply aggregate rebate savings as direct and indirect remuneration (DIR) at the end of the year to reduce overall benefit costs and lower premiums for all enrollees.[100] As noted earlier in our letter, according to one actuarial firm, this practice of using savings from negotiated rebates to keep premiums low has led to a system of "reverse insurance," whereby plans require patients with high drug expenditures to pay more out of pocket, while rebate savings are spread out among all beneficiaries in the form of lower

[98] Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.
[99] Morning Consult Survey for Medicare Today. Nearly Nine in 10 Seniors Satisfied with Medicare Part D. July 2017; MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 15: Status Report on Part D. March 2013.
[100] 82 Fed. Reg. at 56419.

premiums.[101] ***In effect, not sharing a portion of the rebate savings with beneficiaries at the point of sale has resulted in chronically ill Medicare patients with high drug costs subsidizing premiums for healthier enrollees, which is the inverse of how health insurance is intended to work.***

2. For Many Part D Beneficiaries, Cost Sharing for Medicines is Unpredictable and Unaffordable

Beneficiaries have higher and more unpredictable out-of-pocket costs for their medicines in Medicare Part D than for the hospital and physician services they receive in Parts A and B. Those enrolled in fee-for-service Medicare have the option of purchasing supplemental Medigap coverage to limit their Parts A and B out-of-pocket costs. In addition, Medicare Advantage (MA) enrollees have the added benefit of an annual out-of-pocket spending limit for A and B services. These options are not available in the Part D program and beneficiaries have no such safeguards against high out-of-pocket costs. Instead, they face multiple affordability challenges including high cost sharing for brand prescriptions, high annual out-of-pocket costs, and the uneven distribution of out-of-pocket costs throughout the year.

High Cost Sharing for Brand Prescriptions

Financial barriers to treatment are particularly acute for Part D beneficiaries whose medicines are subject to coinsurance (cost sharing set as a percentage of the medicine's cost), particularly when those drugs are covered on a plan's non-preferred or specialty drug tiers. Most Part D plan sponsors impose up to 33 percent coinsurance for medicines on the specialty tier and coinsurance for non-preferred tier medicines can be as high as 40 to 50 percent.[102] What's more, the coinsurance percentage is typically applied to a medicine's undiscounted "list price," even if the Part D sponsor or their PBM has negotiated a substantial rebate for the product.

High coinsurance rates impose a substantial financial burden for beneficiaries, who are typically living on modest or fixed incomes. It is not uncommon for beneficiaries who do not receive the low-income subsidy (LIS) to find out that the required cost sharing for their brand medicines is $250 or more. For example, more than half of all new brand osteoporosis prescriptions, more than 40 percent of all new brand autoimmune and oral antidiabetic prescriptions, and more than 30 percent of all new brand antipsychotic prescriptions brought to a pharmacy in 2016 had cost sharing greater than $250.[103] Not surprisingly, many of these prescriptions went unfilled. Requiring plan sponsors to pass through a share of the negotiated rebates at the point of sale would immediately lower out-of-pocket costs for millions of beneficiaries currently paying coinsurance for their brand medicines.

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[101] Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017. Available at: http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf
[102] Cubanski J, Damico A, Neuman T. Medicare Part D in 2018: The Latest on Enrollment, Premiums and Cost-Sharing. Kaiser Family Foundation. May 2018.
[103] Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.

High Annual Out-of-Pocket Costs

Analysis by the Kaiser Family Foundation shows that more than one million non-LIS beneficiaries incurred out-of-pocket spending high enough to reach catastrophic coverage in 2015, more than twice the number in 2007.[104] Annual out-of-pocket expenses for these patients were significant—more than $3,000, on average—and exceeded $5,200 for one in 10 beneficiaries. Such high out-of-pocket expenses are persistent from year to year for patients with complex health care needs: Medicare Payment Advisory Commission (MedPAC) analysis indicates that 70 percent of beneficiaries who reached catastrophic coverage in one year reached it in the following year as well.[105]

Many Medicare beneficiaries, including seniors and individuals with disabilities, live on modest fixed incomes. In 2016, the median per capita income for the Medicare population was $26,200 and more than a quarter of beneficiaries had incomes below $15,250.[106] With no limit on annual out-of-pocket spending in Part D, even patients who reach catastrophic coverage continue to face high out-of-pocket costs. For the more than one million non-LIS beneficiaries who reached catastrophic coverage in 2015, 40 percent of their total out-of-pocket spending occurred in the catastrophic portion of the benefit.[107] Establishing an annual out-of-pocket spending limit in Part D would provide true catastrophic coverage for beneficiaries with multiple chronic conditions and significant, life-threatening illnesses.

Uneven Distribution of Out-of-Pocket Costs

Expenses for beneficiaries with high annual out-of-pocket costs are heavily concentrated at the beginning of each calendar year. Patients with a serious illness or multiple chronic conditions can rapidly progress through the deductible, initial coverage phase, and the coverage gap within a month or two, resulting in a large upfront cost burden. For example, one study found that Part D beneficiaries with RA, multiple sclerosis, or chronic myeloid leukemia (CML)—whose average annual out-of-pocket spending ranged from $3,900 to $6,300—incurred 25 to 40 percent of these costs in January alone and between 54 and 66 percent of these costs in the first three months of the year.[108] According to the authors, the average out-of-pocket cost for the first prescription filled during the calendar year "nearly equaled or exceeded the average monthly social security benefit" for two of these three conditions. A policy that allowed beneficiaries to more evenly

[104] Cubanski J, Neuman T, Orgera K, et al. No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending. Kaiser Family Foundation. November 2017.
[105] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Improving Medicare Part D. June 2016.
[106] Jacobson G, Griffin S, Newman T, et al. Income and Assets of Medicare Beneficiaries, 2016-2035. Kaiser Family Foundation. April 21, 2017.
[107] Cubanski J, Neuman T, Orgera K, et al. No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending. Kaiser Family Foundation. November 2017.
[108] Doshi JA, Pengxiang L, Pettit AR, et al. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon." *American Journal of Managed Care*. 2017;23(3 Suppl):S39-S45.

spread their annual out-of-pocket spending over the course of the year would help alleviate this substantial upfront financial burden.

3. Changes in Plan Benefit Design Have Shifted More Costs to Patients

The implementation of Part D brought about significant improvements in medication affordability, particularly for seniors with multiple chronic conditions. Early evaluations of the Part D program found significant reductions in rates of cost-related medication nonadherence, including behaviors such as delaying or not filling prescriptions due to cost or skipping doses to make a prescription last longer. However, more recent analysis shows that the prevalence of such behaviors is once again on the rise. According to one study, seniors with four or more chronic conditions reported higher rates of cost-related nonadherence in 2011 than they did in 2007, suggesting an erosion of gains in medication affordability among the sickest Medicare beneficiaries.[109] In part, the authors attribute this deterioration to changes in Part D benefit design, such as increased use of deductibles and higher cost sharing, which have shifted cost burdens onto patients with chronic conditions.

The increased use of complex, multi-tiered formularies and growing prevalence of coinsurance expose patients to a disproportionately high share of the cost of their medicines. Today, the vast majority (95 percent) of PDPs use formularies with five coverage tiers, and 5 percent are now using a sixth tier.[110] While most Part D plans have historically applied coinsurance to specialty tier drugs, in recent years plans have increasingly extended coinsurance to drugs on lower tiers. As a result, the percentage of Part D drugs subject to coinsurance jumped by nearly 20 percentage points between 2015 and 2018. ***Today, 62 percent of all drugs covered by PDPs are covered on a coinsurance tier.***[111]

Meanwhile, the share of brand medicines covered on a plan's preferred drug tier continues to decrease. In 2018, less than one-quarter (23 percent) of brand medicines covered by PDPs were placed on the preferred brand tier, while 32 percent and 44 percent were placed on the non-preferred and specialty tiers, respectively. Relative to the fixed-dollar copays commonly applied to medicines on the preferred drug tier, the increased use of coinsurance-based non-preferred and specialty tiers results in higher and less predictable cost sharing for beneficiaries who rely on brand medicines.

In 2017, CMS also began allowing plan sponsors to offer a "blended" non-preferred drug tier, which consists of both brand and generic drugs. Typical coinsurance on the non-preferred drug tier is 40 percent, but can be as high as 50 percent. ***Allowing plans to include a large number of lower-cost generic drugs on the blended tier results in significantly lower average cost sharing across the tier, with the lower cost sharing for generics masking the disproportionate cost sharing that beneficiaries face for brand medicines.*** For example, despite CMS guidance that

[109] Naci H, Soumerai SB, Ross-Degnan R, et al. Medication Affordability Gains Following Medicare Part D Are Eroding Among Elderly with Multiple Chronic Conditions. *Health Affairs*. 2014;33(8):1435-1443.
[110] Avalere Health. 2018 Medicare Part D Formularies: An Initial Analysis. November 2017.
[111] Id.

the average maximum allowable cost sharing for non-preferred medicines cannot exceed a non-discriminatory threshold of $100,[112] across all PDPs with coinsurance on the blended non-preferred tier (representing 98 percent of all enrollment in PDPs), an average of 72 percent of brand medicines placed on this blended tier had cost sharing that resulted in at least $100 in out-of-pocket costs for beneficiaries in 2018. Similarly, 15 percent of brand medicines placed on these tiers by these same plans resulted in cost sharing of at least $500 and more than 5 percent resulted in cost sharing of more than $1,000.[113]

4. High Cost Sharing Adversely Impacts Beneficiary Access and Adherence to Medicines

As the Congressional Budget Office (CBO) has affirmed, medication adherence plays an important role in reducing the use of other health care services in Medicare.[114] On the other hand, medication nonadherence is associated with poor clinical outcomes and higher overall health care costs.[115] Research consistently shows that patients facing high cost sharing are less likely to initiate or adhere to their prescribed medication regimens:

- Analysis by Amundsen Consulting shows that 38 percent of all new specialty prescriptions filled by Part D beneficiaries beginning therapy for the first time were abandoned at the pharmacy in 2016, and that the likelihood of abandonment was strongly associated with out-of-pocket cost.[116] When beneficiary cost sharing exceeded $250, 71 percent of new specialty prescriptions were abandoned. This level of cost sharing was not uncommon, as nearly 40 percent of all new Part D prescriptions for specialty medicines had cost sharing of more than $250. Even among patients with debilitating or life-threatening illnesses, abandonment rates were alarmingly high. For example, more than 6 out of 10 new oncology prescriptions and more than 7 out of 10 new antipsychotic and multiple sclerosis prescriptions were abandoned at the pharmacy counter when their cost sharing exceeded $250.

- Researchers at the University of Pennsylvania examined the impact of high cost sharing on initiation of tyrosine kinase inhibitors (TKIs), which have revolutionized the treatment of CML. The analysis found that Part D enrollees who did not receive the LIS and were diagnosed with CML were less likely than enrollees who did receive subsidies (and paid only nominal out-of-pocket costs) to fill a prescription for a TKI within six months of

[112] CMS. Announcement of CY 2018 MA Capitation Rates and MA and Part D Payment Policies and Final Call Letter and RFI. April 3, 2017.
[113] Analysis by Avalere Health for PhRMA. June 2018.
[114] CBO. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012.
[115] Boswell KA, Cook CL, Burch SP, et al. Associating Medication Adherence with Improved Outcomes: A Systematic Literature Review. *American Journal of Managed Care*. 2012;4(4):e97-e108.
[116] Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.

diagnosis (45.3 percent versus 66.9 percent). Additionally, non-LIS beneficiaries took twice as long to fill a prescription for a TKI (an average of 50.9 days versus 23.7).[117]

- Another academic study found that for Part D enrollees with RA, high cost sharing was associated with treatment interruptions. Among enrollees who used a Part D biologic in the prior year, those facing high cost sharing were less likely to continue using a Part D biologic relative to those beneficiaries receiving cost sharing subsidies. When Part D enrollees with RA did fill a Part D biologic, those facing high cost sharing were twice as likely to experience an interruption in treatment (defined as a gap of more than 30 days) compared to beneficiaries receiving subsidies.[118]

5. Competitive Incentives Are Key to the Long-Term Sustainability and Affordability of Part D

Medicare Part D, which relies on private market competition to hold down costs for beneficiaries and taxpayers, has been a tremendously successful program. Part D was designed to encourage broad participation of beneficiaries and plan sponsors, and provides beneficiaries with the freedom to choose among dozens of competing private plans, who take on the financial risk of managing Part D costs and compete for enrollment based on premiums, coverage, quality, and service. Having private Part D plan sponsors assume financial risk has been an important part of the program's success. As MedPAC has noted, "When competing plans bear risk, they have an incentive to strike a balance between offering benefits that are attractive to beneficiaries and managing their enrollees' drug spending so that plans' premiums will be affordable."[119] To avoid upsetting this balance, potential changes to the benefit should be examined carefully, with an eye towards fully understanding how such changes could impact the competitive incentives built into the Part D program.

Recent changes made to the standard Part D benefit under the Bipartisan Budget Act of 2018 (BBA) weaken the competitive incentives that have made the program successful. Beginning in 2019, the BBA will reduce the amount a plan sponsor pays towards a beneficiary's costs in the coverage gap from 25 percent to 5 percent for brand medicines—an 80 percent reduction. This reduction in liability, combined with plan sponsors' zero liability in the coverage gap for LIS,[120] sharply reduces the degree to which Part D's private sector plans are at risk for the cost of delivering the benefit, weakening incentives for plans to manage drug spending beyond the initial coverage limit, and threatening to undermine Part D's market-based structure. CMS recently reflected on the BBA's impact in the final Calendar Year (CY) 2019 Call Letter, noting that "we

[117] Doshi, JA., Li, P, Huo, H, et al. Medicare Part D Cost-sharing And Specialty Drug Initiation In Newly Diagnosed Chronic Myeloid Leukemia Patients. *Value in Health*. 2016;19(3):78-86.
[118] Doshi, JA, Hu, T, Li, P, et al. Specialty Tier-Level Cost-sharing and Biologic Use in the Medicare Part D Initial Coverage Period among Beneficiaries with Rheumatoid Arthritis. *Arthritis Care & Research*. 2016.
[119] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Sharing Risk in Medicare Part D. June 2015.
[120] CMS. Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2019. April 6, 2018.

have significant concerns about the impact these changes will have on drug costs under Part D in 2019 and future years, particularly as plan liability in the gap significantly decreases for brand name drugs beginning in 2019."[121]

Actuaries and economists have also questioned whether plan sponsors have begun to overemphasize offering the lowest possible premium at the expense of benefit designs that are affordable for high-cost beneficiaries with significant chronic or life-threatening conditions. First, plan sponsors' practice of applying all rebates as DIR rather than using them to reduce cost sharing at the point of sale suppresses premiums, but as noted above, actuaries have observed that this also creates a system of "reverse insurance," where chronically ill beneficiaries with high spending subsidize costs for healthier enrollees.[122] Notwithstanding the savings from lower premiums, this practice results in higher cost sharing that drives up out-of-pocket spending for millions of beneficiaries with chronic and other serious illnesses. In the absence of change, the value of the benefit will erode over time for the sickest beneficiaries, as these patients bear an ever-larger share of the cost of their medicines.

Second, systematic trends in plan sponsors' bidding practices suggest that plans keep premiums low by shifting risk to the government. Economists have found that relative to actual spending, plan sponsors systematically bid too low on the amount of spending expected in catastrophic coverage, while bidding too high for expected spending in the other phases of the benefit.[123] Underbidding on catastrophic spending allows plan sponsors to suppress growth in premiums, while still receiving reimbursement for a large share of their actual incurred catastrophic coverage costs through additional reinsurance payments made during reconciliation. Since retrospective reconciliation payments are not reflected in plan sponsors' bids, this allows plans with high reinsurance costs to continue offering low premiums. A higher share of Part D payments in 2016 were made through retrospective reconciliation, rather than the prospective risk-based capitation system, suggesting that plan sponsors' liability for managing the benefit may be shrinking.[124]

MEDICARE PART D: Targeted and Measured Reforms Will Improve Affordability, While Preserving the Success of Part D (RFI p. 22694)

Preserving the success of the Medicare Part D program requires targeted and measured reforms that uphold Part D's competitive market-based structure and improve affordability without compromising beneficiaries' access to medicines. Two Part D reforms included in the President's Fiscal Year (FY) 2019 budget proposal would provide much needed financial relief for beneficiaries facing high cost sharing and high annual out-of-pocket costs:

[121] Announcement of CY 2019 MA Capitation Rates and MA and Part D Payment Policies and Final Call Letter. April 2, 2018.
[122] Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017.
[123] Jung J, Feldman R. Growing Reinsurance Payments Weaken Competitive Bidding in Medicare Part D. *Health Services Research*. Epub ahead of print, May 7, 2018; MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Sharing Risk in Medicare Part D. June 2015.
[124] MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report. March 2018.

1. Requiring plan sponsors to pass through a substantial share of negotiated rebates at the point of sale would immediately lower out-of-pocket costs for millions of beneficiaries.

2. Establishing a maximum annual limit on beneficiary out-of-pocket spending would provide a true catastrophic benefit to protect the sickest patients.

In addition, there are several program improvements not specifically contemplated in the RFI that the Administration and Congress could pursue to improve patient affordability and support the long-term stability of the program:

1. Reverse changes made under the BBA that threaten to undermine Part D's successful market-based structure by substantially scaling back plan liability and potentially crowding out privately-negotiated rebates with statutorily-mandated price controls.

2. Fix the looming out-of-pocket "cliff," which will cause a sharp spike in the catastrophic threshold in 2020.

3. Allow beneficiaries to more evenly spread their out-of-pocket payments over the course of the year.

These critical benefit design reforms are the optimal long-term approach for improving affordability in Part D, but allowing manufacturers the option of providing cost-sharing assistance also could help reduce some patients' out-of-pocket costs in the near term.

Applying a Share of Negotiated Rebates at the Point of Sale

The Administration could immediately lower out-of-pocket costs for millions of beneficiaries by requiring Part D plans to apply a substantial portion of negotiated rebates to reduce cost sharing at the point of sale. At the time Part D was implemented, CMS expected that plan sponsors would share a large portion of rebate savings directly with beneficiaries in this manner.[125] Instead, CMS has observed that plan sponsors prefer to report rebates as end-of-year DIR in order to lower plan liability, push down premiums, and increase profits.[126] Both CMS and MedPAC have raised questions about this practice and CMS has expressed concern that reporting all rebates as DIR provides incentives for plan sponsors to steer utilization towards medicines with high rebates, even when lower cost alternatives are available.[127]

Passing through a substantial portion of rebates at the point of sale is the most important step the Administration can take to ensure that beneficiaries directly benefit from the significant price negotiations taking place in the Part D market. This policy change would immediately and visibly lower out-of-pocket costs for millions of seniors, lower government cost-sharing subsidies and reinsurance payments, and realign stakeholder incentives by reducing plans'

[125] 70 Fed. Reg. 4194, 4244.
[126] 82 Fed. Reg. 56419-56420.
[127] 82 Fed. Reg. 56420.

preference for medicines with high rebates.

Plan sponsors and their PBMs have claimed that sharing a portion of rebates at the point of sale would be too administratively complex and would significantly increase costs to the federal government.[128] These claims are inaccurate. First, several private insurers and PBMs have announced plans to offer point-of-sale rebate sharing to their commercial clients, signifying that the infrastructure and the capacity to implement this policy already exist.[129] Second, the cost estimates cited by opponents of this policy change have not accounted for how anticipated behavioral impacts among stakeholders could reshape the market.

Only one study, conducted by actuaries at Milliman, has taken these behavioral changes into account and it concluded that passing through 50 percent of rebates at the point of sale could save the government between $8B (assuming a modest market response) and $73B (assuming a strong market response) over the next 10 years.[130] According to Milliman, savings would be driven by expected changes in formulary strategies that would shift coverage towards medicines with the lowest net costs, as opposed to the highest negotiated rebate. With rebates less "treasured" by plan sponsors and their PBMs, over time their importance to the prescription drug supply chain could change. Importantly, Milliman's estimates do not account for additional savings likely to accrue to Medicare Parts A and B due to improved medication adherence. A recent study by IHS Markit found that passing through a share of rebates just for diabetes medicines alone could reduce overall health care spending (including Parts A and B) for Medicare beneficiaries with diabetes by $20B over the next 10 years.[131]

PhRMA looks forward to continuing to engage with the Administration on an approach to rebate pass through that preserves the incentives for market-based competition in Part D and protects the confidentiality of commercially-sensitive data.

Establishing a Maximum Annual Out-of-Pocket Spending Limit

Current law requires MA plans to apply a MOOP limit on annual patient cost sharing for services covered under Parts A and B. Extending the MOOP to Part D, and establishing a similar out-of-pocket limit for PDP enrollees, would provide parity with coverage for Medicare Parts A and B services and offer catastrophic protection for patients whose conditions require treatment with medicines, rather than surgical or other medical interventions. It would also harmonize coverage

[128] See PCMA and AHIP comment letters submitted in response to CMS-4182-P: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program ("Proposed Rule"). January 16, 2018.
[129] Aetna to Offer Point-of-Sale Pharmacy Rebates to Three Million Customers. *Managed Care*. March 27, 2018; Johnson CY. UnitedHealthcare Will Provide Drug Rebates Directly to Members in Some Plans. *Washington Post*. March 6, 2018.
[130] Milliman. Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates. January 2018. Available at: http://www.phrma.org/report/reducing-part-d-beneficiary-costs-through-point-of-sale-rebates
[131] IHS Markit. Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare. May 14, 2018.

standards between Part D and other insurance markets. Today, when beneficiaries age into Medicare from commercial coverage, they often lose the financial protection of an annual cap on out-of-pocket spending. There is no clinical justification or policy rationale for penalizing Part D enrollees who incur high annual drug expenditures with unlimited cost sharing once they turn 65.

CMS already has the legal authority to create a Part D MOOP for beneficiaries enrolled in Medicare Advantage prescription drug plans (MA-PDs). In establishing the Part A/B MOOP for local MA plans, CMS relied on two MA provisions, both of which have Part D counterparts: (1) the prohibition on discriminatory MA benefit designs in Social Security Act (SSA) § 1852(b)(1)(A), which closely resembles the Part D non-discrimination provision in SSA § 1860D-11(d)(2)(D); and (2) the SSA § 1857(e)(1) authority to add "necessary and appropriate" terms to contracts with MA plans, which is incorporated into Part D via § 1860D-12(b)(3)(D).[132] Therefore, CMS' legal authority for establishing the MA MOOP is fully applicable to a Part D MOOP.

Additionally, the Part D statute states that CMS may waive Part D provisions to the extent they duplicate or conflict with MA provisions.[133] This waiver authority applies here for two reasons:

1. The Part A/B MOOP was established to avoid discouraging individuals with higher than average health care costs from enrolling in MA, so that the plan does not violate the non-discrimination requirement.[134] Similarly, unlimited Part D cost sharing can also discourage individuals who use above-average levels of services from enrolling in an MA-PD, and thus conflicts with the cap on Part A/B cost sharing.

2. The absence of a Part D MOOP undercuts MA plans' ability to coordinate Part C and D benefits. Sicker enrollees may cut back on Part D medicines—skipping doses or not filling prescriptions—as their out-of-pocket costs increase without limit on the Part D side, which in turn may cause avoidable complications and increase their use of Part C services such as hospitalizations.[135] Further, the lack of a Part D counterpart to the A/B MOOP may lead beneficiaries with high health care costs to use Part B drugs even if there are Part D drugs that would be more clinically appropriate. These scenarios illustrate the problems this perverse incentive system can create for coordinating MA plans' Part C and D benefits.

Accordingly, CMS has ample authority to waive Part D requirements to the extent they would otherwise impede its ability to create a Part D MOOP. CMS should use that authority; from both

[132] 74 Fed. Reg. 54634, 54657 (Oct. 22, 2009) (proposed MA and Part D rule for 2011, proposing mandatory MOOPs for local MA plans); 75 Fed. Reg. 19678, 19710-11 (April 15, 2010) (final rule for 2011, finalizing MOOP proposal).
[133] SSA § 1860D-21(c)(2).
[134] 74 Fed Reg. at 54657. Under SSA § 1852(b)(1)(A), CMS may not approve an MA plan if "the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals").
[135] CBO. Offsetting Effects of Prescription Drugs Use on Medicare's Spending for Medical Services. November 2012.

a legal and health care policy perspective, a Part D MOOP would be a sound strategy offering substantial benefits to the MA program and its current and future enrollees.

Distributing Beneficiary Cost Sharing More Evenly Throughout the Year

For beneficiaries with high annual out-of-pocket costs, the structure of the Part D benefit results in an uneven cost distribution, with the highest costs heavily concentrated at the beginning of each calendar year. Therefore, even with a Part D MOOP, beneficiaries will still face significantly high costs in the early months of the year that threaten initiation of treatment and continued adherence to therapy before reaching catastrophic coverage. To make spending more manageable, the Administration could pursue mechanisms that would allow beneficiaries to more evenly spread their annual out-of-pocket payments over the course of the year. In conjunction with a maximum annual out-of-pocket spending limit, this policy change would allow beneficiaries to more accurately predict and budget for their monthly out-of-pocket expenses.

Restoring Competitive Incentives Undone by the Bipartisan Budget Act

The BBA passed by Congress in February 2018 made a significant change to the Part D benefit, reducing plan liability in the coverage gap from 25 percent to just 5 percent for brand medicines. Plan sponsors now have less of a stake in managing Part D expenses above the initial coverage limit, which reduces their incentives to provide benefit designs that are affordable for high-cost beneficiaries with significant chronic or life-threatening illnesses. By limiting the role of competing private plan sponsors and privately-negotiated rebates, BBA threatens a successful market-based program and puts Part D's future in jeopardy. ***The Administration should immediately work with Congress on legislation to mitigate these harmful changes and restore the competitive incentives that have been vital to Part D's success.***

Fixing the Out-of-Pocket Cliff

Another important step that the Administration could take to improve Part D affordability and predictability would be to work with Congress to address the looming out-of-pocket cliff. Changes made under the ACA temporarily slowed the annual rate of increase in the catastrophic threshold, which is the level of TrOOP spending beneficiaries must reach to exit the coverage gap and enter catastrophic coverage. At the end of 2019, the temporary suppression of the growth rate is set to expire, which will cause the catastrophic threshold to jump up suddenly in 2020, as if the growth rate had never been slowed in the first place. This steep increase (roughly $1,250, based on current projections)[136] in the catastrophic threshold is known as the out-of-pocket cliff.

With the help of Congress, the Administration should act this year to phase in the impact of the out-of-pocket cliff and prevent the significant increase in out-of-pocket costs beneficiaries will otherwise face in 2020. Given the annual contracting cycle for Part D, as a practical matter, this

[136] 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund. June 5, 2018.

benefit cut to seniors needs to be addressed before the end of the first quarter of 2019 so plan sponsors can reflect the change to current law in their 2020 plan-year bids.

Allowing Manufacturers to Provide Cost-Sharing Assistance in Part D

The RFI solicits feedback on whether there are circumstances under which allowing beneficiaries of Federal health care programs to utilize copay discount cards would advance public health benefits.[137] Currently, government guidance limits the use of manufacturer cost-sharing assistance cards—referred to in the RFI as copay discount cards and also known as copay discount cards or copay coupons—in Federal health care programs.[138] This guidance—issued by HHS Office of Inspector General (OIG)—suggests that manufacturers can be held liable under the Federal Anti-Kickback Statute if they offer such programs to Part D beneficiaries.[139] While PhRMA believes that the reforms described above are the optimal long-term approach for addressing affordability challenges in Part D, allowing manufacturers to voluntarily offer cost-sharing assistance cards could provide another alternative for reducing some seniors' out-of-pocket costs in the near term.

The immediate financial relief provided by cost-sharing assistance programs could advance public health goals by improving appropriate medication use among Part D enrollees. A substantial body of research demonstrates that lowering out-of-pocket costs for medications plays an important role in improving adherence, promoting better health outcomes, and reducing spending on non-prescription drug services, especially for patients with chronic conditions.[140] As the CBO has affirmed, better use of medicines plays an important role in reducing the use of other health care services in Medicare. CBO credits every 1 percent increase in the utilization of prescription medicines with a 0.20 percent decrease in Medicare Parts A and B spending.[141] Subsequent research suggests that for Medicare beneficiaries with chronic conditions such as diabetes, hypertension, high cholesterol, and congestive heart failure, this offsetting effect may be three to six times as large.[142]

In the commercial market, cost-sharing assistance programs already provide an important source of financial support for patients and have been shown to improve medication use. Multiple studies report that use of cost-sharing assistance is associated with higher adherence and lower

[137] RFI p. 22698.
[138] 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005).
[139] 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005) ("…the core question is whether the anti-kickback statute would be implicated if a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (directly or indirectly through a PAP) incurred by Part D beneficiaries for the manufacturer's product. . . . Simply put, these subsidies would be squarely prohibited by the statute…").
[140] Eaddy MT, Cook CL, O'Day K, et al. How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. *Pharmacy & Therapeutics*. 2012;37(1):45-55.
[141] CBO. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012.
[142] Roebuck MC. Medical Cost Offsets from Prescription Drug Utilization Among Medicare Beneficiaries. *Journal of Managed Care & Specialty Pharmacy*. 2014;20(10):994-995.

rates of therapy discontinuation.[143] For patients facing high risk of prescription abandonment due to high cost sharing, another study found that cost-sharing assistance programs typically reduced patients' monthly out-of-pocket costs to a level where they were much less likely to abandon therapy.[144]

MEDICARE PART D: Part D Reforms Must Not Compromise Patients' Access to Medicines (RFI p. 22694)

PhRMA shares the Administration's goal of modernizing the Part D program to provide beneficiaries with more affordable and predictable out-of-pocket costs. However, we strongly dispute the Administration's assertion that the 5-part plan outlined in the President's FY2019 budget proposal must be implemented as a whole. ***Certain elements of the 5-part plan—as well as other ideas raised for consideration in the RFI—directly contradict the Administration's stated goals of lowering out-of-pocket costs and putting patients first and would have the perverse consequence of harming the sickest and most vulnerable beneficiaries who rely on their Part D coverage.*** Rather than improving the affordability and accessibility of prescription medicines, certain Administration policy proposals would increase costs for patients already facing high out-of-pocket burdens and create new access barriers for vulnerable beneficiaries. These include:

1. Excluding coverage gap discounts from the calculation of TrOOP spending.
2. Reducing the minimum number of required drugs per class from two to one.
3. Increasing coverage restrictions in the protected classes

1. Exempting Coverage Gap Discounts from TrOOP Spending Would Make Medicines Less Affordable for Chronically Ill Beneficiaries

Excluding manufacturer coverage gap discounts from the calculation of TrOOP spending would exacerbate, rather than address beneficiary affordability challenges, and undermines the Administration's goal of reducing out-of-pocket costs for Medicare beneficiaries. By prolonging the amount of time spent in the coverage gap, this change would directly harm millions of chronically ill patients, increasing out-of-pocket spending by hundreds of dollars for those who most rely on medicines to manage their health. Higher out-of-pocket costs for this population would have the unintended consequence of increasing prescription abandonment, medication nonadherence, and premature discontinuation of therapy, leading to poor health outcomes and higher costs elsewhere in the Medicare program.

[143] Daugherty J, Maciejewski KL, Farley JF. The Impact of Manufacturer Coupon Use in the Statin Market. *Journal of Managed Care Pharmacy*. 2013;19(9):765-772; Daubresse M, Andersen M, Riggs KR, et al. Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study. *Pharmacotherapy*. 2017;37(1):12-24.
[144] Stamer CI, Alexander GC, Bowen K, et al. Specialty Drug Coupons Lower OOP Costs and May Improve Adherence at the Risk of Increasing Premiums. *Health Affairs*. 2014;33(10):1761-1769.

Under current law, 2.3 million non-LIS beneficiaries are estimated to reach catastrophic coverage in 2019.[145] ***If the calculation of TrOOP were changed to exclude manufacturer coverage gap discounts, 69 percent (1.6 million) of these beneficiaries would remain in the coverage gap longer and their average annual out-of-pocket costs would increase by 27 percent (from $2,635 to $3,364).***[146] Patients with chronic illnesses—particularly those with congestive heart failure, diabetes, hypertension, high cholesterol, and kidney and liver failure—would be the most affected by the TrOOP change, while the relatively healthy would be unaffected. This proposed change to TrOOP would exacerbate the trend towards less meaningful coverage for sicker beneficiaries, which may threaten the future of Medicare Part D as a successful, market-based coverage model. And for many patients, this policy change would result in annual out-of-pocket costs that exceed 10 percent of the median per capita income of Medicare beneficiaries, which was $26,200 in 2016.[147]

Similarly, researchers at the University of Pennsylvania simulated the impact of the TrOOP change for chronically ill beneficiaries with RA, multiple sclerosis, and CML and concluded that this policy change would subject Part D enrollees to higher, more concentrated out-of-pocket costs during the early months of the year. They also observed that chronically ill beneficiaries who remained in the coverage gap for an extended period because of the TrOOP change would be substantially worse off as a result. For example, annual out-of-pocket spending for beneficiaries with RA would increase by 15 percent, from $3,949 to $4,540.[148]

As the Commonwealth Fund recently noted, "any proposals to change Medicare must proceed with caution. Already-high financial burdens mean any changes to the program must be assessed to safeguard beneficiaries' access and affordability."[149] The Administration's proposal to eliminate coverage gap discounts from TrOOP clearly fails to meet this standard.

2. Eliminating the Two Drug Per Class Requirement Limits Access to Medicines and Could Interrupt or Delay Treatment

PhRMA is greatly concerned about eliminating the Medicare Part D coverage requirement that formularies include at least two drugs per therapeutic class or category. The dilution of this core beneficiary protection in Part D is inappropriate for a host of reasons. It could greatly limit and impede access for patients with complex medical conditions, leading to further health complications when their treatment regimens are compromised. Further, it could result in

[145] Xcenda. Analysis for PhRMA of the 2015 Medicare Part D Event Research Identifiable Files, 10% Sample. Modeling of patient completed by Xcenda based on standard benefit parameters for 2019. Part D and Medicare Advantage Part D Non-LIS enrollment estimates from the Congressional Budget Office April 2018 Medicare baseline.
[146] Id.
[147] Jacobson G, Griffin S, Newman T, et al. Income and Assets of Medicare Beneficiaries, 2016-2035. Kaiser Family Foundation. April 21, 2017.
[148] Doshi JA, Pengxiang L, Pettit AR, et al. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon." *American Journal of Managed Care*. 2017;23(3 Suppl):S39-S45.
[149] Schoen C, Davis K, Willink A. Medicare Beneficiaries' High Out-of-Pocket Costs: Cost Burdens by Income and Health Status. The Commonwealth Fund. May 2017.

additional paperwork and red tape for physicians who treat Medicare patients due to an increase in appeals requests to access appropriate off-formulary medicines.

Having a broad range of treatment options is fundamental to providing good care to all patients, but particularly so for the Medicare population, who are more likely to be affected by multiple chronic conditions. It is critical that patients who are stabilized and well-managed on a therapy—or a combination of therapies—maintain access to the appropriate medicines to prevent further complications, poorer disease outcomes, and greater utilization of other health care services such as emergency department visits and hospitalizations. Commercial insurers clearly recognize the importance of ensuring patients have access to a range of therapies: for a wide variety of medicines commonly used by both commercial and Part D enrollees—including those to treat diabetes, asthma, mental illness, HIV, autoimmune disorders, and multiple sclerosis—100 percent of commercial plans provide coverage for two or more medicines per class.[150]

Each person is unique with genetic and molecular variations that may affect how they respond to or tolerate any given medication. Even within the same class, patients often respond to drugs differently or certain drugs may not be compatible with other prescribed therapies, necessitating a broader range of treatment options than just one per class. A review of 29 studies evaluating the impact of non-medical switching found that among patients with stable, well-controlled disease, the practice of switching to a different, chemically distinct medicine for reasons other than lack of clinical efficacy/response led to poor side effects or nonadherence and was associated with mostly negative outcomes.[151] Of course, these negative outcomes can translate into higher medical costs immediately or in the future, making the practice of non-medical switching seem penny wise and pound foolish.

For autoimmune conditions, such as RA, multiple sclerosis, or inflammatory bowel disease, there is no one-size-fits all approach to treatment. Recognizing that treating physicians and their patients are in the best position to determine appropriate therapies, the physician must always have the authority to decide which product is dispensed to the patient. In addition to patient benefits, there are greater economic savings that result when patients find the right therapy and remain adherent. As an example, patients with RA who responded to tumor necrosis factor inhibitors had lower all-cause medical, pharmacy, and total costs up to three years from initiation of therapy.[152]

[150] Avalere Health. Analysis for PhRMA of the MMIT database of 2018 commercial formularies. June 2018.
[151] Nguyen E, Weeda E, Sobieraj D, et al. Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review. *Current Medical Research and Opinion*. 2016;32(7):1281-1290.
[152] Grabner, M, Boytsov NN, Huang Q, et al. Costs Associated with Failure to Respond to Treatment among Patients with Rheumatoid Arthritis Initiating TNFi Therapy: A Retrospective Claims Analysis. *Arthritis Research & Therapy*. 2017;19(1):92.

Similarly, there is limited clinical evidence to indicate which antipsychotic will be most efficacious for an individual patient.[153] Instead, treatment response is heterogeneous and patients may experience clinically meaningful differences when exposed to different therapies. Because of varied pharmacokinetics and differences in treatment response, clinical guidelines suggest that medication regimens should be determined on an individual basis and that a trial-and-error process involving multiple antipsychotics will often be needed to find the optimal regimen.[154] For patients diagnosed with schizophrenia, formulary restrictions and non-medical switching may lead to treatment interruptions and nonadherence, which contribute to worsened prognosis, increased hospitalization, increased rates of relapse, attempted suicide, and impaired occupational and social functioning.[155]

In the era of curative direct-acting-antivirals (DAAs), researchers are constantly learning more about optimal strategies for treating the various forms of the hepatitis C virus (HCV)—particularly in difficult-to-treat subpopulations. No one treatment regimen is appropriate to treat the broad spectrum of patients living with HCV. There are seven known genotypes of the virus, as well as various subtypes, each associated with different treatment guidelines and recommended DAAs.[156] While some DAAs are pan-genotypic, others are specifically indicated for just one or two genotypes, for certain subtypes of HCV, or for drug resistant forms of HCV. For patients who have failed a previous HCV treatment and those living with comorbid conditions such as HIV; chronic liver disease; liver cancer; or renal impairment, limiting access to one DAA in the class is contrary to clinical guidelines, which recommend the use of different DAAs for different subpopulations. Taken together, the diversity of HCV highlights the importance of patient access to multiple treatment options.

Although there may be many medicines within an individual therapeutic class, the particular therapy that is best suited for a patient is often determined by a specific biological marker or genetic mutation. With the advent of personalized medicines and targeted therapies—where the

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[153] Chien WT, Yip ALK. Current Approaches to Treatments for Schizophrenia Spectrum Disorders, Part I: An Overview and Medical Treatments. *Neuropsychiatric Disease and Treatment.* 2013;9:1311-1332.
[154] Lehman AF, Lieberman JA, Dixon LB, et al. Practice Guideline for the Treatment of Patients with Schizophrenia, Second Edition. *American Journal of Psychiatry*. 2004;161(2 Suppl):1-56.
[155] Keith SJ, Kane JM. Partial Compliance and Patient Consequences in Schizophrenia: Our Patients Can Do Better. *Journal of Clinical Psychiatry.* 2003;64:1308-1315; Velligan DI, Weiden PJ, Sajatovic M, et al. The Expert Consensus Guideline Series: Adherence Problems in Patients with Serious and Persistent Mental Illness. *Journal of Clinical Psychiatry*. 2009;70(suppl 4):1-46; Svarstad BL, Shireman TI, Sweeney JK. Using Drug Claims Data to Assess the Relationship of Medication Adherence with Hospitalization and Costs. *Psychiatric Services*. 2001;52(6):805iceseeMorken G, Widen JH, Grawe RW. Nonn JH, Grawe Grawe JK. Using Drug Claims Data to AsseRehospitalisation in Recent-Onset Schizophrenia. *BMC Psychiatry*. 2008;8:32; Novick D, Haro JM, Suarez D, et al. Predictors and Clinical Consequences of Non-Adherence with Antipsychotic Medication in the Outpatient Treatment of Schizophrenia. *Psychiatry Research*. 2010;176(2-3):109-113; Haynes VS, Zhu B, Stauffer VL, et al. Long-Term Healthcare Costs and Functional Outcomes Associated with Lack of Remission in Schizophrenia: A PostlHoc Analysis of a Prospective Observational Study. *BMC Psychiatry*. 2012;12:222.
[156] CDC. Hepatitis C Questions and Answers for Health Professionals: Management and Treatment. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm; America Association for the Study of Liver Diseases and the Infectious Disease Society of America. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. May 24, 2018. Available at: https://www.hcvguidelines.org/

underlying molecular drivers of disease help identify and direct precise, targeted treatment choices—limiting the number of covered medicines in a therapeutic class reduces the vast potential of breakthrough science to revolutionize care.[157] This is particularly true for many forms of cancer, where the underlying genetic mutations driving cancer cell growth can be targeted by specific personalized medicines. In the treatment of chronic myelogenous leukemia, for example, identification of a specific mutation led to the development of a class of medicines called TKIs that has nearly tripled the 5-year survival rate from 31 to 89 percent.[158] However, cancer cells often develop resistance to specific medicines over time, making it very important for patients to have additional targeted options available as cancer cells mutate and stop responding to treatment.[159]

Furthermore, limiting the scope of coverage within formularies could disproportionately affect and acutely impact patients with rare diseases. Using the U.S. Pharmacopeia Medicare Model Guidelines (UPS MMG) as an example, many agents for rare diseases are not classified at a class level that is granular enough that would be sufficient to ensure patients have access to the most appropriate therapies for their particular condition. Many of these are specific therapies that do not have FDA-approved therapeutic alternatives and are not interchangeable. Most are placed in catch-all "other" classes, and if only one product is required to be covered across a broad, heterogenous class, that could jeopardize the health of a rare disease patient who cannot access treatment in a timely manner if subject to additional utilization management because the product they need is not covered.

Some medicines are approved by FDA specifically for treatment of a condition after another medicine in the class has been tried and failed. If only one medicine per class were required to be covered, patients who are not responsive to the sole medicine covered could experience further treatment delays when subject to utilization management requirements or lengthy appeals processes. Additionally, there are agents that have a narrow therapeutic index, and patients who are stabilized on a medication should not be abruptly switched. What may appear to be minor changes in dose or formulation for medicines within the same class can have a sizable impact on clinical response and may lead to serious therapeutic failures or adverse drug events that could be life-threatening.

Epilepsy is one such condition where not only do patients cycle through several different medicines to find the one that effectively manages their condition, but the anti-epileptic medications to control seizures must also be carefully dosed and monitored. Patients with

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[157] Personalized Medicine Coalition. The Personalized Medicine Report: 2017 Opportunities, Challenges, and the Future. November 2017.
[158] American Cancer Society. Thirty-One Percent 5-Year Survival Rate Reported for Cases Diagnosed During 1991-1992. Cancer Facts & Figures. Available at: http://www.cancer.org/research/cancerfactsfigures/cancerfactsfigures/cancer-facts-figures-2012; Druker BJ, Guilhot F, O'Brien SG, et al. Five-Year Follow-Up of Patients Receiving Imatinib for Chronic Myeloid Leukemia. *New England Journal of Medicine*. 2006;355(23):2408-2417.
[159] American Cancer Society. Treating Chronic Myeloid Leukemia by Phase. December 2017. Available at: http://www.cancer.org/cancer/leukemia-chronicmyeloidcml/detailedguide/leukemia-chronic-myeloid-myelogenous-treating-treating-by-phase

epilepsy often must cycle through four or more antiepileptic drugs (AEDs) both as monotherapy and in combination, and even still, more than half of all patients with newly-diagnosed partial onset seizures fail to achieve seizure control with current first-line monotherapy AEDs.[160] Although there are many therapeutic options for seizures available today, the National Institutes of Health notes that the choice of medication will vary considerably based on several factors including the type of seizures experienced, the lifestyle and age of the patient, frequency of the seizures, interactions with other medicines taken for comorbid conditions, and drug side effects.[161]

Any efforts to lower the minimum number of medicines that need to be covered in each class would be inconsistent with the medical needs of patients and current clinical recommendations. Although medicines may have the same basic mechanism of action, small differences at the molecular level and the site of action mean that medicines within the same class can have variances that may impact how a medicine works and the patient responds. The need to retain coverage flexibility is particularly pronounced for biologic products, which are large protein molecules that differ in functional and structural binding locations, and therefore biologic response. It is imperative to maintain the coverage requirements to ensure beneficiaries have access to a broader range of medicines within a class to best meet their health needs.

3. Part D Plan Sponsors Use the Same Utilization Management Tools as Commercial Insurers

The RFI raises the question of whether Part D plans have a sufficient level of flexibility to manage high-cost medications, including those in the protected classes, and suggests that private payers in the commercial market have more robust utilization management tools.[162] The fact is that commercial and Part D plans use the same utilization management tools to manage access to high-cost medications to ensure appropriate utilization, medical necessity, and potential adverse reactions. In comparison to private payers, Part D plans require utilization management as often or more frequently for many classes of medications.

In creating the Part D program, the Medicare Modernization Act authorized the use of utilization management by Part D plans, saying that PDP sponsors may have "a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate."[163] This authority is further communicated in guidance to Part D plans in chapter six of the Medicare Prescription Drug Benefit Manual, which details the use of utilization management tools for which Part D plans must receive CMS approval, the use of these tools when CMS approval is not required, and guidelines for the application of prior authorization

[160] Brodie MJ, Barry SJ, Bamagous GA, et al. Patterns of Treatment Response in Newly Diagnosed Epilepsy. *Neurology*. 2012;78(2):1548-1554.
[161] NIH National Institute of Neurological Disorders and Stroke. The Epilepsies and Seizures: Hope Through Research. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Epilepsies-and-Seizures-Hope-Through#3109_30.
[162] RFI p. 22695.
[163] SSA § 1860D-4 (c)(1)(A).

specifically.[164] The Part D manual also specifies that use of utilization management should be consistent with best practices, appropriate guidelines, and current industry standards—presumably in relation to the broader commercial market.

In fact, the data show that Part D plan sponsors do consistently manage utilization, both in terms of tier placement and use of utilization management tools. Over the past four years, plan sponsors have placed an increasing proportion of brand medicines on higher tiers. In 2018, PDPs placed an average of 44 percent of brand medicines on the specialty tier compared to 35 percent in 2015, while the proportion of brand medicines placed on the preferred tier dropped from 27 percent to 23 percent over that same time horizon.[165] Part D plan sponsors also apply utilization management tools at a consistent rate as well. For example, across three classes of medicines identified as "high cost" by payers—immune suppressants, immunomodulators, and multiple sclerosis treatments—all PDPs use step therapy or prior authorization for at least one drug in 2018.[166]

When compared to employer plans, Part D plans commonly employ utilization management at consistent or higher rates than the commercial market, including for "high cost" and protected class medicines. For example, PDPs use prior authorization or step therapy on 44 percent of oncology medications on average, while employer plans include these requirements on an average of 32 percent of these medications.[167] Across all oncology subclasses—including alkylating agents, antiandrogens, antiangiogenic agents, antimetabolites, enzyme inhibitors, and molecular target inhibitors—PDPs are more likely to apply utilization management to oncology medicines than employer-sponsored plans. Despite protected class status, use of prior authorization and step therapy for atypical antipsychotics is consistent for both markets—on average, employer plans apply these tools to 14 percent of medications in this class, compared to 13 percent for PDPs.[168]

MEDICARE PART D: Changes to the Six Protected Classes Would Harm Vulnerable Beneficiaries and Are Not Warranted on Clinical, Fiscal, or Legal Grounds (RFI p. 22695)

PhRMA opposes any changes to the six protected classes policy that would reduce beneficiary access to critical medications. We dispute the claim that Part D plan sponsors do not have sufficient tools to manage utilization in the protected classes and question the legality and appropriateness of policy changes that would allow cost considerations to outweigh clinical need—particularly in the case of vulnerable beneficiaries. Increased restrictions on use of medicines in the protected classes are unlikely to produce substantial financial savings in Part D. Instead, such restrictions may disrupt therapy and hinder beneficiary access to medicines, leading to worse clinical outcomes, increased need for costly emergency and hospital care, and higher

[164] Medicare Prescription Drug Benefit Manual, Chap. 6, § 30.2.2.
[165] Avalere Health. 2018 Medicare Part D Formularies: An Initial Analysis. November 2017.
[166] Avalere Health. Analysis for PhRMA of PlanScape database of 2018 Part D formularies. June 2018.
[167] Avalere Health. Analysis for PhRMA of MMIT and PlanScape databases of 2018 commercial and Part D formularies. June 2018.
[168] Id.

overall Medicare costs. In short, restricting access to protected class medicines is flawed from a clinical, fiscal, and legal standpoint and would harm vulnerable beneficiaries.

1. Robust Coverage Protections for the Protected Classes Are Needed to Ensure Vulnerable Beneficiaries Have Access to a Full Range of Necessary Medicines

Access to clinically critical medicines for vulnerable patients has been a cornerstone of the Part D program. When Congress established Medicare Part D, it recognized that robust access to certain medicines is central to the wellbeing of beneficiaries who need those therapies, and that their prescribers need access to the full range of treatment options. For example, a Senate exchange that took place just before enactment of the legislation that created Part D emphasized the many layers of patient protections Congress had purposely built into the program to ensure broad coverage of medications for patients—such as those facing HIV/AIDS, epilepsy, or mental illness—"who need exactly the right medicine for them."[169]

One of the key safeguards referenced in this exchange and others—the Part D non-discrimination provision—remains the law today and prohibits CMS from approving a plan if "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals."[170] As CMS has explained, it "instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[171]

For beneficiaries relying on medicines in the protected classes, many treatments are not interchangeable and there is often little clinical evidence to indicate which medication will be most efficacious for any particular patient. Instead, treatment response is heterogeneous and seemingly "similar" patients may experience clinically meaningful differences when exposed to different therapies. Medicines in the same class often have different side effects as well, or may be counter-indicated when combined with a patient's other therapies.

The clinical considerations that led to the original six protected classes policy are as relevant and as pressing today as when the protected classes were established. Maintaining the existing protected classes policy remains clinically necessary for minimizing adverse outcomes that may otherwise result from therapy interruptions or delays. When patients are unable to receive the medication best suited to their individual needs, worsening of symptoms, avoidable hospitalization, poor prognosis or impaired quality of life all are likely. Delaying optimal treatment for even a short time while trying ineffective treatments may cause irreversible damage. There is no clinical basis for preventing a patient from accessing the particular treatment option that would be most effective—or least harmful—on a timely basis.

[169] 149 Cong. Rec. S5882-03 (Nov. 25, 2003).
[170] SSA § 1860D-11(e)(2)(D).
[171] Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

2. Part D Plan Sponsors Already Have Effective Tools to Manage Utilization in the Protected Classes

Part D plan sponsors have always been able to manage access to most drugs in the six protected classes. Plan sponsors routinely apply restrictions like prior authorization and step therapy to promote selection of certain products over others and are permitted to exclude multi-source brands, extended-release products, and certain medication forms and dosages from their formularies. Plan sponsors can also structure their formularies and beneficiary cost-sharing requirements to influence product selection and negotiate rebates with manufacturers. In classes where generic drugs are available, plan sponsors have been highly effective in driving high rates of generic utilization.

In some instances, coverage of medicines in the protected classes is already *more* restrictive in Part D than in the commercial market. For example, an analysis by Avalere Health compared access to anticonvulsants between commercial health plans and Part D PDPs and found that—despite anticonvulsant's status as a protected class—PDPs had less generous formularies and lower levels of access.[172] Specifically, PDP formularies covered fewer anticonvulsants on average than commercial plans (62 percent versus 80 percent) and a substantially smaller share of all brand anticonvulsants (42 percent versus 76 percent). Relative to commercial plans, PDPs also subjected a larger share of anticonvulsants to either prior authorization or step therapy (13 percent versus 11 percent).

Other analysis similarly demonstrates that utilization management for protected class medicines is no less prevalent in Part D than in the commercial market. As mentioned earlier, relative to employer-sponsored plans, Part D PDPs apply prior authorization or step therapy to a similar share of atypical antipsychotics (14 percent and 13 percent, respectively) and a larger share of oncology medicines (44 percent versus 32 percent).[173] Furthermore, wide variation in the use of utilization management across Part D plan sponsors shows that clinical discretion, not regulation, determines how often these tools are applied in the protected classes. For example, among the top 10 largest PDPs, the share of covered atypical antipsychotics subject to prior authorization or step therapy ranges from 5 percent to 65 percent.[174]

A solid body of evidence shows that Part D plans already negotiate successfully to impact therapeutic choices and secure competitive pricing for medicines in the protected classes. MedPAC reports that over the 2006 to 2014 period (the latest data available), prices for protected class drugs grew more slowly than for Part D prices overall.[175] Part D plans have also been highly successful in driving generic utilization within the protected classes. According to an

[172] Avalere Health. An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans. June 2013.
[173] Avalere Health. Analysis for PhRMA of MMIT and PlanScape databases of 2018 commercial and Part D formularies. June 2018.
[174] Avalere Health. Analysis for PhRMA of PlanScape database of 2018 Part D formularies. June 2018.
[175] MedPAC. Report to the Congress: Medicare Payment Policy. March 2017.

analysis of CMS data by the Pew Charitable Trusts, *the generic utilization rate in the protected classes is higher than for non-protected classes* (92 percent versus 84 percent).[176] MedPAC agrees that protected class status does not affect plan sponsors' ability to drive utilization of generics and reports that accounting for generic substitution, cumulative prices for protected class medicines *decreased* by 13 percent between 2006 and 2014, compared to an 8 percent increase for all Part D drugs.[177]

Similarly, a 2016 report by the QuintilesIMS Institute, now IQVIA, also found that plan sponsors successfully negotiate significant cost reductions for medicines most commonly used by Part D beneficiaries, including medicines in two of the protected classes.[178] Across the 12 most commonly used therapeutic classes of medicines—including antidepressants and anticonvulsants—Part D plan sponsors negotiated an average rebate of 35.3 percent. Accounting for negotiated rebates, the analysis found that the final net costs to the plan sponsor for antidepressants and anticonvulsants were roughly half of the list price. Given the conclusive evidence that Part D sponsors have been able to, and do, negotiate rebates and drive appropriate generic utilization within the protected classes, it is wholly inappropriate as a matter of public policy to allow a vague but vocal interest in "flexibility" on the part of health plans and PBMs to outweigh the Federal government's legitimate (and statutory) interest in preventing discrimination against the sickest patients.

3. Restricting Access to Protected Class Medicines is Unlikely to Produce Substantial Savings in Part D and Could Increase Medicare Costs Overall

Cost containment is clearly one of the Administration's primary motivations in pursuing changes to the protected classes; however, allowing plan sponsors to place additional restrictions on access to medicines in the protected classes is unlikely to produce substantial Part D savings, and could have the unintended consequence of increasing Medicare spending overall.

Two factors limit the potential for the proposed revision of the protected classes policy to yield Part D savings. First, the current high rate of generic utilization sharply limits the ability of plan sponsors to further drive utilization to lower cost therapies. Second, the remaining share of brand utilization in the protected classes is primarily comprised of medications without generic alternatives. In these instances, plan sponsors who seek to use more restrictive utilization management to force non-medical (*e.g.*, cost-based) switching run the risk of disrupting established treatment regimens and worsening clinical outcomes for their most vulnerable beneficiaries. As an example, the Pew Charitable Trust reports that 90 percent of antiretroviral and 22 percent of antineoplastic prescriptions are for brand medicines without generic alternatives, "indicating widespread clinical use that may inhibit PDPs' ability to exclude these drugs from formularies." Furthermore, even in cases where generic drugs are available in a class,

[176] The PEW Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy. March 2018.
[177] MedPAC. Report to the Congress: Medicare Payment Policy. March 2017.
[178] QuintilesIMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates: A Study of Original Branded Products in the U.S. October 2016.

generic therapy may be clinically inappropriate due to safety and efficacy concerns. For example, federal clinical guidelines for the use of antiretrovirals recommend newer combination brand therapies over older generic monotherapies, due to the increased risk of virologic failure and drug resistance associated with monotherapy.[179]

Restricting access to protected class medications may also have the unintended consequence of increasing overall Medicare costs. In particular, stand-alone PDPs—which are not responsible for their enrollees' medical care—may lack the financial incentives to consider the downstream consequences of formulary exclusions and utilization management in the six protected classes, including discontinuation of therapy, poor medication adherence, and increased consumption of inpatient and outpatient services.[180] Higher costs and poor clinical outcomes resulting from access restrictions or suboptimal medication use in the six protected classes are supported by a wide body of evidence. For example:

- Multiple studies demonstrate that Medicare beneficiaries with schizophrenia and low adherence to antipsychotics require significantly more inpatient care and incur significantly higher psychiatric hospital expenditures.[181]

- Compared to adherent patients, individuals 65 and older with epilepsy who are nonadherent to their anticonvulsant medications experience more seizures and more than $2,600 in higher health care costs from increased impatient and emergency department use.[182]

- Among individuals with a transplanted organ, nonadherence to immunosuppressants increases the odds of transplantation organ failure seven-fold, leading to increased health care utilization or premature death.[183]

- Prior authorization requirements for antiretrovirals increase administrative costs for providers and can lead to patients experiencing delays in receiving their medications.[184]

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[179] National Institutes of Health. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. March 27, 2018. Available at: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0

[180] Lavetti K and Simon K. Strategic Formulary Design in Medicare Part D Plans. Working Paper. June 24, 2016.

[181] Offord S, Lin J, Wong B, et al. Impact of Oral Antipsychotic Medication Adherence on Healthcare Resource Utilization Among Schizophrenia Patients with Medicare Coverage. *Community Mental Health Journal*. 2013;49(6):625-629; Roberto P, Brandt N, Onukwugha E, et al. Adherence to Antipsychotic Therapy: Association with Hospitalization and Medicare Spending Among Part D Enrollees with Schizophrenia. *Psychiatric Services*. 2017;68(11):1185-1188.

[182] Ettinger AB, Manjunath R, Candrilli SD. et al. Prevalence and Cost of Nonadherence to Antiepileptic Drugs in Elderly Patients with Epilepsy. *Epilepsy & Behavior.* 2009;14(2):324-329.

[183] Butler JA, Roderick P, Mullee M, et al. Frequency and Impact of Nonadherence to Immunosuppressants After Renal Transplantation: A Systematic Review. *Transplantation.* 2004;*77*(5):769-776.

[184] Casalino LP, Nicholson S, Gans DN, et al. What Does it Cost Physician Practices to Interact with Health Insurance plans? *Health Affairs.* 2009;28(4):w533-w543.; Raper JL, Willig JH, Lin H, et al. Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications in an HIV Clinic. *Oxford Journal of Clinical Infectious Diseases*. 2010;51(6):718-724.

> HIV patients who face drug benefit design changes are also nearly six times more likely to face treatment interruptions than those with more stable coverage, increasing their risk of virologic rebound, drug resistance, and increased morbidity and mortality.[185]

In sum, allowing plan sponsors to place additional restrictions on access to medicines in the protected classes is penny wise and pound foolish. Changes to the existing six protected classes policy are unlikely to generate substantial savings for Part D and could have the unintended consequence of increasing spending in other parts of Medicare.

4. Conditioning Protected Class Status on Changes in List Price Violates Part D's Non-Discrimination Clause

In the discussion of incentives to lower or not increase list prices, the RFI asks broadly what CMS "[should] consider doing, under current authorities, to create incentives for Part D drug manufacturers committing to a price over a particular lookback period."[186] Among other things, the RFI asks whether drugs that have been subject to a price increase over a specified lookback period should be allowed to be included in the protected classes, and whether drugs that have not had a price increase over a lookback period should be treated differently for purposes of protected class exceptions criteria.[187]

We understand the importance HHS attaches to reforms that could encourage manufacturers not to increase list prices. PhRMA supports several polices, which we discuss in detail in Section II of our comments that could help to promote competition and improve patient affordability. At the same time, it is critically important that CMS not undercut foundations of the Part D program that have protected its most vulnerable beneficiaries and made the program successful. We discuss these foundations below.

First, excluding a drug from the protected classes that otherwise belongs there (or otherwise tying protected class status to whether a drug's list price increases over a specified period) is not an appropriate or legally sound way to advance the administration's goal of lowering prices, as two statutory provisions may prevent this: the Part D law's non-discrimination clause (Social Security Act (SSA) § 1860D-11(e)(2)(D)) and its protected classes clause (SSA § 1860D-4(b)(3)(G)). CMS developed the protected classes doctrine at the beginning of the Part D benefit to carry out the Part D law's non-discrimination clause, which prohibits CMS from approving any Part D plan with a design (including a formulary or formulary structure) that is "likely to substantially discourage enrollment by certain [Medicare beneficiaries]."[188] CMS instituted the protected classes policy "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs [in the six protected classes] would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an

[185] Das-Douglas M, Riley ED, Ragland K, et al. Implementation of the Medicare Part D Prescription Drug Benefit is Associated with Antiretroviral Therapy Interruptions. *AIDS and Behavior*. 2009;13(1): 1-9.
[186] RFI p. 22698.
[187] 83 Fed. Reg. at 22698.
[188] SSA § 1860D-11(e)(2)(D).

interruption of therapy for these vulnerable populations."[189] This statement remains true. Excluding a drug otherwise within the six protected classes from protected class status due to a list price increase would therefore violate the non-discrimination clause (even if CMS issued regulations to create an exception to SSA § 1860D-4(b)(3)(G)), by permitting Part D plans with benefit designs that discouraged enrollment by some of Medicare's most vulnerable beneficiaries. Accordingly, the law does not permit compromising its non-discrimination principles in order to promote lower drug prices, and we believe CMS has other tools that will advance the goal of patient affordability and market competition more effectively.

Moreover, tying a drug's protected class status to whether its list price has increased finds no support in the text of the relevant statutory provisions, which instruct CMS to develop criteria to identify classes "of clinical concern"[190] and ban discriminatory benefit designs that could discourage enrollment by certain beneficiaries.[191] In interpreting and applying these provisions, CMS may not consider factors Congress did not authorize it to consider[192]—such as list price movements—and must respect Congress' determination that criteria based on "clinical concern[s]" are in the best interest of the Part D program.

Second, any approach to discouraging list price increases that CMS adopts must not violate the noninterference clause of the Part D statute.[193] As we state elsewhere in this letter, the noninterference clause is a cornerstone of the Part D program and a key reason for the program's success. Any policies pursued by CMS must not (1) interfere in the private negotiations between manufacturers, plan sponsors, or pharmacies; or (2) create a formulary or price structure. For this and other policy reasons, we urge CMS to instead consider the policies discussed in the section of this comment letter on rebates, which we believe provide effective tools for discouraging list price increases.

SECTION V: MEDICARE PART B (RFI p. 22697)

The Medicare Part B benefit provides crucial access to medicines for vulnerable patients who suffer from a range of serious illnesses. It covers a subset of outpatient prescription medicines that are usually administered by a physician to treat patients with complex, serious, often rare conditions who currently have few or no alternative treatment options. The structure of the Part B benefit provides much needed flexibility for physicians to tailor treatment plans to optimize care for these patients. As HHS considers changes to this program, it will be very important to

[189] Medicare Prescription Drug Benefit Manual, Chap. 6, § 30.2.5.
[190] SSA § 1860D-4(b)(3)(G).
[191] SSA § 1860D-11(e)(2)(D).
[192] See, e.g., Nalco Co. v. EPA, 786 F. Supp. 2d 177, 187 (D.D.C. 2011) (rejecting EPA's enforcement action as arbitrary and capricious where it acted based on its stated desire "to level the marketplace for competitors," but the authorizing statute "does not give EPA jurisdiction to control or modify the marketplace").
[193] SSA § 1860D-11(i) ("In order to promote competition under [Part D] and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs").

preserve its strengths in supporting beneficiary access to a range of treatment options and timely delivery of complex care at the site of service that is best for the patient. Preserving drug coverage under Part B is crucial for beneficiaries with serious illnesses.

As HHS considers changes to Medicare Part B, it should pursue approaches that improve value holistically, across the treatment continuum the patient experiences, and empower patients and consumers to make informed choices rather than restricting their choices and treatment options. The Department also should avoid introducing misaligned incentives that would undermine the existing market-based and transparent Average Sales Price (ASP) system. The President's Blueprint states "Millions of Americans face soaring drug prices and higher out-of-pocket costs, while manufacturers and middlemen such as PBMs and distributors benefit from rising list prices…"[194] and calls for bold action to bring down prices for patients and taxpayers, such as increasing transparency and fixing incentives that may be increasing prices for patients.[195] In light of HHS' goals, it is noteworthy that several unique features of Medicare Part B contribute to transparency, stable prices in the program, negotiation, access to care, and predictable cost sharing for beneficiaries:

- **ASP reflects robust negotiation in the commercial market, resulting in savings for beneficiaries and the Medicare program.** Medicare Part B drug reimbursement generally is not based on manufacturer list price or Wholesale Acquisition Cost (WAC). Rather, for most drugs, reimbursement is based on ASP, which reflects the weighted average of all manufacturer sales prices,[196] and includes rebates and discounts that are privately negotiated by health care providers and payers. As a result, it serves as a mechanism for passing discounts negotiated in the commercial market on to Medicare beneficiaries and the Medicare program. Due to this market-based competition, ASP prices are often substantially lower than list prices. Looking at discounts for the 25 medicines with the highest spending under Part B, the ASP represents a weighted average discount of 21.2 percent off the list price.[197]

- **ASP moderates price growth.** CMS' own analysis of the market-based ASP pricing mechanism found that in the third quarter of 2018, the ASP-based Part B payment amount for 11 of the top 50 drugs decreased; and, for most of the higher volume drugs, ASP changed 2 percent or less. CMS notes, "In general, among the top drugs with a decrease, there are a number of competitive market factors at work—multiple manufacturers, alternative therapies, new products, recent generic entrants, or market shifts to lower priced products."[198] A long range analysis of the ASP system supports this finding. The volume weighted ASP for Part B medicines has remained steady year

[194] RFI p. 22692.
[195] RFI p. 22695.
[196] Medicaid and certain other federal discounts and rebates are excluded from ASP. There are special rules for certain classes of drugs (e.g., DME infusion drugs, vaccines, and biosimilars).
[197] Estimates based on analysis by PhRMA using the July 2018 ASP Pricing File, 2018 Medispan files, and 2018 Medicare Part B Drug Spending Dashboard.
[198] CMS, 2018. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2018ASPFiles.html

over year, and price growth for Medicare Part B drugs is below overall medical inflation.[199]

- **ASP is transparent.** Manufacturers report sales to CMS on a quarterly basis, and CMS then calculates and posts the ASP for all Part B medicines in a public data file on the CMS website.

- **Part B offers a predictable cost-sharing structure and supplemental coverage offsets out-of-pocket costs for many beneficiaries.** Cost sharing for Part B medicines is set at 20 percent of the Medicare reimbursement rate. A majority of beneficiaries (over 80 percent) carry supplemental coverage that helps to defray their out-of-pocket costs for Part B medicines, an option that is not available for Part D plans.[200] Recent analysis from Avalere found that, as a result of supplemental coverage, beneficiaries typically have lower out-of-pocket costs for oncology medicines covered in Part B than in Part D.[201]

- **The Part B reimbursement rate covers costs associated with storing and handling the medicine.** Changes to the Part B reimbursement rate would affect providers' ability to stock and handle Part B drugs. As a result, patients would be forced to receive care in more costly settings.[202] Under the current statutory model, the 6 percent add-on rate also accounts for variability in provider practice size, patient population, and location.[203] Critics of the system argue that the add-on creates perverse prescribing incentives; however, there is no compelling evidence to show that doctors make inappropriate prescribing decisions based on reimbursement rates.

- **Part B facilitates access to care for beneficiaries with serious illnesses.** Due to the nature of many medicines in Part B and the diseases that they treat, patients often need to try multiple therapies before finding the appropriate treatment, and physicians and patients need maximum flexibility to tailor treatments to meet patients' needs, consistent with clinical evidence.

- **New and innovative payment models are already being explored in Part B.** CMMI has implemented a number of programs that address Medicare expenditures in Part B more broadly. For example, the Oncology Care Model (OCM) aims to lower Medicare costs by coordinating care more closely for oncology patients and testing a performance-based payment system. OCM is just one of many CMMI models that affect prescribing

[199] The Moran Company. Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2015. December 2016.
[200] Analysis of the 2013 Medicare Current Beneficiary Survey conducted by The Moran Company for PhRMA. June 2017.
[201] Avalere Health. Moving Certain Part B Drugs to Part D, A Proposal Being Evaluated by The Trump Administration, Would Have Disparate Financial Impacts on Patients. May 2018.
[202] Letter to HHS Secretary Alex Azar. March 14, 2018. Available at: https://www.rheumatology.org/Portals/0/Files/Physician-Group-Letter-to-HHS-Drug-Pricing-Proposals.pdf
[203] American Action Forum. Primer: Medicare Part B Drug Payment System. June 19, 2018. Available at: https://www.americanactionforum.org/research/primer-medicare-part-b-drug-payment-system/.

> of Part B medicines. In a recent report, Avalere notes that "[a]lthough CMS did not design the programs covered in this brief specifically to address Part B drugs, providers participating in these programs may modify their Part B prescribing, utilization, and treatment patterns in an effort to ensure that expenditures for all included Medicare services fall under the applicable spending benchmark."[204]

These dynamics successfully balance patient access with controlling costs as evidenced by the fact that Part B medicines remain a small and stable share of Medicare spending. Spending on Part B medicines was just 3 percent of total Medicare spending in 2015 (11 percent of all Part B spending),[205] even as patients gained access to important new treatment advances. HHS should not pursue policy changes to Part B that would reduce access to care or undermine the aspects of the program that have worked well to promote transparent, market-based reimbursement for physician-administered medicines. As discussed below, we are concerned that several of the specific proposals in the RFI could harm patient access to care and undermine delivery of high-quality care in clinically appropriate settings.

MEDICARE PART B: Part B to Part D (RFI p. 22694)

Whether and when a drug is covered under the Part B benefit or the Part D benefit is a distinction that is clearly defined in Medicare law. Generally, Medicare Part B covers medications that require administration by a physician or in a hospital outpatient setting, such as chemotherapy. Many patients who use Part B medicines have serious conditions that require intensive management such as cancer, RA and other autoimmune conditions, severe infections, multiple sclerosis, macular degeneration, genetic disorders, and other rare diseases. Often, these patients are reliant on physician-administered medicines (e.g., intravenous infusions, interocular injections) because they have few or no other treatment options. By contrast, Medicare Part D covers nearly all other types of drugs not otherwise covered by Part B, and most Part D drugs are self-administered products (e.g., oral pills or liquids, simple subcutaneous injections) that are obtained by the patient through a pharmacy.

Moving Part B drugs exclusively to the Part D benefit could increase out-of-pocket costs for many patients and reduce access to care. It also poses operational and administrative challenges for providers, as well as safety issues for patients, because most Part B medicines have complex storage, handling, and preparation requirements that require specific clinical expertise. For the reasons described below, PhRMA does not support moving medicines from Part B to Part D.

[204] Avalere Health. Medicare Part B Drug Payments Implicated in CMMI Models. August 2016. Available at: http://avalere.com/expertise/life-sciences/insights/medicare-part-b-drug-payments-implicated-in-cmmi-models.
[205] Analysis of 2017 Medicare Trustees Report and June 2017 MedPAC Databook conducted by Price Waterhouse Cooper for PhRMA.

Increased Costs for Patients

All else equal, moving Part B drugs to the Part D benefit could increase costs for most patients. If products are shifted from Part B to Part D, beneficiaries would experience an increase in their monthly Part D premiums as Part D coverage broadened to cover more medicines. Beneficiaries would experience these increases whether or not they are prescribed a Part B medicine as the cost of additional benefits would be spread across all policies. We estimate that if all Part B medicines were moved to Part D, Part D premiums could increase by nearly 40 percent.[206]

Shifting coverage of Part B medicines to Part D could also introduce short-term volatility into the Part D market. The overall cost of the Part D benefit would likely increase as plans begin to cover a broader range of medications, and premium changes would likely be less stable year over year as plans adjust to incorporating additional medicines into their bids. In addition, more patients could reach the catastrophic phase of the Part D benefit and this will increase federal spending on reinsurance in the Part D program.[207]

For some beneficiaries, out-of-pocket costs at the point-of-sale would also increase. A government-commissioned study previously examined moving a subset of Part B drugs to Part D and concluded that "as drugs move from Part B to Part D…costs for beneficiaries rise. The increase in beneficiary out-of-pocket costs is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication."[208] On net, previous analyses suggest that Medicare would likely see only a small decrease in total spending as a result of this policy, and that this decrease comes at the expense of beneficiaries, shifting significant costs to them via excessive cost sharing.[209] More recently, an analysis from Avalere Health found that average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies than for those covered in Part B in 2016.[210] Beneficiaries who carry supplemental coverage (a majority of Part B patients) are particularly likely to see higher out-of-pocket costs if their medicines are shifted into Part D.

Reduced Access to Care

Moving Part B medicines to Part D could also reduce patient access to treatment for many life-threatening and debilitating conditions. A subset of Medicare beneficiaries are not currently enrolled in Part D prescription drug coverage. Analysis of similar proposals in the past found that thousands of patients would be without coverage of physician-administered medicines as a result of the shift.[211] Approximately 12 percent of beneficiaries either do not have drug coverage or have coverage that is less generous than Part D, and could be at risk for losing coverage for their

[206] Holcomb, Katie et al. Impact of Moving Medications from Medicare Part B to Part D. June 2018
[207] Id.
[208] Acumen, LLC. Estimating the Effects of Consolidating Drugs under Part D or Part B. August 2011.
[209] Id.
[210] Avalere Health. Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D. May 21, 2018. Available at: http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d
[211] Acumen, LLC. Estimating the Effects of Consolidating Drugs under Part D or Part B. August 2011.

Part B medicines if they were shifted to the Part D benefit.[212] If these patients decided to enroll in Part D as a result of the shift, they may be subject to late enrollment penalties that further increase their premium costs.

If Part B medicines shift to Part D, patients who rely on Part B medicines may experience new barriers to accessing the medication that they and their doctor have identified as the best treatment for their disease or condition. Unlike Part B, which covers all medically necessary services and treatments, Part D plans are generally not required to cover all the medicines within a therapeutic class. Imposing coverage restrictions on Part B medicines would have a significant negative impact on patients. For example, one study examining a proposed model, found that using a cost-effectiveness-based standard to restrict access could result in 62 to 93 percent of patients with RA, multiple sclerosis, non-small cell lung cancer and/or multiple myeloma losing access to the treatments their physicians determined were best for them.[213] Although Part D plans typically do not apply this type of rigid cost-effectiveness standard, they do impose cost sharing and utilization management policies (like prior authorization requirements) based on presumptions of treatment equivalence that may not always be clinically appropriate and can have a similar effect on patient access. For medications where time is a critical factor in treatment, any delays due to benefit verification, prior authorization, or lack of coverage will have negative effects on patient outcomes.

Applying the Part D coverage floor to Part B drugs would also be of concern. The Part D statute requires plans to offer a minimum of two drugs in each USP MMG category or class.[214] Due to issues with the classification of rare genetic disorders, there is potential for plans to exclude coverage for certain diseases altogether.

In addition, restrictions in Part D plans like prior authorization or step therapy can increase administrative burden for providers and delay access to treatment. For example, an analysis of Part D formulary coverage for biologic Disease-Modifying Antirheumatic Drugs (DMARD) used to treat RA found that coverage for individual products ranged from 30 to 100 percent of plans, meaning some products were covered by a minority of Part D plans. While all plans covered at least one product, nearly all plans (97 percent) required prior authorization to access DMARD products.[215] Many of the treatments covered in Part B are complex biologics with few or no other treatment options and the utilization management techniques employed by many Part D plans for these medicines have the potential to delay or prevent patient access,[216] undermining adherence,

[212] MedPAC. Report to Congress: Medicare Payment Policy. March 2017.
[213] Xcenda. Applying Cost-Effectiveness Thresholds to the Real World: Implications on Access for Medicare Beneficiaries. May 30, 2018. Available at: https://www.xcenda.com/insights/phrma-issue-brief-applying-cost-effectiveness-on-access-for-medicare-beneficiaries
[214] *See* 42 U.S.C.S. § 1395w-104(b)(3)(C) (LexisNexis 2018) (codified at 42 C.F.R. § 423.120(b)(2) (LexisNexis 2018))
[215] Yazdany, Jinoos, et al. Coverage for High-Cost Specialty Drugs for Rheumatoid Arthritis in Medicare Part D. *Arthritis & Rheumatology* 2015;67(6):1474-1480.
[216] American Society of Clinical Oncology. American Society of Clinical Oncology Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies. *Journal of Oncology Practice.* 2017;13(11):758-762.

which will lead to poorer outcomes and increasing long-term medical costs for the health care system.[217]

Furthermore, Part D plans have cost sharing as high as 33 percent for the specialty tier, and there is no mechanism for addressing access when there are no reasonable alternative medications with lower cost sharing. Under current CMS regulation and guidance, when a product is placed on a specialty tier in Part D, patients cannot seek formulary exceptions (a process available for medicines in other tiers) by demonstrating medical need for the specialty tier drug. Such an exception might be appropriate when a patient has failed on medicines available on lower-cost tiers, for example. Many of the products in Part B have the potential to fall into the specialty drug category, [218] and would then be exempt from the exceptions process, creating another barrier to access.

Operational Challenges

If coverage for physician-administered medicines shifts to Part D, it could change the providers' process for acquiring these medicines in a way that undermines their ability to customize dosing in response to changing individual patient needs, e.g., using lab values. Experience with Part D covered vaccinations suggests that physicians may not have an administratively simple way to bill Medicare Part D plans. Instead of purchasing medicines directly, providers may need to work with a specialty pharmacy to order medicines for their patients. Currently, more than half of providers prescribe Part D covered vaccines to seniors, but refer beneficiaries to pharmacies to purchase them.[219] In some cases (e.g., certain cancer treatments), physicians may need to make adjustments to the dosing and administration frequency of Part B products at the point of care that aren't easily accommodated in a specialty pharmacy or retail model. Inability of physicians to modify and customize dosing in response to individual clinical outcomes during administration was one of the major complaints that physicians had with CMS' CAP, as discussed in greater detail below. The potential exists to increasingly complicate the entire patient experience from lab work, to medication experience, to the interaction between a patient and their provider and pharmacy.

These operational issues can also compound barriers to patient access. Here another lesson can be drawn from Part D covered vaccines. Physicians who prescribe and administer these vaccinations are often unable to verify beneficiary coverage and cost-sharing liability when they are not included in the Part D plan's network. Also, when physicians cannot file Part D claims,

[217] Iuga, A. O., & McGuire, M. J. Adherence and health care costs. *Risk Management and Healthcare Policy*. 2014;*7*:35–44.
[218] CMS determines a threshold for a specialty drug in their annual call letter and only allows Part D drugs to be placed on specialty tiers if the majority of prescription drug events exceeds the dollar threshold. CMS, Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CY-2016-Specialty-Tier-Methodology.pdf. In 2018 the threshold was $670 per month. CMS, Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf
[219] Avalere Health. Shifting Drugs from Medicare Part B to Part D**:** Learnings from Medicare Coverage of Vaccines. June 2018.

the patient must sometimes pay the provider up front and then submit for reimbursement from their Part D plan, creating a potential financial burden. Another option is for patients to purchase the vaccine directly from the pharmacy and then transport the vaccine to their treating physician's office for administration.[220] In a survey conducted by GAO, 8 in 10 physicians cited the amount of time used to identify beneficiaries' coverage and submit claims as a barrier to administering Part D vaccines. This ambiguity about cost may be discouraging patients from getting vaccinated, despite recommendations from their provider. GAO found that more than 60 percent of physicians report that beneficiaries decline shingles vaccinations about half the time or more. By comparison, only 1 in 10 physicians report that beneficiaries decline pneumococcal vaccinations, which are covered under Part B, half the time or more.[221] Physicians and patients would likely face similar billing and reimbursement barriers if Part B drugs were covered under Part D. While access barriers have been shown to interfere with the administration of a one-time vaccine, switching complicated physician-administered medicines could cause even more disruption for medicines that need to be administered more often—monthly or even weekly.

Of particular concern are the safety issues surrounding patient transportation and handling of complex medications. Under a Part B to Part D scenario, in some cases patients might be encouraged to pick up their medicine at a pharmacy and bring it to an infusion center for administration. This would not only be unnecessarily complicated and time consuming, but poses a significant potential public health hazard in the form of unintended exposures. Many of these medicines have intricate storage, handling, and administration requirements that are best met by a medical professional in a clinical setting for quality, safety, and liability reasons. Improper handling has the potential to be extremely wasteful and put patients at risk. By contrast, the current structure of the Part B benefit facilitates safe and effective use of Part B therapies. This is one of many reasons why Medicare and most commercial plans cover physician administered drugs in the medical benefit and reimburse through a buy-and-bill system.

Challenges Associated with Reducing or Eliminating the Drug Add-on Payment

Proposals to reduce or eliminate the percentage add on to ASP-based payment could make it financially untenable for physicians to provide certain medicines to Medicare beneficiaries. When CMS proposed a Part B drug payment demonstration that would have reduced the ASP add on in 2016, a survey of oncologists, hematologists, and rheumatologists found that physicians expected to realize a financial loss on approximately 40 percent of the products they administer if the Part B Drug Payment Model went into effect.[222] Such losses could lead community practices to close, consolidate, or refer patients to the hospital setting. For patients, this would mean traveling longer distances to obtain care and accelerating the shift to the hospital setting where treatment is more expensive for both beneficiaries and the Medicare program. A study from 2012 found that the average cost sharing for Medicare beneficiaries receiving chemotherapy was 24 percent

[220] Id.
[221] Id.
[222] Xcenda. Provider Survey: Potential Impact of CMS Part B Drug Payment Model Proposed Rule. Conducted for PhRMA. April 2016.

higher in the hospital outpatient setting versus a physician's office.[223] Other data showing cost increases associated with increased provider consolidation are included in our comments below on Site Neutrality for Physician-Administered Drugs. Past proposals to implement these types of changes in Part B coverage and reimbursement have been rejected over concerns that patients may experience treatment delays and higher costs, and that care could shift to more expensive settings.

Concerns with Shifting Part B Medicines to Part D Based on OECD Country Prices

The RFI asks whether Part B medicines should be shifted to Part D when prices in Organization for Economic Co-operation and Development (OECD) countries are lower than prices paid by Part B providers. PhRMA is deeply concerned with this concept, which links Medicare policy decisions to policies in other countries that artificially suppress prices through government-dictated access restrictions and arbitrary cost-effectiveness thresholds.[224] At the same time, because many OECD countries have regulations that effectively prohibit the sale of medicines at U.S. prices, this would move many Part B medicines to Part D with the harms described above.

It is important to recognize that foreign price controls often lead to significant access barriers. Experience in several OECD countries have shown the dangers of the government attempting to make centralized, one-size-fits-all judgments of value. Restrictions imposed by the U.K.'s National Institute for Health and Care Excellence (NICE) have created substantial barriers between patients and life-saving treatments—recent analysis shows that from 2013 to 2017, nearly 92 percent of oncology treatments were given some kind of access restriction.[225] Patients who live in countries that impose centralized value judgements also have access to fewer treatment options—recent data shows that nearly 90 percent of newly launched medicines were available in the U.S., compared to just two-thirds in the U.K., half in Canada and France, and one-third in Australia.[226]

MEDICARE PART B: Part B Competitive Acquisition Program (RFI p. 22697)

Relaunching a CAP in Part B could also reduce patient access to needed therapy and inhibit physicians' ability to provide Part B medicines in their offices. Below, we outline concerns with CMS' 2006-2008 CAP as well as a recent MedPAC proposal to relaunch CAP called the Drug Value Program (DVP). As CMS considers potential approaches it will be important to ensure that any proposal does not undermine the core strengths of the current, market-based ASP system, including: supporting and empowering patients and their physicians in making informed

[223] Avalere Health. Total Costs of Cancer Care by Site of Service: Physician Office vs. Hospital Outpatient. March 2012.
[224] See the additional discussion of foreign price controls in the International section of our comments.
[225] Hughes K and N Jeswani. HTAs Recommendations for Oncology Have Grown More Restrictive Over Time. Avalere Health. June 2018. Available at: http://avalere.com/expertise/life-sciences/insights/htas-recommendations-for-oncology-have-grown-more-restrictive-over-time.
[226] Haninger K. New analysis shows that more medicines worldwide are available to U.S. patients. PhRMA. The Catalyst blog. June 2018. Available at: https://catalyst.phrma.org/new-analysis-shows-that-more-medicines-worldwide-are-available-to-u.s.-patients

decisions from the range of available treatment options, avoiding disruptions or delays in delivery of medically beneficial care in the optimal treatment setting, and avoiding increases in patient costs that can lead to treatment abandonment.

To achieve this goal, it will be important for any competitive bidding proposals to be voluntary for physicians, and workable from the perspective of physicians and patients by reducing administrative burden and supporting quality patient care. It should not use formulary and utilization management tools that prevent patients from accessing care and place unnecessary administrative burden on physicians.

CMS' 2006-2008 CAP

CMS' original Part B CAP faced several challenges, including:

- **Initial payment rates exceeded reimbursements under the ASP system**: Based on Medicare claims processed through the National Claims History File as of June 2008, the cost of drugs administered through CAP exceeded 106 percent of ASP by approximately 3.2 percent in the aggregate for 2006 and 2007. This occurred in part because product utilization under CAP differed from that under buy and bill, which CMS had not accounted for in its payment methodology. CMS also adjusted CAP payments using the producer price index for prescription drugs, which resulted in further overpayments to vendors.

- **Vendor interest**: CMS received bids from vendors under the original CAP solicitation. However, only one vendor (Bioscrip) signed a contract with the agency to participate in CAP.[227]

- **Provider attrition:** CAP suffered from a very high provider attrition rate. At its peak enrollment, the program served just one thousand physician practices. 45 percent of practices participating in the CAP in 2006 opted not to participate in 2007, and 53 percent of practices participating in 2007 opted not to participate in 2008.[228]

In 2008, CMS postponed implementation, citing contractual issues with bidders.[229]

A criticism of the original Part B CAP was that it could have the effect of limiting physicians' ability to tailor treatment to meet the needs of their patients. Concerns with this aspect of the program contributed to low overall enrollment and higher dissatisfaction in targeted specialties like oncology. Oncologists in particular may need to alter the dose, formulation, or drug regimen at the point of care depending on the status of the patient on the day they present for treatment.

[227] RTI International. Evaluation of the Competitive Acquisition Program for Part B Drugs: Final Report. December 2009. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.
[228] Id.
[229] CMS. Competitive Acquisition for Part B Drugs & Biologicals.

CAP required physicians to place an order with the CAP vendor in advance of the patient visit, leaving open the possibility that physicians may not have the appropriate product(s) available if a change was needed the day of treatment.

CAP did include two provisions that were essential to preserving flexibility and access to treatment. The "Furnish as Written" provision allowed physicians to write for a specific National Drug Code (NDC) (e.g., to obtain a specific formulation of a drug that may not be supplied by the CAP vendor). Under this provision, the physician would obtain the drug privately and bill Medicare using the ASP methodology. Similarly, the "Emergency Restocking" provision allowed physicians to administer a CAP drug to a Medicare beneficiary from the physician's own inventory and replace the drug by ordering from the vendor.

Physicians may have lacked the flexibility necessary to administer clinically appropriate treatment absent these two provisions. Use of these two provisions was unexpectedly high under CAP, particularly for patients who had multiple Part B drug claims and those with cancer and chronic conditions. Patients with seven or more CAP drug claims in 2006 received 40 percent of their CAP medicines under emergency restocking.[230] For treatment of some cancers, 30 percent of claims were billed outside of the normal CAP billing procedure. Similarly, for patients with chronic conditions such as RA and asthma, one-third of their claims billed outside of the normal CAP billing process.[231]

Experience with the 2006-2008 Part B CAP underscores the importance of preserving clinical flexibility and patient access under such a program. Even with these provisions, oncologists and other targeted specialists (e.g., rheumatologists, ophthalmologists, and other non-primary care specialties) had lower enrollment and higher dissatisfaction. Nearly one-third of oncology specialists and one-quarter of other targeted specialists said that they were dissatisfied with CAP, compared with just 17 percent of non-targeted specialists.[232] Further, 30 percent of oncology specialists believed their patients were inconvenienced by CAP.[233]

MedPAC's DVP

The MedPAC has proposed an alternative to CAP that seeks to resolve some of the challenges with the 2006-2008 program. However, MedPAC's proposal would severely limit access to treatment for Medicare beneficiaries via restrictive formularies, prior authorization, and step therapy. It would also undermine Part B's market-based reimbursement system by imposing a binding arbitration process to set prices for innovative new medicines. Finally, it could threaten the viability of community practices and encourage costly consolidation by using changes to the ASP reimbursement system to drive physicians into the program. We strongly urge HHS to avoid policies that would have similar consequences for patients and the Medicare program.

[230] RTI International. Evaluation of the Competitive Acquisition Program for Part B Drugs: Final Report. December 2009.
[231] Id.
[232] Id.
[233] Id.

Like CAP, MedPAC's proposed DVP would establish third-party vendors to negotiate prices for Part B drugs. However, these vendors would be permitted to establish formularies and utilization management requirements such as prior authorization and step therapy that could make it more challenging for Part B patients, many of whom have serious and complex conditions, to access the medications they need.

Part B's current structure ensures the availability of a range of treatment options. Due to the personalized nature of many medicines in Part B and the diseases that they treat, patients often need to try multiple therapies before finding the appropriate treatment, and physicians and patients need maximum flexibility to tailor treatments to meet patients' needs, consistent with clinical evidence. For this reason, imposing formularies or other utilization management tools would put patient access to treatment at risk. As discussed above, prescribing flexibility is essential to the management of complex conditions like cancer, RA, rare diseases and other conditions treated with Part B medicines. For example:

- Comorbid conditions can impact a patient's tolerance for the toxicity of certain cancer medications. Patients with heart disease and congestive heart failure may require different medications than patients without these comorbid conditions to avoid serious and life-threatening complications.

- Patients with RA respond differently to biologic DMARD products, making choice of treatments critically important. Physicians frequently try a series of treatments until one is found that the patient responds to. In addition, RA patients often stop responding to one treatment over time, requiring them to shift to a different option.[234]

- Many patients with multiple sclerosis who are receiving an infused Part B medication may be on their second or third line of treatment. Step therapy requirements could force these patients to revisit therapies their physician has already determined are ineffective in managing their disease.

A recent survey of physicians underscores these concerns. 88 percent of oncologists and rheumatologists believe a CAP or DVP program would take care decisions away from the person in the best position to make that decision; more than 87 percent believe it would limit their ability to provide the best care to patients; and 75 percent of providers believe it would increase the administrative burden for their practices.[235]

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[234] American College of Rheumatology. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2012;64(5):632.

[235] Community Oncology Alliance. COA Physician Survey: Medicare Part B Proposals Will Harm Patients, Increase Costs and Bureaucracy. May 2018. Available at: https://www.communityoncology.org/portfolio-items/coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/?portfolioCats=64%2C60%2C67%2C70%2C59%2C69%2C66%2C65%2C63%2C61%2C68%2C51%2C58

Policies like CAP are intended to make Part B more competitive. However, MedPAC's DVP proposal would do the opposite by imposing a binding arbitration process to regulate prices for innovative new medicines. As one commissioner noted, "I am absolutely opposed to arbitration because the message that the Commission is sending is that we believe in free market, but then we don't."[236] Another commissioner also noted that having a regulated price can interfere with market forces that would help to keep costs down.[237]

Finally, MedPAC's DVP would encourage physician participation by reducing the add-on payment to ASP for those physicians who seek to remain in the buy and bill system. The add-on fee accounts for the variability in provider negotiating leverage and therefore the price at which products are purchased; it also helps cover complex storage and handling, other overhead costs, and ongoing patient monitoring. If the add-on payment were reduced further, some providers (particularly those in small practices or rural communities) would likely lose money on many products they administer. As described above, past proposals to implement these types of changes in Part B coverage and reimbursement have been rejected over concerns that patients may experience treatment delays and higher costs, and that care could shift to more expensive settings. These payment policies have the potential to lead to further physician-hospital consolidation, which MedPAC has previously noted, increases Medicare prices paid for physician services.[238] For example, there has been substantial consolidation among outpatient oncology providers and hospitals or health systems. The shift in cancer care to hospital-based settings has led to higher costs to Medicare and its beneficiaries.[239] For further discussion of hospital consolidation see our comments on site-neutral payments below.

MEDICARE PART B: HCPCS Codes as an Incentive to Commit to a Particular Pricing Scheme (RFI p. 22698)

Part B reimbursements are based on a proven, market-based metric that should be preserved. ASP is transparent and dynamic—it reflects commercially negotiated discounts and, as a result, changes over time in response to fluctuations in the market. As CMS notes in its quarterly analysis of the ASP pricing file, "there are a number of competitive market factors at work—multiple manufacturers, alternative therapies, new products, recent generic entrants, or market shifts to lower priced products"[240] that contribute to price stability and even decrease ASP for several products quarter over quarter. As a result, ASP has built-in protections against price

[236] Transcript: MedPAC Public Meeting. Comments by Amy Bricker, April 6, 2017. pp. 65-66. Available at: http://www.medpac.gov/docs/default-source/default-document-library/transcript-04-17-ealizecombinedd14010adfa9c665e80adff00009edf9c.pdf?sfvrsn=0
[237] Transcript: MedPAC Public Meeting. Comments by Kathy Buto, April 6, 2017. p. 71. Available at: http://www.medpac.gov/docs/default-source/default-document-library/transcript-04-17-combinedd14010adfa9c665e80adff00009edf9c.pdf?sfvrsn=0
[238] MedPAC. Report to Congress: Medicare and the Health Care Delivery System. Chapter 10 – Provider Consolidation: the role of Medicare policy. June 2017.
[239] Milliman. Comparing Episode of Cancer Care Costs in Different Settings: An Actuarial Analysis of Patient Receiving Chemotherapy. August 2013.; Milliman. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. April 2016.
[240] CMS, 2018. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2018ASPFiles.html

inflation. Demanding that manufacturers "commit to a price over a particular lookback period" would not only undermine the market-based nature of the ASP reimbursement system, but is also unnecessary. Accordingly, PhRMA opposes tying eligibility for Healthcare Common Procedure Coding System (HCPCS) codes to price commitments.

PhRMA does support issuance of HCPCS codes for Part B drugs on a quarterly basis overall, to reduce administrative burdens and improve patient access to new medicines. Under the current process, CMS assigns HCPCS codes to new drugs on an annual basis. Manufacturers must apply for a HCPCS code for a new drug (either a drug already approved by FDA or shortly expected to be approved) by the first business day of January of year 1 to have the drug considered for a HCPCS code that would take effect on January 1 of year 2. If the drug was not yet approved by FDA when the application was submitted, it must then be approved by March 31 of year 1 or it will not be considered for a HCPCS code that (if granted) would take effect January 1 of year 2. Therefore, a drug approved by FDA on April 1 of year 1 can only be considered for a HCPCS code in year 2 (and would require the full application to be resubmitted in year 2) and then (assuming a code is granted) it would not take effect until January 1 of year 3—21 months after its approval.

The delay in the current HCPCS process creates unnecessary administrative burden for both payers and providers, and results in uncertainty in reimbursement that could be detrimental to patient access to medical advances. Until a HCPCS is assigned, providers must bill for newly approved products using an unlisted or miscellaneous HCPCS code. Because these codes are not specific to a single drug or technology, claims which include unlisted or miscellaneous codes require manual review by payers. This manual claim review process often requires the provider to include additional information on the claim form, such as the drug name, strength, route of administration, and the NDC.

CMS should assign new HCPCS codes for Part B drugs on a quarterly, rather than annual basis. This is simple and doable. In fact, based on an application process separate from the application process for ordinary HCPCS codes, CMS already assigns new drugs a special type of HCPCS code called a "C code" on a quarterly basis (but currently these codes only apply in hospital outpatient departments and therefore do not substitute for an ordinary HCPCS code). The C code process illustrates how simple it would be for CMS to reform the ordinary HCPCS application process for new drugs. Doing so would cut needless complexity and red tape and facilitate patients' access to important new drug therapies that often treat life-threatening or otherwise very serious diseases.

MEDICARE PART B: Site Neutrality for Physician-Administered Drugs (RFI p. 22697)

Payment differentials, and differences in the cost of goods (e.g. the 340B program), incentivize hospital systems to acquire physician practices.[241] Consolidation leads to increased market

[241] Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Affairs*. 2014;33(5):756-63.

power, which allows hospitals to charge more for the same care, which drives up costs of care for patients with both public and private insurance.[242]

Spending on hospitals is increasing rapidly, driving up overall health care costs and premiums. Hospitals accounted for $1.1 trillion in U.S. health spending in 2016, representing 32 percent of NHE, far more than any other category.[243] When hospitals purchase physician practices, prices and spending increase, often without any corresponding increase in quality of care. [244] A recent analysis of Medicare Fee-for-Service claims data between 2008 and 2015 showed a significant shift in site of care for outpatient drug therapies from the physician office to the 340B hospital outpatient setting.[245] Physician-administered chemotherapy medicines are an example of how the shift from the community to hospitals contributes to higher spending. From 2004 to 2014, chemotherapy infusions in hospital outpatient departments increased dramatically, from 16 percent to 46 percent for Medicare patients. Drug spending was more than twice as high in the hospital setting. Had this consolidation not occurred, spending would have been 7.5 percent lower for Medicare infused chemotherapy patients.[246]

To address some of these concerns, in 2016 CMS finalized sections of the Bipartisan Budget Act of 2015 requiring that payments to certain entities for covered services, including physician administered medicines, be site-neutral. Recognizing that a system where Medicare pays for the same service at a higher rate if it is provided in a hospital outpatient department versus a physician's office creates perverse incentives for hospitals to acquire physician offices, CMS issued a regulation stating that certain services provided by certain off-campus hospital outpatient departments would no longer be paid under the Hospital Outpatient Prospective Payment System (HOPPS).[247] The policy became effective in January 2017 but included some exceptions, most notably grandfathering in off-campus sites billing under HOPPS prior to November 2015, and some facilities with new or developing off-campus departments.[248] While CMS has taken some steps to correct policies that incentivize shifts in site of service, additional consideration should be given to potential policies that would help address and prevent anticompetitive behavior that drives increased drug and overall health care spending.

[242] Bai G, Anderson GF. A more detailed understanding of factors associated with hospital profitability. *Health Affairs*. 2016;35(5):889-97.
[243] CMS. NHE Data. 2009-2025 Expenditures and Projections.
[244] Post B, Buchmueller T, Ryan AM. Vertical Integration of Hospitals and Physicians: Economic Theory and Empirical Evidence on Spending and Quality. *Medical Care Research and Review*. 2017: 1-35.
[245] Berkeley Research Group. Site of Care Shift for Physician-Administered Drug Therapies. June 2017. Available at: https://www.thinkbrg.com/media/publication/943_943_Vandervelde_Site-of-Care-Oct-16-2017_WEB_FINAL-2.pdf
[246] Fitch, Kathryn, et al. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman. 2016.
[247] CMS. CMS Finalizes Hospital Outpatient Prospective Payment System Changes to Better Support Hospitals and Physicians and Improve Patient Care. 2016.
[248] CMS. CMS Clarifies Site-Neutral Medicare Reimbursement Exceptions. 2017.

MEDICARE PART B: Site Neutrality Between Inpatient and Outpatient Setting (RFI p. 22697)

PhRMA appreciates the administration's interest in understanding payment policies that may drive patients or physicians to prefer treatment in the outpatient or inpatient setting. We urge HHS to consider how prospective payment systems like the Inpatient Prospective Payment Systems (IPPS) can affect site of care because reimbursement rates are set using historic cost information and may not accurately reflect the resources associated with the current standard of care. IPPS creates three challenges for reimbursement of new medicines, further documented in our comments on the 2019 IPPS Proposed Rule.[249] First, existing Medicare Severity Diagnosis Related Groups (MS-DRGs) may not capture the additional resource utilization associated with a new therapy. In addition, CMS' standards for new technology add-on payments (NTAP), can exclude important new therapies because of small sample sizes or clinical evidence requirements that are unrealistic for therapies that are new to market, particularly if they were approved under an expedited FDA pathway. Finally, even if a manufacturer can clear the bar for approval of a NTAP, the combination of NTAP and outlier adjustments may still be insufficient to facilitate patient access to a beneficial new test or treatment. We encourage HHS to adopt a more holistic approach to accommodating new technologies in future years that considers the multiple levers at the administration's disposal to accurately calibrate reimbursement under the IPPS.

CMS might also consider whether payment distortions are inconveniencing patient and harming clinical outcomes, increasing costs for the health care system. HHS should consider whether improvements in care could be made through payment changes that encourage moving appropriate patients to a different care setting (outpatient infusion or home health), discharging patients earlier when clinically appropriate, or avoiding unnecessary hospitalizations.

SECTION VI: MEDICAID AND AFFORDABLE CARE ACT TAXES (RFI p. 22695)

Medicaid is a joint state and federally funded program that provides comprehensive health coverage to more than 70 million low-income Americans, including children and their parents, pregnant women, the elderly and people living with disabilities.[250] When Congress created the Medicaid Drug Rebate Program in 1990, authorized by Section 1927 of the Social Security Act, it had two main goals—to lower state and federal expenditures for outpatient prescription drugs and to increase Medicaid beneficiary access to prescription drugs.[251] The Medicaid rebate statute requires biopharmaceutical manufacturers to provide substantial mandatory rebates in exchange for guaranteed state coverage of all covered outpatient drugs with limited exceptions. Under the

[249] PhRMA comments on Medicare Program; Hospital IPPS for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and FY 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; CMS-1694-P.
[250] CMS. March 2018 Medicaid & CHIP Enrollment Data Highlights.
[251] H. Rpt. 101-8 8 1, 101st Congress, 2d Session (Oct. 16, 1990).; As of 2018, about 600 biopharmaceutical manufacturers participate in the program along with all fifty states.

statute, participating manufacturers must enter into a national rebate agreement with CMS, and must also enter into agreements to provide discounts to 340B covered entities and to cap prices on sales of their drugs to four federal agencies (the Department of the Veterans Affairs (VA), the Defense Department (DoD), the Public Health Service, and the Coast Guard).[252]

Medicaid rebates for brand medicines have two components: a basic rebate and an additional inflation rebate if the price of a drug rises faster than inflation (based on changes in the Consumer Price Index-Urban). For brand drugs, the basic rebate is the greater of (a) 23.1 percent of the AMP or (b) the difference between AMP and the Best Price (the manufacturer's lowest net price for the drug to any customer with limited exceptions). For example, if a manufacturer's lowest net price to a customer included in the Best Price determinations in a quarter is 70 percent of AMP, then 70 percent of AMP would be the Best Price for every state Medicaid program; the additional rebate is capped by statute at 100 percent of AMP. The additional rebate is added to the basic rebate to get the total unit rebate amount (URA) on each unit dispensed to a Medicaid patient. Manufacturers may also negotiate voluntary supplemental rebates with states in addition to these mandatory rebates.

Prescription medicines represent a small share of Medicaid spending and provide substantial value to the program. In 2016, Medicaid programs spent on average just 5 percent of their budgets on retail prescription medicines, due in large part to the significant rebates received from manufacturers.[253] In contrast, Medicaid programs spent about 9 percent on administrative costs and 31 percent on long term care services.[254] Manufacturers provided $42 billion in rebates in 2017, representing a more than 50 percent discount to states and the federal government.[255] Many states put manufacturer rebates back into their general fund and do not earmark the money for Medicaid or prescription drug purposes, shielding them from the true net cost of medicines. The Medicaid population is particularly vulnerable, with significant health care needs compared to those with private insurance.[256]

Research has shown that better use of prescription medicines can create savings to Medicaid. For example, researchers have found that a 1 percent increase in prescription drug utilization decreases inpatient Medicaid costs by as much as 0.31 percent.[257] Another analysis found that treating HIV/AIDS to viral load suppression saves state Medicaid programs an estimated $1 million per treated patient by preventing future transmissions.[258] It is also estimated that a new

[252] SSA 1927(a), 1927(k)(2).
[253] MACPAC. MACSTATS. 2016.
[254] The Menges Group analysis of FY2016 CMS 64 reports and State Drug Utilization data files. Brand and generic expenditure totals are net of rebates. Data used were predominantly derived from CMS 64 reports.
[255] John Coster Presentation at Alliance for Health Policy, May 11, 2018.
[256] MACPAC. MACStats: Medicaid and CHIP Data Book. December 2016.
[257] Roebuck, C, Dougherty, S. Impact of Medication Adherence on Hospitalization in Medicaid. Poster Presentation at ISPOR 21st Annual International Meeting, Washington, DC. May 23, 2016.
[258] Truven Health Analytics. Impact of pharmaceutical innovation in HIV/AIDS treatment during the highly active antiretroviral therapy (HAART) era in the U.S., 1987-2010: an epidemiologic and cost-impact modeling case study. December 2014.

medicine that delays the onset of Alzheimer's disease by five years could reduce Medicaid spending by $77 billion by 2050.[259]

Since the enactment of the ACA, the Medicaid program has grown and changed significantly, and manufacturer obligations have also increased because of new branded prescription drug taxes, increases in rebate amounts, and the expansion of the 340B program, which has increased 340B discounts. While manufacturer rebates have held down net prescription drug expenditures in Medicaid, the growth in manufacturer rebates and tax obligations is significant. Consequently, for reasons we discuss below, any measures to increase Medicaid rebates or to tax the industry further may not serve the intended purpose of reducing list prices. As CBO and many economists have suggested, imposing mandatory rebates and taxes on drug manufacturers can lead to higher prices for other customers.[260]

The President's drug pricing initiative should further the goals of the Medicaid program and therefore avoid any changes that could ration care or otherwise limit vulnerable Medicaid patients' access to prescription drugs. Accordingly, while we recognize that states have a desire to experiment with Medicaid coverage requirements, we do not support any new approaches that risk compromising Medicaid patients' access to medicines by creating a closed formulary.

MEDICAID AND AFFORDABLE CARE ACT TAXES: ACA Taxes and Rebates (RFI p. 22695)

Since the passage of the ACA, Medicaid has undergone a period of significant growth with an additional 16 million enrollees. Thirty-three states, and the District of Columbia, have adopted the ACA Medicaid expansion.[261] Independent analysts estimate that the ACA will increase prescription drug rebates and industry taxes that brand manufacturers pay by almost $70 billion through 2021.[262] Some of the more significant changes to Medicaid under the ACA include:

- The Medicaid minimum basic rebate increased from 15.1 percent of AMP to 23.1 percent of AMP

[259] Alzheimer's Association. Changing the Trajectory of Alzheimer's Disease: How a Treatment by 2025 Saves Lives and Dollars. Available at: https://www.alz.org/help-support/resources/publications/trajectory_report
[260] CBO. How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry. January 1996.; RxEconomics for Pharmaceutical Industry Labor-Management Association. Medicaid Drug Rebates in Medicare Part D Low-income Subsidy: An Economic Analysis of the Proposed Policy and Its Implications for Multi-Employer Plans. June 18, 2013.
[261] Kaiser Family Foundation. Status of State Action on the Medicaid Expansion Decision. Available at: https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act
[262] PwC. Implications of the U.S. Supreme Court Ruling on Healthcare. Available at: https://www.pwc.com/us/en/health-industries/health-research-institute/publications/pdf/implications-of-the-US-Supreme-Court-ruling-on-healthcare.pdf

- Medicaid rebates were extended to Medicaid MCOs[263]
- The definition of AMP was altered to increase rebate amounts
- Medicaid rebates cover an even larger population due to the expansion of Medicaid and the extension of rebates to Medicaid MCO enrollees
- A new annual fee on sales by brand drug manufacturers that are reimbursed or purchased by certain federal programs (Medicaid, Medicare Part B, Medicaid Part D, and VA and DoD drug programs)[264]
- Expansion of 340B hospital eligibility which has driven program growth in subsequent years

While the Blueprint recognizes that, "drug spending has been held down in the Medicaid program," the adverse consequences of rebate expansion, coupled with the creation of the branded prescription drug industry tax cannot be ignored.[265] Government actuaries and economists have documented the unintended consequences of the Medicaid Drug Rebate Program in shifting costs to other parts of the pharmaceutical market and increasing prices for other customers. Secretary Azar himself has stated that, "both industry practices and government rules—encourages higher and higher list prices."[266] It is also likely that the same problems created by the Medicaid Drug Rebate Program also apply to the ACA industry tax. In fact, the Blueprint recognizes this, stating that "this expansion of [branded prescription drug fees plus Medicaid rebates] may have placed pressure on list prices by forcing drug manufacturers to raise prices overall." Similarly, the Blueprint notes that "the additional billions of dollars in [340B] discounted sales and the cross-subsidization necessary may have created additional pressure on manufacturers to increase list price." Similar concerns have also been raised by:

- CBO, which analyzed the Medicaid Drug Rebate Program's impact on state and federal drug spending and on the broader pharmaceutical marketplace, found that "spending on prescription drugs by non-Medicaid patients may have increased as a result."[267]

- GAO noted that "following enactment of the rebate program, discounts for outpatient drugs decreased significantly because manufacturers raised the prices they charged large private purchasers."[268] GAO also predicted that the larger the group entitled to a rebate, the "greater the incentive" is for manufacturers to increase prices.

[263] In FFY 2016, almost half (49 percent) of all Medicaid expenditures were in Medicaid managed care organizations, up from 24 percent in 2010. Available at: https://www.healthmanagement.com/blog/medicaid-managed-care-spending-2016/
[264] Internal Revenue Service. Annual Fee on Branded Prescription Drug Manufacturers and Importers.
[265] HHS, American Patients First.
[266] Sec. Azar Blueprint remarks, May 14, 2018.
[267] CBO. How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry. January 1996.
[268] GAO. Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes. August 2000.

- The RxEconomics Literature Review found "compelling evidence that the Medicaid Drug Rebate Program has prompted reductions in the rebates extended to private payers, resulting in higher drug prices in [other markets]."[269]

- The Heritage Foundation, which in reviewing the impact of new ACA taxes, including fees on pharmaceutical companies, medical device manufacturers, and health insurance companies, found that these new taxes "will ultimately be passed on to [middle-income families] through higher prices."[270]

The Best Price provision of the Medicaid Drug Rebate Program, designed to give the lowest net unit price given to any other customer (with limited exceptions) to every Medicaid program, has been shown to limit the discounts given to other customers. The Council of Economic Advisors recently highlighted issues related to the Medicaid Drug Rebate Program noting that the "Medicaid Best Price program can create artificially high prices in the private sector under certain conditions."[271] Further, Best Price has posed a challenge to innovation in the pharmaceutical marketplace: numerous sources have found that Medicaid's Best Price rebate provision makes it "unfavorable for drug manufacturers to enter into value-based contracts for their drugs,"[272] and is "in effect setting a floor under prices."[273]

According to third party analysts, the additional rebate (which penalizes AMP increases exceeding the inflation rate) creates perverse incentives for high launch prices. CBO has opined that, "new drugs may be launched at a slightly higher price because of the Medicaid rebate." [274] They also indicate that, "the larger Medicaid's anticipated share in total sales of a drug, the more important that effect is."[275]

Since the enactment of the Medicaid Drug Rebate Program, economists and federal analysts have documented that while the program has reduced prescription drug expenditures in Medicaid, there are negative effects such as increased costs to private payers. Additionally, government experts found that proposals to extend Medicaid rebates to other government programs will likely increase Medicaid spending and negatively affect other drug payers, such as employers in the

[269] RxEconomics for Pharmaceutical Industry Labor-Management Association. Medicaid Drug Rebates in Medicare Part D Low-income Subsidy: An Economic Analysis of the Proposed Policy and Its Implications for Multi-Employer Plans. June 18, 2013.
[270] The Heritage Foundation. Obamacare: Impact on Taxpayers. April 2010. Available at: https://www.heritage.org/health-care-reform/report/obamacare-impact-taxpayers
[271] The Council of Economic Advisers. Reforming Biopharmaceutical Pricing at Home and Abroad. February 2018.
[272] American Action Forum, Current Impediments to Value-Based Pricing for Prescription Drugs. June 2017.
[273] Medicaid Best Price: Health Policy Brief. *Health Affairs*. August 10, 2017. Available at: https://www.healthaffairs.org/pb-assets/documents/Collections/Collection_CMWF_Prescription_Drug_Pricing_May_2018.pdf
[274] CBO. How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry. January 1, 1996.
[275] Id.

commercial market. Specifically, CBO writes that "drug manufacturers would be expected to set higher 'launch' prices for new drugs as a way to limit the effect of the new rebate."[276]

MEDICAID AND AFFORDABLE CARE ACT TAXES: Proposals Related to Maximum Rebate Amount (RFI p. 22695)

The Administration notes that imposing additional liabilities on the biopharmaceutical industry can lead to unintended consequences and cost shifting. However, the RFI also discusses developing proposals to repeal "the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of the Average Manufacturer Price."[277] This cap is a modest safeguard that simply keeps Medicaid rebates from exceeding the payment a manufacturer receives for a drug and from making drugs a profit center for Medicaid. The proposed repeal of the Medicaid rebate cap could lead to further cost shifting for other customers, deepening the price distortions caused by the Medicaid Drug Rebate Program.

Medicaid rebates represent a discount of over 50 percent for all medicines and CBO estimates brand rebates average a discount of 63 percent of AMP.[278] The current cap limits Medicaid rebates to 100 percent of AMP.[279] For some medicines, the Medicaid rebate is already so large that the net cost of the drug (prior to any dispensing fees) is zero. Simply, manufacturers already are providing free drugs to the Medicaid program after rebates; therefore, repealing the cap would provide Medicaid with rebates that exceed the state's payment to the dispensing pharmacy.

Since rebate liability is imposed on individual manufacturers—and over 600 pharmaceutical companies participate in the Medicaid rebate program—removing the cap on rebates is essentially creating a new industry tax that will force manufacturers to pay the government a fee for participation in Medicaid, a program that serves over 70 million people. As the previous reports cited above found, increasing Medicaid rebates and industry taxes will further distort prices in the commercial market and create perverse incentives and pressure to increase launch prices. Finally, manufacturers already hold up their end of the statutory coverage-rebate bargain by paying significant rebates to states for drugs utilized by the Medicaid population. The federal

[276] CBO. Require Manufacturers to Pay a Minimum Rebate on Drugs Covered Under Part D of Medicare for Low-Income Beneficiaries. December 8, 2016.
[277] RFI at 22695.
[278] CBO. Options for Reducing the Deficit: 2017-2026. December 2016. This 63 percent of AMP figure includes the two components of the Medicaid rebate on a brand name drug: (1) the "basic rebate" (23.1 percent of AMP or [AMP minus Best Price], whichever is higher); and (2) the "additional rebate" (the current-quarter AMP minus the inflation-adjusted AMP from the drug's baseline period, which usually is the first full quarter after the drug's launch). This does not take into account supplemental rebates that States may negotiate from manufacturers on top of the federal rebate required under the rebate statute. See also HHS Office of the Assistant Secretary for Planning and Evaluation, Report to Congress, Prescription Drugs: Innovation, Spending, and Patient Access, 10 (Dec. 7, 2016) ("About half of Medicaid gross spending on prescription drugs is returned to the federal government and the states in the form of manufacturer rebates").
[279] § 2501(e) of the ACA.

government and states should not 'profit' off of this new tax by repealing this cap—a policy which will not achieve the goal of lowering list prices and could potentially backfire.

MEDICAID AND AFFORDABLE CARE ACT TAXES: New Approaches (RFI p. 22693)

The Blueprint recognizes that drug spending has "been held down in the Medicaid program by other tools," and the "program's rules prohibit the use of closed formularies, but states [may] use preferred drug lists."[280] Prescription drugs have consistently been a low share of Medicaid spending over the last decade due in large part to the significant rebates states receive from manufacturers, even as the program has undergone extensive expansions.[281] The Blueprint notes that states have multiple cost containment strategies to manage prescription drug spending, but states have expressed a need for more flexibility to limit drug coverage than they currently have under the rebate statute. While we support states' engaging in testing new approaches to providing the best care to their population, we strongly oppose any proposals that ration access to prescription drugs in Medicaid through a closed formulary. The rebate statute reflects a carefully-crafted bargain that guarantees large rebates in exchange for coverage of all covered outpatient drugs.

Today, almost all states have created preferred drug lists and utilize prior authorization to negotiate extra voluntary supplemental rebates from manufacturers.[282] Despite the Medicaid rebate statute's coverage requirements, some states place significant restrictions on medicines in the form of prior authorization or delays in coverage. Additionally, now that Medicaid MCOs serve most Medicaid patients, CMS should consider additional transparency requirements with regards to coverage and access. We strongly encourage CMS to preserve and work to improve access to medicines for vulnerable Medicaid patients. Medicaid patients, compared to those with other types of insurance, have higher rates of complex and chronic health conditions that often require access, without delay, to a broad range of medicines as prescribed by their physicians in order to achieve optimal therapeutic results. In addition to poorer health status, Medicaid patients tend to be more financially vulnerable, with few to no alternative options to obtain the medicines they need. Patients who access health insurance through employers or the individual market often have more options to select different coverage or pay out of pocket when needed.

As the Administration is considering new approaches to Medicaid financing and coverage of new medicines, PhRMA urges the Administration to consider the following principles:

- **Access:** Access for vulnerable Medicaid beneficiaries must be preserved.
    - Medicaid patients must have a streamlined and timely appeals or exceptions process to access any available therapy that recognizes the enormous pressures facing many physicians or prescribers who treat Medicaid patients.

[280] RFI p. 22693.
[281] CMS. NHE Accounts. 2017.
[282] CMS, HHS. Medicaid Pharmacy Supplemental Rebate Agreements (as of March 2017). 2017.

  - Medical providers, in consultation with patients, should be able to determine the medicines that best meet patients' needs. Cost sharing for prescription drugs should not be an access barrier in Medicaid.
  - Any transition to a new approach should ensure patients do not experience a disruption in coverage.

- **Statutory Bargain:** Under the law, manufacturers pay rebates on covered outpatient drugs in Medicaid in exchange for guaranteed coverage that cannot be broken.
  - CMS should not negotiate directly with companies or interfere in private negotiations between manufacturers and states or MCOs.

Any new approach that the Administration is considering must have a rigorous and independent evaluation that looks at the broad impacts of the new approach. A February 2018 GAO report found that the "federal government did not require complete and timely evaluations from the states," so results on the new approaches were not complete and often not made available to the public.[283] New approaches to prescription drug financing must include an analysis of beneficiary access and satisfaction as well as changes in adherence and health outcomes. Only looking at prescription drug spending changes is insufficient to fully evaluate how any new approach will impact the Medicaid population and its patients at large.

SECTION VII: 340B DRUG DISCOUNT PROGRAM (RFI p. 22698)

The 340B Drug Discount Program was created by Congress in 1992 to restore the voluntary drug discounts for uninsured or vulnerable patients that manufacturers provided before the passage of the Medicaid drug rebate statute. As part of the 340B program, manufacturers provide steep discounts averaging about 50 percent[284] on most outpatient medicines to certain types of clinics (known as "grantees") and to qualifying hospitals as a condition of their medicines being covered by Medicaid. PhRMA and our member companies strongly support the 340B program, which when used to benefit patients, plays a significant role in our health care safety net. The 340B program is particularly crucial to supporting the care provided by grantees, which serve our nation's most vulnerable patients. These grantees are on the front lines of public health threats and represent a lifeline for many vulnerable patients without another source of care.

Safety-net clinics must generally meet federal requirements to reinvest any profit derived from reselling 340B medicines into care for uninsured or vulnerable patients as part of their grant requirements. In contrast, current 340B program rules lack any standards for how 340B discounts should be used by 340B hospitals. Hospital use of 340B is concentrated in the disproportionate share (DSH) hospitals that comprise 80 percent of all 340B sales.[285] The lack of program standards for how DSH hospitals use 340B discounts, combined with the significant growth of the program driven by these hospitals, has greatly transformed the 340B program. It is no longer

[283] GAO. Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures. February 20, 2018.
[284] CBO. Prices for Brand-Name Drugs Under Selected Federal Programs. June 2005.
[285] Hatwig C. Apexus Update, 340B Health Summer Conference, 2016.

accurate to characterize the program as primarily focused on care for vulnerable patients by safety-net providers. Instead, more than two thirds of DSH hospitals that participate in 340B provide below national average levels of free and reduced cost treatments to uninsured or vulnerable patients, when compared to all hospitals.[286] As a 2014 *Health Affairs* study on 340B put it, the program has evolved "from [a program] that serves vulnerable communities to one that enriches hospitals."[287]

340B DRUG DISCOUNT PROGRAM: The Growth of 340B (RFI p. 22698)

Today's 340B program is unrecognizable in size and character as compared to the program that was created in 1992. It took 15 years after 340B's enactment (2007) for annual 340B sales to reach $3.9 billion. Yet in the last 10 years, between 2007 and 2017, 340B sales at the 340B price grew by nearly 400 percent to $19.3 billion.[288] The MedPAC May 2015 Report to Congress provides data showing that between 2005 and 2013, 340B sales grew seven times faster than total U.S. medicine spending.[289] Between 2002 and 2017, the number of 340B designated contract pharmacy arrangements increased from 279 to 51,963.[290] Nearly 90 percent of that growth came after HRSA's 2010 sub-regulatory guidance authorizing unlimited contract pharmacy networks. From 2013 to 2017, the number of hospital entities participating in the program tripled.[291] Yet over that same period, 340B purchases as a share of hospitals' total drug purchases consistently and steadily increased,[292] while hospitals' uncompensated care dropped.[293]

This growth has not been accompanied by evidence that patients are more likely to benefit from 340B discounts. In fact, a 2018 study in the *New England Journal of Medicine* found the opposite: 340B-eligible hospital status was associated with serving lower proportions of low-income patients in hematology-oncology and ophthalmology and did not show clear evidence of increased care for, or lower mortality among, low-income patients.[294]

[286] Alliance for Integrity and Reform of 340B. Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program. Spring 2016.
[287] Conti R, Bach P. The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities. *Health Affairs.* 2014;33(10):1786-1792.
[288] Fein A. EXCLUSIVE: The 340B Program Reached $19.3 Billion in 2017 – As Hospitals' Charity Care Has Dropped., *Drug Channels Blog*. May 7, 2018.
[289] Analysis of data from MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015, pp. 11-12.
[290] HRSA OPA Database, January 2017.
[291] GAO. Drug Discount Program: Status of Agency Efforts to Improve 340B Program Oversight. May 15, 2018.
[292] Fein A. 340B Purchases Were More than Half of the Hospital Market in 2016. *Drug Channels Blog.* May 19, 2017.
[293] Fein A. EXCLUSIVE: The 340B Program Reached $19.3 Billion in 2017 – As Hospitals' Charity Care Has Dropped. *Drug Channels Blo*g. May 7, 2018.
[294] Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med.* 2018.

340B DRUG DISCOUNT PROGRAM: HRSA Rulemaking Authority (RFI p. 22699)

As the RFI and Blueprint recognize, the 340B program has grown substantially since its inception, and its current size may have created additional pressures on manufacturers to increase list prices.[295] The RFI asks whether providing HHS with general 340B rulemaking authority could materially affect the elements of the program affecting drug pricing. To be clear, HRSA already has authority to make reforms and it should exercise its authority to update its guidance on four key aspects of the program as described below—a clearer patient definition in line with the statute, meaningful limits on hospital child sites, a reassessment of the contract pharmacy policy, and a more comprehensive and effective duplicate discount prevention guidance. Based on existing guidances, HHS believes it already has authority to provide interpretive guidance in these areas, and it should take action in these key areas promptly. Moreover, as discussed below, currently Apexus—a contractor to HHS—is issuing guidance on 340B issues instead of the government itself issuing guidance. This causes confusion about the status of the guidance and accordingly we would recommend that interpretive guidance on key 340B program issues come solely from HHS.

However, in response to the RFI's questions, we support providing HHS with appropriate 340B rulemaking authority in those areas where such authority would be useful in aligning the program with the text and purpose of the 340B law. It would be important for Congress to provide legislative guidance on the use of such authority and to monitor its use carefully to ensure that it is not used in a way that further promotes unwarranted growth or otherwise adds to the program's unintended consequences; that departs from the program's mission to serve low income and vulnerable patients; that imposes needless burdens on any stakeholders; or harms grantees.

340B DRUG DISCOUNT PROGRAM: The Unintended Consequences of the 340B Program (RFI p. 22699)

The size of the 340B program creates market-distorting incentives that affect consumer prices for medicines, shift care to more expensive hospital settings, and accelerates provider market consolidation. A growing body of evidence from nonpartisan, independent sources, including *The New England Journal of Medicine*, *Journal of the American Medical Association (JAMA)*, the GAO, and others, points to data showing that the 340B program is driving up costs for everyone. Costs are being driven up in at least three ways:

1. **Cost shifting that distorts market prices**: Economists who study the 340B program suggest the current size of the program is leading to cost shifting and higher prices for consumers.[296] A study in *JAMA* noted that list prices for medicines are likely higher than they otherwise would be "to offset revenue losses incurred as a larger number of drug sales become eligible

[295] Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA.* 2013;309(19):1995-1996.
[296] Conti R, Rosenthal M. Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation. *N Engl J Med.* 2016;374:703-706.

for 340B discounts (and thus, fewer drugs are sold at full price)."[297] Some therapeutic areas are particularly impacted by 340B. For example, for certain cancer drugs, sales to 340B hospitals account for 33 percent of *all* Medicare Part B reimbursement.[298]

2. **Perverse incentives to prescribe more medicines or more expensive medicines**: Because the discount on a 340B drug is typically a significant discount on the drug's list price, 340B hospitals make more money when patients take more medicines or when more expensive medicines are prescribed. A 2015 GAO study found that this incentive was driving up costs in Medicare Part B.[299] While the Administration took an important first step towards addressing these incentives in Part B in the 2018 HOPPS rule,[300] hospitals continue to be able to profit from the 340B discounts for other payers.[301] This potential profit seems to be creating thesame incentives in the commercial market. A recent study from the actuarial firm Milliman found higher spending on outpatient medicines for commercially insured patients at 340B hospitals compared to non 340B hospitals.[302] These perverse incentives extend to contract pharmacies. A recent GAO study found that some contract pharmacies receive higher reimbursement for brand 340B prescriptions.[303] Rena Conti, an expert on drug pricing, raised concerns about this GAO finding in a recent interview with *Politico,* noting, "here's a policy that is maximizing revenue for hospitals and contract pharmacies and perversely going against the intent of the program, which is to provide accessible and affordable health care for vulnerable people."[304]

3. **Shifting care from community-based physicians to higher-cost settings**: Many hospitals have leveraged their ability to generate revenue from 340B by buying community-based physician practices and then obtaining 340B discounts for prescriptions written by those physicians.[305] These off-site hospital clinics (known as "child sites") are often located in wealthier areas than the 340B hospitals themselves[306] and have no requirement to treat uninsured or vulnerable patients. These shifts in ownership and site of treatment not only undermine community-based practices but also drive concentration in provider markets,

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[297] Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA.* 2013;309(19):1995-1996.
[298] Drugs sold to 340B hospitals account for 33 percent of *all* Part B reimbursement for breast cancer and multiple myeloma drugs. Vandervelde A, Blalock E. Measuring the Relative Size of the 340B Program: 2012-2017. Berkeley Research Group. July 2017.
[299] GAO. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015.
[300] 80 Fed Reg 59216, (Dec. 14, 2017).
[301] A Vandervelde and E Blalock. Site of Care Shift for Physician-Administered Drug Therapies. Berkeley Research Group. October 2017.
[302] Milliman. Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Hospitals. March 2018.
[303] GAO. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
[304] Karlin-Smith S. Perverse incentives? Why some 340B pharmacies are opting for branded drugs. *Politico.* July 2, 2018.
[305] Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med.* 2018.
[306] Conti R, Bach R. The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities. *Health Affairs*. 33(10).

leading to higher prices for payers, the government, and patients. For cancer care, an analysis by IMS Health found that average commercial costs for administering cancer medicines are typically twice as high at hospital outpatient departments compared to treatment by community-based oncologists.[307]

340B DRUG DISCOUNT PROGRAM: Hospital Outpatient Prospective Payment System (RFI p. 22684)

Last year the Administration took an important first step to try to address some of these market distortions. Citing analysis from the GAO[308] and MedPAC[309] regarding the discrepancy between hospitals' discounted acquisition costs and their full reimbursements for 340B medicines, CMS' 2018 HOPPS final rule took steps to address these incentives by reducing the reimbursement for Medicare Part B drugs for a subset of 340B hospitals. While more still needs to be done to address the program's perverse incentives to prescribe more medicines and more expensive medicines, it is critically important that the reimbursement change remain in place and HRSA follow CMS' lead and begin reforms to address other areas of the program that lead to growth and distort the market, like the overly broad patient definition, and flawed contract pharmacy policy and child site guidances discussed below.

340B DRUG DISCOUNT PROGRAM: Improvements to the 340B Program are Urgently Needed in Key Areas to Refocus the Program to its Intended Purpose (RFI p. 22684)

Guidance released by HRSA has led to legally questionable policies in fundamental parts of the program. Based on evidence from GAO, OIG, analysis in the *New England Journal of Medicine*, *JAMA,* and others,[310] immediate changes are needed in each of the following areas to help refocus the program to its intended purpose:

Patient Definition: The 1996 patient definition should be clarified and updated to more clearly define who is entitled to manufacturer discounts on 340B medicines

The 340B program was originally created to provide manufacturer discounts on covered outpatient drugs to safety-net facilities that serve low-income, uninsured, and other vulnerable patients. Unlike hospitals, grantees are good stewards of that mission and have strict requirements

[307] IMS Institute for Healthcare Informatics. Global Oncology Trend Report: A Review of 2015 and Outlook to 2020. June 2016.
[308] GAO. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015.
[309] MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.
[310] HHS OIG. Contract Pharmacy Arrangements in the 340B Program. February 2014; GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015; Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med.* 2018; Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA*. 2013;309(19):1995-1996; Hirsch BR, Balu S, Schulman KA. The Impact Of Specialty Pharmaceuticals As Drivers Of Health Care Costs. *Health Affairs*. 2014;33(10):1714-1720.

on how they use the revenue generated through the 340B program to help those vulnerable or uninsured populations.

Under the 340B law, a covered entity has access to a 340B discount under the program if the medicine is used for the covered entity's own "patient."[311] The 340B law further prohibits covered entities from reselling or otherwise transferring medicines purchased under the 340B program to anyone but a "patient" of the covered entity (a practice specified in 340B law as "diversion").[312]

Despite this centrality of "patient" to defining the program's scope and assuring that statutory program integrity requirements are met, it has been a quarter of a century since the 340B program was created, and the patient definition still needs correction[313] ―despite a clear consensus that the lack of specificity in the current (1996) patient definition invites abuse. For example:

- "[S]ome 340B covered entities may have interpreted the [patient] definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program…. This [never finalized] clarification provides covered entities with more explicit guidance regarding the relationship between a covered entity and an individual that makes that individual a 'patient' of the covered entity." (HRSA, 2007.[314])
- "HRSA officials told us that the [patient] definition currently includes individuals receiving health care services from providers affiliated with covered entities through 'other arrangements' as long as the responsibility for care provided remains with the entity. However, HRSA does not define 'other arrangements,' and officials told us what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, HRSA has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus … for whom the entity does not actually have the responsibility for care." (GAO, 2011.[315])
- "[C]overed entities … use different methods to identify 340B-eligible [patients and] prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility…. [T]wo covered entities may categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) …. [T]here is inconsistency within the 340B

[311] 42 U.S.C. § 256b(a)(5)(b).
[312] 42 U.S.C. § 256b(a)(5)(B).
[313] We support the general approach to defining a 340B "patient" reflected in HRSA's proposed (now withdrawn) omnibus guidance, taking into account considerations for HRSA grantees in the 340B program. 80 Fed. Reg. 52300 (Aug. 28, 2015).
[314] 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).
[315] GAO. Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. September 23, 2011.

program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible." (HHS OIG, 2014.[316])

- "HRSA has outlined three criteria for who is an eligible patient, but some of these criteria are not clearly defined." (MedPAC, 2015.[317])
- "HRSA's guidance addresses patient eligibility, but leaves room for interpretation as to which of the patient's prescriptions might be eligible in a retail pharmacy setting. In these retail settings, we found that providers, in fact, are making different determinations of what prescriptions are eligible for the 340B discounts." (Oral Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate Health, Education, Labor & Pensions (HELP) Committee, May 15, 2018.)
- "HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements...In its 2014 report, OIG found wide variation in these [340B] eligibility determinations. Different determinations of 340B eligibility appear to stem from the application of the patient definition by 340B providers and their contract pharmacies to a wide variety of prescription-level scenarios. Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not." (Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate HELP Committee, May 15, 2018.[318])

We urge HRSA to correct this problem and promptly eliminate the opportunities for abuse inherent in the current patient definition, which HRSA issued 22 years ago. Much has changed in the health care system since 1996, including a decrease in the number of uninsured Americans, much in part due to Medicaid expansion,[319] and the definition of this key term in the 340B program needs to be updated to reflect the current environment and to ensure a clear and reasonable interpretation of the statutory term "patient" is in place.

As highlighted by HRSA itself along with GAO and OIG, the 1996 patient definition is vague and lacks the specificity needed to provide clear direction to covered entities and manufacturers about who is a patient for 340B discount purposes. [320] This has encouraged covered entities to take broad interpretations of the patient definition guidance and use 340B medicines for individuals who in many instances are those who Congress never intended to qualify for the program.

The 340B statute creates an absolute prohibition on covered entities transferring or selling 340B drugs to individuals who are not patients of the covered entity. Therefore, a clear definition of

[316] HHS OIG. Contract Pharmacy Arrangements in the 340B Program. February 5, 2014.
[317] MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.
[318]Ann Maxwell, HHS OIG, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Examining Oversight Reports on the 340B Drug Pricing Program, May 15, 2018.
[319] Medicaid and CHIP Payment and Access Commission. MACStats: Medicaid and CHIP Data Book, Exhibit 10. December 2017.
[320] Debra Draper, GAO, Testimony Before the Committee on Health, Education, Labor & Pensions, U.S. Senate, May 15, 2018.; Testimony of Ann Maxwell, OIG, Testimony Before the Committee on Health, Education, Labor & Pensions, U.S. Senate, May 15, 2018.

"patient" is a key element of the program and critical to the integrity and long-term sustainability of the 340B program. HRSA has an obligation to update and clarify its 340B patient definition to address the current health care system and to incorporate clear and enforceable standards. HRSA should consider promptly finalizing a new patient definition that contains the core elements proposed by HRSA in its 2015 omnibus guidance (and any other elements necessary to comply with the statute). We believe finalizing such a definition through new guidance would make important strides in bringing the definition current and resolving many of the inconsistencies in the way stakeholders have interpreted this key term. As we indicated in our 2015 comments to HRSA,[321] the patient definition should also address the diverse arrangements and delivery modes of treatment provided by HRSA grantees in the 340B program.

Off-site Hospital Clinics ("Child Sites"): Current guidance on eligibility criteria for child sites is outdated, is driving up costs and consolidation, and should be updated

The 340B law defines the types of hospitals that can participate in the program with great specificity,[322] but never mentions participation of off-campus outpatient facilities associated with these hospitals. Although there is no basis in the statute for including these sites, in 1994, HRSA unilaterally issued guidance dramatically expanding the 340B program by permitting child sites to participate—even if as private DSH hospitals have interpreted, they are only loosely connected to the parent hospital and do not serve a needy population.[323] Child sites have become a major source of the program's growth and incentives. In 1994, there were a total of 34 child sites. By 2016 this had increased to over 15,000.[324]

In addition to accounting for much of the 340B program's explosive growth, the hospital child site policy has shifted the program away from its original goal of helping get discounted medicines to uninsured and vulnerable patients.[325] For example, a 2014 *Health Affairs* study found that child sites are converting 340B "from [a program] that serves vulnerable communities to one that enriches hospitals."[326] The authors of a recent *New England Journal of Medicine* Perspective on 340B state that "hospitals have purchased community practices in part … to expand their footprint into wealthier neighborhoods to 'profit' from the 340B program."[327] Hospitals purchasing physician practices leads to higher costs for many payers and patients because commercial reimbursement for hospital-owned practices are typically higher due to their market power—thereby increasing costs on government payers, commercial insurers, and patients in the form of higher cost sharing and premiums.[328]

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[321] 80 FR 52300.
[322] 42 U.S.C. § 256b(a)(4)(L)-(O).
[323] 59 Fed. Reg. 47884, 47885 (September 19, 1994).
[324] HRSA OPA Database, October 2016.
[325] Vandervelde A, Blalock E. 340B Program Sales Forecast: 2016 – 2021. 2016. Available at: http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf.
[326] Conti M, Bach P. The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities. *Health Affairs*. 2014;33(10): 1786-1792.
[327] Gellad, WF, James AE. Discounted drugs for needy patients and hospitals—understanding the 340B Debate. *New England Journal of Medicine.* 2018;378(6):501-503.
[328] As discussed earlier, while the administration recently made changes to address 340B hospitals' incentives to increase spending in Medicare Part B, that change will likely have a minimal impact on

HRSA should revisit its 1994 guidance given the rampant growth in the number of child sites, the lack of any requirements that these clinics serve a safety-net role, and the evidence that they are leading to higher costs for many patients. Reforms are needed to align HRSA's guidance with the 340B law's text and its goal of improving eligible patients' access to medications, including tightening the eligibility criteria to assess when these outpatient facilities are considered part of a covered entity for 340B program purposes.

Contract Pharmacy: Rampant growth of hospital use of contract pharmacy arrangements must be reined in through updated guidance

Contract pharmacies, which are not mentioned in the 340B statute—have expanded rapidly since HRSA's 2010 expansion of its previous contract pharmacy guidance. The evidence to date shows significant problems with unlimited and unchecked expansion of 340B into the retail pharmacy setting, especially as driven by DSH hospital arrangements. First, covered entities and contract pharmacies generally are not abiding by the compliance safeguards suggested by HRSA in its 2010 guidance.[329] A June 2018 study by the GAO found "weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies."[330] Second, many contract pharmacy arrangements have been cited for duplicate discount violations; moreover, HHS OIG has found that contract pharmacies make compliance with the duplicate discount ban more complicated and OIG and GAO have both found that contract pharmacies also increase the risk of diversion violations.[331] Third, and most concerning, OIG found that unlike grantees, 340B hospitals generally are not sharing discounts with uninsured patients through their contract pharmacies.[332] Without benefit to needy patients, as the 340B program was intended, the dramatic expansion of contract pharmacy arrangements into the for-profit, retail pharmacy sector represents an unreasonable and unnecessary risk to program compliance.

Contract pharmacies can generate higher returns by dispensing 340B prescriptions than non-340B prescriptions, however uninsured patients are not always offered the 340B discounted price at contract pharmacies contracting with DSH hospitals.[333] Despite the fact that the 340B program was designed to ensure increased access to prescription medicines for vulnerable or uninsured patients, the 2014 OIG report found that the majority of hospitals in their study did not ensure that they passed 340B discounts back to uninsured patients who filled their prescriptions at a contract

incentives for future provider consolidation. The new Part B reimbursement changes are by definition limited to the less than one quarter of DSH hospitals' 340B profits derived from Part B fee-for-service sales and the new policy will not impact newly acquired outpatient sites that are not paid under HOPPS.

[329] HHS OIG. Contract Pharmacy Arrangements in the 340B Program, supra, at 1-2.

[330] GAO. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.

[331] HHS OIG. Contract Pharmacy Arrangements in the 340B Program, supra, at 1-2; GAO. Manufacturer Discounts in the 340B Program Offer Benefits but Federal Oversight Needs Improvement, supra, at 28-29.

[332] HHS OIG. Contract Pharmacy Arrangements in the 340B Program, supra, at 14 (only one-third of hospitals surveyed by OIG reported that they passed through 340B discounts to uninsured patients in at least one of their contract pharmacy arrangements, vs. 83 percent of surveyed grantees).

[333] HHS OIG. Contract Pharmacy Arrangements in the 340B Program. February 2014.

pharmacy.[334] In contrast, the grantee covered entities in the OIG study were more likely to have developed systems for their contract pharmacies to pass 340B discounts on to uninsured patients.[335]

Contract pharmacy expansion is also a troubling example of intermediaries diverting resources from 340B's intended purpose of assisting low-income or vulnerable patients. An industry of for-profit pharmacies and their third-party administrators and consultants has developed since 2010 with the goal of maximizing 340B dispensing.[336] These entities financially benefit from taking a share of the markup between the legally mandated 340B price and the higher price paid by patients and insurers. Little to no oversight exists to monitor contract pharmacies and these third-party vendors.

The current unlimited use of contract pharmacies by hospitals is not sustainable and diverts savings from 340B to for-profit pharmacies and other intermediaries. HRSA should use its authority and revisit its current unlimited contract pharmacy policy, particularly as it applies to how contract pharmacies are used by some covered entities such as DSH hospitals. Any new policy must consider what role, if any, hospitals' contract pharmacies should play in a program that has grown significantly over the past eight years and has failed to benefit patients.

*Hospital Eligibility***:** *Hospital eligibility standards are outdated, and the requirements in statute are not well enforced*

With 45 percent of all current acute care hospitals participating in a program that was first intended for true safety-net facilities,[337] the eligibility criteria for DSH hospitals must be reexamined. DSH hospitals qualify for the 340B program based in part on their DSH percentage,[338] an inpatient measure relating to the number of Medicaid and low-income Medicare patients treated in a hospital's inpatient unit. MedPAC reported that it had found little correlation between hospitals' DSH adjustment percentages and whether they had a high percentage of uninsured patients.[339] While changes to the DSH metric must be made legislatively, it is an important issue that the Administration should consider given it has driven growth in the program and does not target the 340B program's intended patient population or even represent an outpatient care metric.

HRSA does have an important role to play in ensuring hospitals that are eligible for the 340B program meet the statutory criteria to be true safety-net facilities. To ensure discounts are for hospitals serving a truly indigent or vulnerable population, HRSA should issue meaningful

[334] Id.
[335] Id.
[336] Senator Charles Grassley. Letter to Walgreens CEO Gregory Watson. July 21, 2013. Available at: https://thebeatatcooleyhealth.files.wordpress.com/2013/08/walgreens-340b-letter-grassley.pdf; Talyst. Benefits to Becoming a Contract Pharmacy. Available at: http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf
[337] MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.
[338] See 42 U.S.C. § 256b(a)(4)(L)-(O).
[339] MedPAC. Report to the Congress: Medicare Payment Policy. March 2007.

eligibility standards for hospitals not owned or operated by a state or local government. The statute requires that all 340B hospitals must be owned or operated by a unit of state or local government or be a private nonprofit hospital that (a) has been formally granted governmental powers by a state or local government; or (b) has a contract with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. Unfortunately, there is little guidance, transparency, or oversight to enforce these requirements. In fact, HRSA does not even review or collect the contracts that make some hospitals eligible for 340B discounts. Instead, the responsibility falls on hospitals to self-report if they believe they no longer meet the requirements. GAO noted that "hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicare or Medicaid could claim 340B discounts, which may not be what the agency intended."[340] This lack of oversight makes it difficult to ensure that contracts are meeting congressional intent. The legislative history states that a private nonprofit hospital that had "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues" could not qualify for 340B under the state and local government contract test.[341] Yet HRSA is not enforcing this requirement, which could easily be done routinely when HRSA recertifies a hospital's 340B eligibility.

340B DRUG DISCOUNT PROGRAM: Program Dynamics (RFI p. 22699)

Role of the Prime Vendor

The RFI asks specifically about the impact of the Prime Vendor Program. The 340B statute created the Prime Vendor Program "under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs."[342] Over the 15 years Apexus has been the recurring awarded Prime Vendor, the role of the 340B Prime Vendor Program has expanded to other areas including education and assistance for all program stakeholders. Importantly, none of these expanded activities are funded by fees paid by covered entities. Under the current model, Apexus is obliged to engage in additional revenue generating activities separate from its 340B communication and training programs. We have concerns that these conflicting obligations impact Apexus' ability to share 340B program information with HRSA in an unbiased way.

We support the concept of Apexus providing basic facts about the program, such as answering the question "can a for-profit hospital participate in the 340B program?" However, we are concerned that due to HRSA's failure to issue updated rules, Apexus' current role has veered into setting policies through the posting of Frequently Asked Questions (FAQs).[343] For example, on the Apexus website:

[340] GAO. Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836 (Sept.2011), p 23.
[341] U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).
[342] Sec, 340B PHSA(a)(8).
[343] Apexus. Frequently Asked Questions. May 23, 2018. Available at: https://www.340bpvp.com/resource-center/faqs

> "HRSA relies on Apexus to communicate policy and provide award-winning education, training, and support to all 340B stakeholders."
>
> "Frequently Asked Questions: Apexus is communicating these HRSA FAQs with the intention of improving program compliance. Additional FAQs may be available to address specific circumstances by contacting Apexus Answers. The removal of an FAQ from the website does not imply that the FAQ is no longer supported by HRSA. Certain FAQs are best applied when details are presented in the appropriate context, according to a specific covered entity's situation, and Apexus Answers can facilitate that level of communication and application."

In some cases, it appears to be setting entirely new policies in key areas including patient definition.[344] This raises concerns about why a third-party contractor—and not HHS—is issuing guidance. Both GAO and OIG have raised concerns that current program rules are overly broad and not well-enforced.[345]

In addition to ceding authority to Apexus for policy communication, HRSA has empowered Apexus with unique sales data and price negotiation access. Apexus has long advertised its unique status as the only group contracting option for those covered entities subject to the statutory group purchasing organization (GPO) prohibition.

> "Q. Why is it permissible for Apexus to establish contracts for the non-GPO account for hospitals subject to the GPO prohibition?
>
> A: Certain hospitals must agree to not participate in a GPO for the purchase of outpatient covered drugs as a condition of eligibility for participation in the 340B program. Apexus, as HRSA's contracted 340B Prime Vendor, is not considered a GPO and is permitted to perform such group purchasing functions on behalf of all entities who voluntarily participate in the prime vendor. The HRSA agreement enables Apexus to contract for outpatient covered drugs and other value-added products on behalf of participating covered entities."

Under its distribution contracts, Apexus has price visibility and can enforce data reporting standards not available to other stakeholders. For example, Apexus states, "Pricing rules with the wholesalers are monitored by the Prime Vendor to support compliance of manufacturers and covered entities." Solutions to improving the role of the prime vendor in the 340B program include HRSA clearly defining activities and providing adequate funding for any 340B Prime

[344] See, for example, FAQ ID: 1442 "Q: May providers that have admitting privileges at our 340B participating hospital be considered eligible providers under the 'other arrangements' provision of patient definition?".
[345] GAO. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015.; HHS OIG. Contract Pharmacy Arrangements in the 340B Program. February 5, 2014.

Vendor Program (or supporting contractor) to eliminate conflicting areas of responsibility, as well as HRSA fulfilling its role as administrator of the program, by providing sufficient and updated program rules and official agency communications.

Inventory Control Models

The RFI specifically asks about 340B inventory control models. The most common 340B inventory model used today is a virtual inventory and replenishment model to track the dispensing and ordering of 340B medicines. Instead of using a physical inventory model where contract pharmacies fill 340B prescriptions from a designated inventory of 340B medicines that are separately stocked and apart from usual inventory, contract pharmacies utilize a "virtual replenishment model" to fill prescriptions from their existing stock, managing their inventory as usual. A 340B third-party administrator (TPA) then reconciles medicines dispensed to 340B patients, and replenishes the contract pharmacy's stock using the covered entity's 340B medicines.

As the program is currently structured, there are no requirements on the time frames or dates for when a claim must be identified and adjudicated as 340B. This allows, and results in, TPAs going back several years in the past, scrubbing adjudicated claims, and submitting them for 340B discounts. Due to HRSA's outdated, vague patient definition and the insufficient methods to prevent duplicate discounts (see below), this type of activity leads to duplicate discounts and diversion. Providing contract pharmacies an easy way to reconcile their claims must be balanced in a way that maintains program integrity.

340B DRUG DISCOUNT PROGRAM: Duplicate Discounts Drive Program Integrity Issues (RFI p. 22699)

Current mechanisms to identify and prevent duplicate discounts are ineffective

The 340B program prohibits covered entities from purchasing a medicine at a 340B discount that also generates a Medicaid rebate claim.[346] Consequently, the law creates an absolute prohibition on duplicate discounts.[347] Despite this clear statutory imperative, current prevention methods do not stop or prevent 340B duplicate discounts. Two primary factors lead to duplicate discounts: 1) insufficient oversight of the 340B program, and 2) the creation and unfettered expansion of contract pharmacies.

The increasing use of contract pharmacies coupled with expansion of Medicaid rebates for medicines used by Medicaid MCO enrollees have exacerbated the problem of duplicate discounts—with HRSA and CMS thus far not taking effective steps to prevent this statutory violation. In 2014, HRSA released guidance that expressly excluded MCO drug utilization from the only mechanism HRSA has developed to prevent duplicate discounts (the Medicaid Exclusion

[346] 42 U.S.C. § 256b(a)(5)(A).
[347] Sec. 340B PHSA(a)(5)(i).

File (MEF)), stating that it needs to develop, in conjunction with CMS, a policy for MCOs.[348] As of 2018, this policy has yet to be developed.

The FY 2017 HRSA covered entity audit data show that two-thirds of all DSH hospitals audited were noncompliant in at least one area, and many were noncompliant in multiple areas.[349] It is not clear how HRSA addressed covered entity violations of program requirements, but at least one Congressional committee found little evidence for strong agency oversight citing that "HRSA rarely terminates covered entities from the 340B program through the audit process."[350]

GAO released a report at the end of June on contract pharmacies which highlights these concerns in clarifying detail. The report found that because HRSA only assesses the potential for duplicate discounts in fee-for-service and not MCOs, "[u]ntil HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, **the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance**"[351] (emphasis added).

Suggestions for Improving Prevention of Duplicate Discounts

HRSA has an explicit statutory mandate "to establish a mechanism to ensure that covered entities comply"[352] with the prohibition on duplicate discounting. We suggest the following for HRSA to comply with its statutory requirement and we are open to working with HRSA to develop other solutions:

1. **HRSA should work with CMS to address duplicate discounts, as HRSA stated it would do in 2014 guidance.** In 2014, HRSA stated it was "working with CMS to develop policy" to prevent duplicate discounts in MCOs.[353] The notice encouraged covered entities and States to work together to develop alternative strategies for preventing duplicate discounts for MCO drugs.[354] This policy or guidance has yet to be developed. In its June 2018 Report to Congress, GAO recommends that HRSA should issue guidance on the prevention of duplicate discounts in MCOs and that it should work together with CMS to achieve this. However, while HRSA concurs with the GAO's

[348] HRSA. 340B Drug Pricing Program Release No. 2014-1. December 12, 2014. The MEF mechanism requires that 340B covered entities either "carve in" (provide 340B drugs to Medicaid patients and report this practice to HRSA, so that these entities are listed on the Exclusion File and State Medicaid programs do not bill manufacturers for rebates on drugs furnished by these entities) or "carve out" (do not provide 340B drugs to Medicaid beneficiaries, so that drugs supplied by a 340B entity to a Medicaid patient triggers a Medicaid rebate, but not a 340B discount). Under the 2014 guidance, this mechanism no longer applies to prevent double discounts on 340B drugs provided to MCO beneficiaries.
[349] HRSA OPA Database Program Integrity FY17 Audit Results. March 6, 2018.
[350] Energy & Commerce Committee's "Review of the 340B Drug Pricing Program."
[351] GAO. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
[352] Sec. 340B PHSA(a)(5(A)(ii).
[353] HRSA. 340B Drug Pricing Program Notice: Clarification on use of the MEF. Release No. 2014-1. December 12, 2014.
[354] HHS OIG. State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016.

findings, it provides insufficient excuses for why such guidance has not been issued and does not provide any concrete detail for when such guidance may be forthcoming.[355] We agree with the GAO, that HRSA and CMS must work together now to enforce the law's duplicate discount ban.

2. **Require a claim modifier.** According to OIG, there are two ways to identify 340B claims, a provider-level method or a claim-level method.[356] The first option is to require covered entities to use the MEF not just for fee-for-service utilization but also for MCO utilization. The second option is to create a claims modifier for all public and private payers, including fee-for-service and MCOs in Medicaid.[357] Last year, CMS began requiring hospitals subject to the new Medicare Part B 340B drug payment reduction, to identify 340B drugs, so many 340B hospitals are already using a claims modifier as part of Medicare reimbursement rules.[358]

HRSA created the contract pharmacy policy out of guidance and therefore, it should take action to implement GAO's recommendations to improve duplicate discount prevention by issuing new or revised guidance. GAO highlighted HRSA's authority to issue new guidance in its June 2018 report when it concluded that "Since the establishment of the 340B Program, HRSA has used interpretive guidance and statements of policy to provide guidance to covered entities regarding compliance.…As such, **we continue to believe that further clarification, whether provided as interpretive guidance, audit procedures, or another format, is necessary to help ensure compliance with program requirements"**[359] (emphasis added).

<u>340B DRUG DISCOUNT PROGRAM: Impact of Commercial Rebates Paid on 340B Discounted Medicines</u> (RFI p. 22699)

A prescription drug with a negotiated commercial rebate can also be subject to a 340B discount. While some manufacturers may include in their contracts with commercial plans that drugs purchased through the 340B program are not eligible for further rebates to the health plan, without a means to prospectively identify 340B-eligible claims at the point of sale (e.g., a claims identifier), these contract terms are difficult to operationalize and enforce. The 340B program is already growing; if manufacturers pay a rebate on a medicine that was already purchased at a large discount, it is likely that this compounds the distortive impact that economists say that 340B discounts already have on prescription medicine prices.[360]

[355] GAO. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
[356] HHS OIG. State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016.
[357] CMS and HRSA could consider specific identifiers for Medicaid MCOs such as IDs on Medicaid patients with BIN/PCN number.
[358] Fed. Reg Vol. 82, No. 217.
[359] GAO. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
[360] Conti R, Rosenthal M. Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation. *N Engl J Med.* 2016;374:703-706.; Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA.* 2013;309(19):1995-1996.

SECTION VIII: COST-SHARING ASSISTANCE CARDS (RFI p. 22698)

Commercial health plans are increasingly using high deductibles, coinsurance, and multiple cost-sharing tiers that push more costs onto the sickest patients. High prescription medicine cost sharing may limit patients' access to needed treatments, reduce adherence, and lead to poor outcomes. Individual manufacturers provide cost-sharing assistance cards, which are referred to as "copay discount cards" in the RFI,[361] in response to a benefit design system that would otherwise leave many patients with unaffordable out-of-pocket costs for their medicines at the pharmacy counter. These cost-sharing assistance cards can improve patient access and adherence to prescription medicines by reducing patients' out-of-pocket burden. This assistance is essential to patient affordability for the sickest patients who need ongoing treatment for chronic conditions such as multiple sclerosis and RA, and rare diseases and conditions. Ensuring patients have affordable access to their medicines is a top priority for PhRMA. Maintaining availability of cost-sharing assistance cards for patients should be a key part of the Administration's efforts to promote access to affordable medicines for patients. Thus, the Administration should not seek to change the current exclusion of cost-sharing assistance cards from the determination of AMP and Best Price, as is contemplated in the RFI. Such a reform would be inconsistent with the statute, would likely raise Medicaid prices (through lower statutorily required rebates if cost-sharing assistance cards were included in the calculation of AMP) for some medicines, and could reduce the availability of this assistance.

The RFI asks about the potential role of cost-sharing assistance cards in government programs.[362] PhRMA's response to those questions are included above in our comments on Medicare Part D.

COST-SHARING ASSISTANCE CARDS: Need for Cost-Sharing Assistance Cards (RFI p. 22698)

In the last decade, commercial health plan designs have shifted more costs to patients through increased use of deductibles and coinsurance.

- When a patient is in the deductible, they typically must pay the list price of their medication up to the deductible amount. Since 2006, deductibles for patients in employer health plans have increased by 300 percent.[363]

- When patients pay coinsurance, they must pay a percentage of costs associated with their health care service or medicine. Patient out-of-pocket spending on coinsurance has increased 67 percent while spending on copays has decreased.[364]

[361] RFI p. 22698
[362] RFI p. 22698.
[363] Claxton, G., Rae, M., Long, M., Damico, A. 2017 Employer Health Benefits Survey. Available at: https://www.kff.org/report-section/ehbs-2017-section-7-employee-cost-sharing/#figure710
[364]Claxton, G., Levitt, L., Rae, M., Sawyer, B. Increases in cost-sharing payments continue to outpace wage growth. Peterson-Kaiser Health System Tracker. June 2018. Available at: https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth

- The share of employer health plans requiring a deductible for prescription medicines has more than doubled from 23 percent in 2012 to 52 percent in 2017.[365]

Deductibles and coinsurance leave patients with high and often unpredictable costs, particularly for their medicines. Average patient out-of-pocket costs for deductible and coinsurance claims for brand medicines are much higher than copay claims.[366] In 2017, more than half of commercially insured patients' out-of-pocket spending for brand medicines was for medicines filled while a patient was in the deductible or with coinsurance, an increase of 20 percent from 2013.[367] Patients with chronic conditions are disproportionately impacted by high out-of-pocket costs.[368] Research has shown that just 7 percent of claims are responsible for over half of all patient out-of-pocket costs for brand medicines.[369] Without cost-sharing assistance cards many of these patients would have trouble paying the out-of-pocket costs for their medicines.

In many cases, individual manufacturers provide cost-sharing assistance cards to lower patients' out-of-pocket burden at the pharmacy counter since patients are often not benefiting directly from rebates. When a patient pays cost sharing for prescription drugs in a deductible or with coinsurance, their cost sharing is typically based on the undiscounted list price. PBMs negotiate discounts on brand medicines on behalf of health plans and employers that substantially reduce the list price. For certain medicines used to treat chronic conditions like asthma, high cholesterol, HCV, and diabetes, these discounts and rebates can reduce list prices by as much as 30to 70 percent.[370] However, the discounts are given in the form of rebates paid directly to the PBM and are not commonly passed through to patients. This creates additional affordability challenges at the pharmacy counter. In contrast, when patients pay cost sharing for medical care from an in-network hospital or physician, deductible and coinsurance payments are based on discounted rates negotiated between the health plan and the provider. Research has shown that sharing

[365] PwC. Health and Well-Being Touchstone Survey 2012-2017.
[366] Devane, K., Harris, K., Kelly, K. Patient Affordability Part One: The Implications of Changing Benefit Designs and High Cost-Sharing. May 2018. Available at: https://www.iqvia.com/locations/united-states/patient-affordability-part-one
[367] Id.
[368] Cox C et al. Examining high prescription drug spending for people with employer sponsored health insurance. Kaiser Family Foundation. October 27, 2017. Available at: https://www.healthsystemtracker.org/brief/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/#item-start
[369] Devane, K., Harris, K., Kelly, K. Patient Affordability Part One: The Implications of Changing Benefit Designs and High Cost-Sharing. May 2018.
[370] QuintilesIMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016.; Gronholt-Pedersen J, Skydsgaard N, Neely J. Novo Nordisk Defends U.S. Diabetes Drug Pricing. *Reuters*. November 4, 2016. Available at: http://www.reuters.com/article/us-novo-nordisk-prices-idUSKBN12Z184; Silverman E. What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean. *W.S.J*. February 4, 2015. Available at: https://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/; Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*. June 29, 2017. Available at: https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices

manufacturer rebates with certain commercially insured patients who have deductibles and coinsurance can save patients up to $800 annually.[371]

Cost sharing for prescription drugs is also unique in that patients must pay the full cost sharing for their medicine to take their medicine home from the pharmacy. In the case of care provided at a hospital or physician's office, patients often pay their cost sharing after care is received and may be able to negotiate a discount with the provider or work out a payment plan to pay over time. Cost-sharing assistance cards are a private market solution to address the challenges patients faced at the pharmacy counter when asked to pay the full cost sharing required by their insurers up-front before getting their medicine.

Higher out-of-pocket costs for prescription medicines can have significant negative impacts on patient health.

- Patients with leukemia who faced high out-of-pocket cost for medicines on a specialty tier were less likely to initiate drug therapy than patients who received an LIS (53 percent versus 21 percent). Patients with high out-of-pocket costs also took twice as long to initiate treatment.[372]

- Research has shown that patients are more likely to abandon or delay starting their anticancer drugs as out-of-pocket costs increase.[373] Only 10 percent of patients abandoned therapy when costs were less than $10 but that rate tripled when costs were above $100.

- New data shows that over half of patients did not start their new brand medicines when their out-of-pocket costs reach $125.[374] Most patients who abandoned their brand drugs do not fill another drug within 90 days, indicating they may not be receiving any treatment for their condition.[375]

[371] Bunger, A., Gomberg, J., Hunter, M., Petroske, J. Point of Sale Rebate Analysis in the Commercial Market: Sharing rebates may lower patient cost and likely has minimal impact on premiums. 2017. Available at: http://phrma-docs.phrma.org/download.cfm?objectid=5F5FD190-AEDD-11E7-833F0050569A4B6C

[372] Doshi JA, Li P, Huo H, et al. High cost sharing and specialty drug initiation under Medicare part D: A case study in patients with newly diagnosed chronic myeloid leukemia. *Am J Manag Care.* 2016;22(4 Suppl):s78-86.

[373] Doshi J, et al. Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *ASCO.* Available at: http://ascopubs.org/doi/abs/10.1200/JCO.2017.74.5091

[374] Devane K, et al. Patient Affordability Part Two: Implications for Patient Behavior and Therapy Consumption. May 2018. Available at: https://www.iqvia.com/locations/united-states/patient-affordability-part-two

[375] IMS Institute for Healthcare Informatics. Emergence and impact of pharmacy deductibles: implications for patients in commercial health plans. September 2015. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf

- RAND researchers found that doubling copays reduced patients' adherence to mental health and asthma medicines by 25 to 32 percent. Their research also found that because of increased cost sharing, emergency room visits and hospitalizations also increased.[376]

Cost-sharing assistance cards help patients who face high out-of-pocket costs for their medicines and can mitigate patient abandonment rates while advancing public health benefits. Patients who utilize cost-sharing assistance cards for brand medicines, including specialty drugs, are asked to pay much higher cost sharing at the pharmacy counter compared to patients who do not use cost-sharing assistance.[377] Coupons help to mitigate this higher cost sharing. Specialty drugs have the highest cost sharing and, in many cases, there are no lower cost alternatives available. Recent analysis by IQVIA found that cost-sharing assistance cards can mitigate patient abandonment rates by up to half.[378] Research has also shown that cost-sharing assistance card use is very low among brand medicines with a generic available. In 2017, only 0.4 percent of commercial claims were filled with a cost-sharing assistance card for brand medicines with a generic alternative.[379]

Even when patients use cost-sharing assistance cards to lower their cost sharing, PBMs have ample tools to manage health insurers' spending on medicines. PBMs can, and often do, subject medicines to prior authorization and step therapy—only allowing medicines to be covered by insurance for patients who have successfully overcome those hurdles and for whom the PBM has determined need the medicine. Additionally, PBMs often use closed formularies that exclude certain medicines. Coverage for those medicines are only available to patients who have successfully gone through an exceptions process. PBM's ability to steer patients to the lowest cost medicine is a key reason why generics account for 90 percent of prescriptions that are dispensed.[380] PBM's ability to use utilization management as part of efforts to drive high use of generics suggests that cost-sharing assistance does not subvert benefit design.

Up until recently, patients reached their deductible and out-of-pocket maximum at the same time, regardless of how they paid the cost sharing required for their medicines. But new programs from some PBMs and health insurers ignore cost-sharing assistance cards when calculating whether patients have reached their deductible or out-of-pocket maximum. In some cases, these programs lead to patients exhausting their cost-sharing assistance, potentially leaving them with unexpected out-of-pocket costs as high as several thousand dollars in order to continue taking their medicine. As discussed above, high out-of-pocket costs make patients more likely to abandon their medicines and become nonadherent, leading to increased health care costs for health plans and employers. These new programs threaten access for patients and could negatively impact patient health. These programs also single out cost-sharing assistance cards.

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[376] Goldman DP, Joyce GF, Escarce JJ, et al. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA*. 2004;291(19):2344-2350.
[377] K. Devane, et al., Patient Affordability Part Three: The Implications of Co-Pay Cards. May 2018. Available at: https://www.iqvia.com/locations/united-states/patient-affordability-part-three
[378] Id.
[379] IQVIA. An Evaluation of Copay Card Utilization in Brands after Generic Competitor Launch. February 2018. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us-location-site/market-access/fact-sheet-evaluation-of-copay-card-utilization-post-loe.pdf
[380]IQVIA. 2017 Medicine Use and Spending. April 2018.

In contrast, patients with commercial insurance benefit from hospitals and doctors forgiving bad debt that patients owe towards the cost sharing in their medical benefit. Even when this cost sharing is not collected by the provider, it still counts towards patients' deductible and out-of-pocket maximum.

COST-SHARING ASSISTANCE CARDS: Price Reporting (RFI p. 22698)

The RFI asks about the impact of ending the current policy of excluding manufacturer-sponsored drug discount programs from the determination of AMP and Best Price.[381] PhRMA strongly recommends that HHS not change the current policy. As discussed below, eliminating the exclusion for manufacturer sponsored drug discount programs would not be consistent with the statute, would be operationally difficult, would likely raise prices in most cases for Medicaid, and could harm patients.

Best Price

Statutory change would be needed to include cost-sharing assistance cards in Best Price determinations. By law, the term "best price" means "the lowest [net-of-discount] price available from the manufacturer during the rebate period to any wholesaler, retailer, health maintenance organization, nonprofit entity, or governmental entity within the United States" subject to specified exclusions.[382] Accordingly, Best Price determinations do not take into account manufacturer discounts to patients as patients are not wholesalers, retailers, health maintenance organizations (HMOs), nonprofit entities, or government entities—as CMS recognized in developing the current regulations.[383] Congress drafted the Best Price provision in the Medicaid rebate statute to give Medicaid "the benefit of the same discounts that other large public and private purchasers enjoy" and did not intend discounts to patients to trigger Best Price. We strongly recommend that Congress not change its current policy for the reasons detailed below.

- Requiring manufacturers to offer their best price to Medicaid is a policy grounded in the idea that Medicaid should benefit from negotiated discounts and should benefit from the best deal available to private insurers. Cost-sharing assistance cards are not negotiated with a payer and no payer pays a price net of cost-sharing assistance cards. Instead, insurers pay a price that is net of negotiated rebates and price concessions, which are already factored into Best Price. In contrast, cost-sharing assistance cards are offered to patients to fill in some of the plan-assigned cost sharing so that medicines are more affordable. Manufacturers typically do not directly control how much of a cost-sharing

[381] RFI p. 22696.
[382] 42 U.S.C.§1396r-8(c)(1)(C)(i)(Social Security Act § 1927(c)(1)(C)(i))(emphasis added).
[383] 77 Fed. Reg. 5318, 5336, 5362 (proposed 42 C.F.R. § 447.505(a)(explaining that CMS is "proposing to revise the term 'best price' at newly proposed § 447.505(a) so that it is consistent with the definition of best price found in section 1927(c)(1)(C) of the Act" and then proposing new language whereby best price is "the lowest [net] price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity in the United States" subject to certain exclusions.

assistance card is used for an individual fill of a prescription—that depends on a patients' level of cost sharing.

- Factoring cost-sharing assistance cards into price reporting metrics would add more complexity to the current system. The amount an individual cost-sharing assistance card pays out is a function of several factors: whether a deductible applies to prescription drugs, the size of that deductible and whether the patient has other medical expenses that apply to that deductible, how many times the patient fills the prescription and whether other medical expenses cause the patient to reach their out-of-pocket maximum.

AMP

For most drugs, AMP is the average price for direct sales to retail community pharmacies and indirect sales to retail community pharmacies through wholesalers.[384] Therefore AMP excludes manufacturer sales, discounts, rebates, and other price concessions to other parties—including patients—and a statutory change would be needed to include cost-sharing assistance cards in AMP calculations. It is not clear what HHS would hope to achieve by amending the statute to include patient discounts in AMP calculations. Such a change would lower AMP, which in turn would lower Medicaid rebates.[385] This would *increase* net drug costs to State Medicaid programs, which we believe is counter to goals of the Administration's reform efforts.

SECTION IX: VALUE-BASED ARRANGEMENTS (RFI p. 22696)

Our health care system is evolving to increasingly reward the value of services, rather than solely reimbursing based on the volume of services provided. As these medicines are becoming increasingly personalized, manufacturers and health plans are exploring innovative payment and coverage approaches in the competitive market that can help improve patient access and affordability. As HHS has repeatedly recognized, these approaches can advance its goal of moving from fee-for-service payments toward payment methods that reward quality and value. For example, CMS Administrator Seema Verma stated last year that innovative products "reinforce our belief that the current healthcare payment systems need to be modernized in order to ensure access to new high-cost therapies, including therapies that have the potential to cure the sickest patients."[386] CMS emphasized that "[a]s part of larger efforts to support the President's priority [of lowering drug costs], CMS is working actively with all stakeholders . . . on innovative

[384] 42 U.S.C. § 1396r-8(k)(1)(SSA § 1927(k)(1). Drugs that are infused, injected, inhaled, instilled, or implanted and are not generally dispensed through a retail community pharmacy have a special AMP formula that includes many sales and price concessions that are not included in standard AMP (so that an AMP for these "5i" drugs can be calculated), but discounts to patients are not part of the 5i AMP. 42 U.S.C. § 1396r-8(k)(1)(A)(i)(IV)(SSA § 1927(k)(!)(A)(i)(IV)).

[385] The rebate for a brand drug equals a basic rebate plus an additional rebate. The total rebate will decline if AMP declines, since this will cause the basic rebate to go down and the additional rebate to go down. The "basic rebate" is the greater of: (1) 23.1 percent of AMP or (2) AMP minus best price. Both of these amounts will decline with a decline in AMP. The "additional rebate" equals [the current-quarter AMP minus the inflation-adjusted AMP from the base period (usually the first full quarter after the drug's launch]; this will also decline with a decline in AMP, holding the base period AMP constant.

[386] CMS. Innovative Treatments Call for Innovative Payment Models and Arrangements. (emphasis added).

payment arrangements" including "outcome-based pricing for medicines in relation to clinical outcomes."[387] In its 2016 final rule on Covered Outpatient Drugs, CMS stated that "[w]e recognize the value of such [value-based payment] arrangements, especially when they benefit patients," and "since these arrangements are unique, we are considering how to provide more specific guidance."[388] Later that year, CMS announced that in subsequent guidance it would seek to generalize lessons learned from common questions and arrangements.[389]

PhRMA greatly appreciates that just last month, FDA issued final industry guidance on manufacturer communications with payers and communications consistent with the label. These guidances are a substantial and positive step forward for manufacturers' ability to communicate about the value of their products.[390] FDA's final payer guidance includes recommendations designed to enable truthful, non-misleading, and appropriate manufacturer communications with payers across a product's lifecycle, which will facilitate communications that can allow payers to provide coverage for new products and indications more quickly. In issuing this guidance, FDA recognized the important role that value-based arrangements can play in advancing patient care:

> The goal is to advance public health benefits such as increased cost savings from informed and appropriate coverage and reimbursement decisions. In this way, we can help ensure patients have more timely access to cutting-edge medical technologies. We can facilitate access by helping to reduce the overall cost of providing these benefits to patients. And in promoting access, we will advance important public health goals.[391]

FDA has made an important step towards addressing one key barrier to value-based arrangements. We urge HHS to continue this momentum, by modernizing the safe harbors to protect value based arrangements and addressing challenges to value-based arrangements associated with Medicaid rebate reporting. These agreements can offer important clinical gains and overall cost savings to payers, providers, and patients throughout the health care system—including Medicaid, Medicare, and their beneficiaries.

As the Administration considers value-based payment and coverage approaches, it is critical that the market determine value rather than the government or other centralized organizations. The competitive market is uniquely well-designed to make complex determinations about the value of medicines as the many heterogeneous payers assess their own needs in light of available evidence. In contrast, policies that would impose a centralized government determination of value would reduce and delay appropriate patient access and lead to suboptimal

[387] CMS. Innovative Treatments Call for Innovative Payment Models and Arrangements. supra.
[388] 81 Fed. Reg. 5170, 5253 (Feb. 1, 2016).
[389] CMS Medicaid Rebate Release No. 99 to Manufacturers, July 14, 2016.
[390] FDA. Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities. June 2018; FDA. Medical Product Communications That Are Consistent With the FDA-Required Labeling. June 2018.
[391] FDA. Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers. June 17, 2018.

outcomes. Experience in several European countries has shown the dangers of the government attempting to make centralized, one-size-fits-all judgments of value. Restrictions imposed by the U.K.'s NICE have created substantial barriers between patients and life-saving treatments—recent analysis shows that from 2013 to 2017, nearly 92 percent of oncology treatments were given some kind of access restriction.[392] Patients who live in countries that impose centralized value judgements also have access to fewer treatment options—recent data shows that nearly 90 percent of newly launched medicines were available in the U.S., compared to just two-thirds in the U.K., half in Canada and France, and one-third in Australia.[393] Ensuring reforms are market based is essential to preserving patient access to a range of treatment options that they identify as high value.

Below we offer suggestions for HHS as it works to drive competition by addressing barriers to value-based arrangements (such as price reporting rules), and potential approaches to indication-based pricing and long-term financing arrangements to consider.

VALUE-BASED ARRANGEMENTS: Value-Based Arrangements and Price Reporting (RFI p. 22696)

PhRMA appreciates HHS' Interest in Value-Based Arrangements and related price reporting changes. As part of the broader shift to value in health care, private payers increasingly are pursuing results- or value-based contracts with biopharmaceutical companies. An expansion of these innovative arrangements would offer an effective, market-based approach to managing drug costs and spurring value-based care, while delivering savings for patients, private payers and the government. Currently, outdated regulations developed for a fee-for-service world are limiting the number, scale, and types of these arrangements.

PhRMA appreciates HHS' continued commitment to facilitating value-based arrangements. We believe that some additional HHS guidance, and a few regulatory changes, could help reduce challenges to value-based arrangements and permit broader adoption. Below we provide a brief overview of value-based arrangements—what they involve, why they matter, and the benefits they offer to federal health programs and their beneficiaries—and then discuss the specific topics on which the RFI seeks input.

Description and scale of value-based arrangements

PhRMA considers value-based arrangements for biopharmaceuticals to be voluntary arrangements between manufacturers and other private entities, such as health plans or risk-bearing providers, in which the price or price concession for a prescription medicine is linked to

[392] Hughes K and N Jeswani. HTAs Recommendations for Oncology Have Grown More Restrictive Over Time. Avalere Health. June 2018. Available at: http://avalere.com/expertise/life-sciences/insights/htas-recommendations-for-oncology-have-grown-more-restrictive-over-time
[393] Haninger K. New analysis shows that more medicines worldwide are available to U.S. patients. PhRMA. The Catalyst blog. June 2018. Available at: https://catalyst.phrma.org/new-analysis-shows-that-more-medicines-worldwide-are-available-to-u.s.-patients

value as determined by the contracting entities. These arrangements can reduce insurers' cost exposure for treatment failures by allowing the manufacturer to share financial risk with the payer. By aligning payments for medicines more directly with their value in improving health outcomes and/or reducing the need for other health care services (such as hospitalizations), value-based arrangements make drug manufacturers accountable for the results their products achieve in a concrete way and can help improve patients' health and maximize the benefits of health care spending.

We recognize that our members can also enter into value-based arrangements with state Medicaid programs, thereby lowering budgetary costs for both the federal government and the state. While the majority of value-based arrangements are between private entities, the government can play an effective role in addressing barriers to innovative market-based arrangements.

Many types of value-based arrangements are occurring between manufacturers and health plans; outcomes-based contracts, which vary costs or discounts based on patient outcomes, are one example. Earlier this year, PhRMA released an issue brief which provides a taxonomy with some of the many possible types of value-based arrangements.[394] The brief describes performance-based contracts such as outcomes-based contracts and conditional treatment continuation arrangements. It also describes indication-based pricing and regimen-based pricing (discussed in the next section) as well as expenditure caps, which are both types of variable pricing arrangements.

As evidence of the increasing proliferation of these contracts, a 2017 Avalere survey of 45 payers representing 183 million covered lives, found that more than half of payers surveyed either had an outcomes-based contract in place or were in negotiations.[395] A survey by PwC found that one quarter of pharmaceutical company executives say their company has participated in a value-based arrangement. Of those who have participated, nearly one-third (32 percent) have engaged in more than 20 of these arrangements.[396] The number of value-based contracts has been increasing. Only 7 private sector risk-sharing contracts were publicly announced from the late 1990s to 2013, but 16 were announced from 2015 through early 2017.[397] PhRMA identified 39 publicly announced value-based contracts by 19 pharmaceutical companies for 25 medicines from 2009 through Q1 2018.[398] Recent data from the Academy of Managed Care Pharmacy and PwC's survey confirm that only a portion of value-based arrangements are publicly announced.[399]

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[394] Id.
[395] Avalere Health. Payer Perspectives on Outcomes-Based Contracting: Avalere 360. May 22, 2017.
[396] PwC. Launching Into Value: Pharma's Quest to Align Drug Prices with Outcomes. September 2017. Available at: https://www.pwc.com/us/en/health-industries/health-research-institute/publications/value-based-drug-pricing.html.
[397] PhRMA. Barriers to Value-Based Contracts for Innovative Medicines: PhRMA Member Survey Results. March 2017.
[398] PhRMA. Value-Based Contracts 2009-2018 Q1. April 2018. Available at: https://www.phrma.org/fact-sheet/value-based-contracts-2009-q1-2018.
[399] Duhig AM, S Saha, S Smith et al. The Current Status of Outcomes-Based Contracting for Manufacturers and Payers: An AMCP Membership Survey. *J Manag Care Spec Pharm.* 2018;24(5):410-415.

Looking forward, IQVIA estimates that there will be 65 outcomes-based contracts from 2018-2022.[400]

While the number of value-based arrangements in the competitive market continue to increase, manufacturers continue to face multiple obstacles to creation of these arrangements. Addressing these challenges would allow more, a greater variety of, and larger scale arrangements to occur.

Benefits of value-based arrangements

As recognized in a recent report by the Duke Margolis Center for Health Policy, "[m]any stakeholders view [value-based agreements] as potentially driving more efficient healthcare delivery, with reductions in overall costs while improving patient outcomes."[401] Importantly, these arrangements also can increase patient access to new therapies, including breakthrough medications for rare and devastating diseases, which could ultimately improve patient outcomes. These products have the potential to transform patients' lives by treating segments of the population in desperate need of medical advances—often people with progressively debilitating diseases who have lacked any effective treatment options. For instance, currently over 1,500 potential gene therapy treatments are in research and development by dozens of pharmaceutical companies, including nearly 600 targeting cancers and 500 for rare and debilitating or deadly conditions.[402] A payer that might otherwise decline to cover a new drug (or that would only cover the drug with significant utilization management restrictions or high cost sharing) due to uncertainties about the expected percentage of its patient population who would benefit from the drug might increase access to the drug if the manufacturer shared the risks of the drug's performance. By reducing a payer's risks (e.g., agreeing to pay a large rebate on units of the drug used by enrollees who do not respond to the drug or achieve a specified outcome, so that the payer cannot end up paying a high net price for low performing products), these agreements may make newer drugs more accessible to patients who will benefit from them and increase competition in relevant drug classes.[403]

There is evidence that payers and PBMs are experimenting with value-based arrangements to drive cost savings. CVS Health described several types of value-based arrangements as tools they used to keep specialty drug cost growth to 3.7 percent in 2017.[404] Avalere found that one-third of payers engaged in these contracts experienced cost savings.[405] Express Scripts also

[400] IQVIA Institute. 2018 and Beyond: Outlook and Turning Points. March 2018.
[401] Duke Margolis Center for Health Policy. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products. December 2017. Available at: https://healthpolicy.duke.edu/publications/overcoming-legal-and-regulatory-hurdles-value-based-payment-medical-products.
[402] Steven Miller. Gene Therapy Holds Great Promise, But Big Price. September 21, 2017. Available at: http://lab.express-scripts.com/lab/insights/drug-options/gene-therapy-holds-great-promise-but-big-price.
[403] See, e.g., Lee Staley. A Drug's Worth: Why Federal Law Makes it Hard to Pay for Pharmaceutical Performance. 98 Boston Univ. Law Review 303, at 310. 2018 ("Tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers. . . .A manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors).
[404] CVSHealth. Drug Trend Report 2017.
[405] Avalere Health. Payer Perspectives on Outcomes-Based Contracting: Avalere 360. May 22, 2017.

engages in several types of value-based arrangements and their Chief Medical Officer, Steve Miller, has recognized the benefit of risk-sharing through these arrangements stating, "[v]alue-based contracting can help to ensure that payors and patients are not on the hook when a treatment isn't effective."[406]

The short-term benefits of value-based arrangements fall into three categories:

- **Value-based arrangements can lower patients' out-of-pocket costs.** From 2015 to 2017, patient copays were 28 percent lower than the market average for certain plans that announced a value-based arrangement. Although data was not detailed enough to directly link lower cost sharing to the value-based arrangement, the results provide a clear indication that such contracts may have led to lower patient cost sharing.[407] Researchers have also found that value-based arrangements can improve patient access to medicines.[408]

- **Value-based arrangements can improve patient outcomes.** Because these arrangements allow manufacturers to reduce payers' risk for suboptimal outcomes or offer new types of discounts that may not be available today, payers may be able to provide broader access to innovative medicines. These arrangements may also allow payers or manufacturers to provide more support for appropriate use of medicines by patients. All of these changes are improving patient outcomes—Avalere's payer survey found that 38 percent of payers engaged in outcomes-based contracts experienced improvements in patient outcomes.[409]

- **Value-based arrangements can reduce costs for the health care system.** For example, if new value-based arrangements can improve the use of medicines for diabetes and help reduce the burden of this disease in the U.S. by only five percent, this could save $9 billion annually in direct medical costs, and improve productivity by an additional $3.4 billion. This would save the country more than $12 billion annually.[410]

In the longer term, if the number and scope of value-based agreements increase, they will likely generate more information on the effects of different products and treatment regimens on different patient populations and subpopulations.[411] Real world evidence on how different

[406] Steven Miller. Gene Therapy Holds Great Promise, But Big Price. September 21, 2017. Available at: http://lab.express-scripts.com/lab/insights/drug-options/gene-therapy-holds-great-promise-but-big-price.
[407] PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.
[408] See, e.g., description of Entresto and Repatha contracts in: Seely E and Kesselheim A. Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" Commonwealth Fund. September 2017.
[409] Avalere Health. Payer Perspectives on Outcomes-Based Contracting: Avalere 360. May 22, 2017.
[410] PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.
[411] For example, one study conducted in Sweden concluded that "stakeholders benefited from analysis of real-world (postmarket) data (in addition to pre-launch, trial-based data)" collected under a value-based pricing agreement. See Deloitte. Value-based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value. 2012. Available at: http://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf.

treatments affect patients with a certain disease (or subgroups of patients with a certain disease) will be available both to providers and patients making individualized, patient-centered treatment decisions, and to payers developing formularies and coverage policies. Over time, this should shift drug utilization toward drugs with greater clinical value and greater ability to reduce hospitalizations and other costly services, resulting in better health outcomes and lower overall health care spending.

Addressing barriers to value-based arrangements could lead to government savings

An expansion of value-based arrangements in MA or Medicare Part D could benefit the government through existing mechanisms. Removing barriers to these arrangements would facilitate broader participation in value-based arrangements by MA and Medicare Part D plans. In addition, under Part D's competitive, market-based structure, innovator companies contract directly with Part D plans, and MA (or MA-PD) plans. Some of these contracts may already reflect value-based arrangements and there continues to be growing interest in pursuing these types of arrangements.[412] To the extent that value-based arrangements improve use of medicines, they could reduce MA plan spending, which could reduce MA plan bids.

Improved use of Part D medicines could reduce spending on medical services under Medicare Parts A and B. In addition, if value-based arrangements reduce plans' risk, they could permit lower plan bids.

Addressing barriers to value-based arrangements could also allow for an expansion of innovative arrangements in Medicaid, thereby reducing Medicaid costs. Manufacturers are negotiating value-based arrangements directly with at least one state through supplemental rebate agreements.[413] In addition, to the extent that manufacturers enter into value-based arrangements with Medicaid Managed Care plans, that could also reduce plan costs and the premiums that these plans charge to states.

Permanent regulatory reforms are needed to address barriers that inhibit value-based arrangements

PhRMA released a member survey last year which highlighted the regulations that our members believe need to be modernized to allow an expansion of value-based arrangements.[414] Price reporting metrics, the federal Anti-Kickback Statute, and FDA rules for manufacturer communications were all prioritized by our members. A 2016 survey of payers also identified the same barriers.[415] In addition, over the past year, the Academy of Managed Care Pharmacy, the

[412] PhRMA discussions with Milliman.
[413] Gleason B. Value-Based Purchasing for Prescription Drugs Takes a Leap Forward in State Medicaid. Pharmaceutical Executive. June 29, 2018.
[414] PhRMA. Barriers to Value-Based Contracts for Innovative Medicines: PhRMA Member Survey Results. March 2017.
[415] Ward A, et al. Regulatory, Legal Uncertainties Are Barriers to Value-Based Agreements. *Health Affairs Blog*. November 4, 2016. Available at: https://www.healthaffairs.org/do/10.1377/hblog20161104.057443/full/.

Network in Excellence in Health Innovation, and the Duke-Margolis Center have all released papers recommending addressing these same barriers to value-based arrangements.[416] We greatly appreciate the recent action by FDA to issue final guidance on manufacturer communications with payers and communications consistent with the label. These guidances are a positive and substantial step forward for manufacturer communications for value-based arrangements.[417] Our suggested changes related to the other barriers are below.

- **Value-based arrangements should be clearly protected under the Anti-Kickback Statute.** Despite the potential benefits of these arrangements, the Federal Anti-Kickback Statute is chilling more widespread adoption. The Anti-Kickback Statute is a broadly worded statute that can inadvertently discourage beneficial low-risk health care arrangements through the threat of civil, criminal, and/or administrative sanctions.[418] To reduce the risk that the broadly worded Anti-Kickback Statute would deter beneficial arrangements, Congress authorized the development of regulatory safe harbors and requires annual solicitation of comments for updating such safe harbors.[419] It is important that the Anti-Kickback Statute safe harbors evolve to support new arrangements that, if properly structured, could help improve health outcomes, promote competition, and contain overall health care spending without raising risk of fraud and abuse. To date, OIG's annual solicitations have elicited at least six proposals to develop a safe harbor for value-based arrangements. In addition, over the past year, the Healthcare Leadership Council released a paper recommending modernization of the Anti-Kickback Statute in the area of value-based care.[420]

[416] Academy of Managed Care Pharmacy. AMCP Partnership Forum: Advancing Value-Based Contracting. *Journal of Managed Care & Specialty Pharmacy.* November 17, 2017.; Network for Excellence in Health Innovation. Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals. March 2017. Available at: https://www.nehi.net/publications/76-rewarding-results-moving-forward-on-value-based-contracting-for-biopharmaceuticals/view; Duke Margolis Center for Health Policy. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products. Available at: https://healthpolicy.duke.edu/publications/overcoming-legal-and-regulatory-hurdles-value-based-payment-medical-products.

[417] FDA. Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities. June 2018; FDA. Medical Product Communications That Are Consistent With the FDA-Required Labeling. June 2018.

[418] Today, the risk of discouraging beneficial arrangements is even greater than in the past. As you know, the ACA added language to the Anti-Kickback Statute stating that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the civil False Claims Act]." 42 U.S.C. § 1320a-7b(g).

[419] 42 U.S.C. § 1320a-7d (requiring an annual solicitation seeking proposals from the public for new or modified safe harbors and Special Fraud Alerts). Even before the 1996 law requiring the annual solicitation for safe harbor proposals, OIG acknowledged the Congressional expectation that it should "formally re-evaluate the anti-kickback regulations on a periodic basis, and . . . solicit public comment at the outset of the review process." Medicare and State Healthcare Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991) (quoting H.R. Rep. No. 85, part 2, 100th Cong. 1st Sess. 27 (1987)).

[420] Healthcare Leadership Council. Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models. February 2017. Available at: https://www.hlc.org/app/uploads/2017/02/HLC_StarkAntiKickback-White-Paper.pdf

The key safe harbors to the Anti-Kickback Statute that are applicable to manufacturers were developed over twenty years ago, and did not anticipate innovative, value-based approaches. We continue to seek creation of a new safe harbor to clearly protect value-based arrangements under the Anti-Kickback Statute and submitted this recommendation to HHS OIG in both 2017 and earlier this year.[421]

- **Value-based contracts necessitate a more modern and flexible approach to price reporting.** Biopharmaceutical companies must adhere to a complex set of government price-reporting rules for calculating ASP in Medicare Part B and Best Price in Medicaid. These highly technical price-reporting rules were established prior to the introduction of innovative payment approaches. While the price-reporting rules do permit biopharmaceutical companies to make reasonable assumptions, to the extent there is ambiguity about how to capture innovative pricing methods in an ASP or Best Price framework this can create uncertainty for manufacturers and payers.

Recommendations for specific price reporting clarifications

Under the Medicaid rebate statute, a drug's "Best Price" is generally the manufacturer's single lowest net price during a quarter "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity" (Best Price-eligible customers), subject to certain limited exemptions.[422] Just one sale during the quarter can therefore set the Best Price. The Medicaid rebates manufacturers must pay on brand drugs include a basic rebate (either 23.1 percent of AMP or AMP minus Best Price, whichever is higher) and an additional rebate (AMP minus the inflation-adjusted AMP from the drug's base date, usually the first full quarter after launch). Given this rebate formula, a state Medicaid program's net payment for a brand drug (the state's payment to the pharmacy or other provider that dispenses or administers the drug, minus the Medicaid rebate it receives from the manufacturer) should be at least as low as—and usually much lower than—the manufacturer's single lowest net price to any Best Price-eligible customer in any non-exempt sale.

In enacting the Medicaid rebate statute in 1990, Congress intended to put Medicaid in the same position as other large-volume payers:

> [Under the Medicaid rebate bill] manufacturers would be limited to charging Medicaid the best price given any bulk purchaser . . . with savings returned to Medicaid through a quarterly rebate . . . [T]he Subcommittee on health and the environment heard testimony that Medicaid pays substantially more for many single-source drugs than do other large purchasers . . . . The Committee believes Medicaid, the means-tested entitlement

[421] PhRMA comments to OIG-125-N. Solicitation of New Safe Harbors and Special Fraud Alerts. February 2017, and to OIG-127-N. Solicitation of New Safe Harbors and Special Fraud Alerts. February 2018.
[422] Social Security Act (SSA) § 1927(c)(1)(C).

> program that purchases basic health care for the poor, should have the benefit of the same discounts on single-source drugs that other large public and private purchasers enjoy.[423]

However, in 1990 Congress did not envision the type of value-based arrangements that are emerging today. Questions have come up about whether the type of pricing arrangements often associated with value-based contracts could sharply reduce Best Price and thus sharply increase the manufacturer's rebate liabilities, thereby serving as a disincentive to value-based contracts. For example, under a value-based agreement where the manufacturer pays a 90 percent rebate on a unit of drug used by a patient who does not respond to the drug, just one non-responding patient to the drug could set Best Price at 10 percent of the drug's usual price.

This unanticipated dynamic can limit the size of performance-based rebate that a manufacturer can offer to a PBM or health plan because of the risk that a poor outcome with a single patient will reset the Best Price, increasing the rebate owed for all Medicaid patients using the medicine. A very low Best Price can also lower a drug's 340B ceiling price (since the ceiling price formula is AMP minus the Medicaid rebate) further increasing the potential cost to companies. Because performance-based contracts can lead to a range of outcomes, and because the risk of a bad outcome is greater with a small population, the challenge associated with Medicaid Best Price is more of a barrier to arrangements with smaller payers or for low volume medicines, such as orphan medicines.

CMS clarification of certain Best Price issues is therefore important to reduce the risk that Best Price rules, which are intended to put Medicaid on an equal footing with other high-volume customers, could unintentionally discourage innovative value-based agreements. While manufacturers can already make reasonable assumptions when ambiguity exists about how to apply AMP or Best Price rules to particular arrangements, clearer guidance that reduces obstacles to value-based agreements could improve patient care and also curb spending without departing from the statute's Best Price provisions—presenting a rare opportunity that we hope HHS will seize.

While other challenges to value-based agreements—particularly lack of clear protection under the Anti-Kickback Statute—would still exist, steps such as issuing clearer guidance or making regulatory changes to price reporting terms to address Best Price uncertainties could help to expand the adoption of value-based agreements that offer the potential for significant health gains and overall health care cost savings.

[423] H.R. Rep. 101-881, 1990 U.S.C.C.A.N. 2017, 2108 (Oct. 16, 1990).

As HHS considers how to address the barrier that Medicaid Best Price poses for value-based arrangements, we recommend it consider the following principles:

- To allow for more innovative approaches and risk sharing, a single poor outcome should not set a new price for Medicaid. This would allow manufacturers to share more risk with commercial health plans.

- Over time Medicaid should be able to derive benefits from value-based contracts.

- Approaches to reporting value-based arrangements should be as simple as possible. This would help avoid creating operational challenges for companies that may prevent development of innovative approaches.

- Manufacturers should continue to have flexibility to make reasonable assumptions in their price reporting, so reporting approaches can evolve to reflect changes in the dynamic market and contracting environment.

Turning to concrete approaches for reducing the risk that the Medicaid rebate statute's Best Price provisions would be construed in a way that needlessly deters value-based arrangements, below we describe three different ideas to reduce Best Price challenges to value-based contracting. These ideas could be implemented separately, or together, to provide manufacturers with greater clarity. The first approach relies on an "averaging" concept already reflected in CMS' regulations under the "bundled sales" definition at 42 CFR § 447.502; whereas the other two approaches (sections 2 and 3) provide two possible legal interpretations of the price reporting terms "unit" and "best price" that CMS could incorporate into is Medicaid rebate regulations, through notice and comment rulemaking, to help ensure that the Best Price regulations provide the same degree of flexibility as the statute itself, and thus do not discourage important value based arrangements unnecessarily.

Finally, in section 4, we respond to the RFI's question about the appropriate cutoff point for restating AMP and Best Price values from previous quarters.

1. Application of the "Bundled Sales" Definition to Value-Based Agreements

CMS could help facilitate value-based arrangements by issuing guidance and confirming the reasonableness of applying the "bundled sale" definition in 42 CFR § 447.502 to value-based agreements. Under this regulation:

> Bundled sale means any arrangement... under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug [at the NDC-9 level], drugs of different types ... or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which

> would have been available had the bundled drugs been purchased … outside the bundled arrangement.
>
> (1) The discounts in a bundled sale … are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.
>
> (2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle. (Emphasis added.)

The regulation thus defines "bundled sale" in a broad manner that includes agreements involving only one drug (NDC-9). The regulatory definition could thus encompass an agreement in which the manufacturer agrees to pay a high rebate on a drug if certain outcomes occur (e.g., the patient does not achieve the same improvement in a certain metric achieved in the drug's clinical trials) conditioned upon the payer's acceptance of a lower rebate on the drug if better outcomes occur. The regulation further requires that the price concessions in a bundled sale must be "unbundled" by allocating them proportionally across all of the units of product covered by the agreement— which in this example would result in the average rebate ultimately paid on the drug under the agreement being allocated to every unit covered under the agreement; the net price of each unit would thus reflect the outcomes patients achieved on average. This discount reallocation process required by the bundled sale definition would thus keep an isolated poor outcome under a value-based agreement from resulting in one unit having a very low unit price that could set the Best Price for the whole quarter.

CMS guidance should specifically recognize the reasonableness of the bundled sales approach by explicitly assuring manufacturers that higher and lower prices under such contracts must be averaged (via the proportional discount reallocation required by 42 CFR § 447.502) in calculating the net unit prices under the bundled sale that would go into AMP and Best Price determinations. This is a straightforward application of the existing regulation that may reduce the impact of an "outlier" result under certain value-based arrangements setting a new Best Price for the quarter, by explicitly assuring.

Specifically, CMS should issue clarifying sub-regulatory guidance describing a bundled sales example in which the manufacturer agrees to pay a higher rebate on a certain drug when patient outcomes fail to meet a specified benchmark, conditioned on the payer accepting lower rebates when patient outcomes do meet the benchmark. For example, the guidance could describe a value-based agreement between a manufacturer and a payer in which the manufacturer agrees to pay higher rebates (by way of example, 40 percent off list price) on a certain drug when patient outcomes do not meet a specified benchmark, conditioned on the payer accepting a lower rebate (10 percent off list price) when patient outcomes do meet the benchmark specified in the agreement. CMS could explain in such guidance that it would be reasonable to treat this agreement as a bundled sale under 42 CFR § 447.502, and thus to allocate the rebates proportionally to the total dollar value of all units of the drug covered by this agreement. If the rebates were allocated in accordance with 42 CFR § 447.502, and ultimately 50 percent of the

units covered by the agreement resulted in patient outcomes that meet the specified benchmark, then each unit would have a rebate of 25 percent off list price. Thus, if the product had a list price of $100 and the manufacturer used list prices in estimating the net price of a payer, the net price to this payer of each unit covered by the bundled value-based agreement would be $75 (which would be used in determining the manufacturer's Best Price for the relevant quarters).

By laying out this type of example in a manufacturer release, CMS could swiftly alert manufacturers that it was reasonable to categorize such an agreement as a bundled sale and thus to allocate rebates and discounts proportionally across all of the units covered by the agreement, thereby "smoothing out" the unit prices that are taken into account in determining AMP and Best Price and reducing the risk that a single poor outcome could set a new Best Price for the drug for the quarter. This smoothing procedure would not always reduce the risk of a poor outcome on one or a small number of units triggering a new and drastically low Best Price; in particular, if the agreement involved a low level of utilization (because, for example, the product treated a very rare disease, or the manufacturer was contracting with a health plan with low enrollment), then the risk of isolated poor outcomes driving Best Price could not be dismissed, as there would be few units to average. But in many or most cases, this approach could help to reduce Best Price risks and CMS guidance to this effect could therefore reduce manufacturer concerns and encourage broader adoption of value-based agreements. The CMS guidance could also advise manufacturers that this approach was not necessarily limited to outcomes-based agreements; another example of a value-based agreement to which the bundled sale definition in 42 CFR § 447.502 could reasonably be interpreted as applying would be an agreement where a manufacturer agreed to sell a product with multiple indications at a low price in circumstances where it was used for a lower-value indication, provided the customer agreed to a higher price when the product was used for a high-value indication.

2. Definition of "Unit"

CMS could also facilitate value-based agreements by amending the definition of "best price" at 42 CFR § 447.505, through notice and comment rule-making, to distinguish between drugs that the manufacturer prices on a per-unit basis (in particular, "traditional" types of arrangements such as fixed per-unit rebates or volume or market share-based per unit rebates) and those it does not price on a per-unit basis. Currently, a value-based agreement where the drug is not paid per unit is treated for Best Price purposes as if the drug is paid per unit, resulting in a distorted "Best Price" figure that experts have pointed out, does not accurately reflect the agreement's pricing arrangement.

For example, a report by the Duke Margolis Center for Health Policy provides a useful example of the problems with taking a value-based agreement in which the drug is not priced on a per-unit basis and forcing it into a per-unit model.[424] A manufacturer may agree to an alternative payment

[424] Duke Margolis Center for Health Policy. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products. December 2017. Available at: https://healthpolicy.duke.edu/publications/overcoming-legal-and-regulatory-hurdles-value-based-payment-medical-products

model where a drug is paid a fixed per-member per-month (PMPM) or per-patient per-month (PPPM) amount (also called capitated or subscription models), regardless of the number of units actually used. Under the current system, such an arrangement is discouraged because manufacturers are required to reduce a PMPM/PPPM arrangement to a "per-unit" basis for Best Price reporting purposes. In other words, a manufacturer could agree to supply however many doses were needed each month by the enrollees in a certain health plan at a fixed per-patient monthly rate of $100; while it may turn out that the plan enrollees use 100-unit doses of the drug in month one and 200 in month two, that does not mean the manufacturer has agreed to supply the drug at a unit price or of $1.00, 50 cents, or any other figure. Yet the current regulations require that the manufacturer calculate a unit price after the fact and use that price in determining Best Price. This may produce a new Best Price—as the manufacturer cannot control the monthly utilization, which could go up or down each month for any number of reasons, thus generating volatile "unit prices"—and thereby discourage manufacturers from pursuing innovative arrangements that could provide customers with needed flexibility in managing drug costs.

Similarly, a manufacturer could enter into a "cost-to-cure" arrangement with a payer or health care provider, in which the manufacturer agreed to supply at a fixed price the doses of a certain drug needed to cure a patient of the disease the drug—however many doses were needed, over whatever period of time, to cure each patient covered by the agreement. Such an arrangement further highlights how innovative new therapies designed to cure disease and conditions, have "outgrown" dated pricing metrics such as a "per unit" basis, and regulatory and sub-regulatory price reporting rules that interpret the statute and can be changed by CMS without waiting for Congress—need to be reexamined and modernized. Here again, a manufacturer may now be required to calculate an after-the-fact "unit price" for the drug—even though the manufacturer was not selling units of the drug, but an outcome (a cure). Thus, to use the fictitious "unit price" in Best Price determinations, would turn a type of value-based agreement that could offer important benefits to payers, health care providers, and patients into a Best Price risk and deter adoption of these agreements.

This is not an unfortunate result dictated by the Best Price statute; it stems solely from regulatory language that does not appear in the statute, and could thus be amended through rulemaking.[425] CMS could amend 42 CFR § 447.505 to fix this problem and clarify that Best Price is the lowest net price from the manufacturer to a wholesaler, retailer, provider, HMO, nonprofit or governmental entity during the rebate period in a non-exempt sale "for a unit of the drug," and carve out value-based arrangements from the definition of "unit." Notably, CMS set a precedent for excluding certain sales from the definition of a "unit" in the ASP context. Under Social Security Act 1847A(b)(2) and (c)(1), ASP is calculated "for a unit," and CMS may establish units and methods for counting units. In the 2005 interim final rule regarding the CAP, CMS decided

[425] Unlike the statute, the regulation states that Best Price is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity in the U.S. "in any pricing structure (including capitated payments)" and that Best Price "must be determined on a unit basis" without regard to package size, special packaging, labeling, or identifiers on the dosage form or product or package. 42 CFR § 447.505(a), (d)(2).

to exclude drugs the manufacturer sells to a CAP vendor from the "unit" definition in 42 CFR § 414.802. CMS stated:

> We were not convinced that we had the statutory authority to exclude sales of CAP drugs from the calculation of ASP . . . however, we recognized the commenters' concerns about the effect of including CAP prices in the calculation of ASP and agree that the best outcomes for both [ASP] and [CAP] would be one in which prices under CAP did not affect payment amounts under [ASP]. We have decided to exclude, for the initial 3-year contract period under the CAP, units of CAP drugs . . . . [I]t is appropriate to implement the exclusion from the ASP calculation because the exclusion is necessary for implementing the CAP, a program that the Congress has expressly identified as an alternative to the ASP payment methodology. [426]

CMS has authority to interpret the "best price" definition by issuing a new regulatory definition (through notice and comment rulemaking) and could amend 42 CFR § 447.505 to specifically reference "unit" in the definition and separately define "unit" as follows:

> (a) Definitions. For the purpose of this section, the following definitions apply:
> **Best price** means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period <u>for a unit of the drug</u> to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any unit pricing structure, in the same quarter for which the AMP is computed.
> * * * *
> **Unit** means a unit of the drug sold or discounted in a transaction in which the price or price concession is either a fixed per unit amount or percentage, or a per-unit amount that varies by volume, market share, <u>or another factor other than health or quality outcomes associated with use of the drug or cost of caring for patients treated with the drug (such as a cap on cost of treatment or an agreement to share treatment costs.</u>[427]

This regulatory change could help facilitate value-based agreements by ensuring that for reporting purposes, "Best price" would distinguish between drugs that the manufacturer prices on a per-unit basis in "traditional" types of arrangements from those it does not price on a per-unit basis. This is a straightforward

[426] 70 Fed. Reg. 70478, 70479 (Nov. 21, 2005).
[427] If these changes were made, it would be unnecessary to revise the language in § 447.505(d)(2) providing that Best Price "must be determined on a unit basis," as Best Price determinations would only take into account products that were priced and sold per unit by the manufacturer.

interpretation of the statutory definition of "Best price" that the agency could do through notice and comment rulemaking.

3. Definition of "Best Price"

CMS could also amend the Best Price definition in 42 CFR § 447.505 to give effect to the statutory language limiting Best Price to a price available "during the rebate period."[428] To that end, CMS could amend § 447.505 to exclude price adjustments that are based on outcomes measured outside of the rebate period (defined as a calendar quarter). This would be an important and useful clarification because value-based arrangements often use metrics that are most appropriately measured over a period longer than a quarter. As a 2017 paper by the Network for Excellence in Health Innovation points out:

> The full value of many pharmaceuticals . . . is often only realized over a longer period than . . . one-year . . . . For example. a drug may promise patients and payer the benefit of reduced hospitalizations, but these reductions may only occur in significant numbers as patients use the drug over a period of years. In such cases, a value-based contract may only make sense if it covers this longer time frame and the payer and manufacturer agree to adjust rebates periodically over a multi-year contract.[429]

CMS could revise 42 CFR § 447.505 to add language defining prices available "during the rebate period," and exclude from that term price adjustments that are only available later because they are based on clinical or cost outcomes measured in a later period. For example, CMS could amend the regulation as follows:

> **Best price** means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. A price available "during the rebate period" does not include a price adjustment that is only available later based on clinical or cost outcomes measured in a later period.

[428] Social Security Act § 1927(c)(1)(C)(i).
[429] Network for Excellence in Health Innovation. Rewarding Results: Moving Forward on Value-Based Contracts for Biopharmaceuticals. March 2017. Available at: https://www.nehi.net/writable/publication_files/file/rewarding_results_moving_forward_on_value_based_contracting_for_biopharmaceuticals_copy1.pdf.

This new regulatory language defining "during the rebate period" would have a solid statutory basis, as it would interpret and implement statutory language in SSA §1927(c)(1) (C)(i) defining Best Price as the lowest price available from the manufacturer to Best Price-eligible customers "during the rebate period."

4. Manufacturer Price Reporting Restatements

The RFI asks whether the period for manufacturers to restate AMP or Best Price values for a past quarter should be lengthened, to accommodate the possibility of extended evaluation timeframes for value-based agreements. Currently manufacturers generally may only restate the AMP and Best Price for a quarter in the 3-year period after the initial filing deadline (30 days after the end of the quarter).[430] As noted above, value-based agreements may base price adjustments on outcomes over a period outside the calendar quarter. And if the outcome that determines price adjustments is for example, whether the patient's disease is in remission one year after treatment, it may take considerably longer to determine whether, for each of the patients treated in a quarter, the disease was in remission one year after treatment. Therefore, it is logical to ask whether value-based agreements may need a longer restatement period than 3 years and we appreciate CMS raising this question. However, on reflection we suggest CMS keep the current three-year restatement window.

In establishing the three-year restatement window in 2003, CMS recognized "the potential burden for States and manufacturers to apply prior period adjustments during a 3-year retroactive timeframe,"[431] but still adopted the three-year timeframe to balance the need for accuracy of data against the need for finality:

> a timeframe for manufacturers to submit revised pricing data to us …streamlines the administration of the Medicaid drug rebate program. Due to recalculations involving hundreds of millions of State and Federal Medicaid dollars … we believe it is essential that a standard timeframe be established within which manufacturers … are permitted to submit revised drug prices. This timeframe will also assist States that would otherwise be required to retain their drug utilization data indefinitely to verify changes in rebate amounts resulting from retroactive manufacturer recalculations.[432]

The three-year restatement window still strikes a reasonable balance between the interest in finality and the interest in incremental improvements in data accuracy. With a longer period for restatements, the states would face a higher risk of reductions in their rebate revenue from past periods, which was a major concern to the states when this issue last arose; CMS stated that: "[t]his rule [establishing the three-year limit on restatements] will have a positive effect on the State

[430] 42 CFR § 447.510.
[431] 68 Fed. Reg. 51912, 51914 (Aug. 29, 2003).
[432] 68 Fed. Reg. at 51912 (emphasis added).

Medicaid agencies. State Medicaid agencies are having difficulty fully funding their Medicaid programs. They will likely be relieved that we are setting forth a rule that will limit their fiscal vulnerability…."[433]

CMS should therefore keep the three-year restatement window for value-based agreements and make clear that (notwithstanding any new data), restatements in AMP and Best Price are neither required nor permitted once the window closes. The interest in ensuring that rebates for a certain quarter are final after three years (thus reducing uncertainty for states and manufacturers and allowing them to close the books) outweighs any potential for improved accuracy that may come from extending the three-year deadline for value-based arrangements.

VALUE-BASED ARRANGEMENTS: Indication-Based Pricing and Coverage (RFI p. 22694, 22696)

As HHS recognizes, payers may cover or pay for a drug differently based on its indication. Variable coverage is generally considered to be a form of value-based insurance design (VBID), a concept in which payers provide better coverage for items and services that are higher value compared with those that are lower value.[434] Indication-based pricing is an arrangement in which the net price of a medicine varies for different indications based on an agreement between the contracting entities.[435] Indication-based pricing is occurring in the commercial market. Express Scripts and CVS Health have both announced that they are engaging in indication-based pricing.[436] Regimen-based pricing, which is closely related to indication-based pricing, is an arrangement in which the net price of a medicine decreases when a patient must take a second medicine to make the treatment regimen more effective.[437] Some pharmaceutical manufacturers have expressed an interest in regimen-based pricing, but we are not aware of any cases where such an arrangement is in place.[438] Below we share principles that we suggest HHS consider as it further explores options related to indication-based coverage, indication-based pricing, and regimen-based pricing.

Indication-based coverage and VBID

PhRMA supports HHS providing health plans more flexibility to pursue VBID, provided that the flexibility brings with it certain requirements to help ensure that VBID can facilitate access to a full range of high-value care. Earlier this year, CMS finalized changes to the MA program,

[433] 68 Fed. Reg. at 51916.
[434] Chernew ME, Rosen AB, Fendrick AM. Value-Based Insurance Design. *Health Affairs*. 2007;26(2): w195-w203.
[435] PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.
[436] Express Scripts. Right Drug, Right Price. March 17, 2016. Available at: http://lab.express-scripts.com/lab/insights/drug-options/right-drug-right-price; Brennan T. Aligning Drug Prices with Value: Value-Based Pharmacy Management. July 11, 2017. Available at: https://payorsolutions.cvshealth.com/insights/aligning-drug-prices-with-value.
[437] PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.
[438] See, e.g. Hirschler B. New cocktails to test limits of cancer drug pricing. *Reuters.* August 3, 2015.

which included expanding flexibility under the uniformity requirements.[439] We appreciated that these changes gave plans greater latitude for VBID in Medicare Advantage, offering plans the opportunity to better align incentives and help ensure health care financing and delivery are designed to improve access to high-value care. VBID also complements health plans' interest in exploring value-based arrangements, because both VBID and value-based arrangements encourage consideration of how the value of a medicine varies between different patients. We also appreciated that CMS also implemented certain patient protections, including requiring that similarly situated enrollees (e.g., all diabetics) are treated the same, requiring that plans ensure that cost-sharing reductions and targeted supplemental benefits are for health care services that are medically related to each disease condition, and ensuring that MA plans do not provide supplemental benefits for many disease conditions, while excluding other higher-cost conditions. These protections are critical to ensuring that VBID approaches in MA do not discriminate against or discourage enrollment of beneficiaries with certain conditions.

As HHS considers providing additional flexibility for health plans, we encourage the above principles to be retained. We suggest that HHS also adopt the following measures to help ensure that VBID can facilitate access to a full range of high-value care:

- VBID should not lead to cost sharing increases for other covered items or services or reductions in the number of medicines on a health plan's formulary;
- VBID cost sharing must be based on an appropriate assessment of value, not price;
- Determination of high-value care should be based on the full body of available evidence, based on a range of study designs; and
- Determination of high-value care must incorporate relevant clinical quality and patient-centered measures and account for changes in evidence, medical practice, and innovations.

Finally, we urge HHS to consider extending plan flexibility to Part D benefits in future rulemaking. We recognize the programmatic complexity of doing so, but also note the absurdity of plans offering enrollees with diabetes zero cost sharing for endocrinologist visits, but charging 33 percent coinsurance for a biopharmaceutical anti-diabetic agent that could avoid the need for some physician or hospital visits all together. Because VBID can complement plans' efforts to implement value-based arrangements—and plans may use the same infrastructure to support both efforts—allowing plans greater flexibility to pursue VBID designs may also encourage more value-based arrangements between plans and biopharmaceutical companies.

[439] [CMS-4182-P] Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

Indication- and regimen-based pricing

As described above, we recognize that health plans and some manufacturers are exploring indication- and regimen-based pricing. As HHS continues to explore these concepts, it will be important to develop approaches that continue to support patient access, support continued innovation, and encourage market competition on value, rather than a myopic focus on lowering prices. To this end, we urge consideration of the following principles:

- Market negotiations should determine the price of each indication between each payer and manufacturer—not government price setting or centralized value assessment.

- Confidentiality of net prices should be maintained to avoid driving all prices in the market to price for a single indication and undermining the objective of variable pricing by indication.

- When negotiating indication-based prices, health plans should make rigorous evaluations that consider the full range of available evidence (including real-world evidence) for the medicine.

- HHS should carefully evaluate any potential impacts to ASP reporting that may result from indication based pricing approaches.

To the extent that HHS pursues indication-based pricing or coverage in Part D, it will be important to consider how this policy would interact with existing beneficiary protections and other structural aspects of the Part D program. For this reason, CMS should also consider the following principles for Part D:

- Beneficiaries should continue to have access to a broad range of pharmacies and should be able to fill prescriptions at the pharmacy of their choice.

- Cost-sharing information for medicines with indication-based prices should be incorporated into Plan Finder and should be easily accessible and understandable for beneficiaries.

- PDPs may require access to medical claims or other diagnostic data necessary to determine the indication a medicine is prescribed for.

VALUE-BASED ARRANGEMENTS: Long-Term Financing (RFI p. 22697)

HHS suggest that states and other payers' budgets may be challenged by new high-cost treatments, which provide benefits over an extended period of time. However, there are examples of other services which can be high cost and provide a benefit which extends over several years. Organ transplants often cost $500,000 to $1 million per patient and neonatal intensive care units

can cost $500,000 in some cases, yet insurers have mechanisms such as reinsurance to manage these costs, rather than spreading the costs over time.[440]

HHS asks about how Medicaid or Medicare should account for the cost of disease averted by a curative therapy paid for by another payer. We oppose efforts that would spread payment for a medicine from public to private payers or vice versa. Such approaches would be extremely complex to implement, undermining any potential benefits. We also believe they are unnecessary. For example, medicines that cure Medicaid patients of disabling conditions can help these individuals develop a higher functioning level which may enable them to earn a higher income and purchase their own insurance. A potential new gene therapy for hemophilia, which would be administered one time, could also lead to substantial savings for payers. In a retrospective study of U.S. health insurance claims between January 2004 and December 2012, annual payers' costs peaked at just under $400,000 for hemophilia A and roughly $450,000 for hemophilia B patients.[441] Finally, we are concerned that spreading payment between public and private payers requires changes to federal health care programs that would essentially require creation of a new, single payer for these medicines. This could encourage commercial payers to deny coverage for these medicines, with the aim of pushing payment for these medicines off to the new payer.

While we have concerns about long-term financing arrangements across public and private coverage, we do recognize that long-term financing arrangements with an individual payer or across multiple insurers within a specific market, e.g., in the commercial market, could support greater patient access or allow patients to spread their costs over multiple years. This is a viable option that could be considered for the appropriate therapy and patient population.

- **Long-term financing in the commercial market:** Long-term payment approaches may be possible in the commercial market today. As an example, Express Scripts is reportedly exploring such an arrangement with a gene therapy company.[442] These types of arrangements are at a very early form of development, and a range of different groups could take the role of spreading the payment over time; this is essentially a financing function, and other entities may be in a better position to offer this service than a pharmaceutical manufacturer.

- **Long-term financing in Medicaid:** As HHS considers new types of arrangements and considers the current barriers to long-term financing in Medicaid, we recommend that these arrangements be voluntary for both states and manufacturers. Also, HHS guidance on these new arrangements should ensure proper coverage and reimbursement for

[440] Bentley TS, Phillips SJ. 2017 U.S. organ and tissue transplant cost estimates and discussion. Milliman Research Report. August 2017.; M Glabman. Million-Dollar Claim Club. *Managed Care Magazine*. March 1, 2009.
[441] Eldar-Lissai A, Hou Q, Krishnan S. The Changing Costs of Caring for Hemophilia Patients in the U.S.: Insurers' and Patients' Perspectives. *Blood.* 2014:124(21):199.
[442] Weintraub A. Payers point to Spark's gene therapy as a model for innovative pricing plans. *FiercePharma*. January 12, 2018. Available at: https://www.fiercepharma.com/financials/payers-point-to-spark-s-gene-therapy-as-a-model-for-innovative-pricing-plans.

medicines in the Medicaid program. Additionally, all arrangements should operate within the current Medicaid drug rebate statute coverage requirements.

Manufacturers that are exploring long-term financing approaches often describe these approaches as being complemented by an outcomes-based contract or other performance-based arrangements.[443] Some manufacturers have identified the same barriers for these arrangements as for value-based arrangements, including the Anti-Kickback Statute, and federal price reporting rules.[444]

SECTION X: NATIONAL SPENDING ESTIMATES (RFI p. 22697)

Reports asserting that drug costs are the primary driver of increases in national health care spending are often based on analyses of medicines' undiscounted list prices.[445] These reports paint an inaccurate picture of the true drivers of national health care spending growth. Even as medicines have played an increasingly important role in health care, changing the course of disease and producing better results for patients, the share of total health care spending devoted to prescription drugs has remained constant at 14 percent.[446] In addition, medicines play a crucial role in controlling future health care costs: researchers have found that every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated $3 to $10 in savings on emergency room visits and inpatient hospitalizations.[447]

In reality, growth in spending on prescription medicines in recent years has fallen to historic lows.[448] Reports that capture the net price of medicines, which properly account for the discounts and rebates negotiated by PBMs and plan sponsors, have found that net price increases for brand medicines have remained in the low single digits for the past several years, increasing just 1.9 percent in 2017, lower than the rate of inflation.[449] Estimates of national health care spending should accurately reflect spending on medicines net of aggregate discounts and rebates in order to appropriately inform policymakers as they make decisions regarding health care spending controls and other payment and reimbursement issues.

[443] Daniel G, Leschly N, Marrazzo J, McClellan M. Advancing Gene Therapies And Curative Health Care Through Value-Based Payment Reform. *Health Affairs Blog.* October 30, 2017. Available at: https://www.healthaffairs.org/do/10.1377/hblog20171027.83602/full/.
[444] Id.
[445] See, e.g., U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Office. Manufactured Crisis: How Devastating Drug Price Increases Are Harming America's Seniors. March 2018.
[446] Altarum Institute. A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail. October 2014, addendum update May 2017.
[447] Roebuck MC, et al. Medical Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. *Health Affairs*. January 2011.
[448] Drug Channels. Who Best Managed the Drug Spending Slowdown in 2017: CVS Health, Express Scripts, MedImpact, or Prime Therapeutics? May 2018. Available at: https://www.drugchannels.net/2018/05/who-best-managed-drug-spending-slowdown.html
[449] IQVIA. 2017 Medicine Use and Spending. April 2018.

NATIONAL SPENDING ESTIMATES: Accuracy of National Spending Data (RFI p. 22697)

Although projections of prescription medicine spending included in the NHE data attempt to capture spending on medicines net of discounts and rebates, they systematically overestimate prescription medicine spending.

As part of their recent review of the accuracy of NHE projections made between 1997 and 2016, CMS actuaries found that the projections for prescription drug spending overestimated drug spending on average and were more inaccurate than the projections made for other types of health spending.[450] In an analysis of NHE projections released since 2000, we found that estimates of prescription drug spending growth made just one-year prior to the publication of actual spending amounts overestimated retail drug spending two-thirds of the time.[451]

Improving the Accuracy and Comprehensiveness of National Spending Data

The RFI asks whether the Medicare Trustees Report, annual NHE publications, Uniform Rate Review Template, and other publications could more accurately collect and report gross and net drug spending in medical and pharmacy benefits.[452] Given the trends detailed above, the actuaries should reassess their methodology for projecting drug spending, including assumptions about the growth of rebates and discounts. As the actuaries themselves have noted, "drug sector growth is historically much more volatile than that of any other sector."[453] CMS should seek the input of outside experts to improve the accuracy of their projections of prescription drug spending and ensure that their estimation methods reflect up-to-date information about the biopharmaceutical market. The Secretary should consider convening a technical panel on the Medicare Trustees Reports so experts in their field can review CMS' assumptions about pharmaceutical spending growth and provide feedback in a public setting.

Currently, NHE data on prescription drug spending is of limited use because it only captures spending on retail medicines. In order to provide a more comprehensive view, the actuaries should consider reporting total drug spending, by including spending for provider-administered medicines in addition to spending for retail medicines. There are a number of sources that attempt to report total medicine spending, including estimates previously released by the Assistant Secretary for Planning and Evaluation.[454] However, these estimates use different methodologies and provide conflicting conclusions about the amount of national spending

[450] CMS. Accuracy Analysis of The Short-Term (10-Year) National Health Expenditure Projections. February 2018.
[451] PhRMA analysis of CMS. NHE 2016. December 2017.
[452] RFI p. 22697.
[453] CMS. Accuracy Analysis of The Short-Term (10-Year) National Health Expenditure Projections. February 2018.
[454] HHS Office of the Assistant Secretary for Planning and Evaluation. Observations on Trends in Prescription Drug Spending. 2016.

attributable to medicines.[455] Including spending for medicines administered by hospitals and physicians as part of the NHE could help remedy this confusion.

Additionally, the actuaries at CMS should consider breaking out prescription drug spending in the NHE into ingredient costs versus distribution and supply chain costs. Over the last decade, with the growth in use of generic medicines, the relative costs of distribution have grown. In addition, recent evidence suggests a shift toward greater spending for services provided by intermediaries. In 2015, brand and generic manufacturers accounted for 70 percent of net drug expenditures, while participants in the pharmaceutical supply chain realized 27 percent.[456] These distribution and management costs account for a growing share of prescription drug spending, and tracking this trend as part of the annual NHE data release would help policymakers better assess the drivers of pharmaceutical spending growth.

Reporting of Part D Net Price Data for Small Molecule, Biologics, and High-Cost Drugs

The RFI asks about how the Medicare Trustees Report and other publications could report drug spending more accurately and whether average Part D rebate amounts "should be reported separately for small molecule drugs, biologics, and high-cost drugs."[457] Importantly, Part D rebate data is subject to several confidentiality provisions: (1) 18 U.S.C. § 1905, the Trade Secrets Act, which generally prohibits federal agencies from disclosing proprietary and confidential data submitted to the government by private parties; (2) Social Security Act (SSA) § 1860D-15(d)(2) and (f)(2), which protects data submitted by Part D plan sponsors to CMS for Part D payment purposes; and (3) SSA § 1860D-2(d)(2), which protects against disclosure of certain aggregate price concession data in a form that could identify a manufacturer or drug pricing.

Any disclosures of average Part D rebate data must conform fully to all of these protections, and compliance with all these provisions would become increasingly difficult: (1) the more granular the categories at which "average" rebate data is disclosed; and (2) the more information HHS discloses, or that is already publicly available, that could be analyzed in conjunction with average Part D rebate data HHS discloses and potentially provide insight into Part D rebates or pricing information regarding a specific drug or manufacturer. Beyond these legal issues, HHS should also bear in mind that the smaller and more granular the categories at which average rebate data is disclosed, the larger the risk that these disclosures would undercut vigorous competition between manufacturers to offer discounts and the higher the resulting Part D drug costs.[458]

[455] Pew Charitable Trusts. A Look at Drug Spending in the U.S. February 2018. April 2018. Available at: http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/a-look-at-drug-spending-in-the-us
[456] Vandervelde A, Blalock E; Berkeley Research Group. The pharmaceutical supply chain: gross drug expenditures realized by stakeholders. May 2017. Available at: http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf
[457] 83 Fed. Reg. at 22697.
[458] See, e.g., Federal Trade Commission letter to the Honorable mark Formby, Mississippi House of Representatives, re SB 2445 (March 22, 2011) (noting that government disclosures of negotiated pricing information can "undercut vigorous competition on drug pricing" and undermine competition between drug

SECTION XI: DIRECT-TO-CONSUMER ADVERTISING (RFI p. 22695)

The RFI notes that HHS may request FDA to consider compelling biopharmaceutical companies to include list prices in DTC advertisements. Such a requirement would not benefit patients, could have the unintended and harmful consequence of deterring patients from seeking care, and would raise legal concerns.

As an initial matter, including the list price of medicines in DTC ads would not meet the Administration's aim of better informing patients. Such information would be potentially confusing to patients because list price is often not the relevant measure for what they actually pay. Patients picking up a prescription medicine often pay a co-pay dictated by their insurance company. Patients without insurance often receive assistance. Insurance companies usually do not pay the full list price because they receive substantial rebates and discounts.

Including list prices in DTC ads could deter patients from seeking care. Research shows that a major benefit of DTC ads is that they promote conversations between patients and their providers.[459] If patients hear or see a list price in a DTC ad, they may erroneously assume that is the price they will be required to pay and that their out-of-pocket costs will be higher than they actually are. Mandating inclusion of list price information could thus mislead patients and would not result in transparency about their out-of-pocket costs. Instead, it could result in the unintended consequence of patients choosing to avoid talking with providers about their health care needs.

Alternative policies could yield meaningful cost and access-related information for patients. Information from stakeholders across the pharmaceutical supply chain have a greater effect on patient costs than medicine list prices. For example:

- Contracts with PBMs may prohibit pharmacists from informing consumers when their medicine's cash price is lower than the price the patient would pay through their insurance plan, or when manufacturer copay assistance could help reduce patient costs. Prohibiting such 'gag clauses' would give patients meaningful cost information.

- Providing real-time benefit information at the point of prescribing can help ensure patients and their providers make informed decisions about choice of treatment based on the patient's actual expected cost information.

- Requiring insurers to provide patients with easy access to information about their prescription drug benefit would also aid decision making by shedding light on formulary

manufacturers to offer discounts); Shepherd J, Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market. *Cornell Law Review Online*. 2013;99:1-22.

[459] FDA. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drug – Summary of FDA Survey Research Results. November 19, 2004.; Prevention Magazine. 2012 Direct to Consumer Advertising Survey.

design and changes, cost sharing, access restrictions such as prior authorization, and the exceptions process, including rates of denials and appeals.

In addition to the policy concerns, any consideration of requiring disclosure of list prices in DTC ads must be squared with FDA's statutory authority and First Amendment restrictions against compelled speech.[460] We do not believe that FDA currently has the statutory authority to impose such a requirement or that such a requirement would be constitutional. Moreover, any such proposal would be a substantive change to FDA's existing regulations and would necessitate notice and comment rulemaking.

SECTION XII: BIOSIMILAR DEVELOPMENT, APPROVAL, EDUCATION, AND ACCESS (RFI p. 22696)

PhRMA members support the development, and delivery of safe and effective biologics, including biosimilars. PhRMA appreciates the balance between incentives for innovation and the need for biosimilar competition struck in the BPCIA.[461] Additionally, PhRMA acknowledges Congress and FDA's continued efforts to implement the BPCIA through the BsUFA II[462] and associated BsUFA II Commitment Letter.[463] These efforts will help provide earlier and more predictable access to biosimilar products, increasing biopharmaceutical competition in the marketplace.

PhRMA acknowledges that FDA has "prioritize[d] ongoing efforts to improve the efficiency of the biosimilar and interchangeable product development and approval process."[464] In light of this prioritization, PhRMA reminds HHS that FDA already has an obligation, under the BsUFA II Commitment Letter, to produce certain information resources and development tools. We encourage FDA to implement these commitments promptly to assure an effective and efficient biosimilar approval process.

We are encouraged by HHS's solicitation of recommendations to improve the Purple Book.[465] In addition to the information that FDA has committed to publish in the BsUFA II Commitment letter, PhRMA urges FDA to revise the Purple Book to state FDA's commitment to making and publishing prompt exclusivity decisions at the time of biologic approval.[466] Prompt publication of this information is essential to provide certainty and transparency to all stakeholders. Specifically, prompt exclusivity decisions allow reference product sponsors the ability to understand much earlier whether their products will be entitled to exclusivity, and prompt

[460] *See, e.g., NIFLA v. Becerra*, 138 S.Ct. 2361 (2018).
[461] BPCIA, Pub. L. No. 111-148 §§ 7001-7002, 124 Stat. 119, 804.
[462] Biosimilar User Fee Act Amendments of 2017, Pub. L. No. 115-52 §§ 401-407, 131 Stat. 1005, 2028.
[463] FDA, Biosimilar Biological Product Reauthorization Performance Goals and Procedures FY 2018 Through 2022.
[464] RFI at 22696.
[465] Id.
[466] PhRMA. Comments to Docket No. FDA-2013-D-1165 at 16-17. October 6, 2014. These comments provide greater detail on recommendations to revise the Purple Book to include prompt information on exclusivity determinations.

publication of those decisions allows potential biosimilar developers to know whether exclusivity will affect the timing of biosimilar application submission and approval. Thus, all stakeholders would benefit from this information and would be able to make more informed investment decisions. PhRMA also encourages FDA to include the name of the Biologic License Application (BLA) holder in the Purple Book.

PhRMA agrees that "[p]hysician education and patient confidence in biosimilar and interchangeable products is critical."[467] To that end, PhRMA supports FDA's continued efforts to raise awareness of the agency's role in the biosimilar approval process, increasing the public's understanding of both biologics and biosimilars, and helping stakeholders understand the data and information that goes into biosimilarity determinations.

PhRMA supports FDA's effort to create a regulatory framework for interchangeability. PhRMA recommends FDA finalize its guidance on interchangeability,[468] with revisions to the draft guidance consistent with PhRMA's comments and guided by the BPCIA and the science.[469]

SECTION XIII: AVAILABILITY OF REFERENCE PRODUCT SAMPLES (RFI p. 22695)

PhRMA appreciates the balance struck by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), which established a framework where after a period of intellectual property (IP) protection, generics would be approvable.[470] Although it is a different framework, the BPCIA relies on a similar premise allowing for the approval of biosimilars once reference product exclusivity has lapsed.[471] Both of these regimes then operate from the starting proposition that IP rights are key to innovation and thus must be respected. Of course, the other side of the balance struck by both Hatch-Waxman and the BPCIA is that once applicable protections have expired, generics and biosimilars should be eligible for approval. To ensure this is possible, reference product samples should be reasonably available under terms consistent with patient safety for bioequivalence and biosimilar testing to allow for their approval and licensure when permitted under statute. Reference product sponsors should not withhold samples to delay generic or biosimilar entry.

AVAILABILITY OF REFERENCE PRODUCT SAMPLES: REMS (RFI p. 22696)

Risk management is an integral part of sound clinical care and an important responsibility of biopharmaceutical innovators. The Food and Drug Administration Amendments Act of 2007

[467] RFI p. 22696.
[468] FDA. Draft Guidance for Industry, Considerations in Demonstrating Interchangeability With a Reference Product. January 2017.
[469] PhRMA. Comments to Docket No. FDA-2017-D-0154. May 19, 2017.
[470] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-147, 98 Stat. 1585 (as amended); PhRMA. Comments to Docket No. FDA-2017-N-3615. November 17, 2017.
[471] BPCIA, Pub L. No. 111-148 §§ 7001-7002, 124 Stat. 119, 804.

gave FDA authority to require a REMS.[472] FDA's REMS authorities allow FDA to impose safeguards to help ensure that medicines that carry high risk are prescribed, distributed and taken appropriately, while at the same time enabling patients to have continued access to the medicine by implementing a safety strategy to manage any known or potential serious risk associated with a medicine.

To impose a REMS, FDA must determine that the REMS is necessary to ensure the product's benefits outweigh its risks.[473] REMS including elements to assure safe use (ETASU) are limited to when FDA has determined that, because of the drug's inherent toxicity or potential harmfulness, the drug may be approved only if, or would be withdrawn unless, the ETASU are required. In addition, if a REMS exists for an already approved drug without ETASU, ETASU will be required if the existing elements of a REMS are not sufficient to mitigate the risks.[474] Any ETASU imposed shall, considering the risks that prompted the REMS, not be unduly burdensome on patient access to the drug and, to the extent practical, minimize the burden on the health care delivery system.[475]

As part of its ongoing REMS authority, FDA can evaluate the impact of one (or more) REMS with ETASU on the health care delivery system and also structure or revise REMS to minimize the impact to the system.[476] PhRMA supports FDA exercising that authority to evaluate whether one or more REMS has had an impact on the availability of generics or biosimilars. After completing such an assessment, FDA could then consider whether there are particular steps the agency might take to revise or modify REMS to allow for sample access while not undermining the patient safety protections the REMS was imposed to provide. For example, depending on the risks the REMS was imposed to mitigate, FDA might require the generic or biosimilar applicant to submit protocols, informed consent documents, and other relevant materials to ensure the safety protections of the REMS were not undermined.

FDA should revise REMS to confirm that provision of samples to generic or biosimilar applicants who have obtained a Safety Determination Letter would not violate the REMS.[477] FDA could also evaluate whether REMS supporting documents might appropriately include information about how generic or biosimilar developers might obtain product samples, including the

[472] Food and Drug Administration Amendments Act of 2007 § 901(b), 121 Stat. 823, 922 (as codified at 21 U.S.C. § 355-1).
[473] 21 U.S.C. § 355-1(a)(1), (2)(A).
[474] Id. § 355-1(f)(1)(A)-(B).
[475] Id. § 355-1(f)(2)(C)-(D).
[476] Id. § 355-1(f)(5)(B), (g)(4).
[477] FDA. Draft Guidance for Industry, How to Obtain a Letter from FDA Stating that Bioequivalence Studies Protocols Contain Safety Protections Comparable to Applicable REMS for RLD. December 2014. We note that FDA has taken the position that the contents of a REMS may include only "safety-related elements."; Janet Woodcock. Letter to Kumar Sekar. August 17, 2013, Docket No. FDA-2009-P-0266. However, this position does not preclude FDA from including, in REMS supporting documents, a statement that providing samples, in certain circumstances (e.g., upon receipt of a Safety Determination Letter) for purposes of bioequivalence or biosimilar testing, does not violate the REMS. The existing template language in REMS approval letters merely reminding sponsors of 21 U.S.C. § 355-1(f)(8) may not provide sufficient assurance that supplying samples is not a violation of REMS.

information that the generic or biosimilar developer might be required to provide FDA in order to obtain a Safety Determination Letter. Finally, FDA might consider whether it is fully exercising its authority under the current statute.

AVAILABILITY OF REFERENCE PRODUCT SAMPLES: Additional Measures (RFI p. 22696)

Although PhRMA supports FDA taking appropriate measures within its existing statutory authority to address product sample access issues, legislation may be useful to fully address the issue. We take seriously the concerns raised about REMS and other distribution systems being used to delay generic entry. We are actively engaged with policymakers to develop policy solutions that ensure the timely transfer of samples to generic manufacturers without risking patient safety or establishing a tool that creates an incentive for predatory litigation.

PhRMA would support an appropriate statutory solution, but has concerns with the proposals introduced to date. For example, we are concerned that the CREATES Act[478] would undermine the role of FDA in access decisions for products with REMS with ETASU and would encourage frivolous litigation. We would support a proposal that instead codifies within the FDCA an authorization process for access to samples for products with REMS with ETASU. We also would encourage safeguards in any new cause of action including affirmative defenses for license holders that offer samples at commercially reasonable terms as well as statutory assurance that providing samples would not violate REMS.

SECTION XIV: FIXING GLOBAL FREELOADING (RFI p. 22697)

The RFI appropriately identifies the problem of global free riding, whereby advanced economies are relying on U.S. patients to bear a disproportionate share of the cost to develop innovative medicines.[479] Furthermore, as highlighted in the U.S. Trade Representative's recent Fact Sheet on its Engagement on Pharmaceutical and Medical Device Issues, too many countries are undervaluing and/or undermining U.S. IP.[480] Recognizing these problems, the RFI asks what can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the U.S. and other developed countries.[481] In addition, the RFI seeks input on what policies the U.S. government should pursue in order to protect IP rights and address concerns around compulsory licensing in this area.[482]

To research, develop and deliver new treatments and cures for patients who need them around the world, biopharmaceutical innovators must be able to secure and effectively enforce patents and protect regulatory test data. They must be able to obtain timely marketing approval for new medicines and make those therapies available to patients according to reimbursement rules and

[478] S. 974, 115th Congress (2017); H.R. 2212, 115th Congress (2017)
[479] RFI p. 22697.
[480] USTR Fact Sheet. USTR Engagement on Pharmaceutical and Medical Device Issues. April 2018.
[481] RFI p. 22967.
[482] Id.

procedures that are fair, transparent, reasonable, and non-discriminatory, and that appropriately value and reward patented pharmaceuticals. With the right policies and incentives in place at home and abroad, they can continue to bring valuable new medicines to patients and contribute powerfully to the American economy and jobs.

In recent years, however, America's biopharmaceutical sector has witnessed a surge in the number of trading partners that impose arbitrary or unreasonable pricing and reimbursement policies and/or steal U.S. IP. In many countries, governments are the principal payer of medicines and effectively dictate prices. Too often, this dominant position is used to benefit domestic drug companies and wholesalers at the expense of innovators in the U.S.

Foreign governments employ multiple price control measures in tandem to artificially depress the market value of U.S. innovative medicines, including:

- **International Reference Pricing**, where developed markets reference prices in poorer countries or countries that undermine incentives for innovation.

- **Therapeutic Reference Pricing**, where trading partners require innovative medicines to have similar prices as older medicines.

- **Health Technology Assessment**, where governments arbitrarily apply low thresholds on the value of innovative medicines.

- **Mandatory Price Cuts and Clawbacks**, which act as perverse incentives against developing treatments for new indications and patient-centered formulations.

- **Compulsory Licensing**, where governments threaten to steal IP as a negotiating ploy.

- **Discriminatory Practices**, by which U.S. companies are denied due process and a level playing field, including through non-transparent decisions and localization measures.

The 2004 Department of Commerce Report on this issue demonstrates how, as more countries enact price controls and similar measures, the burden for financing medical advances will be increasingly borne by U.S. patients and biopharmaceutical innovators, while patients abroad will suffer decreased access to improved therapies over the long term.[483] Such threats significantly undervalue U.S. innovation and threaten good-paying U.S. jobs and the development of pioneering therapies.

In the Report—which the President's 2019 budget indicates is being updated—Commerce found that tackling foreign price controls in just a few countries could "increase[] the flow of [new

[483] Department of Commerce. Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation. Commerce Report. December 2004.

medicines] by three to four per year,"[484] generating increased competition in the U.S. marketplace and savings for U.S. patients. Economists agree, and have concluded time and again, that when biopharmaceutical companies have more resources to invest in research and development (R&D), it leads to more innovation and competition and better health outcomes. For example, lifting government price controls in other wealthy countries would:

- Increase the number of new treatments available by 2030 by 9 percent—equivalent to 8-13 new drugs in that year.[485]

- Increase life expectancy for an American aged 15-years-old today by 1.1 years.[486]

- Increase welfare gains of $10 trillion for Americans and $7.5 trillion for Europeans over the next 50 years, reflecting improved length and quality of life.[487]

In turn, there is overwhelming evidence that where there are more competing medicines, the market forces costs down:

- Within a year of the introduction of a breakthrough HCV cure, there were multiple competitors in the market that enabled payers to negotiate deep discounts for these medicines in exchange for favorable formulary placement. Competition drove rebates from about 22 percent in 2014 to discounts ranging from about 40-65 percent today, as well as lower WAC prices.[488]

- In the case of new cholesterol-lowering medicines, called PCSK9 inhibitors, despite initially claiming that the medicines could "wreak financial havoc," Express Scripts, the nation's largest PBM, ended up including them on its national list of covered medicines, thanks in part to substantial negotiated discounts and aggressive utilization management policies. According to the company, "[w]e were able over the course of tough negotiations to get good economics on both products."[489]

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[484] Id.
[485] Schwartz TT, et al. The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health, Precision Health Economics. May 2018. Available at: https://www.ispor.org/ScientificPresentationsDatabase/Presentation/81984?pdfid=54396
[486] Id.
[487] Goldman D, Lakdawalla D. The Global Burden of Medical Innovation. The Brookings Institution. January 30, 2018. Available at: https://www.brookings.edu/research/the-global-burden-of-medical-innovation/
[488] Silverman E. The Hepatitis C Scorecard: Gilead is Trouncing AbbVie, but at a Price, *W.S.J. Pharmalot Blog*. February 12, 2015. Available at: https://blogs.wsj.com/pharmalot/2015/02/12/the-hepatitis-c-scorecard-gilead-is-trouncing-abbvie-but-at-a-price/
[489] Pollack A. Express Scripts Says It Will Cover 2 New Cholesterol Drugs. *New York Times*. October 6, 2015. Available at: https://www.nytimes.com/2015/10/07/business/express-scripts-says-it-will-cover-2-new-cholesterol-drugs.html?_r=1

As the Report also notes, "the benefits for consumers in the United States from deregulation of foreign drug prices and increased R&D would be expected to rise as a result of savings from hospitalization, fewer missed work days, and other medical cost savings. Obviously, aggressive reforms among the OECD countries would accelerate this effect."[490] For example:

- The use of cholesterol-lowering statin drugs has cut hospitalizations and saved the U.S. health care system at least $5 billion.[491]

- Every $24 spent on new medicines for cardiovascular diseases in OECD countries saves $89 in hospitalization costs.[492]

- Treating high blood pressure according to clinical guidelines would result in annual health system savings of about $15.6 billion.[493]

- New HCV cures have the potential to reduce future U.S. health care spending by $115 billion.[494]

- In the fight against Alzheimer's disease, a new medicine that delays the onset of Alzheimer's disease by five years would avoid $367 billion annually in long-term care and other health care costs by 2050.[495]

In addition to lowering overall health care costs, appropriate use of medicines can increase worker productivity by reducing rates of absenteeism and short-term disability.[496]

Recognizing the benefits of addressing free riding by other developed countries, here are four recommended actions that this Administration could take to end the most unfair and discriminatory trade practices faced by the U.S. innovative biopharmaceutical industry.

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[490] Department of Commerce. Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation. Commerce Report. December 2004.
[491] Grabowski D, Lakdawalla D, et al. The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence And Broaden Treatment. *Health Affairs*. October 2012.
[492] Lichtenberg F. Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003. National Bureau of Economic Research. May 2008.
[493] Cutler, DM, Long G, et al. The Value of Antihypertensive Drugs: A Perspective on Medical Innovation. *Health Affairs*. January 2007.
[494] Milliman. An Actuarial Approach to the Incremental Cost of Hepatitis C in the Absence of Curative Treatments. September 2015. Available at: http://www.milliman.com/uploadedFiles/insight/2015/20150915_Incremental-Cost-of-HCV-White-Paper.pdf.
[495] Mandel M. The Folly of Targeting Big Pharma: The biggest driver of rising health-care spending is the cost of labor, not drugs. *W.S.J. Op. Ed*. December 10, 2015. Available at: https://www.wsj.com/articles/the-folly-of-targeting-big-pharma-1449792625.
[496] Carls GS, Roebuck MC, et al. Impact of medication adherence on absenteeism and short-term disability for five chronic diseases. *Journal of Occupational and Environmental Medicine*. July 2012.

1. Secure Strong Commitments in Global, Regional and Bilateral Negotiations

Global, regional, and bilateral trade and investment negotiations provide critical opportunities to build on the existing foundation of international rules and to secure commitments necessary to drive and sustain 21st Century biopharmaceutical innovation. Recognizing this opportunity, Congress has identified unreasonable foreign pricing and reimbursement policies as major concerns to be addressed in trade negotiations. Specifically, the Trade Promotion Authority (TPA) legislation, pursuant to which the Administration is renegotiating NAFTA, identifies as a principal negotiating objective for free trade agreements "to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for United States products." As noted in the TPA's legislative history, ensuring full market access "includes setting the reimbursement amount based on competitive, market-derived pricing or an equivalent process, such as one that appropriately recognizes the value" of innovative products.

The existing NAFTA does not contain pharmaceutical pricing and reimbursement obligations, and yet such obligations are critically needed to address market access barriers faced by the U.S. innovative biopharmaceutical industry in our closest trading partners. In particular, Canada's Patented Medicine Prices Review Board (PMPRB) imposes price caps solely on patented medicines in both the public and private segments of the Canadian market. This unfairly undervalues innovative U.S. medicines. Conversely no price caps are imposed on generics, thereby bolstering domestic Canadian generic interests. Canada has recently proposed sweeping regulatory changes to the PMPRB to remove the U.S. from its reference pricing system in favor of South Korea and other countries that are poorer and/or have onerous price control policies. They have also proposed a value assessment system for medicines in Canada modeled on existing systems abroad that have delayed access and produced poor health outcomes, like in the U.K. In turn, the Canadian Government is proposing to use these mechanisms to further drive down prices in the private insurance market. Obligations should be secured through NAFTA renegotiation to appropriately value innovation and ensure a level playing field.

In addition, Mexico has failed to fulfill its obligations under NAFTA and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure that regulatory data submitted to obtain marketing approval of pharmaceutical products in Mexico are protected against unfair commercial use and unauthorized disclosure. Mexico fails to provide effective regulatory data protection for biologic medicines. Despite numerous judicial orders in Mexico compelling federal agencies to provide such protection for biologics, the Mexican government has yet to implement this NAFTA obligation. Mexico should pass regulations to provide greater certainty regarding the extent and durability of Mexico's commitment to protecting and promoting innovation.

2. Enforce and Defend Global, Regional, and Bilateral Rules

The Administration should use all available tools and leverage to ensure America's trading partners live up to their obligations in global, regional, and bilateral trade and investment agreements. Modernizing existing trade agreements and stepping up enforcement activity in the months ahead will be critical to end discriminatory pricing policies and to address longstanding IP challenges around the world—particularly in countries that are U.S. trade and investment agreement partners, that have made important unfulfilled WTO accession commitments and that benefit from U.S. trade preference programs.

In this regard, the Administration has already taken a strong initial step to secure a commitment from Korea to amend its Premium Pricing Policy to ensure that consistent with its obligations in the Korea-United States free trade agreement (KORUS), it does not discriminate against U.S. biopharmaceutical manufacturers.[497] And yet, as outlined in PhRMA's 2018 Special 301 submission, there are many elements of Korea's pricing and reimbursement system that are not consistent with its commitment to appropriately recognize the value of patented pharmaceuticals. PhRMA and its members stand ready to engage with both the Korean and U.S. governments on broader reforms to Korea's pricing and reimbursement system to ensure that Korea faithfully and comprehensively implements its KORUS commitments to the U.S.

Furthermore, contrary to Korea's commitment in KORUS, recent Court decisions in Korea inappropriately restrict the availability of patent term extensions, which enable U.S. innovators to seek restoration of a portion of the patent term lost due to lengthy regulatory approval processes. Left standing, these decisions will negate the value of patent term extensions in Korea.

Similarly, in recent years, Australia has made significant changes to its pricing and reimbursement policies, making it more difficult for Australian patients to access innovative medicines. Of particular concern is an arbitrary and broad-based retroactive price reduction which was applied to all medicines listed on Australia's Pharmaceutical Benefits Scheme (PBS) for five or more years, and which disproportionately impacts foreign companies. Such *ad hoc* price cuts, along with other onerous conditions placed on PBS-listed medicines and price-depressing measures such as health technology assessment, are creating significant uncertainty and lost revenues for U.S. innovators.

Moreover, Australia is unfairly tipping the scales in commercial patent disputes by encouraging competitors to launch at risk and discouraging innovators from enforcing their patents. Since 2012, the Australian government has sought "market-sized damages" from innovators that have unsuccessfully sought to enforce patent claims. Those damages are designed to compensate Australia's PBS for any higher price paid for a patented medicine during the period of a provisional enforcement measure. It exposes innovators to significant additional compensation claims that are difficult to quantify and were not agreed to at the time provisional enforcement

[497] USTR Fact Sheet. New U.S. Trade Policy and National Security Outcomes with the Republic of Korea. March 28, 2018.

measures were granted. The size of these additional claims equates legitimate patent enforcement with patent abuse. Allowing governments or other non-parties to a patent dispute to collect market-size damages undermines legal certainty, predictability, and the incentives patents provide for investment in new treatments and cures. Contrary to its trade agreements with the U.S., Australia is failing to value innovation appropriately and is seriously hampering innovative companies' ability to protect their patents.

3. Ensure that Foreign Government Pricing and Reimbursement Policies are Transparent, Provide Due Process, are Non-Discriminatory, and Appropriately Value U.S. Innovation

PhRMA members are, and seek to be, partners in solutions to health care challenges facing patients and their communities around the world. However, some governments have proposed or implemented pricing and reimbursement policies that discriminate against medicines made in America, do not appropriately value innovation, and lack predictable, transparent, and consultative processes. For example, just last year, Japan approved sweeping changes to its pricing policies that significantly undermine Japan's pro-innovation environment and its efforts to carry its fair share of the costs of global R&D efforts. Like earlier price-cutting measures, the new framework was developed behind closed doors without meaningful opportunities for input from key stakeholders, including the innovative pharmaceutical industry. Despite strong engagement by the U.S. government throughout 2017, Japan reduced the scope of products covered by its Price Maintenance Premium (a program intended to ensure that innovative medicines are not hit by draconian price cuts), and imposed new company requirements that benefit Japanese manufacturers over U.S. innovators in pricing.

Particularly onerous pricing practices in several developed economies include international reference pricing, therapeutic reference pricing, and health technology assessment. These practices dictate the terms of market access for our industry and can result in significant negative impacts on patients and America's biopharmaceutical industry, including by eviscerating the expected benefit of IP protections. Moreover, such measures can undermine the ability of biopharmaceutical innovators to bring new medicines to patients who need them and to invest in future treatments and cures.

The U.S. government can play a critical role in ensuring transparency and due process of pricing and reimbursement policies, as well as in highlighting the global benefits to patients that result from a reduction in trade barriers. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 called for the Administration to develop a strategy to address foreign price controls on pharmaceuticals and related practices through bilateral and multilateral trade negotiations. PhRMA believes that the cornerstone of any such strategy must be a proactive U.S. trade policy focused on: (i) addressing discriminatory government price controls and related practices; and (ii) highlighting the global benefits for patients from the potential groundbreaking research that could result from a reduction in key trade barriers. Completing the update of the 2004 Commerce Report on Pharmaceutical Price Controls in OECD Countries will be an

important first step in identifying the worst offenders and developing a comprehensive strategy using all available levers to address this important issue.

4. Leverage All Available Trade Tools to Combat Abuse of Compulsory Licensing

Too often, foreign governments threaten compulsory licensing to compel innovators to lower pharmaceutical prices—even where the medicine is being sold at the price originally dictated by the government. For example, Colombia recently threatened to issue a compulsory license (CL) for an innovative cancer medicine, even though the medicine was being sold in the country at the price mandated by the government. While Colombia did not issue the CL, it did force a drastic mandatory price cut to levels as if the patent on the medicine did not exist.

Often with the support of multilateral organizations, countries around the world are issuing or currently considering CLs on a wide range of innovative medicines. Last year, Malaysia issued a CL for one HCV treatment, and Saudi Arabia took action with equivalent effect for another. Colombia is now assessing whether to grant another petition that ultimately is seeking the imposition of a CL on the whole class of HCV medicines. American inventions are at risk in Chile, El Salvador, Peru and Russia. The fact that CLs have now been issued in countries across Asia, Africa, and Latin America has emboldened governments to follow through on threats and diminished what little leverage innovators have in price negotiations.

Where specific and credible threats of compulsory licensing arise, the U.S. government must defend American innovators and engage relevant authorities abroad. The U.S. government must make common cause with other like-minded governments, and push back in multiple multilateral organizations and other fora that are seeking to erode IP protections. Furthermore, the U.S. government should not provide unilateral trade benefits like Generalized System of Preferences (GSP) or allow countries to accede to organizations such as the OECD until those countries have demonstrated that they are prepared to offer a level playing field to U.S. innovators.

* * * *

On behalf of PhRMA and our member companies, thank you for consideration of these comments. We look forward to working with you to address the many important issues discussed in the RFI.

Sincerely,

Lori M. Reilly
Executive Vice President,
Policy, Research & Membership

James C. Stansel
Executive Vice President & General Counsel

COMMENTS OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

SUBMITTED TO THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

CONCERNING RIN 0906-AB08, 340B DRUG PRICING PROGRAM PROPOSED OMNIBUS GUIDANCE

OCTOBER 27, 2015

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TABLE OF CONTENTS

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October 27, 2015

BY EMAIL (340BGuidelines@hrsa.gov)

Captain Krista Pedley
Director, HRSA Office of Pharmacy Affairs
5600 Fishers Lane, Room 8W10
Rockville, Maryland 20857

Re: 340B Drug Pricing Program Proposed Omnibus Guidance; Regulatory Information Number 0906-AB08

Dear Captain Pedley:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the proposed 340B program omnibus guidance (the Proposed Guidance) published by the Health Resources and Services Administration (HRSA).[1] PhRMA is a voluntary, non-profit organization representing the nation's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to lead longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone.

PhRMA supports the 340B program, which was enacted to help make prescription drugs more accessible to uninsured or vulnerable patients, and these comments are intended to help assure the program is both strong and sustainable into the future. Over the years, we have been concerned that the program has grown into something that is no longer centered on strengthening the care provided to needy patients. We would like to be very clear and emphasize that the grantees and true safety net hospitals participating in the 340B program are dedicated to serving these patients, and we value and strongly support their work. Notably, HRSA grantees typically must demonstrate that they serve a specified vulnerable population on an income-based, sliding-fee scale and are required to reinvest any additional resources derived from their grants into services for those populations. Grantees and the true safety net hospitals are a key part of our nation's public health infrastructure and it is crucial that they can continue to use the 340B program to support this important role. These requirements placed on grantees also help assure that the 340B program is used appropriately. In contrast, hospitals face no such requirements. While some hospitals provide a significant amount of charity care and use 340B to strengthen that safety net role, other hospitals provide relatively little charity care.[2] PhRMA supports reforms instituted by HRSA that advance the goals of preserving the program for grantees and safety net hospitals -- and the patients they serve -- and preventing abuse by parties that simply see the program as another source of revenue. To the extent that statutory changes may be required to reform certain parts of the 340B program in order to achieve these goals, we would support those reforms as well.

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1 80 Fed. Reg. 52300 (Aug. 28, 2015).

2 GAO, "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals." June 2015.

Several factors have led the 340B program to have "expanded beyond its bounds," as one former Secretary of Health and Human Services noted in 2014.[3] One source of this growth is the lack of safeguards necessary to adhere to the statutory framework and to ensure its integrity and sustainability. This has contributed to the lack of focus on directing 340B discounts to the vulnerable and needy patients the program was created to serve. In other cases ill-advised 340B policies and weak oversight have allowed program benefits to be diverted from serving the program's intended beneficiaries.

At this juncture, it is critically important that HRSA institute major reforms to re-align the 340B program with its authorizing statute and ensure that its benefits flow to underserved patient populations. The Proposed Guidance takes some important steps in that direction. In particular, the Proposed Guidance would add greater clarity to the definition of a covered entity "patient" who may receive a 340B drug, and would therefore reduce opportunities for abuse. PhRMA has several refinements to suggest to the proposed patient definition (which we detail below), but overall we support the approach HRSA has taken as it would reduce the uncertainty about when an individual is properly considered a "patient" of a covered entity and reduce the potential for unintended program growth.

In other important areas, however, we are concerned that the Proposed Guidance would solidify or even exacerbate problems rather than reduce them. To cite some key examples, the Proposed Guidance does not clarify the criteria for private hospitals to participate in the 340B program -- even though the Government Accountability Office (GAO) recommended in 2011 that HRSA clarify the 340B eligibility criteria for private hospitals,[4] and in the intervening four years the percentage of U.S. hospitals participating in the 340B program (created to help needy and vulnerable patients served by safety net providers) has grown from 33% to 40%,[5] even as the percentage of Americans without health insurance drops. HRSA's failure to propose any standards for determining when a private hospital is 340B-eligible based on a contract with a State or local government to provide care for low-income people who are ineligible for Medicare and Medicaid is particularly disappointing, because setting clear standards for a hospital to fit within this eligibility category could benefit low-income, uninsured individuals.

PhRMA was also surprised and dismayed that HRSA made no proposals to curb the sharp and abusive growth in "child sites" of 340B hospitals that are not actually an integral part of the covered entity hospital and thus not legally entitled to participate in the 340B program -- and that increasingly are serving higher-income communities instead of the patient mix that makes their "parent" hospital 340B-eligible.[6] Hospital acquisitions of formerly independent community physician practices -- which account for many of these new "children" -- are trending

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[3] President's fiscal year 2015 health care proposals: hearing before the Committee on Finance, US Senate. April 10, 2014. Statement of Kathleen Sebelius. Kathleen Sebelius, US Secretary of Health and Human Services.

[4] GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept. 23, 2011) at 23, 32, 34-36.

[5] GAO, Manufacturer Discounts in the 340B Program Offer Benefits, supra, at 20 (nearly one-third of U.S. hospitals participated in the 340B program at that time); GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 5, 2015) at 1 (currently, approximately 40% of U.S. hospitals participate in the 340B program).

[6] See e.g., Rena M. Conti and Peter B. Bach, The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities, *Health Affairs*, 33 no. 10 (2014): 1786-1792.

upward,[7] and Medicare typically pays higher rates for care provided at these acquired practices once they are characterized for billing purposes as hospital outpatient sites.[8] The availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenues than independent physician offices for administering the same medicine.[9] This opportunity creates financial incentives for 340B hospitals to purchase independent physician practices and bring them under the 340B umbrella, and recent studies suggest that these incentives are in fact driving 340B hospital acquisitions of formerly independent physician practices.[10] This current state of affairs of the 340B program goes beyond legislative intent -- and text. The hospital "child site" is a doctrine developed by HRSA alone, which should not be used to extend 340B eligibility to offsite facilities -- including formerly independent physician practices -- that are distinct from the covered entity hospital and serve distinct patient populations that the 340B program was not created to assist. PhRMA had expected that HRSA would not simply ignore this growing problem. This issue calls for HRSA's prompt and focused attention.

Further, the Proposed Guidance would not establish any limits on contract pharmacy arrangements -- even though the number of contract pharmacies has increased dramatically since 2010, these arrangements (which are not mentioned in the 340B law) have been cited by GAO and the HHS Office of Inspector General (OIG) as increasing diversion and double discounting risks, and a 2014 OIG report suggests that 340B hospitals' contract pharmacies generally do not pass 340B discounts through to low-income, uninsured patients. Often it is not until after the point of sale that an individual who filled a prescription at a contract pharmacy is identified as a covered entity "patient" who was dispensed a "340B drug" -- too late to provide a discount to the patient at the point of sale.

Another serious problem that the Proposed Guidance does nothing to solve is increased violations of the 340B law's ban on duplicate discounts (where a manufacturer sells a drug at a 340B discount and is then billed for a Medicaid rebate on the same unit). Due to a combination of two factors -- HRSA's 2010 policy ending its previous limits on contract pharmacies, and the fact that the Affordable Care Act (ACA) extended Medicaid rebates to Medicaid managed care

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[7] These trends have raised concerns about increased costs to Medicare and the entire health care system. See Baltic, Scott. "Monopolizing Medicine: Why hospital consolidation may increase healthcare costs," Medical Economics. February 2014.

[8] See IMS Institute for Healthcare Informatics. Innovation in cancer care and implications for health systems. Published May 2014. See also Berkeley Research Group. Impact on Medicare payments of shift in site of care for chemotherapy administration. White paper. Published June 9, 2014.

[9] According to a 2013 Congressional Budget Office (CBO) report, the average total Medicaid rebate on brand drugs (the "basic rebate" plus the "additional rebate") was about 58% of Average Manufacturer Price (AMP) in 2011. See Options for Reducing the Deficit: 2014 to 2023 at pg. 234 (Nov. 2013). The 340B ceiling price is AMP minus the drug's Medicaid rebate. CBO's estimate of the average Medicaid rebate for a brand drug thus puts the average 340B ceiling price at about 42% of AMP.

[10] New data from Avalere Health finds that 340B hospitals are more likely than other hospitals to purchase independent physician offices that administer medicines. Avalere Health. Hospital acquisitions of physician practices and the 340B program. White paper. Published June 8, 2015. The study authors found that 61 percent of hospitals identified in the study as potentially acquiring physician practices participated in the 340B program compared to a 45 percent 340B participation rate among all hospitals in the dataset. Also, a 2014 *Health Affairs* study concluded that 340B is a "powerful contributor" to driving these hospital acquisitions of physician practices. Bradford Hirsch, Suresh Balu and Kevin Schulman, "The Impact of Specialty Pharmaceuticals As Drivers of Health Care Costs," Health Affairs. October 2014 vol. 33 no. 10 1714-1720.

organization (MCO) utilization -- identifying and preventing duplicate discounts have become increasingly difficult over the past five years. But the Proposed Guidance merely advises covered entities to take unspecified steps to prevent duplicate discounts. This failure to embrace any solutions to the growing duplicate discount problem is a major concern. We are especially disappointed because PhRMA prepared a white paper for HRSA in 2014 with a number of thoughtful recommendations to reduce the risk of duplicate discount violations, but none of our recommendations on this issue are even discussed in the Proposed Guidance. To make things worse, HRSA has made several proposals that would increase the complexity of covered entities' carve-in/carve-out policies and thus affirmatively frustrate duplicate discount prevention and increase HRSA's own administrative burdens as it continues to audit and engage in oversight activities.

We urge HRSA to address these critical problem areas, and to build on its clearer "patient" definition, in its final omnibus guidance while also introducing some necessary flexibilities for grantees. We appreciate the challenges HRSA faces in issuing guidance that will help covered entities and manufacturers in complying with the statute, and all the efforts HRSA put into developing the Proposed Guidance. The improved "patient" definition is critical to the integrity of the 340B program and we strongly support HRSA's approach. In addition to the top-priority points just highlighted, we have comments on many issues raised by the Proposed Guidance, and we look forward to further dialogue with HRSA on these issues.

Our key recommendations can be summarized briefly as follows:

Ensuring Clarity in the Final Omnibus Guidance and the Overall Body of 340B Guidance

- To ensure that the final omnibus guidance is comprehensive, consistent, and complete, we recommend that HRSA: (1) state clearly in the final guidance that it supersedes all prior guidance on the topics covered; (2) explicitly incorporate into the final guidance the substance of all prior guidance that HRSA intends to keep applying; (3) clarify the status of 340B prime vendor pronouncements; (4) resolve inconsistencies between some of its statements in the Proposed Guidance itself, and between statements in the Proposed Guidance and other HRSA documents; and (5) list a post-publication date on which the final guidance becomes effective.

Grantee Eligibility

- We request that HRSA provide more detail with respect to certain grantee eligibility issues, and permit sub-recipients of federal grants that meet criteria we specify below to register independently for the 340B program.

Hospital Eligibility

- HRSA should specify that private nonprofit hospitals that are 340B-eligible due to being "formally granted governmental powers" by a state or local government must be granted (1) actual governmental powers (not anything less than "powers," such as authorization to perform activities "on behalf of" a unit of government), (2) that relate directly to the provision of healthcare (not unrelated or loosely-related powers).

- HRSA should specify that for a private nonprofit hospital to be 340B-eligible due to "a contract with a State or local government to provide health care services to low income

individuals [ineligible for Medicare and Medicaid]," (1) the hospital must submit the contract to HRSA, and (2) HRSA must review the contract and confirm that it requires the hospital to provide at least a specified amount of care to low-income people ineligible for Medicare and Medicaid (with the specified minimum threshold selected so as to ensure that a minor contract to care for this population cannot confer 340B eligibility).

- HRSA should list on the 340B covered entity database whether each hospital is 340B-eligible because it is (1) publicly owned or operated; (2) a private nonprofit hospital formally granted governmental powers by a State or local government (in which case the database should also list the power granted to the hospital, the unit of government that granted the power, and the instrument that granted the power and its date); or (3) a private nonprofit hospital with a contract with a State or local government to provide health care services to low-income individuals ineligible for Medicare and Medicaid (in which case the database should also include specified information about the contract that supports 340B eligibility).

The GPO Prohibition

- HRSA should not finalize its proposal permitting an exception to the GPO prohibition if a hospital cannot obtain a drug at the 340B price or at WAC, as the statute makes compliance with the GPO prohibition an unwaivable condition of eligibility for DSH, cancer, and children's hospitals.

Hospital Child Site Eligibility

- Reforms are needed to reconcile the hospital "child site" concept with statutory eligibility criteria:
    - HRSA should reaffirm that a hospital "child site" must be an "integral part" of the covered entity hospital, but with strengthened standards that improve clarity for stakeholders and assure alignment with the text and purpose of the 340B law. Specifically, HRSA should specify that to be an "integral part" of a covered entity hospital, an outpatient facility must: (1) meet the provider-based standards in 42 C.F.R. § 413.465; (2) be wholly owned by the hospital; and (3) be listed as reimbursable on the hospital's Medicare cost report and have Medicare outpatient charges.
    - HRSA should further specify that a hospital child site must: (1) provide the full range of outpatient health care services; (2) adhere to the parent hospital's charity care policy; and (3) adhere to the sliding scale fee schedule (if any) of the parent hospital for providing covered outpatient drugs to low-income patients who lack minimum essential coverage.
    - Finally, HRSA should specify that a hospital child site must serve a similar patient mix as the patient mix that makes the parent hospital 340B-eligible, and should impose a temporary moratorium on enrollment of new child sites for nonprofit private hospitals while it develops and implements appropriate standards to meet this criterion.

The "Covered Outpatient Drug" Definition

- HRSA should abandon its proposal to broaden the definition of "covered outpatient drug." In particular, HRSA's Proposed Guidance would narrow the Medicaid rebate statute's "limiting definition" so that it would only apply to a drug provided as part of specified services listed in

the statute when Medicaid pays for the drug via a bundled payment, and Medicaid actually is the payor in that instance. HRSA should instead return to its longstanding guidance conforming to the Medicaid rebate statute and the 340B law.

Individuals Eligible to Receive 340B Drugs

- PhRMA appreciates HRSA's efforts to spell out the elements of the "patient" definition, which are essential to improving program integrity. We generally support the six criteria HRSA proposes to define a covered entity patient. We also recommend certain refinements to the six criteria, including certain refinements that are needed to ensure that the patient definition does not inadvertently hinder grantees' ability to carry out their mission.
    - PhRMA supports HRSA's proposed criterion that a "patient" must receive a health care service at a registered covered entity site listed on the public 340B database.
        - We support the principle that an individual who receives services from an "affiliated" entity is not a covered entity patient and recommend that HRSA restate its previous guidance clarifying that this principle applies in the ACO context.
        - HRSA should also specify explicitly that a visit by an individual to a contract pharmacy of a covered entity neither establishes nor refreshes a "patient" relationship between an individual and a covered entity.
    - PhRMA supports HRSA's proposed criterion that the individual must receive health care services from a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity (such that the covered entity may bill for the provider's services). To improve clarity, HRSA should specify that the covered entity must be accountable for the care provided by the independent contractor. We also believe it would be appropriate for HRSA to recognize a limited exception to this element for certain entities that have grant-related obligations to provide a medical home model of care or otherwise to coordinate care for certain patient populations.
    - PhRMA supports HRSA's proposed third criterion that an individual must receive a drug that is ordered or prescribed by the covered entity provider as a result of the service described in the second criterion. We also support HRSA's clarification that a patient relationship cannot be established merely by the dispensing or the infusion of a drug.
    - PhRMA agrees that to be a patient, the individual's health care must be consistent with the scope of the Federal grant, project, designation, or contract of the grantee. However, it is important that HRSA apply this same approach to private hospitals that are 340B-eligible by virtue of being formally granted a governmental power or having a contract with a State or local government to care for low-income individuals who are not eligible for Medicare and Medicaid.
    - PhRMA supports the proposed criterion that the individual's drug must be ordered or prescribed pursuant to a health care service classified as outpatient. HRSA should also clarify that for insured patients, the service provided to the individual must be billed and paid for as an outpatient service. HRSA should also specify that this element of the patient definition would preclude filling "discharge prescriptions" with 340B drugs, but should state specifically that "discharge prescriptions" do not include prescriptions filled

by non-hospital (grantee) covered entities that are responsible for managing the care of the individual both before hospital admission and after discharge.

  - PhRMA agrees with HRSA that the individual's healthcare records must be accessible to the covered entity and demonstrate that the entity is responsible for care. We recommend specifying that the records of a "patient" must not only be "accessible" to the covered entity, but maintained, owned, controlled, and possessed by the covered entity. In addition, we recommend HRSA specify that the provider/patient relationship must be "ongoing."

- PhRMA agrees with the principle that covered entity employees are not "patients" unless all elements of the patient definition are met.

- We support HRSA's retention of the special patient definition for ADAPs.

- PhRMA supports telemedicine services, and we agree with HRSA that telemedicine services in the 340B context must be provided in compliance with all applicable State and Federal laws and all 340B program requirements. We recommend that HRSA create a carefully-crafted opening for grantees to develop a 340B "patient" relationship via real-time audiovisual encounters if key safeguards (including an initial face-to-face visit) and applicable State and Federal laws are followed.

Drug Inventory/Replenishment Models

- PhRMA agrees with HRSA's statement that covered entities are responsible for requesting 340B pricing at the time of the original purchase; however, the Proposed Guidance apparently would permit transactions to be reclassified as 340B drug purchases after the fact. To resolve this paradox, we recommend that HRSA adopt standards whereby (1) entities and their agents must design systems adequate to identify patients (and non-patients) at the time a drug is dispensed or administered; (2) entities with well-designed real-time patient identification systems may reclassify a drug as a 340B drug within 30 days of the purchase, and with notification to the manufacturer and a clear audit trail (and not otherwise); and (3) manufacturers must always be notified of any improper 340B purchases.

Duplicate Discounts

- PhRMA recommends that all stakeholders -- including HRSA, CMS, State Medicaid agencies, covered entities, and manufacturers -- work together collaboratively to develop solutions to prevent duplicate discounts. Below we list a menu of several recommendations to help achieve this objective:

  - HRSA should require covered entities to identify prescriptions for 340B "patients" when the prescription is written, which would enable both in-house and contract pharmacies to identify a prescription as one filled with 340B drugs at the point of service.

  - HRSA should work with CMS to require that Medicaid MCOs issue pharmacy benefit cards that include an individual's Medicaid managed care status, rather than just listing the BIN/PCN for the MCO sponsor.

- HRSA should work with stakeholders to create a 340B "National Database on States' Processing Requirements" that would provide information assisting covered entities and contract pharmacies to identify Medicaid MCO enrollees.
- HRSA should not finalize its several proposals to permit covered entities' carve-in/carve out policies to become more complicated, and instead should require one carve-in/carve out decision across all of a covered entity's sites and for all Medicaid payors.
- HRSA should require that, when billing Medicaid or other payors, covered entities and their contract pharmacies should use a system like that developed by the National Council for Prescription Drug Programs (NCPDP) -- or revised and refined by NCDCP -- to identify claims filled with 340B drugs.
- HRSA should work with CMS to create a standardized claims-level reporting format for drug utilization data that accompanies Medicaid rebate invoices submitted to manufacturers, and also standardize the method for identifying and documenting utilization of 340B drugs across Medicaid.
- HRSA should work with CMS to require that all Medicaid utilization data submitted to manufacturers (both FFS and Medicaid MCO) contain the "Pharmacy Identifier" field so that manufacturers can verify that the data has been correctly screened for duplicate discounts, or can communicate with the State about potential errors.
- HRSA should work with CMS to require that the utilization data accompanying Medicaid rebate invoices include additional specified fields that would assist manufacturers in identifying potential duplicate discounts.
- HRSA should work with CMS to require that contract pharmacies report the NPI number of the covered entity (not their own NPI number) when submitting or retroactively identifying a claim for a 340B drug. We also urge HRSA and CMS to develop a mechanism whereby the Exclusion File flags contract pharmacy claims even if the 340B entity itself has developed a method to avoid dispensing 340B drugs to Medicaid FFS and MCO beneficiaries and thus does not submit its NPI number to the Exclusion File.
- 340B entities or contract pharmacies that fail to follow the recommended requirement to adopt a system like the NCPDP 340B identification system should have an affirmative obligation to report to the MCOs that they do not use the required 340B identifier system; MCOs must then be required to exclude all claims from covered entities that do not comply with the 340B identifier system from the utilization data they report to the State.
- HRSA should work with CMS to ensure that Medicaid MCOs review their claims retroactively back to 2010 (when Medicaid MCO utilization first became subject to Medicaid rebates) to make sure they have not previously invoiced State Medicaid programs for 340B drugs, and make corrections as appropriate.

- HRSA should clarify that a manufacturer may dispute instances of duplicate discounts with States via the Medicaid rebate dispute resolution process, but is not required to do so (because covered entities are always ultimately responsible for compliance with the statutory prohibition of duplicate discounts).

Contract Pharmacy Arrangements

- Studies by GAO and the OIG suggest that the use of contract pharmacies presents heightened diversion and double discount risks and (in the hospital context) has resulted in few benefits to patients. Therefore, PhRMA recommends that, at a minimum, HRSA impose reasonable limits on the use of contract pharmacies to balance their heightened compliance risks against any benefit these arrangements are providing to covered entity patients. Specifically:

  - HRSA should limit the number and geographic scope of permissible contract pharmacy arrangements. With certain exceptions, PhRMA recommends that covered entities be permitted to contract with no more than five contract pharmacy locations at any given time, all of which must be located within lower-income census tracts served by the covered entity.

  - Where a covered entity offers a charity care policy or has a sliding fee scale, then its contract pharmacies should be required to follow those policies when dispensing 340B drugs to covered entity patients.

  - HRSA should seek an HHS OIG study and report on covered entity/contract pharmacy arrangements, which should include recommended safeguards to reduce duplicate discounting and diversion within contract pharmacies and reforms to target these arrangements exclusively at improving access to medicines for uninsured or vulnerable patients of covered entities. HRSA should establish a moratorium precluding any covered entity (except those described in 42 U.S.C. § 256b(a)(4)(A)-(K)) from entering into a new or expanded contract pharmacy arrangement until HRSA has evaluated the OIG's report, issued proposed guidance based on OIG's findings and recommendations, and then issued final guidance taking into account public comments.

  - HRSA should require covered entities to conduct annual, independent, on-site audits of their contract pharmacies, and relevant third parties, to identify program violations.

  - HRSA should establish a moratorium barring covered entities (except those described in 42 U.S.C. § 256b(a)(4)(A)-(K)) from registering any mail order contract pharmacies (including pharmacies licensed to dispense specialty drugs) until HRSA has conducted a thorough examination of the risks posed by these arrangements, and set forth clear, auditable, and specific standards to prevent program violations with respect to these arrangements.

  - Both HRSA and manufacturers should be permitted to audit contract pharmacies (and other relevant third parties) directly, to ensure compliance with program requirements.

  - HRSA should establish more stringent requirements regarding covered entities' written agreements with their contract pharmacies, with robust safeguards to ensure that the contract pharmacy adheres to all 340B program requirements, and measures describing specifically how compliance will be achieved. All agreements should be registered with HRSA and made available to HRSA on request.

The "Must Offer" Requirement

- When the PPA is amended to incorporate the "must offer" language, HRSA should reiterate its previous conclusion that this language incorporates HRSA's long-standing policy against treating covered entities less favorably than non-340B customers (rather than adopting a new and different "forced sale" requirement that potentially could result in manufacturers being required to disadvantage non-340B customers). We also recommend that HRSA update all of the PPA's provisions to conform with current law.

- PhRMA disagrees with HRSA's assertion that by executing a PPA, a manufacturer agrees to subsequent statutory and regulatory changes that are not incorporated into the PPA. We urge HRSA to retract this position, as it is unsupported by the statute or the PPA.

Limited Distribution Networks

- We oppose HRSA's proposal to require that manufacturers: (1) report information on their limited distribution networks; (2) seek HRSA's approval before putting a limited distribution arrangement into effect; and (3) agree to have submissions on their limited distribution arrangements published on the HRSA 340B website. HRSA lacks any authority to adopt such requirements, and should not attempt to finalize this proposal.

Procedures for Issuance of Refunds and Credits

- The 340B statute requires HRSA to establish procedures for manufacturers to issue refunds to covered entities in certain circumstances; while the Proposed Guidance proposes a 90-day refund period, it does not actually establish any procedures for making refunds. PhRMA recommends that HRSA engage in an ongoing dialogue with stakeholders to develop the required procedures, and ensure they work as smoothly as possible and avoid undue burdens. With respect to HRSA's specific refund proposals:

    - PhRMA opposes HRSA's proposal that manufacturers refund or credit covered entities within 90 days of a "determination" that an overcharge occurred. Because 340B ceiling prices are based on Medicaid rebate metrics that are subject to restatement for 36 months after initially filed, it would be inappropriate for HRSA to require refunds any time before the 36 month restatement window closes and 340B ceiling prices for a given quarter are frozen. Manufacturers also should be permitted a reasonable time to recalculate 340B ceiling prices based on the final restated pricing, calculate entity-specific refund amounts, and then to deliver the refund payments. PhRMA recommends that HRSA allow an additional four quarters (after the 36 month restatement period) for final delivery of refund payments.

    - PhRMA opposes HRSA's proposal to abrogate manufacturers' common law right of offset. The 340B law does not preclude offsets or authorize HRSA to do so. In fact, the law makes sub-ceiling prices voluntary, whereas HRSA's proposal to forbid offsets would effectively make sub-ceiling prices mandatory in cases where the initially-calculated ceiling price turned out to be too low. HRSA must therefore establish a policy recognizing that manufacturers may net overcharges and undercharges associated with ceiling price recalculations.

    - PhRMA urges HRSA not to preclude exceptions for de minimis amounts. Establishing a de minimis standard would reduce transaction costs and administrative burdens for both

manufacturers and covered entities, and it would be consistent with a long-standing line of case law holding that agencies may establish de minimis requirements to statutes they administer unless Congress has clearly precluded such exceptions -- which is not the case here.

Manufacturer Recertification

- PhRMA requests HRSA to provide greater specificity regarding its proposal to create a "manufacturer recertification" process (e.g., what information would be required to "recertify" the manufacturer as a 340B program participant, what type of "supporting documentation" it would need, under what circumstances such documentation would be requested). If HRSA wishes to create a manufacturer recertification process, it should propose specific standards and then publish them for notice and comment.

Rebate Option for AIDS Drug Assistance Programs

- PhRMA supports HRSA's proposal that ADAPs may receive 340B rebates if they purchase a drug at an amount exceeding the 340B ceiling price or if they pay for the patient's health insurance premium and pay the cost-sharing on the drug. We understand that this latter proposal would permit 340B rebates as long as the ADAP pays the patient's share of the premium plus the patient's cost-sharing.

- PhRMA supports HRSA's proposal that the amount owed to an ADAP for a covered outpatient drug would be equal to the full Medicaid unit rebate amount.

- PhRMA agrees that no covered entity may obtain 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price. We urge HRSA to clarify in its final guidance that non-ADAP covered entities may not bill ADAPs for drugs purchased at the 340B price, and thus trigger a duplicate discount (or take the 340B discount for itself rather than the ADAP).

HHS Audits of Covered Entities

- PhRMA opposes HRSA's proposal to extend a notice and hearing process to covered entities found in violation of the GPO prohibition, and to permit entities to demonstrate that the violation was an isolated error. HRSA's proposal is inconsistent with the statute. The 340B law prohibits certain hospitals -- as a condition of eligibility -- from obtaining covered outpatient drugs through a GPO or other group purchasing arrangement. There is no authority for HRSA to waive this eligibility condition.

- PhRMA urges HRSA to provide specific details as to what would constitute a "systematic" duplicate discount or diversion violation that would warrant removing a covered entity from the 340B program; at a minimum, a systematic violation would be one that occurs over and over and over again.

Manufacturer Audits of Covered Entities

- PhRMA agrees with HRSA's examples of what would provide "reasonable cause" to suspect diversion or duplicate discounts, and we agree that these examples are not exhaustive. We recommend that HRSA's final guidance on "reasonable cause" remain consistent with the Proposed Guidance.

- We support HRSA's proposal that in an HHS audit of a covered entity, HHS must be provided access to all of the covered entities records pertaining to compliance, including those of any child site or contract pharmacy. HRSA should also emphasize in its final guidance that such records are equally available to manufacturers where pertinent to a manufacturer audit.

HHS Audits of a Manufacturer and its Contractors

- In general, PhRMA agrees with HRSA's proposals regarding HRSA's ability to audit manufacturers, including providing manufacturers a notice and hearing process, and potentially to implement a corrective action plan. HRSA's proposal, however, provides that HHS also could audit relevant records of any of the manufacturer's contractors. This goes beyond HRSA's statutory authority, which extends only to manufacturers and wholesalers (and covered entities),[11] and we therefore recommend that HRSA correct this language in its final guidance. HRSA's final guidance also should recognize that its authority to audit wholesalers does not confer any responsibility on manufacturers for ensuring a wholesaler's cooperation with HRSA in any audit.

Covered Entity Audits of Contract Pharmacies

- PhRMA supports HRSA's proposals regarding covered entity audits of contract pharmacies, but given the widespread problems and increased compliance risks associated with contract pharmacies, PhRMA recommends more stringency. We urge HRSA to require that covered entities have annual independent on-site audits conducted of contract pharmacies. Covered entities also should be required to submit the results of these annual audits to HRSA along with a corrective action plan if their audit reports have found 340B program violations.

Public Health Emergencies

- Generally, PhRMA supports HRSA's proposal to provide for "flexibilities" regarding certain aspects of the 340B program in instances where the HHS Secretary has declared a public health emergency, however, we request that HRSA explain (1) how it would decide when a particular public health emergency warranted an exception to 340B requirements; (2) whether it believes it could grant exceptions to statutory requirements; and (3) whether any final guidance would replace the current guidance on public health emergencies that appears on HRSA's website. HRSA also should assure stakeholders that it will exercise these flexibilities very carefully, only when needed, and in a manner consistent with the 340B statute.

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[11] 42 U.S.C. § 256b(b)(5)(C), (d)(1)(B)(v).

I. ENSURING CLARITY IN THE FINAL OMNIBUS GUIDANCE AND THE OVERALL BODY OF 340B GUIDANCE

HRSA's Proposed Guidance covers a wide range of topics, many of which have been addressed in various documents, including Federal Register notices and policy releases, over the life of the program. PhRMA urges HRSA to state clearly in the final omnibus guidance that it supersedes all prior guidance on the topics covered, and also to ensure that the substance of all prior guidance that HRSA intends to keep applying is explicitly incorporated into the final guidance. As the Office of Management and Budget's Bulletin for Agency Good Guidance Practices emphasized, in developing significant guidance documents "agencies should be diligent to identify for the public whether there is previous guidance on an issue and, if so, to clarify whether that guidance document is repealed by the new significant guidance document completely and, if not, to specify what provisions in the previous guidance document remain in effect."[12] This will be critically important to ensure that stakeholders are not left guessing as to whether certain portions of prior HRSA guidance remain in force, and will make the final guidance an "omnibus" guidance document, as intended.

We also urge HRSA to clarify its views on 340B program issues communicated by the 340B prime vendor. It is unclear to many stakeholders why the 340B prime vendor (currently Apexus) is empowered to communicate HRSA's view on 340B program issues or why FAQs and other statements by the 340B prime vendor should be taken as HRSA interpretations of the 340B law or otherwise given weight on issues concerning 340B program requirements. Formal documented clarification by HRSA (rather than only oral assurances by OPA and Apexus staff) of the status of prime vendor FAQs and other materials would minimize confusion for all stakeholders.

We recommend that in the final guidance HRSA also take the opportunity to resolve and eliminate inconsistencies between some of its statements in the Proposed Guidance itself, and between statements in the Proposed Guidance and other HRSA documents. With respect to resolving inconsistencies within the Proposed Guidance itself, we think that the potential for inconsistencies can be reduced by structuring the final guidance to consolidate the discussion of a particular topic in one place. The Proposed Guidance in several cases contains inconsistent or potentially inconsistent pronouncements on certain topics in the initial preamble-like discussion (Section II, "Summary of the Proposed Guidance") vs. the later Section III, "Proposed Guidance." Bringing all the discussion of a particular issue together in one place may help HRSA to identify and then resolve conflicting or potentially conflicting statements that now appear in the Proposed Guidance, which will improve clarity and readability and reduce uncertainties for stakeholders.

Finally, we recommend that the final guidance list a date after its publication on which it becomes effective (i.e., HRSA will not rely on any new statutory interpretations contained in the guidance until after the listed effective date.

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[12] 72 Fed. Reg. 3432, 3436 (Jan. 25, 2007).

II. 340B ELIGIBILITY

A. Grantee Eligibility

HRSA's discussion in the Proposed Guidance of non-hospital (grantee) eligibility states:

> An associated site [which is defined as "a health care delivery site which is not located at the same physical address as a non-hospital covered entity, but is part of and delivers outpatient services for the non-hospital covered entity"] which is authorized to provide health care services through the scope of a Federal grant, Federal project, Federal designation or Federal contract of a covered entity as defined in Section 340B(a)(4)(A)-(K) of the PHSA may be eligible to participate in the 340B Program . . . The child site will be listed on the public 340B database, and can purchase and use 340B drugs, if the Departmental division which oversees such grant, project, designation or contract verifies the eligibility.[13]

It is unclear whether an associated site would need to be part of the same corporate entity as the non-hospital covered entity, or whether it could be a separate corporate entity. HRSA should clarify that an associated site must be part of the same corporate entity as the non-hospital covered entity. Permitting an associated site to be part of a separate corporate entity that does not itself qualify to participate in the 340B program would expand the program beyond the intent of the 340B statute.

HRSA also proposes permitting "sub-recipients of federal grants" to register independently for the 340B program if they receive "eligible Federal funds, or in-kind contributions purchased with eligible Federal funds."[14] We are not aware of any statutory provision authorizing an organization to participate in the 340B program by virtue of receiving in-kind contributions purchased with federal funds. We ask that HRSA clarify this point, and also clarify whether this eligibility theory is limited to clinics that treat sexually transmitted diseases or tuberculosis, as a HRSA FAQ suggests.[15] In addition, it is unclear whether the "sub-recipients"

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13 80 Fed. Reg. at 52316.

14 80 Fed. Reg. at 52301.

15 An FAQ on HRSA's 340B website provides as follows:

> Can the receipt of in-kind contributions through section 317 or 318 of the Public Health Service Act (PHSA) qualify an entity for participation in the 340B Drug pricing Program? What are in-kind contributions for purposes of 340B Program Eligibility?
>
> An entity receiving in-kind contributions through section 317 or 318 may qualify for the 340B Drug Pricing Program provided all the remaining 340B requirements are met. Qualifying in-kind contributions must be paid for by section 317 or 318 grant funds to qualify a site as 340B eligible. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

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HRSA discusses are "child sites" of a parent covered entity or different organizations that receive a sub-grant from a grantee covered entity.[16] While we would appreciate more detail regarding this proposal, we support the concept of permitting sub-recipients of federal grants to be eligible non-hospital covered entities listed independently on HRSA's database and independently responsible for compliance with all program requirements provided that sub-recipients are limited to separately incorporated entities that (i) receive a sub-award of a portion of a grantee's grant from the grantee; and (ii) would themselves meet the requirements to be a grantee or are Hemophilia Treatment Centers determined to meet the requirements of a sub-recipient grant of the Maternal and Child Health Bureau HRSA Hemophilia grant program.

B. Hospital Eligibility

All 340B hospitals -- whether disproportionate share (DSH) hospitals, free-standing cancer hospitals, children's hospitals, sole community hospitals, rural referral centers, or critical access hospitals -- must (among other things) meet specified standards covering the hospital's relationship with the government: i.e., the hospital either must be publicly owned or operated, or must be a private nonprofit hospital (1) "formally granted governmental powers" by an unit of State or local government, or (2) that has a "contract with a "State or local government to provide health care services to low-income individuals who are [ineligible for Medicare and Medicaid]."[17] The two private hospital categories collectively account for 80% of 340B sales to DSH hospitals (which in turn account for about 81% of all 340B sales to hospitals).[18]

With respect to a private nonprofit hospital that is "formally granted governmental powers," the Proposed Guidance (which is similar to a 2013 policy release)[19] provides that "[e]xamples of governmental powers include, but are not limited to, the power to tax, issue government bonds, and act on behalf of the government."[20] PhRMA appreciates HRSA providing these examples. However, we are concerned by the idea that the power to "act on

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See HRSA website for 340B Drug Pricing Program FAQs under the topic "340B Program Eligibility" available at: http://www.hrsa.gov/opa/faqs/index.html. The 317 and 318 references relate to 42 U.S.C. § 256b(A)(4)(K), which lists as 340B-eligible "an entity funded under Public Health Service Act section 318 (relating to the treatment of sexually transmitted diseases) or section 317(j)(2) (relating to treatment of tuberculosis), but only if the entity is certified by the Secretary pursuant to paragraph [256b(a)](7)." HRSA's 340B website identifies PHSA §§ 317 and 318 as 42 U.S.C. §§ 247b as and 247c, respectively; our review of these provisions did not shed any light on why the receipt of in-kind donations financed under these provisions would make an organization 340B-eligible.

[16] HRSA's proposed, but never finalized, 2007 notice relating to the definition of a "patient" included a brief discussion on "subgrantees and subcontractors," which seemed to indicate that these subawardees are separate organizations from the covered entity grantee. 72 Fed. Reg. 1543, 1546-47 (Jan. 12, 2007).

[17] 42 U.S.C. § 256b(a)(4)(L)(i), (M) - (O).

[18] Sales data from Apexus Update 2015 -- 340B Coalition Winter Meeting; Number of Entities from Avalere Health analysis of the 340B database in March 2015.

[19] "Clarification of Eligibility for Hospitals that are not Publicly Owned or Operated," Release No. 2013-3 (March 7, 2013).

[20] 80 Fed. Reg. at 52301. Guidance also states that "governmental powers" do not include "powers generally granted to private persons or corporations upon meeting of licensure requirements, such as a license to practice medicine or provide health care services commercially." Id. We agree with this statement, except that "governmental powers" should not include "provid[ing] health care" (whether "commercially" or non-commercially) because providing healthcare is an activity or in some circumstances an obligation, but it is not a "power."

behalf of the government" is a "governmental power," because this could mean anything. This phrase could introduce ambiguity and invite any private nonprofit hospital seeking to avail itself of 340B discounts to assert that it is carrying out some activity -- providing healthcare, filing reports on communicable disease outbreaks, providing information to the public on community health care resources, etc. -- "on behalf of" a unit of government, and thus has been granted "governmental powers" that make it 340B-eligible. We urge HRSA to distinguish clearly in its final guidance between exercising a bona fide governmental "power" and simply performing an activity. Equally important, HRSA should require that the governmental powers in question must directly relate to the provision of healthcare (as opposed to some type of power unrelated to the provision of healthcare, e.g., the power of eminent domain). This common sense approach would help to ensure that the 340B program does not further expand beyond the limitations envisioned by Congress.

With respect to the second 340B eligibility pathway for private nonprofit hospitals -- having "a contract with a State or local government to provide health care services to low income individuals [ineligible for Medicare and Medicaid]"[21] -- the Proposed Guidance is substantively the same as HRSA's current guidance.[22] HRSA would require that the hospital and a representative of the governmental unit in question submit a statement that "a contract is currently in place between the private nonprofit hospital and the state or local government to provide health care services to low-income individuals who are not entitled to Medicare or Medicaid."[23] The contract "should create enforceable expectations for the provision of health care services, including the provision of direct medical care."[24]

Notably, HRSA does not propose: (1) that the hospital submit the contract to HRSA; or (2) that the contract require the hospital to provide any particular amount of care to low-income people ineligible for Medicare and Medicaid. A 2011 GAO report identified the lack of these requirements as deficiencies in HRSA's guidance on private hospital eligibility. GAO stated:

> HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals. Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.[25]

In enacting the 340B law, Congress expressly emphasized that it would not allow participation by a private nonprofit hospital with "a minor contract to provide indigent care which

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21 42 U.S.C. § 256b(a)(4)(L)(i).

22 "Clarification of Eligibility for Hospitals that are not Publicly Owned or Operated," Release No. 2013-3 (March 7, 2013).

23 80 Fed. Reg. at 52301.

24 80 Fed. Reg. at 52301.

25 "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement." (Sept. 2011) at 23 (emphasis added).

represents an insignificant portion of its operating revenues," and described the law as reducing drug costs for "specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans."[26] By failing to specify that a minor contract to provide care to low-income uninsured individuals cannot make a private hospital 340B-eligible, HRSA invites abuse, by opening the program to many private hospitals that Congress never intended to become 340B-eligible. This failure to set any minimum threshold for the contractually-required care provided to low-income uninsured individuals likely also accounts for the startling percentage of U.S. hospitals that participate in 340B today. As noted earlier, the GAO reported recently reported that a full 40% of U.S. hospitals now participate in the 340B program; similarly, RAND estimates that 340B hospitals now account for approximately 48% of outpatient hospital visits in the U.S.[27]

In its final guidance, HRSA should follow GAO's recommendations and take the opportunity to: (1) require that a hospital seeking 340B eligibility based on a contract with a unit of government to care for low-income individuals ineligible for Medicare and Medicaid submit the contract for HRSA to review (which would enable HRSA to check whether the contract creates "enforceable expectations" for the provision of "direct medical care," as well as the amount of care required); and (2) provide that a hospital's contract with a state or local government will only make the hospital 340B-eligible if the contract requires the hospital to provide more than a minor amount of medical care to low-income uninsured patients (as determined by whether the level of care required under the contract meets or exceeds a specified threshold).

HRSA should also list each hospital's eligibility pathway on the 340B covered entity database. Specifically, HRSA should include in the database whether a hospital is 340B-eligible because it is (1) publicly owned or operated; (2) a private nonprofit hospital formally granted governmental powers by a unit of State or local government (in which case the database should also list the power granted to the hospital, the unit of government that granted the power, and the instrument that granted the power and its date); or (3) a private nonprofit hospital that has a contract with a State or local government to provide health care services to low-income individuals who are ineligible for Medicare and Medicaid (in which case the database should also list the unit of government with which the hospital has contracted, the date of the contract, and a summary of the hospital's specific contractual obligations to provide healthcare for low-income individuals ineligible for Medicare and Medicaid). To promote transparency in the program, this information then could be made available to stakeholders by incorporating into the HRSA 340B database a hospital sub-category that would identify how each individual hospital is eligible under the program.

To participate in 340B, all hospitals (except critical access hospitals) must meet a statutorily prescribed disproportionate share (DSH) adjustment percentage for the most recent cost reporting period.[28] Although PhRMA understands that HRSA may not deviate from the DSH adjustment percentages set forth in the statute, we wanted to take this opportunity to mention the problems associated with using the DSH metric for 340B eligibility purposes. The

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[26] H.R. Rep. 102-384 (II) (1992), 12 (emphasis added).

[27] The RAND Corporation, The 340B Prescription Drug Discount Program: Origins, Implementation, and Post-Reform Future at 8 (2014).

[28] The minimum percentage is 11.75% for DSH, cancer, and children's hospitals and 8% for sole community hospitals and rural referral centers.

DSH adjustment percentage has two flaws as a 340B eligibility criterion. First, the DSH adjustment percentage reflects care provided to low-income Medicare and Medicaid patients, but does not account for care provided by a hospital to uninsured or charity care patients who the 340B program is intended to benefit. Second, the DSH metric only reflects inpatient care, while the 340B program is limited to outpatient drugs. As a result, a hospital could potentially provide no charity care – inpatient or outpatient – and satisfy the applicable DSH adjustment percentage requirement.

In 2011, GAO concluded that "current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage... [and while] nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA."[29] Further, GAO noted:

> as the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is critically important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted.[30]

While the distortions in 340B eligibility associated with the DSH adjustment percentage await a legislative solution, they also increase the importance of HRSA using its existing tools to target hospital eligibility appropriately. Therefore, we urge HRSA to establish appropriate criteria in its final guidance for determining whether private hospitals have been "formally granted governmental powers" or have a contract with a state or local government to care for low-income uninsured individuals. Particularly given the large percentage of 340B sales these private hospitals account for, to align the 340B program with its statutory purpose and avoid the unintended consequences GAO warned about, it is essential that HRSA interpret the private hospital eligibility criteria in a reasonable and specific manner.

C. The GPO Prohibition

By law, DSH, children's, and cancer hospitals are ineligible for the 340B program if they obtain "covered outpatient drugs"[31] through a GPO or other group purchasing arrangement.[32] In its Proposed Guidance, HRSA proposes three exceptions to the GPO prohibition:

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29 "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," supra, at 34.

30 "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," supra, at 34.

31 PhRMA understands that in some cases there may be confusion as to whether these covered entities may purchase vaccines through a GPO or other group purchasing arrangement. For clarity, PhRMA recommends that HRSA state in its final guidance that the GPO prohibition only relates to purchases of covered outpatient drugs, and does not apply to vaccines as they are excluded from the definition of "covered outpatient drug" under Social Security Act § 1927(k)(2)(B).

32 42 U.S.C. § 256b(a)(4)(L)(iii).

- An off-site outpatient facility not participating in 340B or listed on the 340B database may purchase covered outpatient drugs through GPOs if it has a separate purchasing account and does not provide drugs purchased through GPOs to the parent hospital or 340B-participating child sites;

- A hospital would not lose 340B eligibility by providing a 340B drug to an "inpatient" whose status is later changed to outpatient by a third party or due to a hospital review; and

- An exception would be allowed "to prevent disruptions in patient care" if the hospital "cannot access a drug at the 340B price or at [WAC]," provided that the hospital documents the facts surrounding the purchase, provides HRSA with the name of the drug, and describes its attempts to purchase the drug at the 340B price and WAC before purchasing through a GPO.[33]

PhRMA is puzzled by the third proposed exception. As a practical matter, we do not understand how a drug could be unavailable at both the 340B price and WAC, yet somehow be available for purchase via a GPO. Perhaps, the exception is meant for when a hospital has GPO inventory on hand but no 340B or WAC priced product available for immediate patient use. In any case, we are unaware of any statutory provision that would permit such an exception. Accordingly, we recommend that HRSA not finalize this proposed exception and instead recognize that the statute makes compliance with the GPO prohibition a condition of eligibility for DSH, cancer, and children's hospitals. HRSA may not extend eligibility to hospitals that are ineligible to participate due to violating an applicable eligibility requirement, and should make this point clear.

The Proposed Guidance also states that a "large number of hospitals use replenishment models to operationalize the 340B Program," and refers to HRSA's 2013 guidance on the interaction between replenishment models and the GPO prohibition.[34] HRSA states that where a 340B hospital subject to the GPO prohibition uses a replenishment model and orders drugs based on actual prior usage, it may not "tally 340B-ineligible outpatient use for drug orders on a GPO account" (because this amounts to buying covered outpatient drugs via a GPO).[35] Under the Proposed Guidance, hospitals must maintain records demonstrating that replenishment models/split billing software are not being used "contrary to statute."[36]

As explained further in Section VI.B, a 340B drug should only be dispensed to an individual who is clearly identified -- at the point of sale -- as a "patient" of the 340B covered entity. We believe that the concepts of "re-characterizing" a drug dispensed to an individual not initially identified as a "patient," or "banking,"[37] are inappropriate and invite diversion. If HRSA

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33 80 Fed. Reg. at 52305.

34 80 Fed. Reg. at 52305 (referencing Policy Release No. 2013-1, "Statutory Prohibition on Group Purchasing Organization Participation" (Feb. 2013)).

35 80 Fed. Reg. at 52305.

36 80 Fed. Reg. at 52305.

37 80 Fed. Reg. at 52308.

were to permit re-characterization (which PhRMA opposes) then HRSA should: (1) establish a short and specified timeframe after which no re-characterization could take place; and (2) require that any covered entity wishing to re-characterize must first notify the manufacturer and provide the manufacturer with a fully transparent audit trail demonstrating that any units of drug the entity seeks to re-characterize as 340B drugs were not initially purchased under 340B, did not generate a Medicaid rebate, and were dispensed to a covered entity "patient" in the quarter for which the covered entity is seeking the 340B price.

D. Hospital Child Site Eligibility

1. Proposed Guidance and Background

The 340B law makes certain hospitals eligible for 340B participation. The statute describes these hospitals with great specificity. But the statute never mentions outpatient facilities associated with a 340B hospital. It was HRSA that decided that outpatient facilities of a 340B hospital may participate in 340B, and decided which outpatient facilities may participate. In 1994 guidance (which remains in effect), HRSA reasoned that certain off-site outpatient facilities could properly participate in 340B because

> Section 340B(a)(4)(L) describes a subset of "hospitals" as defined in section 1886(d)(1)(B) of the Social Security Act as eligible to participate in the program. Because section 1886 addresses Medicare payment for hospital inpatient services only, the scope of the term "hospital" has been limited to the hospital inpatient services. However, section 340B deals exclusively with outpatient drugs. Although Congress clearly intends this narrow definition be used to identify the Medicare disproportionate share hospitals which are eligible for section 340B drug discounts, we do not believe it is reasonable to use this same definition to limit where the section 340B outpatient drugs can be used. Some disproportionate share hospitals offer outpatient services in off-site or satellite outpatient facilities. Further, the movement of nonprofit hospitals in recent years has been to reorganize and offer a variety of services, other than traditional inpatient hospital services, through separate divisions, lines of business, or entities. Therefore, for purposes of section 340B drug discounts, a further interpretation of "hospital" is needed.[38]

The 1994 guidance further concluded that an outpatient facility of a 340B hospital may participate in 340B if it is an "integral part" of the hospital (as evidenced by the facility being "a reimbursable facility included on the hospital's Medicare cost report").[39]

Under the Proposed Guidance, an off-site outpatient facility would be eligible to participate in 340B if: (1) the site is listed on a line of the hospital's Medicare cost report that is

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[38] 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994) (emphasis added). This guidance only addressed DSH hospitals, because they were the only category of 340B-eligible hospital at that time. Outpatient facilities that are permitted to participate in 340B and registered with HRSA are now called "child sites."

[39] 59 Fed. Reg. at 47886.

reimbursable; and (2) the services provided at the site "have associated outpatient Medicare charges and costs."[40] The second requirement apparently means that the child site must provide at least some Medicare-reimbursed outpatient services. For outpatient facilities of children's hospitals, the Proposed Guidance would require that the registration demonstrate that the site: (1) is an integral part of the hospital; and (2) would be included on a reimbursable line on a Medicare cost report and have reimbursable charges and costs if a cost report were filed.[41]

Although HRSA currently uses the "cost report test" as a way to determine whether an outpatient facility is an "integral part" of the 340B hospital, the Proposed Guidance does not mention the underlying integral part standard (except with respect to children's hospital child sites). We recommend that HRSA provide that an off-site outpatient facility may not participate in 340B (even assuming it passes the cost report test) unless it is an integral part of a 340B hospital. While the cost report test may often be a good indicator that a facility is an integral part of the hospital, this will not always be the case. Moreover, Medicare's rules on when a facility may be listed as reimbursable on a hospital cost report are not fully transparent.[42]

Our understanding is that HRSA generally reviews relevant sections of the cost report to see if the outpatient site in question is included as reimbursable, but does so without looking behind the hospital's decision to treat a facility as reimbursable on the cost report, and thus without applying any substantive standards to this issue, which is problematic. Moreover, even determining whether a particular facility is included as reimbursable on the hospital's cost report is not always straightforward; for example, HRSA has previously said that it reviews additional documentation (beyond the cost report) "in cases where the name of the clinic is not the same as the [name on the] cost reporting listing"[43] -- thus raising questions about the transparency and objectivity of the cost report test, even apart from whether it is grounded in any substantive standards.

It is crucial that HRSA retain the "integral part" test and develop clear standards for its application. The requirements that a facility be listed as reimbursable on the hospital's cost report and have outpatient services paid by Medicare are necessary but not sufficient conditions for recognizing an outpatient facility as an integral part of a covered entity hospital. Unless a hospital outpatient facility is truly an integral part of the covered entity hospital, there is no statutory basis for treating the facility as 340B-eligible -- or for treating patients of that facility as patients of the covered entity hospital. We discuss the integral part standard and how it should be applied below.

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40 80 Fed. Reg. at 52302 (emphasis added).

41 80 Fed. Reg. at 52302.

42 However, Medicare regulations indicate that an outpatient facility must be provider-based in relation to the main hospital in order to be treated as reimbursable on the hospital's cost report. This is because (1) costs of servicing "free-standing" facilities must be eliminated from the allowable costs shown in the hospital's cost report, which "may be done by including the costs of the free-standing entity on the cost report as a non-reimbursable cost center" (42 C.F.R. § 413.24(d)(7)) and (2) a "free standing" facility is one that is "not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity" (the categories covered by the provider-based regulation) (42 C.F.R. § 413.65(a)(2)).

43 October 21, 2011 HRSA letter to Senator Charles Grassley responding to questions about the 340B program.

2. HRSA's "Integral Part" Guidance

HRSA's current guidance, published in a 1994 final notice, set out its policy on when outpatient facilities of a 340B hospital could participate in 340B. In explaining its reasoning, HRSA emphasized that the off-site facility should be well integrated with the hospital:

> When a [hospital] attempts to certify multiple components as a single hospital for purposes of Medicare certification, it must follow guidelines developed by HCFA [now CMS]. These guidelines (Provider Certification, State Operation Manual, section 2024) establish tests to determine whether an additional hospital facility, geographically separated but in the same metropolitan area, is a separate facility from or a component of a single hospital. These tests include: (a) all components subject to the control and direction of one common owner (i.e., governing body) which is responsible for the operational decisions of the entire hospital enterprise; (b) one chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all components; (c) integration of the organized medical staff (e.g., all medical staff members having privileges at all components); and (d) one chief executive officer through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of all components . . . .
>
> If the off-site clinic meets these tests, it would be included in the [hospital's] Medicare cost report. This test clearly determines whether a facility is an integral part of a . . . hospital, and is an appropriate standard to determine [340B] eligibility. It incorporates Medicare criteria that are not ambiguous and forms an independent and objective basis on which to determine eligibility.[44]

Based on this reasoning, HRSA adopted the following policy: "The outpatient facility is considered an integral part of the 'hospital' and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report."[45]

3. Medicare's "Provider-Based" Regulation

As noted above, HRSA's 1994 guidance on hospital outpatient facilities referenced guidance from § 2024 of the Centers for Medicare & Medicaid's (CMS') State Operations Manual. As described by HRSA, this manual provision only permitted an outpatient facility to be treated as part of a hospital if certain tests were met regarding integration of the outpatient facility and the hospital.[46] CMS revised this manual provision at some point after 1994, and it no

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[44] 59 Fed. Reg. at 47885 (emphasis added).

[45] 59 Fed. Reg. at 47886.

[46] HRSA described these tests as follows: "(a) all components [of the hospital] subject to the control and direction of one common owner (i.e., governing body) which is responsible for the operational decisions of the entire hospital

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longer lists specific criteria for outpatient facilities to be certified as part of a single hospital, but does provide that "where two or more previously separate hospitals merge, all locations of the surviving hospital must meet the criteria found in [State Operations Manual] § 2004" and "all non-hospital providers . . . that state they are part of a single hospital must meet the criteria for provider-based designation in § 2004 in order to be treated as a single hospital for payment purposes."[47] In turn, section 2004 refers to the provider-based rules at 42 C.F.R. § 413.65.[48] Thus, the State Operations Manual provision HRSA cited in its 1994 guidance now leads to 42 C.F.R. § 413.65, Medicare's provider-based regulation.

The provider-based regulation, promulgated after HRSA's 1994 guidance, is designed to determine whether a particular facility is "a subordinate and integrated part of the main provider"[49] (generally a hospital), and thus may bill Medicare as a part of the hospital.[50] As CMS has explained, the provider-based regulation "provides a high level of assurance that a facility complying with [the regulation] is, in fact, an integral and subordinate part of [the main provider] and does not accord provider-based status to facilities that . . . have only a nominal relationship with [the main] provider."[51]

The requirements for "provider-based" status generally parallel the types of integration requirements cited in HRSA's 1994 guidance. While these requirements vary to some extent for different types of facilities (e.g., off-campus facilities must satisfy additional requirements not applicable to facilities on the hospital campus), the provider-based regulation includes requirements on (among other things) common licensure of the hospital and the facility; integration of clinical services performed by the hospital's and the facility; financial integration of the hospital and facility; common ownership and control of the hospital and facility; common administration and supervision of the hospital and facility; and public awareness that the facility is part of the hospital.[52] HRSA proposed in 2007 to use the provider-based regulation to decide

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enterprise; (b) one chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all components; (c) integration of the organized medical staff (e.g., all medical staff members having privileges at all components); and (d) one chief executive officer through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of all components." 59 Fed. Reg. at 47885.

47 CMS, State Operations Manual § 2024.

48 CMS, State Operations Manual § 2004 (emphasis added).

49 CMS Program Memorandum A-03-030 (Apr. 18, 2003).

50 A "provider-based entity" means "a provider of health care services . . . that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section." 42 C.F.R. § 413.65(a)(2).

51 67 Fed. Reg. 49981, 50088 (Aug. 1, 2002).

52 42 C.F.R. § 413.65(b)(3)(ii). Currently, a hospital is not required to obtain CMS' approval to treat a particular entity as provider-based, but it may do so at its option by submitting to CMS a form attesting that the facility in question meets the relevant tests for provider-based status. CMS determines whether the facility is provider-based in relation to the hospital after the hospital submits a completed form attesting to the facility's compliance with the applicable provider-based criteria and (for an off-campus facility) supplies "documentation of the basis for its attestations."

whether an outpatient facility of a covered entity hospital could participate in 340B, explaining that:

> In order for an outpatient facility of a DSH to be eligible for the 340B program, it must be demonstrated that the outpatient facility is an integral part of the DSH. . . . HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 CFR 413.65 is appropriate for facilities eligible under the 340B Program. Compliance with the rule for provider-based facilities would provide clear guidance to DSHs that wish to prescribe 340B drugs to patients at these outpatient facilities and ensure that the individuals are truly patients of the DSH.[53]

4. Summary of PhRMA Recommendations Regarding "Child Site" Status for Hospital Outpatient Facilities

As discussed earlier, the 340B statute makes certain hospitals 340B-eligible, but does not provide that any of their associated outpatient facilities are 340B-eligible, or even mention 340B hospitals' outpatient facilities. It was HRSA that decided that certain outpatient facilities of a 340B hospital could share the hospital's 340B status. Originally, 340B eligibility criteria, was based upon a formula that reflected the activity at the (parent) hospital in terms of the needier patients that the hospital served. Yet, HRSA has failed to set up any guardrails on outpatient expansion. To make HRSA's outpatient facilities approach defensible, however, any off-site outpatient facility that is treated as a part of the hospital for 340B purposes must be a genuinely well-integrated part of the hospital, which shares the characteristics of the hospital that make it 340B-eligible.

To provide a defensible basis for allowing an off-site hospital facility that is not described in the 340B law to participate in the 340B program, HRSA should establish several criteria. First, HRSA should reaffirm its substantive "integral part" concept, but with strengthened standards that would provide greater clarity for stakeholders and assure alignment with the text and purpose of the 340B law. In its final guidance, HRSA should therefore specify that to be "an integral part" of a covered entity hospital, an outpatient facility must: (1) meet the provider-based standards in 42 C.F.R. § 413.465;[54] (2) be wholly owned by the hospital; and (3) be listed

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[53] 72 Fed. Reg. 1543, 1545, (Jan. 12, 2007) (emphasis added).

[54] HRSA states in the Proposed Guidance that is has previously explored the use of 42 C.F.R. § 413.65, but many hospitals choose not to seek provider-based designation for outpatient facilities "even though these facilities may qualify" and it has had "difficulty in verifying whether outpatient facilities and clinics meet provider-based standards." 80 Fed. Reg. at 52302. However, if HRSA wants to avoid difficulties in verifying provider-based status, HRSA could require that hospitals get provider-based determinations approved by CMS -- which is an option under the provider-based regulation if a hospital wishes to be certain that a particular facility qualifies as provider-based; this would also provide a simple mechanism for testing whether hospital facilities that assertedly qualify as provider-based actually do.

Moreover, HRSA's reference to past comments on the use of the provider-based regulation likely refers to the March 13, 2007 letter of 340B Health (then called Safety Net Hospitals for Pharmaceutical Access (SNHPA)). This letter brazenly complained that facilities that assertedly "may meet the eight regulatory standards [for provider-based status]" but that CMS does not designate as provider-based facilities include "ambulatory surgical centers, home health agencies, ESRD facilities, and skilled nursing facilities." SNHPA March 13, 2007 letter to HRSA, "Comment on

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as reimbursable on the hospital's Medicare cost report and have Medicare outpatient charges.[55] We also recommend a more stringent review of the cost report. Specifically, HRSA should confirm that there are outpatient claims on the report for service dates within the most recent 12 month period. In addition, HRSA should require that the actual name of the child site appears on the cost report listing -- not a different name, or just a bundled dollar figure representing multiple clinics. There should be no "piecing together" of various external documents needed to confirm the identity of the child site.

PhRMA is deeply concerned about the explosive growth in hospital "child sites" generally, and in particular about 340B hospital-acquired physician practices that are treated as 340B-eligible "hospital outpatient departments" following the acquisition. There is no public policy reason or statutory basis for these new children to be partaking of 340B benefits when they are distinct from the safety net "parent" and (consistent with the fact that they are not an integral part of the parent) serve a different demographic than a true safety net facility. This trend is extending the 340B program -- a drug discount program intended for safety net facilities that serve the uninsured and vulnerable --much deeper into our healthcare system than Congress intended and the law permits, while taking the program further and further from its mission.

This problem helps to highlight the importance of HRSA requiring that "child sites" of 340B hospitals must meet the provider-based standards in 42 C.F.R. § 413.65. The provider-based regulation has a special provision with particular relevance to free-standing physician practices that are acquired by a hospital, which provides that: "A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility [i.e., not a provider-based facility], unless CMS determines the facility has provider-based status."[56] This provision indicates that an acquired physician practice (assuming it is not located on the hospital campus) could not qualify as a provider-based entity unless the hospital went through the attestation process and obtained a CMS determination that the practice qualified as provider-based in relation to the hospital -- which would require that the practice actually be a well-integrated part of the main hospital, as indicated by specific tests set out in the regulation. In light of the growing (and often inappropriate) expansion of the 340B program to these hospital acquired physician practices, it is more important than ever to apply the provider-based rule as a safeguard in this context. PhRMA urges HRSA to do so.

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Proposed Guidelines on 340B Patient Definition (Published in 72 Fed. 1543, 1546 (January 12, 2007))," at 16, 17 (emphasis added). Congress plainly did not make ASCs, home health agencies, ESRD facilities, or nursing facilities eligible to participate in the 340B program. Consequently, it should not be necessary to take any special measures to keep these various facilities out of the program -- they are just not hospitals of any sort, child or otherwise. If requiring that hospital "child sites" have provider-based status helps to keep these facilities out of this program for which they are ineligible, however, then this is more evidence about how critically importance it is for HRSA to institute this reform.

[55] PhRMA understands that there may be some hospitals that do not serve Medicare patients. We think that it would be appropriate for HRSA not to apply the requirement that there be Medicare outpatient charges in these limited instances.

[56] 42 C.F.R. § 413.65(b)(4) (emphasis added).

We also recommend that a child site must: (1) provide the full range of outpatient health care services (not just drugs or drug administration services); (2) adhere to the parent hospital's charity care policy; and (3) adhere to the sliding scale fee schedule (if any) of the parent hospital for providing covered outpatient drugs to low-income patients who do not have minimum essential coverage (as defined in section 5000A(f) of the Internal Revenue Code). Further, HRSA should require the 340B hospital to demonstrate, when seeking to register a would-be child site, that the site serves similar patient mix as the parent (i.e., the hospital should demonstrate that the child site serves a patient population with a mix of low-income and uninsured patients similar to that of the parent hospital's outpatient and emergency departments).

To implement this policy, HRSA should develop a methodology, with stakeholder input, to determine whether a hospital outpatient facility has a similar percentage of low-income patients as the parent hospital.[57] As it will take some time to develop such methodology (in addition to refining any documentation requirements to be applied to the remainder of the child site criteria), it would be appropriate and sensible for HRSA to put a temporary moratorium on enrollment of new child sites for nonprofit private hospitals as it considers this issue. Such a moratorium is critically important because recent research suggests that hospital child sites increasingly are located in areas serving patient populations that are more affluent than the parent hospital's patient population, and that the 340B statute was never intended to assist.[58] "Compared to 340B DSH hospitals," this study reports, their child sites "served communities with lower poverty rates and higher mean and median income levels than their 340B DSH parents did," thus "suggesting that the expansion among DSH hospitals run counter to the program's original intention."[59] Given that the 340B law does not even refer to off-site outpatient facilities being 340B-eligible in the first instance, there clearly is no justification for admitting those facilities to the 340B program if they are not even integral parts of 340B hospitals that share the characteristics making the parent 340B-eligible by serving a disproportionate share of the uninsured, or underinsured and indigent patient population.

III. THE "COVERED OUTPATIENT DRUG" DEFINITION

The 340B law applies to "covered outpatient drugs," and defines this term by reference to Social Security Act § 1927(k).[60] Social Security Act § 1927(k)(3), the limiting definition, excludes from the definition of covered outpatient drugs a drug that is "provided as part of or as incident to and in the same setting as [specified services, including hospital inpatient and outpatient services]" and "for which payment may be made under this title [Social Security Act title XIX, the Medicaid statute] as part of payment for [the specified services] and not as direct

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[57] The DSH metric is not available to evaluate whether an outpatient facility serves a patient mix similar to the parent as it is based solely on inpatient days; therefore HRSA would need to evaluate different candidate measures that could be used to assess whether an outpatient facility serves low-income patients (or perhaps low-income Medicare and Medicaid patients specifically) to the same extent as the covered entity hospital.

[58] Rena M. Conti and Peter B. Bach, The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities, *Health Affairs*, 33 no. 10 (2014): 1786-1792.

[59] Conti and Bach, The 340B Drug Discount Program; Hospital Generate Profits By Expanding to Reach More Affluent Communities, supra, at 1790.

[60] 42 U.S.C. § 256b(b)(1).

reimbursement for the drug."[61] In the Proposed Guidance, HRSA repeats its 1994 guidance stating that:

> in the settings identified in the limiting definition, "if a covered drug is included in the *per diem* rate (i.e., bundled with other payments in an all-inclusive, a per visit, or an encounter rate), it will not be included in the [340B Program]. However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program."[62]

This longstanding guidance is consistent with the covered outpatient drug definition in Social Security Act § 1927(k), and thus consistent with the 340B law.[63]

HRSA's Proposed Guidance, however, would then broaden what would be considered a "covered outpatient drug" under the 340B program by interpreting the limiting definition in such a way that it would only apply to a drug provided as part of the services listed in the statute when Medicaid pays for the drug via a bundled payment and Medicaid actually is the payor in that instance. Specifically, HRSA states that: "[A] drug provided as part of a hospital outpatient service which is billed to any other third party or directly billed to Medicaid would still qualify as a covered outpatient drug."[64] This statement -- which apparently would make any drug a "covered outpatient drug" whenever it is not reimbursed by Medicaid (or when it is reimbursed by Medicaid, but not in one of the specified settings or not in a bundled payment) -- is inconsistent with the language in Social Security Act § 1927(k)(3) referring to a drug provided in specified settings for which payment "may be made under [Medicaid]" as part of a bundled payment."[65] Under HRSA's proposed interpretation, for example, a drug provided to an inpatient who is covered by Medicare would be considered a "covered outpatient drug." This cannot be reconciled with the covered outpatient drug definition in Social Security Act § 1927(k), which is expressly incorporated by the 340B law.[66]

HRSA must return to the description of "covered outpatient drug" articulated in its 1994 guidance, which conforms to the statute. The statutory definition also avoids unworkable consequences that would flow from the definition in the Proposed Guidance. For example, HRSA's proposed definition of "covered outpatient drug" could extend the GPO prohibition (providing that, as a condition of 340B eligibility, certain hospitals not obtain "covered outpatient drugs" through a group purchasing arrangement)[67] to virtually any drug, since the prohibition applies to "covered outpatient drugs" and at the time of purchase any drug could end up being reimbursed by a payor other than Medicaid and could thus be a "covered outpatient drug" under the proposal. In addition, the proposed definition implies that a drug's status as a "covered

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61 Social Security Act § 1927(k)(3).

62 80 Fed. Reg.at 52306 (quoting 59 Fed. Reg. 25510, 25513 (May 13, 1994).

63 42 U.S.C. § 256b(b)(2).

64 80 Fed. Reg.at 52306 (emphasis added).

65 Emphasis added.

66 42 U.S.C. § 256b(b)(1).

67 42 U.S.C. § 256b(b)(4)(L)(iii).

outpatient drug" could vary from State to State and unit to unit depending partly on whether -- in any particular case -- the drug was reimbursed by a State Medicaid program via a bundled payment; a drug's "covered outpatient drug" status could thus vary among and even within States (e.g., a State Medicaid program might have different payment methodologies for the drug in different settings specified in § 1927(k)(3), or a State's fee-for-service Medicaid program might have a different payment methodology for the drug than one of its Medicaid MCOs).

IV. INDIVIDUALS ELIGIBLE TO RECEIVE 340B DRUGS

A. The Six Proposed Elements of the 340B "Patient" Definition

The 340B law prohibits covered entities from reselling or otherwise transferring drugs purchased under the 340B program to anyone but a "patient" of the covered entity.[68] Thus, a clear definition of "patient" is critical to the integrity of the 340B program. However, throughout the history of the program, there has been great confusion as to when an individual qualifies as a "patient" of a covered entity; as a result, the GAO stated in 2011 that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity" and "[a]s a result of the lack of specificity in the guidance, [HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity."[69] In addition, the OIG observed in a report focused on contract pharmacy arrangements:

> Covered entities . : . reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements. Covered entities appear to have differing interpretations of what HRSA guidance requires . . . there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.[70]

The "patient" provisions in the Proposed Guidance, if finalized, would make important strides in clarifying the patient definition and resolving many of the inconsistencies in the way stakeholders have interpreted this key term. We appreciate HRSA's efforts to spell out the elements of the patient definition, which are essential to improving program integrity. However, we recognize that there may be some instances where the proposed patient definition could unintentionally hinder grantees' ability to provide services within their scope of grant.[71] In our

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68 42 U.S.C. § 256b(a)(5)(B).

69 "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" at 23. GAO-11-836. Sept. 2011.

70 OIG, Contract Pharmacy Arrangements in the 340B Program, OIE-05-13-00431 at 16. Feb. 2014.

71 For example, state Sexually Transmitted Disease (STD) and Tuberculosis (TB) programs provide necessary public health medications purchased under the 340B program to patients who have not received a prescription from a provider associated with the STD/TB program. It is our understanding based on meeting with grantees that when

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comments we tried to identify sections of the guidance that could unintentionally frustrate grantees' ability to carry out their mission effectively, and to craft recommended refinements to avoid these problems. But we recognize that additional flexibility may be necessary, as it has been difficult to identify and evaluate all the consequences -- intended and unintended, for a variety of covered entity types with different missions and ways of operating -- in the 60 day comment period allotted. We urge HRSA to work with all stakeholders through a public and transparent process to ensure the new patient definition adopted in its final guidance is carefully crafted to promote clarity and program integrity, and to avoid unnecessary rigidities that might impede the ability of grantees and safety net hospitals to advance 340B program goals.

HRSA would interpret a "patient" of a covered entity "on a prescription-by-prescription or order-by-order basis," such that six requirements would have to be met for an individual to be a "patient" of a covered entity in the context of a particular prescription or order.[72] Below we provide our comments on each of the six proposed criteria, in turn, and on HRSA's remarks explaining each criteria.

1. *"The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database."*[73]

PhRMA supports this criterion, as it establishes a critical link between the individual receiving the services and the covered entity site. This criterion makes clear that an individual who receives services from a covered entity provider, but not at a site listed on the 340B database for the covered entity, "even as follow-up to care at a registered site,"[74] would not be considered a patient.

The Proposed Guidance also specifies that an individual receiving care from an organization with an "affiliation arrangement" with a covered entity is not a patient of the covered entity.[75] This principle is similar to HRSA's 2012 guidance clarifying that just because a person receives care from one organization in an Accountable Care Organization (ACO) that includes a covered entity does not mean that the individual is a patient of the covered entity,[76] and presumably also would apply in the ACO context. To remove any ambiguity or need to consult earlier guidance on a closely related point, however, we recommend that HRSA restate its previous ACO guidance in the final version of the omnibus guidance.

Finally, we recommend that HRSA specify explicitly that a visit by an individual to a contract pharmacy of a covered entity neither establishes nor refreshes a "patient" relationship between an individual and a covered entity. This is implicit in HRSA's statement that the

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STD/TB programs provide necessary treatment to patients diagnosed by a private provider, the STD/TB programs pay for the entire cost of the medication purchased at the 340B price. HRSA should focus on these groups as two of the types of entities that target the populations the 340B program was intended to serve.

72 80 Fed. Reg. at 52306.

73 80 Fed. Reg. at 52306.

74 80 Fed. Reg. at 52306.

75 80 Fed. Reg. at 52306.

76 340B Drug Pricing Program Notice Release No. 2012-2 "Clarification of Covered Entity Eligibility Within Accountable Care Organizations." (May 23, 2012.)

individual must receive care at a registered "facility or clinic site" (as well as the principle that merely dispensing a drug does not create a patient" relationship), but to promote clarity HRSA should spell out this point.

2. *"The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider."*[77]

PhRMA strongly supports this proposal. It eliminates language in the 1996 patient definition treating a patient of a provider under "contractual or other arrangements" with a covered entity as a patient of the covered entity. This loose "other arrangements" language has been a long-standing concern due to the potential for abuse it creates. For example, HRSA observed in its 2007 proposed patient clarification:

> Some [hospitals] have been contracting with health care providers to create a loose affiliation model for outpatient health care services. . . . . The individuals enrolled in these programs are treated by health care providers too loosely affiliated with the covered entity for the ongoing responsibility to rest with the covered entity for the patient's health care resulting in the use of . . . 340B drugs. This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits.[78]

The GAO also reported on HRSA's concern that the "other arrangements" language in the patient definition was so vague, stating that:

> HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However, HRSA does not define "other arrangements," and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity . . . does not actually have the responsibility for care.[79]

Covered entities are institutions (e.g., hospitals or clinics) that can only provide care and establish "patient" relationships through individual healthcare professionals who act on behalf of the entity. Only a healthcare professional who is either an employee or an independent

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77 80 Fed. Reg. at 52306.

78 72 Fed. Reg. at 1546-47 (emphasis added).

79 GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvements, supra, at 23.

contractor that works at the covered entity facility and assigns the right to bill and collect payment for his or services to the covered entity can treat a patient on behalf of the covered entity. An employee or independent contractor works under the supervision of the covered entity and the covered entity is responsible for the care provided to the patient -- including the quality of care. To emphasize this point, we recommend that HRSA specify in the final guidance that an independent contractor must be acting on behalf of the covered entity such that the entity would be accountable for the care provided by the independent contractor.

We agree with HRSA that "[s]imply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B Program purposes,"[80] and appreciate HRSA's examples of covered entity-provider relationships that qualify as independent contractor relationships (i.e., faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs).[81] We also recommend that HRSA state explicitly in its final guidance that the first element of the definition always applies (i.e., the covered entity employee or independent contractor must provide the care at a registered covered entity site listed on the public 340B database), because each one of the six elements of the patient definition must be satisfied. Further, we support HRSA's clarification that a prescription from a provider at a non-covered entity to which a patient is referred by a covered entity is not eligible for a 340B discount.[82]

PhRMA supports HRSA's statement that "[p]rescriptions that result from referrals to non-340B providers are not 340B-eligible," but that "when the patient returns to the covered entity for ongoing medical care, subsequent prescriptions written by the covered entity's providers may be eligible for 340B discounts."[83] While individuals may receive care from several entities, for an individual to be considered a patient of a covered entity with respect to a particular prescription, a covered entity provider should write the prescription.

However, we also recognize that special circumstances may be presented in a case where an entity is 340B-eligible by virtue of a HRSA grant that requires it to operate a medical home model of care or otherwise to coordinate the care of certain patient populations. In those cases, ensuring that the patients served by the grantee entity are referred to other providers as appropriate and closely coordinating with those providers are central to the grantee entity's ability to fulfill its grant obligations. Creating a 340B-related financial disincentive for making referrals may be problematic for such entities and could compromise their ability to fulfill their mission to make medical care accessible to their patients as well as requirements of their grants. Consequently, we consider that it would be appropriate for HRSA to recognize a limited exception to the ordinary referral principle for such grantee entities, permitting them to fill prescriptions with 340B drugs that are written by providers to whom the grantee referred its patient for medical services or treatment. In crafting this exception, HRSA should take care to ensure that its standards for such qualifying referrals are clear and auditable and that it does not result in two covered entities claiming 340B discounts on the same prescription.

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80 80 Fed. Reg. at 52306.

81 80 Fed. Reg. at 52306.

82 80 Fed. Reg. at 52306-52307.

83 80 Fed. Reg. at 52306-52307.

3. *"An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2)."*[84]

PhRMA supports this element of the "patient" definition. Coupled with the overarching "prescription-by-prescription or order-by-order" requirement, this element helps to ensure that the proper nexus exists between the service that was provided to an individual and a drug resulting from the service that generates a 340B discount. PhRMA supports this interpretation, and recommends confirming in the final guidance that a covered entity cannot provide one type of care to a person and dispense or administer a 340B drug to the person for something unrelated (e.g., provide dental services to an individual and dispense an antidepressant). We suggest HRSA specify that the 340B prescription must be directly related either to the individual's primary diagnosis or a comorbidity of that diagnosis. Such a requirement is reasonable, easily operationalized, and auditable.

The Proposed Guidance also clarifies that a patient relationship cannot be established merely by the dispensing or the infusion of a drug.[85] This is an important clarification that HRSA should finalize. Because HRSA adds that dispensing or infusion alone "without a covered entity patient-to-provider encounter" does not establish a patient relationship, HRSA also should specify that infusion of drug is not considered a "covered entity patient-to-provider encounter."

4. *"The individual's health care is consistent with the scope of the Federal grant, project, designation, or contract."*[86]

PhRMA supports this element, however, we ask that HRSA provide greater clarity regarding exactly what would constitute health care "consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract."[87] HRSA would limit this principle to grantees. HRSA does not propose to apply this approach -- where a "patient" must be an individual who receives services from a covered entity consistent with the reason why the entity is 340B-eligible -- to hospitals. Yet it should. For example, HRSA should specify that where a private nonprofit hospital is 340B-eligible because it has a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid, a "patient" of the hospital must receive services under that contract. Likewise, for a private nonprofit hospital that is 340B-eligible because it has been formally granted governmental powers, a "patient" of the hospital should be an individual who receives healthcare services furnished by the hospital in connection with its governmental powers.

Requiring that a "patient" of a covered entity hospital receive the services for which Congress made the hospital 340B eligible would promote the purposes of the 340B law (which was intended to allow participation by a private nonprofit hospital that contracts to care for "low-income individuals who are not eligible for Medicaid or Medicare," but not by a private nonprofit hospital with "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues")[88] and would make the "patient" definition more symmetrical as

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84 80 Fed. Reg. at 52307.

85 80 Fed. Reg. at 52307.

86 80 Fed. Reg. at 52307.

87 80 Fed. Reg. at 52307.

88 H.R. Rep. 102-384 (II) (1992), 12.

between grantees and hospitals. HRSA has not even sought to explain why it would apply this principle to grantees but not hospitals, and we see absolutely no rational basis for this disparate treatment of covered entity grantees and hospitals. Accordingly, HRSA should specify in the final guidance that a "patient" of a private hospital that is 340B-eligible by virtue of having a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid must receive care under that contract.

5. *"The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient."*[89]

In the Proposed Guidance, HRSA recognizes that because the 340B law creates an "outpatient" drug discount program, an individual can only be considered a patient of a 340B entity if his or her healthcare is billed as outpatient to the patient's payor, or (for self-pay patients) classified as outpatient under the covered entity's "documented auditable policies and procedures."[90] PhRMA agrees with HRSA and supports this proposed standard. HRSA should also clarify that for insured patients, the service provided to the individual must be billed and paid for as an outpatient service.

We note that this element of the patient definition would preclude filling "discharge prescriptions" with 340B drugs, and we support that result. HRSA should note this specifically in the final guidance. In addition, HRSA should state specifically in the final guidance that "discharge prescriptions" do not include prescriptions filled by non-hospital (grantee) covered entities that are responsible for managing the care of the individual both before hospital admission and after discharge.

6. *"The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care."*[91]

Under HRSA's Proposed Guidance, to be considered a patient of a covered entity, an individual must have an "established relationship such that the covered entity maintains auditable health care records" demonstrating that all elements of the "patient" definition are satisfied, including the covered entity's retention of responsibility for the individual's healthcare.[92] The records must show that "all of the [patient] criteria above were met for every prescription or order resulting in a 340B drug being dispensed or accumulated through a replenishment model."[93] PhRMA supports this concept, but believes that further specificity would be useful.

First, we urge HRSA to make clear in the final guidance that the records of a "patient" must not only be "accessible" to the covered entity, but must be maintained, owned, controlled, and possessed by the covered entity. This would mean that the records are either physically stored or immediately accessible.

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89 80 Fed. Reg. at 52307.

90 80 Fed. Reg. at 52307.

91 80 Fed. Reg. at 52307.

92 80 Fed. Reg. at 52307.

93 80 Fed. Reg. at 52307.

Second, we recommend HRSA specify that the provider/patient relationship must be "ongoing." HRSA's 2007 proposed clarification provided that the covered entity must have "ongoing responsibility" for "the outpatient health care service that results in the use of (or prescription for) 340B drugs," and that "[t]o demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the [340B hospital] or the qualified provider-based facility of the [hospital] within 12 months after the time of the referral."[94] This 12-month standard is reasonable and appropriate. Thus, we recommend that HRSA specify in its final guidance that the 340B provider/patient relationship may begin with an individual's first visit to a covered entity (provided all other elements of the patient definition are met), but that this relationship will end if the individual does not visit the covered entity within 12 months following the visit that resulted in the 340B prescription. Therefore, a prescription filled with a 340B drug could not be refilled with a 340B drug 13 months later if the individual has not gone back for a visit to the covered entity in the intervening period.

B. Covered Entity Employees

HRSA's Proposed Guidance states that covered entity employees are not considered "patients" unless all elements of the patient definition are met.[95] PhRMA supports this clear principle conforming to the 340B law. We also agree with HRSA that this principle has always been laid out in HRSA's guidance.

C. AIDS Drug Assistance Programs (ADAPs)

PhRMA agrees with HRSA's proposal to reaffirm its longstanding position that "an individual enrolled in a Ryan White HIV/AIDS Program AIDS Drug Assistance Program funded by Title XXVI of the PHSA will be considered a patient of the covered entity for purposes of this definition."[96]

D. Telemedicine

The Proposed Guidance states that "the use of telemedicine involving the issuance of a prescription by a covered entity provider is permitted, as long as the practice is authorized under State or Federal law and the drug purchase otherwise complies with the 340B Program."[97] To put this issue in some context, "telemedicine" has many definitions but generally involves "the use of electronic information and communication technologies to provide and support health care when distance separates participants."[98] HRSA defines "telehealth" (which is sometimes

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94 72 Fed. Reg. at 1543, 1544 (Jan. 12, 2007).

95 80 Fed. Reg. at 52307.

96 80 Fed. Reg. at 52307.

97 80 Fed. Reg. at 52306.

98 A Guide to Assessing Telecommunications in Health Care, Institute of Medicine (now named the National Academy of Medicine) Committee on Evaluating Clinical Applications of Health Care, 1996. See also, e.g., Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, Federation of State Medical Boards (FSMB) (April 2014), adopting the American Medical Association's definition of "Telemedicine" as "the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare

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used interchangeably with telemedicine) as "the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration."[99] As explained recently by the Agency for Healthcare Research and Quality, telehealth "encompasses several technologies that have been applied to a wide range of health conditions, populations, and settings," which "makes it challenging to quickly and easily monitor the body of evidence as the technology and the evidence base is rapidly expanding."[100] These technologies include real-time interactive audiovisual technologies, store-and-forward technologies that transmit information not in real time, remote patient monitoring, and mobile health services.

PhRMA supports telemedicine services, as they can play an important role in improving individuals' access to needed care that otherwise may not be available. Further, in many instances, telemedicine offers the potential to reduce healthcare costs and to reduce individuals' travel costs and increase their satisfaction with care.

We agree with HRSA that telemedicine services must be provided in compliance with all applicable State and Federal laws and (in the 340B context) all 340B program requirements. However, it is important to be mindful that 340B prescriptions often involve a heightened financial incentive that is not present in other telemedicine encounters, which potentially could encourage the use of telemedicine in circumstances where it does not benefit patient care. For example, recent GAO work suggests that 340B hospitals prescribe many more drugs to Medicare beneficiaries than comparable non-340B hospitals, raising questions about whether financial incentives for 340B prescribing adversely affects patients' quality of care.[101] To reduce the possibility for abuse, HRSA should remind covered entities to pay careful attention both to 340B program requirements and to applicable legal requirements imposed by other Federal laws and by State laws (including Federal and State privacy laws). For example, any prescribing of medications to an individual by a physician located at a distant site (or any dispensing by an out-of-state pharmacy) would implicate State laws, which vary significantly.[102] Should HRSA address telemedicine in its final guidance, safeguards to protect and promote the quality of care also would be important. For example, the American College of Physicians (ACP), in a new position paper with a series of thoughtful recommendations on telemedicine,

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delivery by replicating the interaction of a traditional, encounter in person between a provider and a patient." American Medical Association, Council on Ethical and Judicial Affairs, Fundamental Elements of the Patient-Physician Relationship (1990).

99 HRSA Glossary and Acronyms, http://www.hrsa.gov/ruralhealth/about/telehealth/glossary.html#t

100 AHRQ, Evidence-Based Practice Center Technical Brief Protocol, Project Title: Telehealth Evidence Map, www.effectivehealthcare.ahrq.gov (Aug. 11, 2015).

101 GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 5, 2015).

102 See e.g., American Medical Association, Telemedicine: Is Prescription Writing Allowed? (providing in part that "While the AMA supports the practice [of prescribing using telemedicine], it is essential that a physician-patient relationship exists. The issues that arise are when does that relationship develop, can that relationship be established through remote interaction alone (i.e., in the absence of any physical encounters), and if a relationship exists is it permissible for the physician to issue prescriptions. The second question is where States differ the most"). http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/telemedicine.page.

emphasizes that telemedicine has both the promise to improve access to care and potential drawbacks.[103] The ACP notes, for example, that

> [Telemedicine] presents several challenges to maintaining continuity of care and a strong patient-physician relationship. . . . Several variable factors (such as the medical history provided to the consulting physician by the patient, ability of the consulting physician to access the patient's electronic health record, or even technology failure) may increase the likelihood that the [telemedicine] visit may become an orphan event in the medical history, leaving the patient's physician or health care team without knowledge of the visit, prescriptions that may have been written, or recommendations. In addition, not being able to do a physical examination hinders certain therapeutic elements associated with touch or interpersonal communication and raises concerns about the accuracy of diagnoses when the physician cannot touch the patient to, for example, detect tenderness or swollen glands.[104]

While telemedicine can "potentially be a beneficial and important part of the future of health care delivery," ACP concludes, it is "also important . . . to balance the benefits of telemedicine against the risks for patients."[105] We support this approach of balancing telemedicine benefits against risks. Accordingly, it is important to consider the key benefits of telemedicine. Then HRSA-Administrator Mary Wakefield explained those benefits well at a 2012 Institute of Medicine conference on telemedicine:

> Telehealth is a key component in ensuring access to health care services in isolated geographic areas across the United States. More effective deployment of telehealth technologies will enhance our ability to better serve the health care needs of those in rural and frontier parts of the country. However, telehealth is important not just for rural communities, but for the underserved community.[106]

As Administrator Wakefield also noted, HRSA's grantees serve the "underserved and vulnerable populations."[107] Therefore, given both the unanswered questions about telemedicine and the urgency of improving access to care for the underserved and vulnerable, HRSA should focus on creating a carefully-crafted opening for grantees to develop a 340B "potential"

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[103] Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper, Ann. Intern Med. doi:10.7326/MIS-0498 (2015).

[104] ACP Position Paper on Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings, supra (footnotes omitted) (emphasis added).

[105] ACP Position Paper on Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings, supra.

[106] Institute of Medicine (now the National Academy of Medicine), The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary (2012) (emphasis added).

[107] Institute of Medicine, The Role of Telehealth in an Evolving Health Care Environment, supra.

relationship via real-time audiovisual encounters if key safeguards and applicable State and Federal laws were complied with.[108]

As part of these safeguards, it would be critical for HRSA to specify that to be considered a "patient" of a covered entity an individual must be seen initially at a registered facility of the covered entity for an in-person visit. This minimum safeguard serves two important purposes. First, it helps to reduce the visits highlighted by ACP of prescribing for an individual without a physical examination, which raises concerns about the accuracy of diagnoses. Second, the face-to-face encounter at the entity's registered site provides important evidence of a legitimate physician-to-patient relationship. This latter issue is important in light of the heightened financial incentives (as noted above) that exist in the 340B context. Without the assurance that an individual who receives telemedicine services from a 340B grantee has had a face-to-face encounter with a covered entity provider, allowing a telemedicine encounter to generate a 340B prescription could invite abuse and put individuals at risk of receiving sub-standard or unnecessary care. We believe that HRSA should also require that, to renew a patient relationship, a face-to-face visit should occur at least every 12 months.

If HRSA decided to craft criteria in its final guidance whereby grantees could use appropriate telemedicine encounters to develop a 340B "patient" relationship in specified circumstances, HRSA should specify clearly: (1) how "telemedicine" was defined for this purpose;[109] (2) what safeguards (apart from satisfying the usual elements of the "patient" definition, and the requirements for an initial and annual face-to-face visit discussed above) would need to be satisfied to protect the quality of care,[110] and what documentation a grantee would be required to maintain in order to show that each one of those safeguards were followed; and (3) what procedures a grantee would need to follow to (a) determine and document the State and Federal laws that applied to the encounter (and any resulting prescription) and the specific requirements of these laws, and (b) document the fact that all applicable requirements had been followed. Without these basic due diligence and documentation practices, it would not be possible to verify whether a particular telemedicine encounter by a grantee could properly be used to develop a 340B "patient" relationship and thus to test for compliance with these aspects of the "patient" definition.

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[108] HRSA also should encourage all covered entities to use telemedicine modalities as an important adjunct to the care provided under a physician-patient relationship built on traditional face-to-face visits between the physician and patient. Telemedicine can have a key role in expanding the information that can be analyzed and the interactions that can occur in those relationships, such as enabling remote monitoring of patients with chronic conditions.

[109] We note that at one point the Proposed Guidance states that "the use of telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) is permitted, as long as the practice is authorized under State or Federal law and otherwise complies with the 340B Program." 80 Fed. Reg. at 52307 (emphasis added). Certainly many practices are permitted if they comply with all applicable 340B program requirements and State and Federal laws; however, HRSA should make clear in its final guidance that such a broad and vaguely-described group of practices (including "other health care arrangements") may not be used by any covered entity (including a grantee) for purposes of establishing a 340B "patient" relationship. Otherwise HRSA could negate its efforts to clarify the criteria for 340B "patient" status.

[110] For example, The Federation of State Medical Boards' Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine recommends several safeguards to promote the safety and quality of care in the telemedicine context. PhRMA believes these safeguards are worthy of HRSA's consideration

V. DRUG INVENTORY/REPLENISHMENT MODELS

Covered entities use replenishment systems to tally the drugs dispensed to various types of patients (such as inpatients, 340B-eligible outpatients, and other outpatients) and then replenish the drugs used for each patient type by reordering from the appropriate account (e.g., GPO, 340B, non-340B outpatient). PhRMA strongly supports HRSA's proposed clarifications that "[t]o avoid a violation of the statutory prohibition on diversion, a covered entity that utilizes a drug replenishment model may only order 340B drugs based on actual prior usage for eligible patients of that covered entity"[111] and that "[i]f the covered entity improperly accumulates or tallies 340B drug inventory, even if it is prior to placing an order, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of [the diversion prohibition]."[112]

HRSA also describes two categories of reclassifications with respect to 340B drug purchases made through replenishment models:

- "[E]rrors in purchasing data" that are identified and corrected within 30 days of the initial purchase; and
- A process sometimes called "banking," in which "covered entities have attempted to retroactively look back over long periods of time at drug purchases not initially identified as 340B eligible," and then "attempt to re-characterize these purchases as 340B eligible," (in which event the entity should "first notify manufacturers and ensure all processes are fully transparent with a clear audit trail").[113]

We agree with HRSA that a distinction exists between "banking" and the immediate and regular (30-day) correction of inadvertent purchasing errors. However, both of these practices depart from HRSA's principle that "[c]overed entities are responsible for requesting 340B pricing at the time of the original purchase"[114] and (since HRSA apparently would permit both practices), the Proposed Guidance as a whole appears to undercut HRSA's first principle that entities must request 340B pricing at the time of the initial purchase. To give effect to this first principle and set out a clear and internally consistent set of ground rules, we recommend that HRSA adopt the following standards in its final guidance:

- Entities and their agents must design all patient-identification systems so that "patients" (and non-patients) can properly be identified at the time a drug is dispensed or administered (and replenishment activities follow from these real-time correct "patient" identifications);

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111 80 Fed. Reg. at 52319.

112 80 Fed. Reg. at 52308. We also support HRSA's recognition that "[a] similar violation would occur if the recorded number of 340B drugs does not match the actual number of 340B drugs in inventory, if the covered entity maintains a virtual or separate physical inventory." Id.

113 80 Fed. Reg. at 52308.

114 80 Fed. Reg. at 52308.

- Entities with well-designed real-time patient identification systems may reclassify a drug as a "340B drug" (with prior notification to the manufacturer and a clear audit trail) if an error nevertheless occurs and the error is detected and corrected within 30 days of the initial purchase; and

- Errors identified at any time before or after the 30-day period that result in improper 340B purchases must always be notified to the manufacturer and corrected promptly after they are identified.

Finally we support HRSA's proposed clarification that covered entities should conduct regular reviews of 340B drug inventory to ensure that any inventory discrepancy is accounted for and properly documented to demonstrate that 340B drugs are not diverted." We also agree that covered entities should follow standard business practices to return unused or expired drugs purchased at the 340B price and appropriately account for waste of such drugs, and that covered entities should maintain policies and procedures, as well as auditable records, regarding 340B drug inventory discrepancies to assist in meeting this standard.

We urge HRSA to incorporate these important program integrity principles as HRSA conducts its audits of covered entities. We are concerned that HRSA's audit protocol may not be capturing violations of the GPO and/or diversion prohibitions that result from inappropriate replenishment practices. We believe it is imperative from a program integrity perspective for HRSA to ensure that its oversight and audit activities are identifying noncompliant replenishment practices and pursuing appropriate corrective action and enforcement requirements in cases of identified violations.

VI. DUPLICATE DISCOUNTS

A. Background and Current Landscape

The 340B law's "duplicate discount" ban prohibits covered entities from purchasing a drug that generates a Medicaid rebate claim at a 340B discount.[115] This is an absolute prohibition, and the intent of this statutory provision is zero instances of double discounts. Since the inception of the 340B program, identification and prevention of duplicate discounting has been an ongoing challenge for covered entities, CMS, State Medicaid programs, and manufacturers. Although historically only drugs for Medicaid fee-for-service (FFS) beneficiaries triggered Medicaid rebates, the ACA extended the rebate requirement to drugs used by Medicaid MCO enrollees. The inclusion of MCO utilization in State Medicaid rebate invoices, coupled with the proliferation in the use of contract pharmacies, has sharply increased the risk of double discount violations.

Today duplicate discount violations are a widely acknowledged and growing problem. For example, a recent OIG report found evidence that some 340B providers have violated basic requirements designed to prevent contract pharmacy arrangements from generating duplicate discounts.[116] Even HRSA's own audit experience demonstrates extensive evidence of duplicate

[115] 42 U.S.C. § 256b(a)(5)(A)(ii).

[116] OIG, Contract Pharmacy Arrangements in the 340B Program, February 4, 2014.

discounts -- as of October 2015, in 343 audits (since 2012), 73 have involved duplicate discount findings. PhRMA is an important stakeholder in the 340B program, and has made a number of submissions detailing several thoughtful and substantive recommendations that, if implemented, would reduce the risks of duplicate discounts. Our comment letter to CMS on its 2012 proposed rule for covered outpatient drugs under the Medicaid rebate program included several practical recommendations in this regard. In 2014, PhRMA submitted a white paper to HRSA entitled Current State of the 340B Duplicate Discount Prohibition and Proposed Solutions for Program Compliance that provided a comprehensive analysis of the heightened double discount problems that exist today and included several solutions for HRSA's consideration. In June 2015, PhRMA submitted a comment letter to CMS on its Medicaid Managed Care proposed rule, in which we included a robust discussion detailing MCO-related duplicate discount challenges and our proposed solutions.

On the face of HRSA's Proposed Guidance, it appears that PhRMA's recommendations have not been adequately considered. Not only did HRSA fail to respond to or acknowledge our 2014 white paper, but none of its recommendations were even acknowledged in HRSA's Proposed Guidance -- not as proposals for stakeholders to consider, and not even as ideas that HRSA thoughtfully considered, assessed, and rejected as unworkable or flawed in some way. Notably, the Proposed Guidance briefly refers to "certain modifiers and codes which identify individual claims as associated with 340B drugs and therefore not eligible for rebate" (including NCPDP identifiers), but then asserts without any explanation that "[s]uch billing instructions are beyond the scope of the 340B program."[117] We disagree. A method to prevent double discounts is squarely within the scope of the 340B program and in fact should be a top HRSA priority. HRSA has an express statutory mandate "to establish a mechanism to ensure that covered entities comply" with the prohibition on duplicate discounting.[118] As discussed below, the mechanism that HRSA has established currently is insufficient to satisfy this mandate.

HRSA must not ignore this problem; since the current mechanism does not "ensure" covered entity compliance, HRSA must replace, enhance, or supplement the mechanism to ensure compliance and thus fulfill its statutory mandate. We appreciate HRSA's statement that "[r]isks of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements," and "therefore, in accordance with the statutory requirement under 340B(a)(5)(B)(ii) to establish a mechanism to prevent duplicate discount violations, HHS will examine these systems and determine if adjustments have to be made to the system to prevent duplicate discounts,"[119] We can assure HRSA that adjustments are necessary and overdue.

As noted above, the law requires "the [HHS] Secretary [to] establish a mechanism to ensure that covered entities comply" with the duplicate discount prohibition.[120] HRSA established the Medicaid Exclusion File as that mechanism. Covered entities may "carve-in" 340B drugs (use 340B drugs for their Medicaid patients) or "carve-out" (buy drugs for their Medicaid patients outside the 340B program). Entities must inform HRSA -- "by providing their Medicaid billing number" -- if they carve-in; this information is then reflected in the Exclusion File

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117 80 Fed. Reg. at 53209.

118 42 U.S.C. § 256b(a)(5)(A) (emphasis added).

119 80 Fed. Reg. at 52309 (emphasis added).

120 42 U.S.C. § 256b(a)(5)(A).

that permits "States and manufacturers [to] know that drugs purchased under that billing number are . . . not eligible for a Medicaid rebate."[121] In a June 2011 report, the OIG found that most States are not using the Exclusion File, but it was not clear whether these States had developed reliable alternative methods of identifying duplicate discounts.[122] Moreover, as described below, even if a State uses the Exclusion File, it will not prevent duplicate discounts in all instances. Recall that the statutory objective is zero instances of double discounts.

PhRMA was surprised and disturbed by HRSA's proposal to permit covered entities to make more complicated carve-in/carve-out decisions, especially in light of the ongoing and widespread violations of the duplicate discount prohibition. Specifically, under the Proposed Guidance, HRSA would permit covered entities to make different carve-in/carve-out decisions for FSS Medicaid beneficiaries and MCO beneficiaries, and even MCO-by-MCO.[123] HRSA apparently would also permit different elections by parent and child sites.[124] Further, the Proposed Guidance seeks comments on alternative mechanisms to allow covered entities to "take a more nuanced approach to purchasing," e.g., only using 340B drugs for Medicaid patients "when appropriate for service delivery."[125] Although we do not understand exactly what HRSA means by this, one thing is clear -- now is not an appropriate time to introduce more complicated and "nuanced" aspects to the double discount problem; now is the time to reduce double discount risks instead of increasing them. If HRSA were to finalize these proposals (which we oppose), the challenges that HRSA, covered entities, and State Medicaid programs would face in developing a system that could effectively handle all of the complex variations HRSA is proposing would be substantial and the permitted variations inevitably would reduce the ability to detect and prevent duplicate discounts. HRSA's proposals would move the system further away from zero tolerance of duplicate discounts, to benign neglect.

In the Proposed Guidance, HRSA also includes a number of broad recommendations, but fails to provide any meaningful detail as to how the recommendations would be operationalized. For example, HRSA "encourages covered entities, States, and Medicaid MCOs [to] work together to establish a process to identify 340B claims" and states that "covered entities should have mechanisms in place to be able to identify MCO patients."[126] However, HRSA does not require (or even discuss) any specific mechanisms. HRSA also states that "covered entities and States should continue to work together on various methods to prevent duplicate discounts on Medicaid MCO drugs."[127] This is accurate but incomplete. Prevention of duplicate discounts cannot be left solely to covered entities and States, but -- as discussed in our recommendations, below -- will require HRSA itself to cooperate with stakeholders and to enlist the cooperation of multiple parties, including CMS.

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121 HRSA, 340B Release No. 2013-2, "Clarification on Use of the Medicaid Exclusion File."

122 HHS OIG, State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs (June 2011). The report found that 30 States did not use HRSA's Exclusion File, ten because they believed it to be inaccurate; but neither of the alternative methods used by the 30 States "necessarily ensures accurate identification of 340B claims."

123 80 Fed. Reg. at 53209.

124 80 Fed. Reg. at 52309.

125 80 Fed. Reg. at 53209.

126 80 Fed. Reg. at 52309 (emphasis added).

127 80 Fed. Reg. at 52309.

HRSA acknowledges in the Proposed Guidance that "[r]isk of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements."[128] PhRMA applauds HRSA for publicly acknowledging this fact. Having done so, HRSA should not further expand this risk. Also, HRSA states that it will examine its systems to determine "if" adjustments are needed to the system to prevent duplicate discounts[129] (adjustments certainly will be needed). The Proposed Guidance provides that due to the heightened risks of duplicate discounts, contract pharmacies listed on the 340B database will be presumed not to dispense 340B drugs to Medicaid FFS or MCO patients.[130] Under the Proposed Guidance, contract pharmacies could not dispense 340B drugs to Medicaid beneficiaries unless HRSA approves an agreement to prevent duplicate discounts between the contract pharmacy, covered entity, and State Medicaid program or MCO, in which event the contract pharmacy would be listed on the 340B database as dispensing 340B drugs to (certain) Medicaid beneficiaries.[131] However, HRSA says nothing about how duplicate discounts could be prevented in the context of a contract pharmacy dispensing 340B drugs to Medicaid beneficiaries, and thus about what specific criteria HRSA would require in order to approve an agreement "to prevent duplicate discounts" in that context. We recommend that HRSA either identify specific standards that would need to be adopted in such agreements -- if genuinely effective standards actually can be identified -- or simply provide that contract pharmacies must not dispense 340B drugs to Medicaid beneficiaries and to achieve this must have an effective, tested method for identifying Medicaid FFS and MCO beneficiaries. In addition, pharmaceutical manufacturers should have access to any such agreement to facilitate the review and dispute process (and potentially avoid costly, burdensome, and time-consuming audits).

B. Key Problems Inhibiting Duplicate Discount Prevention and Detection

As context for our proposed solutions, it is important to have a clear understanding of the most significant challenges in preventing duplicate discounts. Two of the major obstacles that now inhibit the prevention of duplicate discounts relate to contract pharmacies and to Medicaid MCOs. These are independent but intersecting problems, both of which were highlighted by a 2014 OIG report on contract pharmacies.[132] The OIG's contract pharmacy report has provided a better understanding of the double discount problem generally and in the contract pharmacy setting specifically.

The OIG's findings reinforce the concerns that PhRMA has identified in our own analyses of duplicate discount problems. Of 30 covered entities surveyed by OIG, 22 reported that, to prevent double discounts, their contract pharmacies do not dispense 340B drugs to Medicaid beneficiaries -- but two of these 22 entities acknowledged they did not know whether their contract pharmacies dispense 340B drugs to Medicaid MCO beneficiaries,[133] and covered entities' contract administrators reported "difficulties" identifying Medicaid MCO beneficiaries, for two reasons:

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128 80 Fed. Reg. at 52309.

129 See 80 Fed. Reg. at 52309.

130 See 80 Fed. Reg. at 52309.

131 See 80 Fed. Reg. at 52309.

132 HHS OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 2014).

133 OIG Contract Pharmacy Report at 12.

- Pharmacies use the Bank Identification Number and Processor Control Number (BIN/PCN) on patients' health cards to identify the payor for a prescription, but BINs/PCNs for Medicaid MCO plans are "not readily available"; and
- Many insurers that operate Medicaid MCO plans and private plans use the same BIN/PCN for both.[134]

Given these difficulties in identifying Medicaid MCO beneficiaries, it is likely that many contract pharmacies -- and in-house covered entity pharmacies as well -- are dispensing 340B drugs to Medicaid MCO beneficiaries without knowing it. Therefore, even contract pharmacies that believe they are not dispensing any 340B drugs to any Medicaid beneficiaries are probably doing so. This is particularly troubling in the contract pharmacy context, because currently claims for 340B drugs that are dispensed by contract pharmacies will not be flagged and excluded from Medicaid rebate invoices via the Medicaid Exclusion File, since contract pharmacies bill for drugs using their own NPI (not the covered entity NPI), and contract pharmacy NPIs are not listed in the Medicaid Exclusion File. As a consequence, 340B drugs that are dispensed to Medicaid beneficiaries by contract pharmacies will be included in Medicaid rebate invoices and generate prohibited double discounts.

Of the 8 covered entities reporting to the OIG that their contract pharmacies do dispense 340B drugs to Medicaid beneficiaries, 6 did not report any method to prevent double discounts[135] -- even though HRSA's current guidelines expressly require that covered entities "fully meet[ ] statutory obligations of ensuring against . . . creating a situation that results in a State Medicaid program seeking a rebate on a discounted drug."[136] Moreover, only 5 of these covered entities notified their State Medicaid program of this practice and none notified HRSA[137] -- even though HRSA's current guidelines require entities' agreements with contract pharmacies to ensure that "[n]either party will use drugs purchased under 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported . . . HRSA."[138] Therefore a full 20% (6/30) of the covered entities surveyed by the OIG reported to OIG that they were in violation of basic, very straightforward HRSA requirements designed to reduce duplicate discount risks.

Thus, as we have previously advised HRSA, the OIG's findings reinforce PhRMA's concern that HRSA's only current mechanism to prevent duplicate discounts (the Medicaid Exclusion File) is often not preventing duplicate discounts associated with drugs (1) used by Medicaid MCO enrollees; or (2) dispensed by contract pharmacies.

Another breakdown in duplicate discount prevention occurs at the point of sale, because at that point a contract pharmacy typically does not determine whether an individual is a "patient" of a 340B entity with which the pharmacy contracts and thus whether the prescription

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134 OIG Contract Pharmacy Report at 13.

135 OIG Contract Pharmacy Report at 13.

136 75 Fed. Reg. at 10278.

137 OIG Contract Pharmacy Report at 13.

138 75 Fed. Reg. at 10278 (emphasis added).

should be classified as a 340B prescription.[139] In most cases, contract pharmacies retroactively determine whether prescriptions were filled with drugs purchased under the 340B program, and 340B claims therefore are not designated as such by the pharmacy at the time of dispensing. According to 340B Health (formerly the Safety Net Hospitals for Pharmaceutical Access, or SNHPA), the trade association for 340B hospitals, the "overwhelming majority of pharmacies do not know at the time a claim is processed whether or not it relates to a 340B drug."[140] In-house 340B pharmacies also identify 340B "patients" and prescriptions filled with "340B drugs" retroactively in some cases. This retroactive identification of 340B patients and 340B drugs makes it more difficult to flag 340B drugs as such and therefore drives up the risk of duplicate discount violations. Further, retroactive identification of 340B patients and prescriptions makes it infeasible to pass along discounts to 340B patients at the point of sale.

Another key challenge in identifying and preventing duplicate discounts stems from the fact that the data that manufacturers receive with quarterly State Medicaid rebate invoices do not identify 340B purchasing. The current invoicing for Medicaid rebates -- for both FFS and MCO utilization -- provides little or no ability to verify/audit Medicaid rebate claims. Thus, it is difficult for a manufacturer to identify instances of 340B/Medicaid duplicate discounts based solely on the data included on the invoice. Specifically, the Medicaid invoice data typically provide only an aggregated summary of NDC-level utilization for the applicable quarter,[141] which means that manufacturers lack claims-level detail (e.g., identification of the provider, date of service, etc.). Moreover, Medicaid rebates may be invoiced on a lagged basis; thus even if a manufacturer were able to identify a specific provider and date of service associated with a rebate claim, the Exclusion File status of the 340B covered entity at the time of the invoice may not be the same as when the manufacturer receives a rebate invoice. Simply put, the data CMS currently requires States to include on Medicaid rebate invoices does not provide the type of claims-level data that manufacturers would need in order to identify duplicate discounting violations.

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[139] See, e.g., Wellpartner Policy Watch, ACA Medicaid Managed Care Rebates and the 340B Exemption available at: http://www.wellpartner.com/aca-medicaid-managed-care-rebates-and-the-340b-exemption/. ("The in-house method lends itself to real-time 340B claims identification and billing. By contrast, adjudication of 3rd-party claims through community pharmacies does not – in most cases, the pharmacy does not know the 340B status of a prescription or patient at the point of sale and cannot flag such a claim for billing and tracking. 340B identification, purchasing, and replenishment are generally carried out post-adjudication.")

[140] Safety Net Hospitals for Pharmaceutical Access, Letter to Jason Helgerson, "Concerns Regarding Identification of 340B Medicaid Managed Care Claims," December 19, 2011 at 2, available at http://www.snhpa.org/files/SNHPA_Letter_and_Testimony_Regarding_NY_340B_Medicaid_Managed_Care_Claims_12-19-2011.pdf.

[141] See CMS Medicaid Drug Rebate Program Notice No. 158 (July 13, 2011) at 11. CMS Form R-144, which is the form that States use to provide Medicaid drug utilization data to manufacturers, provides for States to submit data in an aggregated format (as opposed to a claim level format). Further, the form does not currently require that States report to manufacturers -- or even collect -- the NCPDP 340B identifiers for claims filled by drugs purchased under the 340B program.

C. Recommendations to Prevent Duplicate Discounts

No single stakeholder working in isolation can solve the growing problem of duplicate discounting in the 340B program. It is essential that all stakeholders -- including HRSA, CMS, State Medicaid agencies, covered entities, and manufacturers -- work together collaboratively to develop and implement solutions to prevent duplicate discounts. As noted above, the statutory objective is zero instances of duplicate discounts. Below we provide a menu of several recommendations to help achieve this objective, which we urge HRSA to select from in in its final guidance.

- First, HRSA should require covered entities to identify prescriptions for 340B "patients" when the prescription is written (e.g., through a simple notation on the prescription), which would enable both in-house 340B pharmacies and 340B contract pharmacies to identify a prescription as one filled with 340B drugs at the point of service. HRSA itself suggested this approach in its 2010 contract pharmacy guidance.[142] If HRSA instructs 340B entities and their contract pharmacies to use this approach, pharmacies and 340B entities need only use NCPDP's point-of-sale 340B identifier (which we discuss further below) to identify 340B claims and ensure that State Medicaid programs will exclude them from Medicaid rebate invoices. Importantly, adopting this recommendation also would facilitate passing through all or part of the 340B discount to covered entity patients.

- Second, HRSA should work with CMS to require that Medicaid MCOs issue pharmacy benefit cards that include an individual's Medicaid managed care status, rather than just listing the BIN/PCN for the MCO sponsor. This will help contract pharmacies to identify these individuals as Medicaid beneficiaries and thus flag the prescriptions dispensed to them as being ineligible for 340B drugs. It also will assist 340B providers that carve out Medicaid beneficiaries to identify these individuals as Medicaid beneficiaries (and thus to carve them out accordingly).

- Third, HRSA should work with other stakeholders to create a 340B "National Database on States' Processing Requirements" that would provide information assisting covered entities and contract pharmacies to identify Medicaid MCO enrollees. Although several data points could be listed in such a database, they should include the BINs/PCNs for Medicaid MCOs or their PBMs. This information would help (but not be sufficient by itself) to identify Medicaid MCO enrollees as such, so that a 340B contract pharmacy (or an in-house pharmacy of an entity that carves out Medicaid beneficiaries) could avoid filling claims associated with these plans with 340B drugs.

- Fourth, HRSA should not finalize its several proposals to permit covered entities' carve-in/carve out policies to become more complicated, and instead should require one carve-in/carve out decision across all of a covered entity's sites and for all Medicaid payors. As discussed above, we do not believe the Medicaid Exclusion File could work effectively if

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[142] 75 Fed. Reg. 10272, 12079 (March 5, 2010). The "suggested contract provisions" for entities to consider including in contract pharmacy agreements provide: The pharmacy will dispense covered drugs only in the following circumstances: (a) upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone . . . by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. Id.

HRSA were to permit the type of multi-faceted carve-in/carve our policies described in the Proposed Guidance. This is not the time to introduce new complexities into the prevention of double discounts.

- Fifth, HRSA should require that, when billing Medicaid or other payors, covered entities and their contract pharmacies should use a system like that developed by the National Council for Prescription Drug Programs (NCPDP) -- or revised and refined by NCDCP -- to identity claims filled with 340B drugs. Under this system, pharmacies place the value of "20" in the Submission Clarification Code field when a prescription is identified at the point of sale as being filled with 340B drugs.[143] For physician-administered drugs billed by a clinic, the "UD modifier" should be required on claims to identify those that involve drugs purchased under 340B.

- Sixth, HRSA should work with CMS to create a standardized claim-level reporting format for drug utilization data that accompanies Medicaid rebate invoices submitted to manufacturers, and also standardize the method for identifying and documenting utilization of 340B drugs across Medicaid, i.e., uniform reporting elements and formats and uniform rules for identifying 340B drugs should apply across MCOs and FFS Medicaid, and across all States. Without such standardization at the claim-level, States may continue to develop individualized homegrown reporting systems that make auditing 340B status determinations practically impossible. A comprehensive and uniform rebate invoice, along with the underlying claims-level detail, is also essential, as it would help both States and manufacturers to identify 340B drug utilization and to reduce the resources needed to validate and pay rebate claims. Requiring consistency in reporting across Medicaid will also benefit 340B entities by streamlining the way 340B claims are identified and reported. Among other things, CMS should require the comprehensive use of the NCPDP 340B identification systems for claims for 340B drugs (and use of the "UD modifier" on claims for physician-administered 340B drugs), as well as require the use of HRSA's Exclusion file to identify claims that involve 340B drugs. To promote efficiency and to enable these mechanisms to function effectively, they must be used across the board, i.e., CMS must require State Medicaid programs to flow down these requirements to pharmacies, other providers that serve Medicaid beneficiaries, and Medicaid MCOs (which the State must require also to flow down to pharmacies and providers serving their beneficiaries).

- Seventh, HRSA should work with CMS to require that all Medicaid utilization data that States submit to manufacturers (both FFS and Medicaid MCOs) contain the "Pharmacy Identifier" field so that manufacturers can verify that the data has been correctly screened for duplicate discounts, or to communicate with the State to determine whether the utilization data includes drugs dispensed by a 340B pharmacy. The data also must include the NCPDP 340B identification data element.

- Eighth, HRSA should work with CMS to require that the utilization data accompanying the Medicaid rebate invoices submitted include (in addition to the data elements noted above and those that CMS proposed to require on rebate invoices in its 2012 proposed rule

[143] NCPDP also has a mechanism to inform payors when a determination is made retroactively that a claim previously billed and paid involved 340B drugs. For more information on NCPDP's 340B identification systems, see NCPDP's 340B Information Exchange Reference Guide, version 1.01 (July 2011) § § 4.1-4.3.

regarding covered outpatient drugs)[144] the following: (1) Date of Service; (2) Service Provider Identifier Qualifier; (3) Service Provider Identifier; (4) Prescription/Service Reference Number; (5) Product/Service Identifier; (6) Quantity Dispensed; (7) Days Supply; (8) Fill Number; and (9) NPI number.[145]

- Since States would only be able to meet these reporting obligations by requiring that pharmacies or other providers that dispense or administer drugs to Medicaid FFS or MCO beneficiaries include all these same data elements on their claims to the State or the Medicaid MCO, CMS should require States to flow down to Medicaid MCOs and pharmacies (or other providers that bill Medicaid for drugs) all of the same reporting requirements that should be applied to the State. CMS also should explicitly require States and MCOs to adopt reporting requirements to identify 340B drugs purchased by a provider such as a clinic, to preclude duplicate discounts on such drugs; the mechanism to do this in the clinic setting is to identify 340B drugs using a UD modifier.

- Ninth, with respect to the NPI number included on State invoices to manufacturers, it is critical that HRSA work with CMS to require that contract pharmacies report the NPI number of the covered entity -- and not their own NPI number -- when submitting or retroactively identifying a claim for a 340B drug. Because contract pharmacy NPIs currently are not listed in the Exclusion File, and contract pharmacies currently bill 340B drugs under their own NPIs, a claim filled by a contract pharmacy would not have the 340B entity's NPI and the Exclusion File would therefore not enable Medicaid to exclude 340B claims from Medicaid rebate invoices even if the covered entity's NPI were listed in the Exclusion File. Consequently, a claim for a 340B drug dispensed by a contract pharmacy could not be flagged and excluded from rebate invoices based on information in the Exclusion File. In addition, we urge HRSA and CMS to work together to develop a mechanism whereby the Exclusion File flags contract pharmacy claims even if the 340B entity itself has developed a method to avoid dispensing 340B drugs to Medicaid beneficiaries -- including MCO beneficiaries -- and thus does not submit its NPI number to the Exclusion File.

- Tenth, 340B entities or contract pharmacies that fail to follow the recommended requirement to adopt the NCPDP 340B identification system should have an affirmative obligation to report to the MCOs that they do not use the required 340B identifier system. To avoid duplicate discounts, MCOs must then be required to exclude all claims from covered entities that do not comply with the 340B identifier system from the utilization data they report to the State.

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[144] CMS proposed that States must report the following data on FFS utilization, and on MCO utilization for MCOs providing drug benefits, to manufacturers and CMS:

> Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data: (1) The State code; (2) National Drug Code; (3) Period covered; (4) Product FDA list name; (5) Unit rebate amount; 6) Units reimbursed (7) Rebate amount claimed; (8) Number of prescriptions; (9) Medicaid amount reimbursed; (10) Non-Medicaid amount reimbursed; and (11) Total amount reimbursed. [77 Fed. Reg. 5318, 5366 (proposed 42 C.F.R. § 447.511(a), (c)) (Feb. 2, 2012).]

[145] With the exception of the NPI element, this information is provided to manufacturers under the Medicare Part D Coverage Gap Discount Program Agreement to help manufacturers verify claims.

- Finally, and importantly, given the heightened risk of duplicate discount violations in the MCO/contract pharmacy context -- as recognized by OIG in its 2014 contract pharmacy report[146] and also by HRSA itself in the Proposed Guidance[147] -- HRSA should work with CMS to ensure that Medicaid MCOs review their claims retroactively back to 2010 (when Medicaid MCO utilization became subject to Medicaid rebates pursuant to the ACA) to make sure they have not previously invoiced State Medicaid programs for drugs subjects to 340B discounts. If any such invoicing has occurred, the MCO must be required to correct the utilization data as promptly as possible. To ensure that a correct review of past claims can be conducted, Medicaid MCOs also should be required to flow down this retrospective review obligation to their network pharmacies. CMS also should expressly require that any corrections of past claims discovered by the MCOs be forwarded to the State, which must then submit revised utilization data to manufacturers.

PhRMA would welcome the opportunity to meet with HRSA (or to meet with HRSA and CMS) to discuss any of these recommendations if that would be helpful.

D. Repayment

HRSA states in the Proposed Guidance that covered entities found in violation of the duplicate discount prohibition "may be required to repay manufacturers if duplicate discounts have occurred . . ."[148] As a threshold matter, covered entities are always responsible for violations of the statutory prohibition on duplicate discounts.[149] That said, manufacturers should be permitted to exercise one of two options to recoup monies attributed to duplicate discounts. Currently, manufacturers either recover the monies from the covered entities themselves, e.g., via a check or a credit and rebill, in which case a Medicaid rebate is appropriate. Alternatively, manufacturers use the dispute resolution process to resolve the issue with the State Medicaid agency, in which case (assuming the drug was identified as a 340B drug in the Medicaid dispute resolution process) a Medicaid rebate would not be due. PhRMA urges HRSA to clarify in its final guidance that although a manufacturer may choose to resolve instances of duplicate discounts with individual States via the dispute resolution process, this is not the required mechanism -- the statute makes clear that covered entities are always ultimately responsible for compliance with the statutory prohibition of duplicate discounts.[150]

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146 HHS OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 2014).

147 80 Fed. Reg. at 52309.

148 80 Fed. Reg. at 52309. (emphasis added.)

149 42 U.S.C. § 256b(a)(5)(A).

150 42 U.S.C. § 256b(a)(5)(A) states "A covered entity shall not request payment under title XIX of the Social Security Ace [42 U.S.C. § 1396 *et seq.*] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. § 1396dd(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. § 1396r-8].

VII. CONTRACT PHARMACY ARRANGEMENTS

In the Proposed Guidance, HRSA acknowledges that contract pharmacies increase duplicate discount risks.[151] The GAO and the HHS OIG have both reported that contract pharmacies increase diversion risks as well.[152] But the Proposed Guidance would continue HRSA's current policy of allowing any covered entity to have an indefinite number of contract pharmacies, rather than proposing any limitations on covered entities' use of contract pharmacies. In addition, HRSA proposes that, "[i]f permitted under applicable State and local law, a covered entity may contract with one or more pharmacies on behalf of its child sites, or a child site may contract directly with a pharmacy." HRSA also suggests that covered entities may contract with one contract pharmacy site or with a "pharmacy corporation to include multiple pharmacy locations."[153] Particularly in light of the heightened risks associated with the use of contract pharmacies (as described below), we urge HRSA to demonstrate its commitment to preventing diversion and duplicate discounts and to abandon these proposals. Instead HRSA must take steps to rein in the use of contract pharmacies and reduce the compliance risks they pose.[154]

By way of background, HRSA published guidelines in 1996 creating the theory that covered entities could use contract pharmacies.[155] Accordingly, HRSA has complete discretion to limit or eliminate the use of contract pharmacies by covered entities. The 1996 Guidelines permitted a covered entity with no in-house pharmacy to contract with one outside pharmacy to receive 340B drugs and then dispense those drugs to patients of the covered entity. Thus, these guidelines were confined to circumstances where the covered entity may have been unable to participate in the 340B program except through a contract pharmacy.

HRSA lifted these restraints in 2010, when it issued new guidelines that "replace[d] all previous 340B Program guidance documents addressing non-network contract pharmacy services".[156] The 2010 Guidelines eliminated all restrictions on the types of covered entities that could use contract pharmacies and on the number of contract pharmacies a covered entity could use, providing that, "[i]n addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies."[157]

In the preamble to the 2010 Guidelines, HRSA dismissed stakeholder concerns that a limited number of "demonstration projects," where eleven covered entities used contract

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151 80 Fed. Reg. at 52309.

152 GAO, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement, at 28; OIG, Contract Pharmacy Arrangements in the 340B Program, at 1-2.

153 Notably, HRSA does not discuss how these various contract pharmacy arrangements must be listed in the 340B database.

154 As a threshold matter, we note that the 340B law does not authorize HRSA to permit the use of contract pharmacies. We do not address this issue further in this comment letter, as we believe that today all concerned can at least agree that the evidence on risks vs. benefits of contract pharmacies calls for limits on their use.

155 61 Fed. Reg. 43549 (Aug. 23, 1996).

156 75 Fed. Reg. at 10277.

157 75 Fed. Reg. at 10277-10278.

pharmacies as test cases, did not provide HRSA with sufficient evidence to justify a dramatic expansion of contract pharmacy arrangements.[158] HRSA similarly rejected calls for enhanced penalties and consequences in connection with diversion or duplicate discounting, stating that "there are appropriate safeguards in place, based on the parameters of the program."[159]

The 2010 Guidelines made clear that HRSA was allowing multiple contract pharmacies at that time because (1) HRSA believed it had fully assessed the risk of diversion and double discounting and found them negligible; and (2) the potential benefits to patients appeared significant. Thus, HRSA explained that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities," plus "the [Alternative Methods Demonstration Project] provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity."[160] HRSA concluded that: "Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site."[161] But the premises on which HRSA based its 2010 Guidelines have proved incorrect, and HRSA's current policy has sacrificed program integrity.

In 2014, the HHS OIG issued a troubling report suggesting that HRSA's lack of safeguards around the use of contract pharmacies has compromised program integrity with few benefits to patients -- at least not from hospital covered entities' contract pharmacies. HRSA's failure to require that covered entities pass along any savings to 340B patients means that the grantees have largely passed through 340B savings to uninsured low-income patients and the hospitals largely have not. Specifically, the OIG's study, which included 15 DSH hospitals and 15 FQHCs, found a startling disparity: of the 15 DSH hospitals in the study, approximately 47% (seven hospitals) did not pass along discounts to uninsured patients in any of their contract pharmacy arrangements;[162] whereas only 7% of the sampled grantees (one grantee) did not pass along discounts to uninsured patients in any of its contract pharmacy arrangements.[163]

In addition, the OIG report identified serious compliance violations and found that, "contract pharmacy arrangements create complications in preventing diversion."[164] Covered entities' contract administrators, which may decide which prescriptions dispensed by a contract pharmacy are 340B-eligible, "use different methods to identify 340B-eligible prescriptions," which leads to "differing determinations of 340B eligibility across covered entities." For example, some administrators classify as 340B-eligible all prescriptions written by physicians that split their time between a covered entity and a non-covered entity, while others treat none of these prescriptions as 340B eligible and still others make case-by-case decisions.[165]

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158 75 Fed. Reg. at 10273.

159 75 Fed. Reg. at 10274.

160 75 Fed. Reg. 10272, 10273 (March 5, 2010) (emphasis added).

161 75 Fed. Reg. at 10273 (emphasis added).

162 Id.

163 These percentages are not precise because for four of the covered entities in the sample, it was unclear whether contract pharmacies offered the discounted 340B price to uninsured patients. See id. at 14.

164 HHS OIG, Contract Pharmacy Arrangements in the 340B Program, supra at 1.

165 OIG Contract Pharmacy Report at 9.

The OIG also found that "contract pharmacy arrangements create complications in preventing duplicate discounts." Six of eight contract pharmacies that dispensed 340B drugs to Medicaid beneficiaries told OIG they lacked even "a method to avoid duplicate discounts," some covered entities disclosed that they did not even know whether their contract pharmacies dispense 340B drugs to Medicaid beneficiaries, and others admitted "difficulties" identifying Medicaid MCO beneficiaries.

HRSA itself is (and has been) well aware of the rampant violations in the 340B program involving contract pharmacies. In November 2013 HRSA published on its website a chart of audit results that showed that when HRSA audited a covered entity and uncovered diversion, duplicate discounting, or both, about half of the time the diversion or duplicate discounting involved drugs dispensed at contract pharmacies.[166] Merely skimming the audit results displayed on HRSA's website confirms that these violations continue to exist. Of the 103 audit results listed for FY2015, approximately one third include violations involving contract pharmacies.[167]

In addition to the compliance risks stemming from HRSA's 2010 Guidelines, the evidence suggests that few of the patient benefits HRSA expects from this policy have materialized. As discussed in Section VI.B, typically a contract pharmacy does not determine whether an individual is a "patient" of a 340B entity with which the pharmacy contracts and thus whether the prescription should be classified as a 340B prescription until sometime after the prescription has been filled. This suggests that the covered entity may not be "assum[ing] responsibility for establishing [the 340B drug's] price" as the 2010 Guidelines require.[168] Presumably, HRSA believed it was "essential" that the covered entity assume responsibility for the price so that savings could be passed along to its patients. This concept is implicit in HRSA's preamble discussion of drug pricing approaches in its 1996 Guidelines. Specifically, HRSA noted that:

> some [covered entities] may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost . . . using the savings to reach more eligible patients and provide more comprehensive services . . . A modest section 340B price markup, with savings realized from the discounts used by covered entities only for purposes of the federal program . . . does not appear to be inconsistent with the drug pricing program."[169]

As noted above, however, benefits to patients from the use of contract pharmacies are by no means assured. The OIG's contract pharmacy report found that 60% of the 30 covered entities OIG sampled reported that they passed through 340B discounts to uninsured patients in at least one contract pharmacy arrangement, but 27% of the covered entities (eight entities)

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166 HRSA, Program Audit Results Chart (Nov. 4, 2013), available at http://www.hrsa.gov/opa/programintegrity/auditresults/auditreportcurrent.pdf.

167 HRSA FY2015 audit results, available at http://www.hrsa.gov/opa/programintegrity/auditresults/fy15auditresults.html

168 See 75 Fed. Reg. at 10277.

169 61 Fed. Reg. at 43551.

charged uninsured patients the full non-340B price in all of their contract pharmacy arrangements, and for another 13% it was unclear whether 340B discounts were passed through to uninsured patients.[170] Moreover, seven of the eight entities that did not pass along discounts to uninsured patients in any of their contract pharmacy arrangements were DSH hospitals[171] -- and while OIG's sample included 15 DSH hospitals and 15 FQHCs, DSH hospitals actually account for roughly 81% of 340B purchases,[172] suggesting that the largest volume of 340B users are generally not using their contract pharmacies to pass through discounts to uninsured patients.

The OIG reported that "[a]ll but one administrator reported being able to allow covered entities to offer the discounted 340B price to uninsured patients at contract pharmacies," but "some covered entities choose not to do so."[173] While recognizing that ""[n]either the 340B statute nor current HRSA guidance address [whether covered entities must pass discounts through to patients]," the OIG emphasized that "if covered entities do not [pass through], uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies,"[174]

Benefitting patients was the whole rationale for contract pharmacies. HRSA adopted its current policy allowing an unlimited number of contract pharmacies because the previous policy "restrict[ed] the flexibility of covered entities in meeting the needs of their patients," responding to comments that "some patients currently face transportation barriers . . . obstacles that limit their ability to fill prescriptions [at the covered entity]" and "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements."[175] But patients receive no benefit from going to a pharmacy they could have gone to anyway, without the contract pharmacy arrangement, and paying the same full price they could have paid without the contract pharmacy arrangement.

As HRSA's current policy on contract pharmacies is premised on the theory that the use of contract pharmacies presents low risk and improves patient access -- and this premise has proven wrong -- PhRMA recommends that, at a minimum, HRSA impose reasonable limits on the use of contract pharmacies to balance their heightened compliance risks against any benefit these arrangements are providing to covered entity patients. Below we set forth our recommendations:[176]

- First, HRSA should limit the number and geographic scope of permissible contract pharmacy arrangements. Today, there are covered entities with over 100 contract

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170 OIG Report at 13-14.

171 OIG Contract Pharmacy Report at 14.

172 Sales data from Apexus Update 2015 -- 340B Coalition Winter Meeting; Number of Entities from Avalere Health analysis of the 340B database in March 2015.

173 OIG Contract Pharmacy Report at 14.

174 OIG Contract Pharmacy Report at 14.

175 75 Fed. Reg. at 10273.

176 Many of HRSA's proposals for contract pharmacy arrangements are couched as "expectations" in the Proposed Guidance. PhRMA recommends couching these proposals more strongly to convey the urgency of these reforms more accurately given the widespread compliance violations that currently exist in the program.

pharmacy arrangements, some of which are more than 50 miles away and can include large mail order pharmacies. The need for such contract pharmacy networks is difficult to reconcile with the notion that covered entities must serve individuals who legitimately qualify as patients of the covered entity; further, the research suggests that in many cases contract pharmacies are located in higher income communities.[177] PhRMA recommends that covered entities be permitted to contract with no more than five contract pharmacy locations at any given time, all of which must be located within lower-income census tracts (as determined by HRSA using American Community Survey data) served by the covered entity. We believe certain exceptions would be appropriate, as follows:

- Covered entities described in 42 U.S.C. § 256b(a)(4) (A)-(K).[178]
- Rural hospitals (specifically, hospitals eligible to participate in the 340B program under 42 U.S.C. § 256b(a)(4)(N) or (O)).
- Circumstances where a covered entity files a publicly available exception request with HRSA, seeking authorization to establish a particular contract pharmacy arrangement in a higher-income census tract and explaining why in that particular case such a contract pharmacy would best meet the needs of low-income patients of the covered entity, and HRSA grants the request to establish one of the five contract pharmacies in the census tract requested. HRSA's decisions on such requests also should be publicly available.

- Second, where a covered entity offers a charity care policy or has an obligation to have a sliding fee scale (e.g., under a grant that makes the entity 340B-eligible), then its contract pharmacies should be required to offer patient access at the point of sale to the entity's prescription drug charity care benefit and its sliding fee scale. In addition, covered entities should have in place, at each contract pharmacy, a mechanism for documenting the income and insurance status of each covered entity patient who fills a prescription at the contract pharmacy and the amount each patient pays to receive 340B drugs at the contract pharmacy.
- Third, we encourage HRSA to seek an HHS OIG study and report on covered entity/contract pharmacy arrangements, which should address the methods and amounts of remuneration exchanged between covered entities and contract pharmacies, the extent to which contract pharmacies are used by hospitals and grantees, compliance concerns associated with covered entities contracting with mail order pharmacies, and the extent to which contract pharmacies improve access to medicines by covered entity patients. The report should include recommendations that address safeguards to reduce duplicate discounting and diversion within contract pharmacies and reforms to target these arrangements exclusively at improving access to medicines for uninsured or vulnerable patients of covered entities. HRSA should also encourage ongoing OIG monitoring of these issues, ideally in annual OIG reports.

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[177] See, e.g., Berkeley Research Group Contract Pharmacy Mapping Analysis, http://www.thinkbrg.com/media/publication/459_Vandervelde_ContractPharmacyMappingAnalysis.pdf

[178] These are grantee covered entities that traditionally have operated under requirements that have followed the original intent of the 340B program, including using contract pharmacy services to increase access for vulnerable populations.

- Fourth, HRSA should establish a moratorium precluding any covered entity (except those described in 42 U.S.C. § 256b(a)(4)(A)-(K)) from entering into a new or expanded contract pharmacy arrangement at least until HRSA has evaluated the OIG's initial report on contract pharmacies (described above), issued proposed guidance based on OIG's findings and recommendations, and then issued final guidance taking into account public comments.

- Fifth, HRSA should require covered entities to conduct annual, independent, on-site audits of their contract pharmacies (which should be required to maintain separate inventories of 340B drugs) to identify program violations. To be effective, these audits should also extend to any third party with which the covered entity contracts for services related to the 340B program. We appreciate HRSA's renewed emphasis on its "expectation" for annual independent audits of contract pharmacies,[179] but we believe the annual independent audit must be (1) on-site; and (2) mandatory. HRSA already established an expectation for annual independent audits of contract pharmacies in 2010, yet the OIG's 2014 contract pharmacy report found that few entities (only 7 out of the 30 in the study) retained independent auditors for their contract pharmacy arrangements.[180] Even more concerning, the OIG found that four of the covered entities neither monitor their contract pharmacies nor retain independent auditors.[181]

- Sixth, HRSA should establish a moratorium barring covered entities from registering any type of mail order contract pharmacies, including pharmacies licensed to dispense specialty drugs, in the 340B program unless and until HRSA has: (1) conducted a thorough examination of the risks posed by these arrangements, either on its own, or in collaboration with an independent government agency, such as the OIG or GAO; and (2) set forth clear, auditable, and specific standards for the prevention of program violations with respect to these arrangements, including a requirement that covered entities attest that the use of mail order pharmacies is the only available mechanism to secure prescription drug access for their patients, and that the covered entity has implemented controls to prevent program violations. In addition, HRSA should establish a policy specifying that the use of mail order pharmacies in the 340B program should be limited to serve the needs of the covered entities' patients who would otherwise lack access to prescription drugs (e.g., home-bound patients, patients in rural areas). However, PhRMA recommends HRSA to exempt any grantee from the moratorium, so long as the grantee is providing 340B drugs within the scope of its grant.

- Seventh, both HRSA and manufacturers should be permitted to audit contract pharmacies (and other third parties that provide 340B-related services for covered entities) directly, to ensure compliance with program requirements. Adequate recordkeeping requirements also should be in place to ensure that these audits can be accomplished. We agree with HRSA's proposal for a 5-year record retention requirement.

- Eighth, covered entities should be required to have a written agreement with each contracted entity, including with each location of a pharmacy contracted to dispense 340B drugs to patients of the covered entity, which should include robust representations and

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179 80 Fed. Reg. at 52311.

180 OIG Contract Pharmacy Report at 15.

181 Id.

warranties to ensure that the contracted entity will adhere to all 340B program requirements. Measures describing specifically how compliance will be achieved should be clearly set forth in the agreement. Covered entities should maintain, and ensure that each contract pharmacy maintains, auditable records that pertain to the compliance of the covered entity and the contracted entity. Further, all agreements should be registered with HRSA and made available to HRSA upon request.

VIII. MANUFACTURER RESPONSIBILITIES

A. The "Must Offer" Requirement

The ACA amended the 340B statute to provide that "each [PPA] . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[182] HRSA has not yet amended the PPA to include this "must offer" requirement, but has just taken steps to start this process. The Proposed Guidance states that "[u]nder the PPA, a manufacturer must offer all covered outpatient drugs . . . to covered entities participating in the 340B Program at no more than the statutory 340B ceiling price," and that by executing the PPA "a manufacturer agrees to all 340B Program statutory requirements, including statutory and regulatory changes that occur after execution of the PPA."[183]

PhRMA disagrees with HRSA's assertion that by executing a PPA, a manufacturer agrees to subsequent statutory and regulatory changes that are not incorporated into the PPA. HRSA points to no authority for this assertion; there is nothing in the 340B statute that supports this position, and nothing in the PPA that supports this position (unlike the Medicaid Drug Rebate Agreement, which explicitly requires manufacturers to comply with certain subsequent changes in the Medicaid rebate statute and implementing regulations).[184]

Aside from the issue of when the "must offer" provision takes effect, its proper interpretation warrants some discussion. As noted above, it provides that the PPA shall require manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[185] HRSA has previously interpreted this language as reflecting HRSA's traditional "non-discrimination" policy. We agree that the must offer provision codifies HRSA's long-standing non-discrimination policy (rather than adopting a new and different "forced sale" requirement that potentially could result in manufacturers being required to disadvantage non-340B customers). HRSA's non-discrimination policy is expressed in its May 2012 guidance in the context of alternate allocation procedures for drugs in shortage. In that guidance, HRSA required that manufacturers implementing allocation procedures "must demonstrate that 340B

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182 42 U.S.C. § 256b(a)(1).

183 80 Fed. Reg. at 52311(emphasis added).

184 Specifically, the Medicaid Drug Rebate Agreement requires manufacturers "[t]o comply with the conditions of 42 U.S.C. section 1396s changes thereto, and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer." Rebate Agreement Between the Secretary of Health and Human Services and Manufacturer, Enclosure A § II(c) (emphasis added).

185 42 U.S.C. § 256b(a)(1).

providers are treated the same as non-340B providers,"[186] and pointed to its 1994 guidelines providing that:

> manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective [and] . . . must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program.[187]

HRSA explained in the 2012 guidance on allocation programs that "[t]his policy is consistent with section 340B(a)(1) of the Public Health Service Act which requires manufacturers to 'offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at an price."

We recommend that HRSA amend the PPA to add the must offer language, and also reiterate its conclusion that the must offer language incorporates HRSA's long-standing policy against treating covered entities less favorably than non-340B customers. HRSA could re-emphasize that conclusion at the time it amended the PPA to include the must offer language, or beforehand; certainly the final omnibus guidance would present a good opportunity to address that point. This interpretation would allow continuation of HRSA's sensible approach of permitting manufacturers to limit purchases by 340B and non-340B purchasers alike in certain situations in a nondiscriminatory manner.

When HRSA amends the PPA to activate the "must offer" provision, PhRMA also recommends that HRSA do a full update of the PPA to conform with current law.[188] The PPA includes a number of outdated definitions.[189] Keeping the PPA up to date will serve the important purpose of ensuring that manufacturers know all of their rights and obligations under the 340B program, and can find them all catalogued in an up-to-date source; and will prevent the PPA from becoming a stagnant and (worse) affirmatively unhelpful document that could cause confusion.

B. Limited Distribution Networks

Under the Proposed Guidance, HRSA would expand its current guidance on allocation programs for drugs in short supply to require written notification from manufacturers concerning limited distribution arrangements, stating that this proposal is "pursuant to" the must-offer requirement.[190] HRSA recognizes that:

> [c]ertain covered outpatient drugs may be required to be dispensed by specialty pharmacies (e.g., drugs approved with a [REMS]...). As a result, certain manufacturers may use a

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186 "Clarification of Non-Discrimination Policy," Release No. 2011-1.1 (May 23, 2012).

187 59 Fed. Reg. 25110 (May 13, 1994) (emphasis added).

188 HRSA's current efforts do not appear to provide for a full update of the PPA.

189 These include, for example, the PPA's definitions of Average Manufacturer Price and Wholesaler.

190 80 Fed. Reg. at 52312.

> restricted network of certified specialty pharmacies, which do not fall under the terms of a contract pharmacy agreement or wholesaler contract for the distribution of drugs to a covered entity.[191]

Manufacturers "may develop a limited distribution plan" in such cases, but "the plan will be reviewed by HHS to ensure that the manufacturer is treating 340B covered entities the same as all non-340B providers."[192] HRSA would request five specified categories of information concerning the limited distribution plan, including "[a]n explanation of the product's limited supply or special distribution requirements and the rationale for restricted distribution among all purchasers" and "an assurance that manufacturers will impose these restrictions equally on both 340B covered entities and non-340B purchasers."[193] If HRSA has "concerns," it would "work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the 340B Web site."[194]

As a threshold matter, HRSA lacks any authority under the 340B law to require manufacturers to report information on their limited distribution networks; to require that manufacturers seek HRSA's approval before putting a limited distribution arrangement into effect; or to require manufacturers to agree to have submissions on their limited distribution arrangements published on the HRSA 340B website. These types of far-reaching powers could create great disruption in the drug distribution system (especially as HRSA lacks the resources and workforce that would be needed to review and clear limited distribution plans promptly), and nothing in the 340B statute suggests that Congress authorized HRSA to set up a prior review process that could delay distribution of drugs to patients, or to publish sensitive and potentially proprietary information on its Web site. Accordingly, HRSA should not finalize this proposal.

We note also that HRSA has not proposed any definitions, and it has used different terminology describing the arrangements that would be covered by this proposal in different parts of the Proposed Guidance. Thus, if HRSA were to finalize this proposal as it stands, exactly what types of arrangements it would apply to is unclear.

As a substantive matter, PhRMA believes that manufacturers may limit distribution of covered outpatient drugs through a subset of distributors, so long as this limited distribution model is applied in the same manner to 340B and non-340B purchasers, and it offers all covered entities at least one avenue to purchase at 340B prices.[195] HRSA should take the opportunity to specify this clearly in the final guidance.

C. Procedures for Issuance of Refunds and Credits

The 340B statute (as amended by the ACA) requires HRSA to establish "procedures for manufacturers to issue refunds to covered entities, in the event there is an overcharge by the manufacturers," both in "routine instances of retroactive adjustments in relevant pricing data"

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191 80 Fed. Reg. at 52312.

192 80 Fed. Reg. at 52312.

193 80 Fed. Reg. at 52312.

194 80 Fed. Reg. at 52312.

195 A pharmacy (including a specialty pharmacy or radiopharmacy) is not a "distributor."

and in exceptional circumstances (e.g., erroneous or intentional overcharges).[196] HRSA proposes that "the manufacturer must refund or credit that [overcharged] covered entity an amount equal to the price difference between the sale price and the correct 340B price for that drug, multiplied by the units purchased" and do so within 90 days of "the determination by the manufacturer or HHS that an overcharge occurred."[197] HRSA would not permit exceptions for de minimis amounts and would not permit offsets. A covered entity that fails to cash a manufacturer's check for an undisputed repayment amount within 90 days would waive its right to repayment. Manufacturers would submit to HRSA "price recalculation information, an explanation of why the overcharge occurred, how the refund will be calculated, and to whom refunds or credits will be issued."[198]

As a threshold matter, while HRSA's Proposed Guidance purports to "establish[] clarity around the procedures for issuing refunds and credits in the event that there is an overcharge,"[199] HRSA has yet to establish any procedures at all. As noted above, the 340B statute explicitly requires HRSA to establish procedures for manufacturers to issue refunds to covered entities.[200] HRSA's proposal that manufacturers should issue refunds within 90 days does not fulfill HRSA's mandate to establish procedures. Rather, HRSA itself must develop procedures that are designed to work as smoothly as possible and to anticipate and avoid unintended negative consequences that could be disruptive to the program and to manufacturers' operations. PhRMA urges HRSA to consider the administrative burdens and operational difficulties that manufacturers and 340B covered entities could face in connection with the refund procedures, and to develop the procedures based on an ongoing dialogue with stakeholders that will be essential to minimizing the costs and burdens that ultimately result from the refund system.[201] Concurrently, HRSA should establish refund reconciliation and documentation standards to ensure the accuracy, transparency and auditability for confirming initial covered entity ceiling price purchases, as well as verification of associated subsequent manufacturer ceiling price adjustment refund amounts. To that end, we encourage HRSA to engage groups with expertise in remittance advice processing and documentation to assist in developing these detailed standards.

We appreciate that in this Proposed Guidance HRSA has started a discussion of refund related issues and procedures. We have comments on several of the specifics HRSA proposes.

First, HRSA's proposal that manufacturers refund or credit covered entities within 90 days of the determination that an overcharge occurred is both unrealistic and unclear. HRSA does not explain what constitutes a "determination" that an overcharge has occurred. As recognized in the statutory language, manufacturers make "routine pricing restatements." These restatements occur frequently, as certain rebate or other discount data may be known

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196 42 U.S.C. § 256b(d)(1)(B)(ii).

197 80 Fed. Reg. at 52312.

198 80 Fed. Reg. at 52312.

199 80 Fed. Reg. at 52312.

200 42 U.S.C. § 256b(d)(1)(B)(ii).

201 As discussed below, an exception for de minimis amounts would go a long way to reduce these administrative burdens and operational difficulties.

only on a lagged basis. This is particularly common in the Best Price context. Manufacturers may not know the actual net price realized by a customer within 30 days after the end of the calendar quarter -- or in fact within a lengthy period, under some contracts -- and so manufacturers must adjust the Best Price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer. To capture these adjustments, manufacturers may restate the Best Price and AMP for a particular period for 36 months after the initial price reporting.[202]

Because CMS permits recalculations in Medicaid rebate metrics for 36 months after the initial price reporting, the 340B ceiling prices derived from those metrics could also change during the 36-month restatement window. Consequently, it would be inappropriate for HRSA to mandate manufacturer ceiling price adjustment refunds any time before the 36 month restatement window closes and 340B ceiling prices for a given quarter are frozen. In addition, manufacturers should be permitted a reasonable time to recalculate 340B ceiling prices based on the final restated pricing, and then to process the refund payments. It would be administratively burdensome (and perhaps infeasible) for manufacturers to recalculate 340B ceiling prices for all of their products, determine which 340B covered entities were entitled to a refund and in what amounts, and then deliver any refunds due, within a 90-day timeframe. PhRMA recommends that HRSA allow an additional four quarters (after the 36 month restatement period) for final delivery of refund payments to 340B covered entities.

Second, PhRMA opposes HRSA's proposal to preclude offsets. HRSA states that "[a] manufacturer may only calculate the refund by NDC, and would not be allowed to calculate refunds in any other manner, including . . . netting purchases."[203] No explanation is given for this proposal not to allow offsets and it has no support in the 340B law or elsewhere.

Manufacturer restatements in AMP or Best Price may result in increases or decreases to 340B ceiling prices. Unless retroactive increases and decreases in ceiling prices are treated symmetrically, manufacturers could effectively be required to give 340B covered entities prices below the correct ceiling price in many cases, as they would charge an initial ceiling price that turned out to be too low and then would be unable to recoup their undercharge by offsetting overcharges to the same covered entity. For several reasons, this is not a reasonable reading of the 340B law. HRSA would be compelling manufacturers to provide sub-ceiling prices on some 340B drugs, even though the law expressly provides that sub-ceiling prices are voluntary.[204]

In addition, common law principles of "offset" or "setoff" give manufacturers a right of offset in circumstances such as these. Yet HRSA would take those rights away, with no authorization for doing so in the 340B law. The 340B law simply refers to manufacturers making "refunds" when there are "overcharges" -- there is no suggestion that "refunds" are to be calculated without taking into account amounts due to the manufacturer, or that the determination of whether an "overcharge" has occurred is to be made without account for amounts due to the manufacturer. As the Supreme Court has explained, "The right of setoff (also called "offset") allows entities that owe each other money to apply their mutual debts

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202 42 C.F.R. § 447.510(b),(d)(3).

203 80 Fed. Reg. at 52312.

204 42 U.S.C. § 265b(a)(10).

against each other, thereby avoiding 'the absurdity of making A pay B when B owes A."[205] This absurdity is exactly what HRSA proposes to require here: HRSA would be asserting the authority to force manufacturers to pay out money to covered entities that actually owe the manufacturer money, ignoring debts they were owed by the covered entity. As commentators have emphasized, "It is generally well recognized that the use of setoff promotes efficiency, simplicity and fairness in everyday business transactions. The right of setoff is an equitable remedy that has historically been respected by the laws of every state.[206] This is an important right that has cannot be arbitrarily abrogated with no hint in the 340B law that it was intended to authorized such a result.

Finally, we note that offsets are customary business practice -- as well as a routine part of the Medicaid rebate program, from which 340B ceiling prices are derived -- and HRSA has always emphasized that 340B entities should not be "single[d] out for restrictive guidelines" but are subject to "customary business practices."[207]

In short, HRSA must establish a policy recognizing that manufacturers may net overcharges and undercharges associated with ceiling price recalculations. Such a policy would be consistent with the 340B law; consistent with the Medicaid rebate restatement process; and consistent with manufacturers' common law rights.

Third, PhRMA urges HRSA not to preclude exceptions for de minimis amounts. Establishing a de minimis standard would reduce transaction costs and administrative burdens for both manufacturers and covered entities, and it would be consistent with a long-standing line of case law holding that agencies may establish de minimis requirements to statutes they administer unless Congress has clearly precluded such exceptions[208] -- which is not the case here. As the Court of Appeals for the D.C. Circuit has explained:

> Categorical exemptions may . . . be permissible "as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered de minimis" . . . The ability to create a de minimis exemption " is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design."
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> As long as the Congress has not been "extraordinarily rigid" in drafting the statute . . . "there is likely a basis for an implication of

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[205] Citizens Bank of Maryland v. David Strumpf, 116 U.S. 286, 289 (1995), citing Studley v. Boylston Nat. Bank, 229 U.S. 523, 528, 33 S.Ct. 806, 808, 57 L.Ed. 1313 (1913).

[206] A Creditor's Right to Setoff: When Does a Creditor Impermissibly Improve Its Position: Ben Caughey, 29-JAN Am. Bankr.Inst.J.32 (Dec/Jan 2011).

[207] 59 Fed. Reg. at 25110, 25114.

[208] As explained by commentators: "Unless Congress has clearly said otherwise, agencies will be permitted to make de minimis exceptions to statutory requirements by exempting small risks from regulatory controls .. .. Unless Congress has clearly said otherwise, agencies will be permitted to decline to regulate past the point where regulation would be economically or technologically feasible." A new Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis, R.W. Hahn and C.R. Sunstein, 50 U. Penn. L Rev. 1489, 1510 (May 2002).

> de minimis authority to provide [an]" exemption when the burdens of regulation yield a gain of trivial or no value."
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> [Environmental Defense Fund v. EPA] 82 F.3d 451, 466 (D.C. Cir. 1996), quoting Alabama Power Co. v. Castle, 636 F.2d 323, 360 (D.C. Cir. 1979). Unless it has been "extraordinarily rigid" in expressing itself to the contrary, that is, the Congress is always presumed to intend that "pointless expenditures of effort" be avoided.[209]

Likewise, a de minimis exception to the 340B refund provisions also would be consistent with a number of precedents where de minimis thresholds have been used in analogous circumstances. For example, in the Medicaid rebate context, CMS permits States not to invoice a manufacturer for Medicaid rebates for a quarter, if that quarter's rebates do not exceed a de minimis amount -- $50 per labeler code.[210] CMS has noted in this context that States should "consider the cost-effectiveness of pursuing invoice collection."[211] CMS has exercised its authority to create this de minimis principle even though the Medicaid rebate statute does not speak explicitly of not billing for small amounts that may not be cost-effective to collect.

We think it would be reasonable to establish a de minimis amount and then provide that the manufacturer would still have to make a refund below the de minimis threshold if a covered entity expressly requested such a refund -- in effect, making the de minimis exception a presumption that a covered entity could overcome if a very small refund warranted the effort of requesting it. But it would not be reasonable to prohibit any use of a de minimis threshold, as HRSA now proposes.[212]

Finally, the Proposed Guidance states that manufacturers would submit to HRSA the "ceiling price recalculation information [and] an explanation of why the overcharge occurred."[213] In most instances an "overcharge" would only have occurred because manufacturers have to sell to covered entities at the ceiling price in effect for that quarter, as calculated based on Medicaid rebate metrics from two quarters earlier[214] -- this is the only way to calculate the 340B ceiling price at the time of sale -- but if the ceiling price for a quarter is later recalculated based on restated data from two quarters earlier, then it will differ (and will be lower in some cases). In other words, most "overcharges" will stem from what the 340B law calls "routine instances of

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209 Ass'n of Administrative Law Judges v. FLRA, 397 F.3d 957 (D.C. Cir. 2005)

210 CMS, Medicaid Drug Data Guide for Labelers, § 7.1.

211 CMS, Medicaid Drug Rebate Dispute Resolution Program (for States), § II.2, available at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/bestpracst.pdf.

212 PhRMA also would be amenable to adopting a de minimis exception for those instances in which a covered entity notifies a manufacturer of a refund due the manufacturer.

213 80 Fed. Reg. at 52321.

214 The 340B ceiling price equals the AMP minus the Medicaid Unit Rebate Amount (URA), calculated based on the AMP and Best Price values initially filed with CMS. Those values would reflect sales from two quarters earlier because they would be the most recent values available at the time that a 340B ceiling price for a quarter needs to be set. After the AMP and URA for a quarter are initially filed and used to set the 340B ceiling price, they may later be restated with CMS.

retroactive adjustments to relevant pricing data," in which event this may be the only explanation needed of an "overcharge."

D. Manufacturer Recertification

HRSA proposes to create a manufacturer recertification process under which HRSA would "list manufacturers as participating in the 340B program" if they annually update their 340B database information.[215] Manufacturers also "should provide [HRSA] with any changes to 340B database information as changes occur" and HRSA could request supporting documentation.[216] According to the Proposed Guidance, "[t]his process is designed to prevent pricing violations and improve the accuracy of the public 340B database."[217]

PhRMA requests HRSA to provide greater specificity regarding its proposals. Specifically, HRSA does not explain what information would be required to "recertify" the manufacturer as a 340B program participant, what type of "supporting documentation" it would need, and under what circumstances such documentation would be requested. Further, there are no timelines proposed as to when manufacturers would be required to update their 340B database information, or how long HRSA would take to confirm that the manufacturer has successfully "recertified." HRSA also should specify applicable timelines associated with any submission or review of supporting documentation. Finally, since we do not know what information will be required for purposes of the recertification, we do not understand how the process will prevent pricing violations (and HRSA does not provide an explanation). We recommend that HRSA propose the specific requirements, including timelines, that manufacturers would be required to meet, and then publish these standards for notice and comment.

IX. REBATE OPTION FOR AIDS DRUG ASSISTANCE PROGRAMS

HRSA proposes that ADAPs choosing to use the rebate option (either solely or as part of the "hybrid" option) would be eligible for 340B pricing if the ADAP makes a "qualified payment" of covered outpatient drugs. A payment would be considered a qualified payment if the ADAP: (1) purchases drugs at a price above the 340B ceiling price; or (2) purchases the patient's health insurance (by paying the premium), and pays the cost-sharing on that drug.[218] This proposal is based on two conclusions HRSA reached: (1) "that the use of ADAP funds to make a qualified payment . . . constitutes a purchase [for 340B program purposes]"; and (2) "that the payment by the ADAP of a copayment, coinsurance, or deductible, in the absence of also paying for the health insurance premium, is too attenuated within the context of the 340B Program to constitute a 'purchase.'"[219] We understand that under scenario two this proposal would permit 340B rebates as long as the ADAP pays the patient's share of the premium plus

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215 80 Fed. Reg. at 52312.

216 80 Fed. Reg. at 52312.

217 80 Fed. Reg. at 52313.

218 80 Fed. Reg. at 52313.

219 80 Fed. Reg. at 52313.

the patient's cost-sharing. PhRMA supports this proposal. We urge HRSA to implement this policy in a way that avoids any disruption to patient care.[220]

Under the Proposed Guidance, the rebate owed to the ADAP for a drug would equal the Medicaid unit rebate amount (URA), regardless of the amount expended by the ADAP to pay the patients' health insurance premium and cost-sharing.[221] HRSA stated that it "considered a percentage rebate whereby an ADAP would be entitled to a percentage of the rebate on a dispensed drug contingent on the percentage of the total cost of the drug borne by the ADAP" but decided this approach would be unworkable.[222] PhRMA appreciates that HRSA considered this alternative approach that arguably would result in a more equitable result for manufacturers. However, PhRMA understands that such an approach would add complexity to an already complex program, and thus we support HRSA's proposal that the amount owed to an ADAP for a covered outpatient drug would be equal to the full Medicaid URA.[223]

Finally, the Proposed Guidance cautions that "no covered entity may obtain 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price."[224] However, HRSA does not identify any particular mechanism that ADAPs should use to prevent this. PhRMA supports this general principle, and urges HRSA to clarify in its final guidance that this issue concerns 340B duplicate discounts (as opposed to Medicaid/340B duplicate discounts). We also urge HRSA to specify the mechanism for preventing these "double 340B" discounts and, in particular, to provide that non-ADAP covered entities may not use 340B drugs in instances where an ADAP is the payer. In other words, non-ADAP covered entities may not bill ADAPs for drugs purchased at the 340B price, and thus trigger a duplicate discount (or take the 340B discount for itself rather than the ADAP).

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220 HRSA may want to work with Congress to confirm and further solidify this approach.

221 80 Fed. Reg. at 52314.

222 80 Fed. Reg. at 52314.

223 HRSA also proposes that ADAPs would be "expected" to submit claims-level data to a manufacturer to receive a rebate. 80 Fed. Reg. at 52313. PhRMA supports HRSA's proposal for ADAPs to submit claims-level data. We urge HRSA to work with stakeholders to determine the right data points necessary for manufacturers to process claims appropriately and ensure that no double discounting occurs, and that would not be unnecessarily burdensome to ADAPs. We also ask HRSA to make submission of claims-level data accompanying the ADAP's invoice to the manufacturer a requirement, rather than an expectation. HRSA should establish a workable policy within a timeframe that is reasonable to ensure that ADAPs are able to implement the proper reporting mechanisms to meet HRSA's requirements.

224 80 Fed. Reg. at 52313-52314.

X. PROGRAM INTEGRITY AUDIT PROVISIONS

A. HHS Audits of Covered Entities

The Proposed Guidance includes a number of audit-related proposals,[225] including a proposal for a "notice and hearing process" to allow covered entities to challenge adverse audit findings and/or other instances of noncompliance.[226] Under this process, HHS would notify a covered entity of a proposed adverse finding, and the entity would have 30 days to respond. If a final determination of noncompliance were made, the covered entity could be removed from the 340B program, or could be permitted to remain in the program if it submitted and complied with a corrective action plan. Entities found in violation of the 340B statute must repay affected manufacturers for 340B purchases "made after the date the entity first violated the statutory requirement" (this statement necessarily must refer to eligibility-related violations).[227]

Under the Proposed Guidance, HRSA would extend the notice and hearing process to "covered entities found in violation of the GPO prohibition," and would permit entities to demonstrate that "the GPO violation was an isolated error as opposed to a systematic violation."[228] HRSA proposes that "[i]f the covered entity were to demonstrate the GPO violation was an isolated incident and the covered entity is currently in compliance, the covered entity will be permitted to remain in the 340B Program upon submission of a corrective action plan." HRSA's proposal is inconsistent with the statute. As HRSA knows, the 340B law prohibits -- as a condition of eligibility -- disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals from "obtain[ing] covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."[229] When such a hospital is in violation of the GPO prohibition, it is not a "covered entity" under the 340B program, and HRSA does not have the discretion to permit "non-systematic" non-compliance with the statute. Simply put, a hospital is either eligible or ineligible for the 340B program. Corrective action plan or not, HRSA may not expand the 340B program to hospitals that do not meet statutory eligibility criteria.[230] PhRMA urges HRSA to abandon this impermissible approach in its final guidance.

With respect to violations of the duplicate discount or diversion prohibitions, PhRMA urges HRSA to provide specific details as to what would constitute a "systematic" violation that would warrant removing the covered entity from the 340B program. Because statutory monetary penalties for covered entities are minimal, removal from the 340B program is the only meaningful deterrent for covered entity compliance. Thus, it is important that covered entities have notice as to what behavior will result in removal from the program. PhRMA recommends, at a minimum, that a systematic violation would be one that occurs over and over and over again.

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[225] In the Proposed Guidance, HRSA proposes a five year record retention standard for both covered entities and manufacturers. PhRMA believes this time period is appropriate, and supports this proposal.

[226] 80 Fed. Reg. at 52314.

[227] 80 Fed. Reg. at 52315.

[228] 80 Fed. Reg. at 52305.

[229] 42 U.S.C. § 256b(a)(4)(L)(iii), (M).

[230] Our comments are not limited to ineligibility solely related to the GPO prohibition, but apply for all instances of ineligibility according to the terms of the statute, e.g., loss of grant funding, failure to maintain auditable records, etc.

B. Manufacturer Audits of Covered Entities

Consistent with existing guidance, HRSA states that to audit a covered entity a manufacturer must establish "reasonable cause."[231] To satisfy reasonable cause, a manufacturer would have to "document[] to HHS's satisfaction that a reasonable person could conclude, based on reliable evidence, that a covered entity, its child sites, or contract pharmacies may have violated either [the duplicate discount or diversion prohibition]."[232] HRSA provides a few examples of what could constitute reasonable cause, as follows:

- significant changes in quantities of specific drugs ordered by a covered entity without adequate explanation by the covered entity;
- significant deviations from national averages of inpatient or outpatient use of certain drugs without adequate explanation by the covered entity; and
- evidence of duplicate discounts provided by manufacturers or State Medicaid agencies.[233]

In addition, "a covered entity's refusal to respond to manufacturer questions related to 340B drug diversion and duplicate discounts may also be construed as reasonable cause."[234] PhRMA supports HRSA's proposal, and agrees that these examples would constitute reasonable cause for a manufacturer to audit a covered entity. PhRMA also agrees that the list of examples is not exhaustive. We recommend that HRSA's final guidance on "reasonable cause" remain consistent with the Proposed Guidance.

Under the statute, a covered entity must permit the Secretary and the manufacturer to audit "the records of the entity that directly pertain to the entity's compliance" with the statutory prohibition against duplicate discounts and diversion. In HRSA's discussion in the Proposed Guidance of HHS audits of covered entities, HRSA explains that "HHS must be provided access to all records pertaining to compliance, including those of any child site or pharmacy which is under contract with the covered entity." PhRMA agrees that all such records -- including those of child sites and contract pharmacies -- are relevant to determining a covered entity's compliance with the prohibition on duplicate discounts and diversion. HRSA does not explicitly state that such records must be provided pursuant to manufacturer audits, however. PhRMA urges HRSA to clarify in its final guidance that such records are equally pertinent in the context of manufacturer audits and thus manufacturers also should be provided records of child sites and contract pharmacies, as applicable.

Finally, HRSA's current audit guidelines contemplate circumstances in which multiple manufacturers may have the same concern about a particular covered entity's practices. According to the current guidance:

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231 80 Fed. Reg. at 52315.

232 80 Fed. Reg. at 52315.

233 80 Fed. Reg. at 52315.

234 80 Fed. Reg. at 52315.

> Consistent with Government auditing standards, the organization performing the audit shall coordinate with other auditors, when appropriate, to avoid duplicating work already completed or that may be planned. Only one audit of a covered entity will be permitted at any one time. When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's compliance with [duplicate discount and diversion prohibitions], the Department will determine whether an audit should be performed by the (1) Government or (2) the manufacturer.[235]

PhRMA recognizes that HRSA has limited resources and that it may take time for HRSA to take on the audit itself in such circumstances. Therefore, HRSA should provide that in cases where multiple manufacturers with overlapping concerns wish to have an audit conducted, the manufacturers may coordinate on audits of the same covered entity so that an audit may promptly proceed and the covered entity will not be overwhelmed by multiple back-to-back audits.

C. HHS Audits of a Manufacturer and its Contractors

The Proposed Guidance provides for HHS audits of "a manufacturer or wholesaler that manufacturers, processes, or distributes covered outpatient drugs in the 340B Program."[236] HRSA also proposes a notice and hearing process, and the potential for a manufacturer to implement a corrective action plan. In general, PhRMA would support HRSA's proposal regarding manufacturer audits; however, we have two comments regarding HRSA's specific proposal. First, we note that the 340B statute specifically permits HRSA to audit "manufacturers and wholesalers" to ensure program integrity.[237] HRSA's proposal provides that HHS would audit "all relevant records retained by the manufacturer or any of its contractors (such as wholesalers) . . ." This goes beyond HRSA's statutory authority, which extends only to manufacturers and wholesalers (and covered entities). We recommend that HRSA correct this language in its final guidance to be consistent with the statute. Second, HRSA's statutory authority to audit wholesalers does not confer any responsibility on manufacturers for ensuring a wholesaler's cooperation with HRSA in any audit. HRSA should recognize this point in its final guidance.

D. Covered Entity Audits of Contract Pharmacies

In the Proposed Guidance, HRSA refers to its 2010 contract pharmacy guidance[238] that recommended that covered entities conduct annual audits of contract pharmacies. The Proposed Guidance "further clarifies the expectations of this recommendation."[239] Given the widespread problems and increased compliance risks associated with contract pharmacies (as described in Section VII), PhRMA recommends that HRSA require (as opposed to simply

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235 61 Fed. Reg. 65406 at 65409 (Dec. 12, 1996).

236 80 Fed. Reg. at 52315.

237 42 U.S.C. §§ 256b(d)(1)(B)(v).

238 75 Fed. Reg. at 10272 (March 5, 2010).

239 80 Fed. Reg. at 52311.

recommend) that covered entities have annual independent on-site audits conducted of contract pharmacies. This requirement also should extend to any third party administrators or other vendors providing 340B-related services for a covered entity. These audits should be performed by an independent third party, and should follow Government Accepted Auditing Standards.[240] Covered entities also should be required to submit the results of these annual audit reports to HRSA within 30 days of completion. In addition, covered entities should submit a corrective action plan to HRSA at that same time if their audit reports have found 340B program violations.

XI. MISCELLANEOUS

A. Public Health Emergencies

PhRMA noticed that HRSA's Proposed Guidance provides for "flexibilities" regarding certain aspects of the 340B program in instances where the HHS Secretary has declared a public health emergency.[241] Specifically, HRSA states that "unique circumstances . . . arise during a public health emergency declared by the Secretary" and proposes to allow "certain flexibilities for demonstrating that an individual is a patient of a covered entity in these situations (e.g., limited medical documentation or a site not listed in the 340B database)."[242] In the contract pharmacy context, HRSA proposes to makes special provision for public health emergencies by permitting covered entities to request additional contract pharmacy locations under a public health emergency.[243] Also, HRSA envisions mid-quarter covered entity additions or deletions in a public health emergency situation.[244]

The Proposed Guidance provides little information about how HRSA would decide when a particular public health emergency warranted an exception to 340B requirements and precisely what exceptions were needed, nor does it explain whether it believes it can grant exceptions to statutory requirements (e.g., the diversion ban). HRSA also does not reference its current guidance published on its website, "340B Flexibilities During Disasters,"[245] or explain whether it intends the Proposed Guidance (once finalized) to replace its current website guidance. The guidance on the HRSA website appears to limit 340B "flexibilities" to 340B providers "participating in disaster relief efforts."

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240 We think this requirement is important, as the covered entity itself may not have the same incentive to detect violations that an independent auditor would have.

241 These emergency declarations are made under 42 U.S.C. § 247d (which is scheduled to terminate on September 30, 2018, and permits public health emergency determinations where a disease or disorder presents a public health emergency or a public health emergency (including infectious disease outbreaks or bioterrorist attacks) "otherwise exists)." Public health emergencies terminate after 90 days unless the Secretary declares before then that the emergency no longer exists, or renews the emergency determination.

242 80 Fed. Reg. at 52307-52308.

243 80 Fed. Reg. at 52310-52311.

244 80 Fed. Reg. at 53112, 52318.

245 The guidance on 340B Flexibilities During Disasters is available at: http://www..hrsa.gov/opa/emergencies.html.

PhRMA urges HRSA to clarify these points in its final guidance. In general, PhRMA understands and supports the notion that certain emergencies may necessitate certain "flexibilities." That said, it is important that HRSA exercise these flexibilities very carefully and only when needed. In addition, the exercise of any flexibilities should not depart from statutory requirements or other standards that are central to the integrity of the 340B program.

* * *

We hope our comments are useful to HRSA, and we would be happy to discuss these issues with you if you have any questions or need clarification. PhRMA greatly appreciates HRSA's consideration of our concerns and we stand ready to assist with any of the issues raised in our letter. Please contact Sylvia Yu at 202-835-3496 (syu@phrma.org) or Karyn Schwartz at 202-835-3491 (kschwartz@phrma.org) with any questions.

Sincerely,

Lori Reilly
Executive Vice President
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October 11, 2016

BY ELECTRONIC FILING (http://www.regulations.gov)

Captain Krista Pedley
Director, HRSA Office of Pharmacy Affairs
5600 Fishers Lane, Room 8W10
Rockville, Maryland 20857

Re: 340B Drug Pricing Program Proposed Rule on Administrative Dispute Resolution, RIN 0906-AA90

Dear Captain Pedley:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the 340B program proposed rule on Administrative Dispute Resolution (ADR) published by the Health Resources and Services Administration (HRSA).[1] PhRMA is a voluntary, non-profit organization representing the nation's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to lead longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billon in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone.

PhRMA supports the 340B program, which was enacted to help make prescription drugs more accessible to uninsured or vulnerable patients. Our comments are intended to help assure that in future years the program is strong, sustainable, and administered fairly and consistent with the 340B statute. A fair, efficient, and expeditious ADR process is central to achieving these goals. We hope our comments will help HRSA to build the foundations necessary for a well-functioning ADR process and ultimately (once the ADR foundations are in place) to issue a new proposal that will lead to such an ADR process. For reasons detailed below, however, we are concerned that at this juncture the proposed rule would establish an ADR process prematurely, before key ground rules that must necessarily shape the ADR process have been established. We also have many suggestions on additional aspects of a sound ADR process that we hope will ultimately be useful to HRSA in crafting such a process.

Briefly stated, our key recommendations can be summarized as follows:

- *Overarching Issues.* PhRMA agrees with HRSA that a 340B ADR process should be designed to facilitate fair, efficient, and timely resolution of claims. Today, the conditions for creating such a process are not in place. Manufacturers have no realistic ability to use the ADR process before the current audit guidelines have been reformed, since an audit is the gateway to the ADR process for a manufacturer. And more generally, threshold issues that should shape a fair and sound ADR process have not yet been addressed.

[1] 81 Fed. Reg. 53381 (Aug. 12, 2016).

Accordingly, PhRMA recommends that, before HRSA seeks to develop an ADR process, HRSA must put the foundations in place, i.e.: (1) reform its audit guidelines; (2) develop manufacturer refund procedures for cases where 340B ceiling prices change due to restated Medicaid rebate metrics; (3) finalize the process for calculating ceiling prices and imposing civil monetary penalties; and (4) finalize the 340B mega-guidance.

- *340B Administrative Dispute Resolution Panel.* HRSA should designate an HHS ALJ to decide 340B disputes and allow for flexibility in determining whether one or three ALJs are needed to decide the dispute on a claim-by-claim basis.

- *Duties of the ADR Decision-Makers*. HRSA should provide parties with the opportunity to present evidence live in front of the ADR decision makers. Further, HRSA must develop protections to ensure that all proprietary or otherwise confidential information that is disclosed during the ADR process remain secret.

- *Claims Permitted.* We urge HRSA to recognize that, in accordance with the 340B statute, manufacturers may bring ADR claims if the manufacturer itself or another manufacturer has conducted an audit of that covered entity. We also ask HRSA to recognize that claims that a covered entity is not eligible for the 340B program or that a hospital outpatient facility does not meet HRSA's "child site" criteria are diversion claims and can therefore be resolved through the ADR process, because an ineligible entity or facility is not providing 340B drugs to legitimate 340B "patients." Finally, a party should be able to bring ADR claims based on a dispute concerning the dollar amount attributable to a violation.

- *Requirements for Filing Claims.* HRSA should toll the three-year limitation period for manufacturer ADR claims, from the point when a manufacturer first seeks to conduct an audit until the audit is finished. All claims should be accompanied with documentation that describes previous good faith efforts to resolve the dispute. HRSA should also consider including a documentation requirement concerning the materiality of the claim.

- HRSA should list separate documentation requirements for the three different overcharge claims a covered entity might assert against a manufacturer: (1) claims that the initial purchase price of a drug purchased by the covered entity exceeded the ceiling price at that time; (2) claims that the purchase price of a drug should have been adjusted downward later and a refund should have been issued at a specified later point in time, but was not issued within the time period required under the yet-to-be-developed refund procedures; or (3) claims that the covered entity tried unsuccessfully to buy at the ceiling price, was wrongfully denied the 340B price due to manufacturer fault and without justification, and due to the wrongful denial of the ceiling price, the entity purchased the drug at a price exceeding its ceiling price.

- *Consolidation of Claims.* We recommend that HRSA require both covered entities and manufacturers to affirm that they will not bring any individual claims against the other party that overlap with any claims they wish to consolidate. We also suggest that HRSA only permit consolidation of claims in which the overcharges involve substantially the same

NDCs and quarters. For consolidated manufacturer claims, HRSA should add a requirement that: (1) all manufacturers assert covered entity duplicate discount violations, diversion violations, or both arising out of the same policy or practice by the covered entity; and (2) all manufacturers assert these violations during the same time period. HRSA must also recognize manufacturers' right to pursue claims (consolidated or otherwise) through a trade association or other agent of their choice.

- *Deadlines and Procedures for Filing Claims*. Advance notification of potential claims and the opportunity to resolve them are crucial. Accordingly, manufacturers should have the same advance notice of potential claims as covered entities who learn of such claims due to a prior audit.

- *Responding to a Submitted Claim*. We recommend that HRSA change the period to respond to claims to 60 days with potential extensions if needed.

- *Information Requests.* We oppose HRSA's approach to information requests, which in effect makes manufacturers responsible for obtaining information from third parties. HRSA must not finalize this approach, which the statute does not permit. With regard to the timeline for information production, HRSA should provide the responding party 60 days to respond (with extensions where needed). In addition, manufacturers must have the right to submit information requests in the event that they are unable to obtain all relevant information during an audit or new information relevant to the dispute arises. Therefore, to accord with basic standards of fairness, HRSA must allow manufacturers to submit information requests regarding disputes just as covered entities can.

- *Final Agency Decision*. HRSA should use a "preponderance of the evidence" standard to decide 340B disputes. Once the panel reaches its decision, HRSA should mandate the issuance of a summary that includes a transparent analysis of the reasons for the decision, without disclosing any proprietary or otherwise confidential information. HRSA should also recognize that the panel decision is binding on the parties involved in the dispute (unless otherwise overturned by a court), but is not binding on third parties. Lastly, if HRSA is considering using the ADR decision as part of a proceeding to seek sanctions against the losing party, HRSA should (1) notify that party of any sanction or enforcement action under consideration, along with the basis for the potential sanction, (2) adhere to all statutory and regulatory provisions governing the imposition of the sanction in question; and (3) not seek sanctions based on an ADR decision that is under review in a court action.

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I. OVERARCHING COMMENTS ON THRESHOLD ISSUES

PhRMA agrees with HRSA that a 340B program ADR process should be "fair, efficient, and [facilitate] timely resolution of claims."[2] To that end, an ADR process must be built on fair and well-defined ground rules that adhere to the 340B law. Otherwise the ADR process -- which should enhance program integrity by providing a balanced, efficient, and prompt mechanism to enforce clear ground rules -- will not meet these key criteria. PhRMA and its member companies appreciate the efforts that HRSA has made to date to establish those ground rules. But much remains to be done: the foundations that must shape a sound ADR system are not yet in place. As a result, the sequence of HRSA's activities must be re-ordered; before we can have a fair ADR process that resolves disputes based on clear ground rules consistent with the 340B law, we need the foundations.

We have four key concerns about the missing foundations for a well-designed ADR process:

First, HRSA has not made -- or even proposed -- the reforms to its 340B audit guidelines that must be put into place before a fair and efficient ADR system could be established. For manufacturers, an audit is the gateway to the ADR process. A manufacturer may not initiate an ADR proceeding absent a prior audit that provides a basis for asserting that a covered entity has violated the diversion or duplicate discount prohibitions.[3] Yet the existing guidelines for manufacturers to audit 340B entities, issued in 1996,[4] suffer from critical defects that make manufacturer audits nearly infeasible. The result is a blocked gateway to the ADR process for manufacturers. And a one-sided ADR system in which covered entities can institute ADR claims but manufacturers face nearly insuperable barriers to instituting ADR claims would weaken confidence in the integrity of the 340B program.

HRSA recognized the barriers to manufacturer audits presented by the 1996 audit guidelines -- and the resulting barriers to manufacturer ADR claims -- when it issued an Advanced Notice of Proposed Rulemaking on ADR in 2010. At that time, HRSA stated:

> The alternative dispute resolution provisions in the Affordable Care Act set forth that manufacturers must conduct an audit of a covered entity prior to bringing [an ADR] claim. HRSA currently has guidelines regarding the requirements for initiating an audit (61 FR 65406). However, over the history of the 340B program manufacturers have rarely utilized the process in the guidelines to conduct an audit. HRSA invites comments on whether it is appropriate or necessary to modify the guidelines concerning audits prior to implementing the administrative dispute resolution regulation or whether the current final guidelines are sufficient.[5]

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[2] 81 Fed. Reg. at 53385.

[3] 42 U.S.C. § 256b(d)(3)(A), (B)(iv).

[4] 61 Fed. Reg. 65406 (Dec. 12, 1996).

[5] 75 Fed. Reg. 57233, 57235 (Sept. 20, 2010) (emphasis added).

As detailed in the comments submitted by PhRMA and many other program stakeholders, there are good reasons why manufacturers have rarely utilized the audit process, and substantial modifications to the 1996 audit guidelines are necessary prior to implementing an ADR regulation; in fact, substantial reforms in the 1996 audit guidelines are necessary before HRSA can even propose an ADR regulation. After raising this issue in 2010, however, HRSA has now issued a proposed ADR regulation without reforming the audit guidelines or even acknowledging the need for reforms.

The 1996 audit guidelines have critical problems that prevent the possibility of a fair and efficient ADR system. These are strong words but fully warranted:

- The 1996 audit guidelines do not permit audits of covered entities by manufacturers' internal audit staff and instead require that manufacturers hire an outside auditing firm in order to exercise their audit rights.[6] This barrier to manufacturer audits is not consistent with the 340B law, which provides that "the manufacturer" may audit covered entities for diversion and duplicate discount violations, subject only to HRSA procedures on the "number, duration, and scope of audits."[7] Nothing in this statutory provision permits HRSA to ban manufacturer audits and require that manufacturers hire outside auditors. The statute's ADR provisions reinforce this point, stating that HRSA's ADR regulations shall require that "a manufacturer conduct an audit" as a prerequisite to an ADR proceeding.[8] HRSA may not substitute "an outside auditor hired by a manufacturer" for "a manufacturer" and thereby create barriers to manufacturer audits not found in the statute.

- Further, the 1996 guidelines state that "confidential patient information and/or proprietary information which [outside] auditors may access will not be disclosed to the manufacturer."[9] This could deny manufacturers access to details underlying audit conclusions that they might need to prove an ADR claim, and it is unnecessary because manufacturers' internal audit staff are entirely capable of safeguarding confidential information.

- In the few cases where manufacturers have conducted audits, we understand that HRSA's requirement that they hire outside auditors has resulted in audits costing a minimum of $50,000-$100,000. As a result, audits are cost-prohibitive unless the scale of an entity's diversion or duplicate discounts is large enough that manufacturers can expect to recover at least $50,000-$100,000 from doing the audit. This sends a message that diversion and duplicate discounting violations will rarely result in audits and manufacturer recoveries, providing little incentive for covered entity compliance efforts.

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[6] 61 Fed. Reg. at 65409.

[7] 42 U.S.C. § 256b(a)(5)(C).

[8] 42 U.S.C. § 256b(d)(3)(B)(iv) (emphasis added).

[9] 61 Fed. Reg. at 65409.

- HRSA's 1996 guidelines create a further barrier to manufacturer audits by "requir[ing] manufacturers to submit an audit work plan for [HRSA's] review and to establish reasonable cause."[10] The requirement that manufacturers establish "reasonable cause" to believe a violation has occurred before they can conduct an audit exceeds HRSA's statutory authority -- which is limited to establishing procedures concerning the "number, duration, and scope of audits,"[11] and prevents random audits that are central to deterrence.

- Finally, HRSA's 1996 audit guidelines provide that even if multiple manufacturers have reasonable cause to audit a covered entity: "Only one audit of a covered entity will be permitted at one time." When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's compliance with [the diversion or duplicate discount prohibitions] the Department will determine whether an audit should be performed by the (1) Government or (2) the manufacturer."[12] This policy would prevent a manufacturer (and possibly all affected manufacturers) from conducting an audit in cases where a covered entity is being audited by another manufacturer or HRSA. This barrier to manufacturer audits is just one more reason why the 1996 audit guidelines must be thoroughly reformed before a fair and well-functioning ADR process could be developed.

Second, the 340B law requires HRSA to "develop procedures for manufacturers to issue refunds to covered entities in the event there is an overcharge by the manufacturers," including oversight to ensure that refunds are issued accurately and in a reasonable period of time both in routine instances of retroactive adjustment to relevant pricing data and in exceptional circumstances.[13] HRSA has yet to develop or even propose those procedures, which are necessary prerequisites to an ADR process. In circumstances where an alleged manufacturer "overcharge" stems from a routine restatement in the underlying Medicaid rebate metrics that set the 340B ceiling price, there is no "overcharge" unless a manufacturer has failed to provide a refund to the covered entity within the time period established by HRSA's refund procedures. PhRMA has previously recommended to HRSA that this time period should be set at four years after the initial filing of the Medicaid rebate metrics that establish the 340B ceiling price for a particular quarter. Four years makes sense because manufacturers have three years to restate rebate metrics[14] (and therefore restated metrics and revised ceiling prices are not yet final before this three-year period has run), and once a finalized ceiling price for a past quarter can be determined manufacturers need time to calculate refunds to specific covered entities and deliver refunds. We continue to recommend that HRSA adopt a four-year period for refunds that stem from revised ceiling prices associated with routine restatements in Medicaid rebate metrics. But for present purposes the key issue is that HRSA has not established any time period for these refunds, as it has yet to establish the required refund procedures.

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[10] 61 Fed. Reg. at 65406.

[11] 42 U.S.C. § 256b(a)(5)(C).

[12] 61 Fed. Reg. at 65409 (emphasis added).

[13] 42 U.S.C. § 256b(d)(1)(B)(ii).

[14] 42 C.F.R. § 447.510(b).

Without the refund procedures, no "overcharge" can occur in a case based on restated Medicaid rebate metrics and an ADR process that permits "overcharge" claims based on restated rebate metrics would be premature.

Another problem with permitting "overcharge" claims based on restated Medicaid rebate metrics is that (as previous PhRMA comments have explained) the yet-to-be-established refund procedures must permit offsets of covered entity overpayments and underpayments to a manufacturer. If 340B ceiling prices are to be determined by the final restated rebate metrics for a drug for a particular quarter, then final ceiling prices will be lower than the initial ceiling price in some cases and higher than the initial ceiling price in other cases. A manufacturer cannot be held responsible for an "overcharge" if the net amount it owes to a covered entity is zero or negative. We need refund procedures that recognize this basic principle before an ADR process can be established.

Third, an overcharge cannot be determined until HRSA has finalized its proposed regulations on calculating 340B ceiling prices and civil monetary penalties. We believe that refund procedures are necessary prerequisites to such final regulations (as explained in previous PhRMA comments). There are additional aspects of the ceiling price calculation that also must be finalized before ceiling prices may be determined that provide the basis for HRSA's password-protected confidential ceiling price disclosure system[15] and ultimately for an ADR process that resolves "overcharge" claims. Until we have appropriate final ceiling price regulations and the password-protected disclosure system in place, the foundations for an ADR process that resolves overcharge claims are missing.

Finally, HRSA has not yet finalized its proposed 340B mega-guidance -- which will establish final guidelines describing 340B "patients" as well as duplicate discount violations. Diversion violations (where a covered entity provides 340B drugs to individuals or entities other than "patients") and duplicate discount violations are the basis for manufacturer-ADR claims.[16] Accordingly, final guidance on these issues is a necessary predicate to an ADR process for the resolution of manufacturer claims.[17]

In short, critical foundations for crafting an ADR process are missing. We urge HRSA to establish those foundations and then to issue a new proposal for an ADR process that is fair and built on clear, final ground rules that are essential to resolve overcharging, diversion, or duplicate discounting disputes.

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[15] 42 U.S.C. § 256b(d)(1)(B)(iii).

[16] 42 U.S.C. § 256b(d)(3)(A).

[17] For example, HRSA's proposed megaguidance includes a requirement that for an individual to be a "patient" of a covered entity, the covered entity must "maintain[ ] access to auditable healthcare records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each drug." 81 Fed. Reg. 52300, 52319 (Aug. 28, 2015). Assuming that this guideline is finalized, it would have important implications for what a manufacturer would need to establish in order to show that 340B drugs were furnished to an individual who did not qualify as a "patient" in violation of 42 U.S.C. § 256b(a)(1)(B), as a manufacturer could prove such a violation based on an absence of auditable records establishing a patient relationship.

II. 340B ADMINISTRATIVE DISPUTE RESOLUTION PANEL

A. Members of the 340B ADR Panel

HHS must "designate or establish a decision-making official or decision-making body within the Department of [HHS]" to resolve 340B ADR claims.[18] PhRMA believes that the qualifications and independence of the 340B ADR decision-making official or body are the keys to establishing an ADR process that facilitates the "fair, efficient, and timely resolution of claims."[19] To promote these objectives, it is important that the ADR decision-makers both be independent and have expertise in the 340B program, so that they are well-positioned to make high-quality, impartial decisions.

With these objectives in mind, we believe that the HHS Secretary should designate one or more HHS Administrative Law Judges (ALJs) to decide 340B ADR claims. An ALJ would be in the best position to resolve 340B disputes because ALJs have the professional background and legal training to decide administrative law issues correctly, and using an ALJ would help to ensure an objective evaluation of each dispute by separating the dispute resolution function from HRSA's day-to-day activities and duties. ALJs are also subject to hiring, compensation, rotation, evaluation and discharge protections that help promote their independence.[20] Designating a subset of the HHS ALJs to decide 340B ADR claims (when they arise) would enable these ALJs to develop expertise on 340B issues through training and repeated experience, and would thus promote consistent, well-reasoned decisions that are recognized as fair by all program stakeholders.

We encourage HRSA to allow for flexibility in deciding how many ALJs are needed to decide an ADR claim, allowing for some variation based on the complexity of a claim and other appropriate factors. We recommend designating one full-time ALJ to oversee and participate in all 340B disputes, with the authority to assign a panel of three ALJs (in total) when needed for a particular dispute.[21] This flexibility to use one or three ALJs to resolve a dispute could help to conserve resources (which is important), but we emphasize that above all the ADR process should be structured to promote carefully-reasoned, high-quality decision-making; a panel of three ALJs should thus be used to resolve a dispute whenever warranted to achieve this goal.

We believe it would be unnecessary and undesirable to involve an ex-officio, non-voting HRSA representative in the ADR dispute resolution process, and therefore we do not support this proposal. We believe that HHS ALJs who are designated to decide 340B disputes should be capable of resolving these disputes by reference to the 340B statute, regulations, and written HRSA guidance, without seeking unwritten HRSA advice or guidance that might depart from the published program guidance available to stakeholders.

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[18] 42 U.S.C. § 2566b(d)(3)(B)(i).

[19] 81 Fed. Reg. at 53385.

[20] *See* 5 U.S.C. §§ 3105, 7521, 5372, 3344, 1305.

[21] When more than one ALJ is needed to resolve a dispute given its complexity, then we recommend using a panel of three to avoid ties.

If using HHS ALJs to decide 340B disputes is not feasible, HRSA should develop a corps of talented decision-makers that are selected based on their understanding of and expertise in the 340B program. All selected HHS employees should be formally trained on the 340B program and evaluated based on their performance (i.e., careful reasoning, adherence to the law, fairness and objectivity) in deciding 340B disputes.

B. Conflicts of Interest

HRSA proposes that, to promote fairness and objectivity, each proposed member of an ADR panel[22] would be screened prior to reviewing a claim and not allowed to conduct a review if any conflicts of interest exist (for example, conflicts regarding the parties involved or the subject matter of the claim).[23] HRSA would screen potential panel members for conflicts of interest in accordance with U.S. Office of Government Ethics policies and procedures. PhRMA supports this proposal. However, the Office of Government Ethics rules are not designed specifically for government employees performing adjudicative functions. Therefore we suggest that HRSA supplement those rules with the conflict of interest standards for Medicare ALJ in 42 C.F.R. § 405.1026.

Given the importance of avoiding conflicts of interest to "ensure an unbiased and fair review of the claims,"[24] HRSA also should propose regulations on "[t]he specific procedures for screening members of the panel prior to their service on the 340B ADR Panel" instead of addressing those procedures in "future guidance."[25]

C. Duties of the ADR Panel

The proposed rule refers to ADR panels deciding disputes based on documentation provided by the parties and does not propose live hearings to help clarify factual or legal questions pertinent to the dispute.[26] PhRMA recommends that HRSA provide both parties with the opportunity to discuss the issue live in front of the ADR panel. Relying exclusively on a paper record could potentially lengthen the ADR process if the documents were interpreted differently by the parties and further clarification were needed before proceeding. Discussing the issue live allows questions arising from the paper records to be resolved efficiently (rather than submitting back and forth written responses), promoting prompt and high-quality decisions. By enabling parties to present evidence and respond to panel questions orally, HRSA can provide a forum where information is shared among affected parties and where the parties can witness the panel's decision-making process firsthand. The decision makers (which we believe should be ALJs, as discussed above) will also be able to clarify exactly what factual and legal issues are in dispute between the parties more easily with the opportunity to ask questions of the parties live.

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[22] In the rest of this letter, when we make recommendations related to the "panel," we are using the term "panel" to suggest our recommendation of 1 or 3 ALJs, not the specific type of panel that HRSA is proposing.

[23] 81 Fed. Reg. at 53382.

[24] 81 Fed. Reg. at 53382.

[25] 81 Fed. Reg. at 53382.

[26] 81 Fed. Reg. at 53382-83.

PhRMA supports HRSA's proposal that the panel may "review claims in a session closed to the parties involved, including any associations or organizations, or legal counsel representing the parties," [27] provided that the parties have the opportunity for a live discussion. A closed session in which ALJ panel members can discuss the dispute among themselves can help to produce a well-reasoned decision and promote the integrity of panel decisions. We do not support the proposal for the panel to consult with subject matter experts within HRSA regarding 340B program requirements for reasons noted earlier, as we believe disputes are best resolved based on the 340B statute, regulations, and written program guidance.

Finally, we urge HRSA to develop safeguards to ensure that all proprietary or otherwise confidential information in the parties' written submissions or disclosed at a live discussion is protected. Covered entity ADR claims must allege overcharges and therefore will necessarily hinge on confidential information *(i.e.,* the correct ceiling price for a drug vs. the price charged to the covered entity) and manufacturer claims of diversion or duplicate discounts could also include some confidential information. HRSA should specify that (1) protective orders must be issued to protect all confidential information that is used in an ADR proceeding (including information on 340B ceiling prices that a covered entity received via HRSA's password-protected system for allowing covered entities access to ceiling prices); (2) information provided to the ADR panel will not be used or disclosed except for purposes of resolving the dispute; and (3) the summary of the decision that is made publicly available at the conclusion of the ADR proceeding must be redacted to delete any confidential information.

HRSA recognized in its September 2010 ANPRM that "[p]rocedures to ensure the confidentiality of information discovered will … need to be developed,"[28] but the proposed rule does not address confidentiality procedures. This will be a critical issue for HRSA to address when it issues a new proposed rule (which we believe will be necessary both for the reasons discussed in Section I above and due to the need to propose confidentiality procedures).

We also recommend that HRSA and ADR panel members keep the existence of an ADR proceeding confidential until the process has concluded and a redacted summary of the decision has been publicly released (and also require parties to a proceeding to keep the existence of the proceeding confidential until the release of the redacted summary). We make this suggestion because allegations of misconduct can cause damage to a party even when they later prove to be unfounded.

III. CLAIMS

A. Claims Permitted

HRSA would permit a manufacturer to bring claims that a covered entity has violated the prohibition against duplicate discounts or diversion "after a manufacturer has conducted an audit of a covered entity."[29] This wording is similar to one of the two statutory provisions on manufacturer claims, i.e., the provision stating

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[27] 81 Fed. Reg. at 53382.

[28] 75 Fed. Reg. at 57235.

[29] 81 Fed. Reg. at 53383.

that the ADR regulations shall "require that a manufacturer conduct an audit of a covered entity pursuant to 42 U.S.C. § 256b](a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity."[30] Importantly, this language permits a manufacturer to bring an ADR claim if a manufacturer (that manufacturer itself or another manufacturer) has audited the covered entity and the claim is based on findings from the audit. It is critical for HRSA to make sure that stakeholders understand this point, as it has often been assumed that a manufacturer can only bring an ADR claim if it has itself conducted an audit of a covered entity -- but the statute is not actually that limiting.

In fact, one passage in the proposed rule suggests that HRSA itself may not have realized that a manufacturer may bring an ADR claim against a covered entity based on an audit of the entity by another manufacturer. The proposed rule states at one point: "while HRSA is proposing, as required by the 340B statute, an ADR process that allows manufacturers to consolidate claims against a covered entity, we recognize the operational challenges presented by the statutory requirement for a manufacturer to first audit the covered entity. HHS is, therefore, seeking comment on how manufacturers requesting a consolidated claim against a covered entity can satisfy the audit requirement." [31] The statute answers this question by allowing a manufacturer to bring an ADR claim against a covered entity based on an audit of the entity by another manufacturer; manufacturers requesting a consolidated claim against a covered entity could therefore satisfy the audit requirement by virtue of one audit conducted by "a manufacturer." [32] If a manufacturer has conducted an audit and discovered that the covered entity has a certain policy or practice that necessarily results in diversion or duplicate discount violations affecting drugs of multiple manufacturers, it would be inefficient to require that each manufacturer that has sold 340B drugs to the entity in the circumstances associated with that violation must do its own audit (and re-document the violative policy or practice that has already been documented) in order to bring an ADR claim. Moreover, the statute does not require such duplicative audits.

We recognize that the reliance of manufacturers on another manufacturer's audit will require information sharing. (Information sharing will also be needed for manufacturers or covered entities to bring consolidated claims.) We expect that appropriate information-sharing protocols can be worked out at a future point. But it is important for HRSA to make very clear at the outset that each manufacturer will not be required to conduct its own audit of a covered entity in order to bring an ADR claim against the entity, (either on its own or jointly with another manufacturer or manufacturers).

Consistent with the statute, HRSA proposes that manufacturers could bring claims, after a manufacturer has conducted an audit of a covered entity, that the entity violated the prohibition on duplicate discounts or diversion.[33] We support this proposal, and believe it would encompass claims that an entity does not meet the 340B program's eligibility criteria. Because an entity that is not eligible for the 340B program does not

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[30] 42 U.S.C.§ 256b(d)(3)(B)(iv). The other pertinent statutory provision (42 U.S.C. § 256b(d)(3)(A)) would more broadly permit a manufacturer ADR claim "after the conduct of audits as authorized by subsection [§ 256](a)(5)(C)," which could be an audit by the manufacturer bringing the ADR claim, another manufacturer, or HRSA.

[31] 81 Fed. Reg. at 53384.

[32] 42 U.S.C. § 256b(d)(3)(B)(iv).

[33] 81 Fed. Reg. at 53383.

have any legitimate 340B "patients," all sales or other transfers of 340B drugs by that entity amount to diversion. Accordingly, claims of ineligibility are effectively a subset of diversion claims. Therefore, we urge HRSA to recognize that manufacturers may bring claims that an entity is ineligible for participation in the 340B program or was ineligible over a certain period (including claims that hospitals subject to the GPO prohibition were out of compliance with this eligibility requirement).

Similarly, a manufacturer may bring a claim based on a hospital outpatient facility not meeting HRSA's "child site" criteria, as outpatient facilities that meet these criteria are permitted to participate in the 340B program as child sites of 340B hospitals on the theory that they are integral parts of the hospital.[34] When an outpatient facility is not an integral part of a covered entity hospital, the individuals it serves necessarily are not "patients" of the covered entity hospital, and 340B drugs sold or transferred to those individuals have thus been diverted to individuals who do not qualify as patients of the covered entity. Likewise, any 340B drugs sold or transferred to inpatients violate the diversion prohibition, as 340B "patients" are limited to individuals receiving outpatient care from the covered entity.

A final issue concerning manufacturer ADR claims involves situations where a covered entity admits that it engaged in diversion or duplicate discounting, but there is still a dispute the parties cannot resolve as to the dollar amount attributable to that violation. HRSA should specify that manufacturers may bring ADR claims to resolve those types of diversion or duplicate discount disputes.

B. Requirements for Filing a Claim

PhRMA generally supports HRSA's proposal that claims must be filed within three years of the date of the sale or payment associated with the alleged violation, and after that point the claim is time-barred. However, manufacturer claims must be preceded by an audit and this time frame does not account for the realities of an audit process. Manufacturers' experience with audits of covered entities is very sparse (for reasons discussed earlier), but suggests that these audits take several years before they are completed. Since HRSA would require that a manufacturer audit be completed (not just initiated) prior to a manufacturer filing an ADR claim, the three-year limitation period could easily be exhausted by the time the audit prerequisite to a manufacturer ADR claim has been satisfied. In contrast, covered entities are not saddled with the audit prerequisite and would thus have ample opportunity to file an ADR claim within the proposed three-year limitation period. Therefore, we urge HRSA to toll the three-year period for manufacturer ADR claims, from the point when a manufacturer first seeks to conduct an audit until the audit concludes with the completion of the audit report and the covered entity's written response to the audit report (i.e., the limitation period for a manufacturer audit would be three years plus the tolling period to satisfy the audit prerequisite that applies to manufacturers).

PhRMA agrees with HRSA's observation that the ADR process is not intended to replace good-faith efforts between manufacturers and covered entities to resolve disputes and instead "should be considered a last resort in the event that good faith efforts to resolve disputes have not been successful."[35] To reinforce that

[34] See, e.g., 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994)(the cost report standard selected by HRSA "determines whether a facility is an integral part of a DSH hospital").

[35] 81 Fed. Reg. at 53382.

point, we recommend that HRSA require that all claims -- whether filed by manufacturers or by covered entities -- should be accompanied by a summary of the prior good faith efforts to resolve the dispute. HRSA should further specify this summary may include good faith efforts to resolve the dispute that were made as part of an audit process. HRSA should also consider adding a requirement that claims may not involve *de minimis* amounts, and therefore claims by manufactures and covered entities should both include documentation demonstrating that a material amount is in dispute between the parties. Such a requirement would help to ensure that the ADR process is not used in a manner that wastes the resources of the parties or HHS.

For a covered entity claim, HRSA proposes that the claims must include documents sufficient to demonstrate a covered entity's claim that it has been overcharged by a manufacturer, along with any supporting documentation requested by HRSA. "Such documentation" may include: (1) "a 340B purchasing account invoice which shows that the purchase price by NDC, less any taxes and fees"; (2) the 340B ceiling price for the drug during the quarter(s) corresponding to the time period(s) of the claim"; and (3) documentation of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of overcharging."[36] We have several suggestions for refinements in this proposal.

First, to improve the efficiency of the ADR process, HRSA should require that covered entity claims include documentation establishing that, during the quarters when an alleged overcharge occurred, the entity was listed as a covered entity on HRSA's 340B database. HRSA should ensure that copies of the covered entity database from past quarters are archived and made publicly available on HRSA's website to facilitate this showing. Further, any covered entity hospital claims should identify the specific facilities that allegedly were overcharged and include documentation that the outpatient facilities that were allegedly overcharged during a particular quarter were listed as child sites of the covered entity hospital in the 340B database during the relevant quarter. Similarly, covered entity claims should specify any overcharges associated with drugs dispensed by contract pharmacies and should include documentation that the dispensing pharmacy was listed as a contract pharmacy of the covered entity on the HRSA database when the alleged overcharge occurred.

Second, the documentation requirements for 340B covered entity claims should differentiate between three potential types of claims that a covered entity might assert, and the entity should be required to identify the type of claim it is asserting. Covered entity claims potentially could assert: (1) that the initial purchase price of a drug purchased by the covered entity exceeded the ceiling price at that time; (2) that the purchase price of a drug should have been adjusted downward later and a refund should have been issued at a specified later point in time, under the yet-to-be-developed refund procedures, but was not issued within the time period required under the refund procedures; or (3) that the covered entity tried unsuccessfully to buy at the 340B ceiling price, was wrongfully denied the 340B price due to manufacturer fault and without justification (such as, for example, an allocation program to address a shortage situation that precluded a sale to the entity), and due to the wrongful denial of the ceiling price, the entity purchased the drug at a price exceeding its ceiling price.

[36] 81 Fed. Reg. at 53383.

These overcharge scenarios differ in significant ways and call for somewhat different requirements concerning the information and documentation that must accompany that type of claim. Therefore we recommend that HRSA list the separate requirements for each type of overcharge claim. For example, scenario two claims cannot be pursued until and unless HRSA develops the refund procedures the 340B law requires it to establish, as there is no overcharge unless a manufacturer did not issue a refund by the time it was due. Once the refund procedures are established, HRSA should require that an overcharge claim based on an assertion that the drug's ceiling price had declined since the sale and should have resulted in a refund to the covered entity be accompanied by documentation establishing that the covered entity: (1) requested the refund in writing; (2) provided the manufacturer with all documentation required by the refund procedures to establish its right to a refund; and (3) did not owe money to the manufacturer from past underpayments that offset any refund it was otherwise due.

Third, HRSA should refine its description of the information that a covered entity must furnish with its claim regarding the "340B ceiling price for the drug during the quarter(s) corresponding to the periods) of the claim." On this point, the proposed rule states that:

> Pursuant to section 340B(d)(1)(B) of the PHSA, HHS is developing a system to verify the ceiling price of a 340B drug and allow covered entities to access and verify the ceiling price. Until such system is developed, HHS has access to ceiling price data and will ensure that the 340B ADR panel will also have access as they evaluate any particular claim. Covered entities will be able to access ceiling price information through this system, which may lessen the burden in submitting the information accompanying a claim.[37]

We agree with HRSA's general approach of requiring that covered entity claims include ceiling price information that comes from the password-protected system HRSA must establish under 42 U.S.C. § 256b(d)(1)(B) to provide covered entities with ceiling prices. However, HRSA should provide more explicitly that: (1) a covered entity claim must state that an authorized representative of the covered entity contacted HRSA on a specified date through the password-protected system and was advised that the ceiling price for a specific NDC-11 was $X during the quarter(s) at issue; and (2) covered entities will not be permitted to bring ADR claims that call for second-guessing the accuracy of the pricing data in HRSA's password-protected system).

We are troubled by HRSA's statement that "until such system is developed, HRSA has access to ceiling price data and will ensure that the 340B ADR Panel will also have access as they evaluate any particular claim." The suggestion that the ADR panel could be given access to ceiling price data in advance of HRSA establishing the password-protected ceiling price system does not mean that a covered entity could access ceiling prices before the password-protected system had been established. In fact, covered entities have no way to learn ceiling prices before HRSA sets up the password-protected system. Ceiling prices are highly sensitive, confidential information: this is why the statute requires that the password-protected system "limit[ ] such access to covered entities and adequately assure[ ] security and protection of

[37] 81 Fed. Reg. at 53383.

privileged pricing data from unauthorized re-disclosure."[38] Until such time as the password-protected system has been established, covered entities cannot claim they were overcharged because they do not know what the correct ceiling price was for a drug; they have no basis for alleging that the correct ceiling price for a certain NDC-11 in a certain quarter was $X. HRSA should not permit covered entities to file ADR claims based on speculation that the ceiling price for a certain NDC-11 in a certain quarter was some amount exceeding the purchase price they paid, hoping that the ADR panel would have access to ceiling price data that substantiated their speculation. If such a procedure were permitted, it would turn covered entity ADR claims into nothing more than fishing expeditions that could be used to harass manufacturers and waste HHS resources by the filing of speculative ADR claims.

C. Consolidation of Claims

Under the proposed rule, covered entities would be permitted to consolidate claims against a manufacturer if the consolidated claim lists each covered entity and provides documentation and/or information from each covered entity demonstrating that the covered entity meets all the requirements for filing a claim; the claim is accompanied by a letter requesting and consenting to consolidation; and the claim involves the "same drug or drugs" of the manufacturer.[39] Consolidated claims could be pursued by an association or organization representing the relevant covered entities if all of the entities are members of the association or organization, the claim is accompanied by a letter requesting consolidation and documenting that each covered entity consents to the association or organization asserting a claim on its behalf, and all other requirements for a consolidated claim are satisfied.[40]

PhRMA generally supports these proposals. We also suggest HRSA require that covered entities explicitly state that they will not seek to assert (and have not asserted) any individual claims that overlap with the consolidated claims, and clarify that the requirement for a consolidated claim to involve "the same drug or drugs" means that the alleged overcharges must involve substantially the same NDCs and quarters. For example, HRSA should not permit consolidation of a claim that involves ten NDCs and ten quarters if the only commonality is that all of the covered entities purchased at least one of the ten NDCs in at least one of the ten quarters. The statutory requirement that HRSA's ADR regulations include "provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs"[41] clearly permits HRSA to issue regulations requiring that consolidated covered entity claims meet basic commonality requirements.

With respect to consolidated manufacturer claims, the statute provides that HRSA's ADR regulations must "permit the ADR decision-making official or body, at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the

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[38] 42 U.S.C. § 256b(d)(1)(B)(iii) (emphasis added). We ask that HRSA specify what penalties it would impose if covered entities make unauthorized re-disclosures of ceiling price data received through the password-protected system. It is crucial that appropriate steps are taken to deter misuse of ceiling prices or carelessness.

[39] 81 Fed. Reg. at 53383.

[40] 81 Fed. Reg. at 53383.

[41] 42 U.S.C. § 256b(d)(3)(B)(vi).

judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness or economy of resources."[42] HRSA thus proposes that a consolidated manufacturer claim against a covered entity must list each manufacturer and include documentation and/or information from each manufacturer demonstrating that it meets the requirements for filing a claim and that each manufacturer consents to the consolidation, and seeks comments on: (1) the grounds under which consolidation would be consistent with fairness and economy of resources; and (2) how manufacturers seeking to pursue a consolidated claim can satisfy the audit requirements.[43]

PhRMA generally agrees with those requirements for consolidated manufacturer claims identified above that HRSA has specified. We would suggest adding a requirement that each manufacturer state that it will not assert (and has not asserted) an individual claim that overlaps with the consolidated claim.

We have addressed earlier in this comment letter how manufacturers seeking to pursue a consolidated claim may satisfy the audit requirement. That is, either each manufacturer must have conducted its own audit or the claim must be based on an audit by at least one manufacturer (since the statute only requires audit by "a manufacturer" as a prerequisite to an ADR claim). As noted earlier, procedures for proper information sharing will need to be worked out for any type of consolidated claim, including a consolidated manufacturer claim based on a single audit.

With respect to the requirement for consolidated manufacturer claims to be consistent with fairness and economy of resources, we recommend that HRSA look for guidance to Federal Rule of Civil Procedure 20(a) on permissive joinder of claims, which seeks to promote the goals of fairness and economy of resources in civil litigation.[44] Under that rule, persons may be joined as plaintiffs in one lawsuit if their claims "aris[e] out of the same transaction, occurrence, or series of transactions or occurrences" and "any question of law or fact common to all plaintiffs will arise in the action."[45] In the circumstances of a joint manufacturer 340B ADR claim against a covered entity, we believe that these tests would be satisfied under the following circumstances:

(1) Each manufacturer seeking to pursue a consolidated claim must assert that the covered entity engaged in the same 340B violation (i.e., all manufacturers must assert duplicate discount violations by the covered entity, all manufacturers must assert diversion violations by the covered entity, or all manufacturers must assert both duplicate discount and diversion violations by the covered entity) arising out of the same policy or practice by the covered entity (e.g., a covered entity's failure to keep auditable records demonstrating that 340B drugs are limited to individuals who meet the 340B "patient" requirements); and

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[42] 42 U.S.C.§ 256(b)(2)(3)(B)(v).

[43] 82 Fed. Reg. at 53383-84.

[44] See, e.g., Maverick Entertainment Group v. Does, 810 F. Supp 2d 1, 12 (D.D.C. 2011) ("the requirements for permissive joinder are liberally construed in the interest of convenience and judicial economy in a manner that will secure the just, speedy, and inexpensive determination of the action") (internal quotation omitted).

[45] Fed R. Civ. Proc. § 20(a)(1).

(2) Each manufacturer must assert violations by the covered entity during substantially the same time period.

Finally, HRSA must recognize manufacturers' right to pursue claims (consolidated or otherwise) through a trade association or other agent of their choice. While the 340B law does not explicitly permit manufacturers to pursue consolidated claims through a trade association, the law also does not prohibit this. HRSA's statement, that the statute "does not permit consolidated claims on behalf of manufacturers by associations or organizations representing their interests"[46] is incorrect. Nothing in the statute limits a manufacturer's right to pursue an ADR claim through an agent of its choice. Therefore, we urge HRSA to recognize that manufacturers may pursue an individual or consolidated claim through a trade association or other agent.

D. Deadlines and Procedures for Filing Claims

HRSA proposes that parties filing claims should send written notice to the opposing party within three business days of submitting the claim. We support this proposal, but also want to reinforce the importance of parties having advance notice of potential claims and the opportunity to resolve them informally. Therefore, just as covered entities have advance notice of potential claims due to a prior audit, manufacturers should know about a potential covered entity claim so that the parties can make good faith efforts to resolve the claim. Such an early notification requirement for covered entities would reinforce HRSA's efforts to limit the ADR process to disputes that cannot be resolved informally and would be consistent with the requirement suggested earlier in this letter that any claim (whether asserted by a manufacturer or covered entity) must be accompanied by documentation of prior good faith efforts to resolve the dispute.

E. Responding to a Submitted Claim

The proposed rule would require that the opposing party submit a written response to a claim within 20 business days after being notified that the claim will move forward, and does not mention any possibility of time extensions.[47] We recommend that HRSA provide more flexibility, especially as manufacturers may not have had adequate prior notice of the subject of the claim. The proposed 20 business day response time frame does not provide manufacturers sufficient time to review the data underlying a claim, assess the factual and/or legal questions raised by the claim, and prepare a response. Consolidated claims in particular may not be feasible to evaluate and respond to in anything close to 20 days. Thus, we recommend that HRSA adopt a more appropriate time frame (60 days) with the possibility of extensions where needed.

IV. INFORMATION REQUESTS

PhRMA opposes HRSA's proposal that manufacturers would be "responsible for obtaining relevant information or documents from wholesalers or other third parties that facilitate sales or distribution of the

[46] 81 Fed. Reg. at 53384 (emphasis added)

[47] 81 Fed. Reg. at 53384.

[manufacturer's] drugs to covered entities."[48] By making manufacturers responsible for obtaining information from third parties such as wholesalers, HRSA would be effectively compelling manufacturers to establish contracts with wholesalers having terms that are not mandated by law and not part of industry practice. The proposed rule's information production provisions should not force on manufacturers a new type of relationship with wholesalers. And the 340B law does not permit HRSA's proposed approach; it states explicitly that HRSA's regulations shall establish procedures for covered entities to "obtain … information and documents from manufacturers and third parties," [49] not "from manufacturers, which shall be responsible for obtaining information and documents from third parties." Accordingly, HRSA will need to rethink its approach to the issue of obtaining information from wholesalers. It cannot shift this function to manufacturers.

Regarding the timelines for production, HRSA's proposal to require that manufacturers "fully respond" to covered entities' information requests within 20 business days (with only one, 15-day potential extension) [50] is too short to permit a party to identify, gather, and produce the requested information. Allowing the parties sufficient time to respond to information requests will help ensure that all responsive information is produced, and promote the overall accuracy and integrity of the ADR process. Therefore, HRSA should provide the responding party 60 days to respond, and allow for reasonable extensions of time as determined by the panel.

PhRMA disagrees with HRSA's proposal that covered entities (but not manufacturers) may discover or obtain information and documents relevant to an ADR claim. The statute's silence with regard to manufacturer information requests does not prevent HRSA from establishing an even-handed ADR process that results in decisions based on all of the relevant facts. It is important to understand that, while the 340B law gives manufacturers the right to audit a covered entity's records regarding compliance with the duplicate discount and diversion prohibitions,[51] the audit process is not an adequate substitute for the right to submit information requests in an ADR proceeding. A covered entity's compliance with reasonable audit requests made by a manufacturer is by no means assured; HHS does not police responsiveness to audit requests in the way it will be policing responses to discovery requests in ADR proceedings. To ensure that manufacturers may obtain all relevant non-privileged information that is not unduly burdensome to produce, HRSA's regulations should recognize that manufacturers may submit formal information requests regarding the dispute.

Finally, PhRMA strongly support HRSA's proposal to require the ADR Panel to review information requests to ensure that they are reasonable and within the scope of the asserted claim.[52] We also urge HRSA: (1) to adopt additional safeguards to prevent any overly burdensome or otherwise unreasonable information requests; and (2) to make clear that privileged information need not be produced.

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[48] 81 Fed. Reg. at 53384.

[49] 42 U.S.C. § 256b(d)(3)(B)(iii).

[50] 81 Fed. Reg. at 53388 (proposed 42 C.F.R.§ 10.22(b), (c)(2)).

[51] 42 U.S.C. § 256b(a)(5)(C).

[52] 81 Fed. Reg. at 53384.

V. FINAL AGENCY DECISION

HRSA proposes that the ADR Panel will issue a draft report to the parties for their comments, then issue a final agency decision letter that will be binding on the parties unless overturned by a court of competent jurisdiction. The panel may (but would not be required to) issue a summary of its decision.[53] PhRMA generally supports HRSA's proposal, but believes that HRSA should: (1) require the timely publication of summaries; (2) ensure that the summaries redact all proprietary or otherwise confidential information; (3) set forth the conclusions of fact and conclusions of law reached by the panel; and (4) otherwise ensure that the summaries provide a meaningful description of the panel's reasoning that enables stakeholders to understand how the panel resolves interpretive or other legal questions. Meaningful summaries also would help to ensure disputes are being resolved consistently, and provide a record for court review. HRSA should require that the panel issue summaries that are as transparent about its analysis as possible without disclosing proprietary or otherwise confidential information of any sort. We believe this recommendation, together with our previous recommendation of having 340B ADR panels made up of ALJs, will help to generate fair and well-reasoned decisions that promote confidence and trust in the ADR process.

HRSA also proposes that ADR panels would decide disputes by determining "whether there is adequate support to concede that a violation . . . has occurred."[54] PhRMA recommends that HRSA instead adopt a "preponderance of the evidence" standard, which is a more common and better understood standard for resolving disputes than "adequate support."

Further, HRSA should specify that HRSA's final decision is binding on the parties, unless the decision is overturned by a court, but is not binding on third parties who are not party to the ADR proceeding. The basis for this recommendation can be found in the 340B statute, which states that the ADR decision "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction."[55]

Finally, the proposed rule states the panel's final decision letter would be submitted to HRSA "to take enforcement action or apply sanctions, as appropriate."[56] We recommend that HRSA specify that it intends to use the panel's final decision as a basis for seeking sanctions against a manufacturer or a covered entity. Specifically, HRSA should notify the affected party of the sanction under consideration and the specific aspects of the decision that support the potential sanction, and also should comply with all statutory and regulatory requirements for imposing the sanction. We strongly support prompt corrective actions but in some cases sanctions will be governed by a separate set of regulations and hinge on findings that go beyond whether a violation has occurred (such as intent requirements). We also recommend that HRSA await court disposition of any decision where a party has sought judicial review of the ADR decision before HRSA takes steps to assess sanctions.

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[53] 81 Fed. Reg. at 53385.

[54] 81 Fed. Reg. at 53383.

[55] 42 U.S.C. § 256b(d)(3)(C)(emphasis added).

[56] 81 Fed. Reg. at 53385.

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PhRMA appreciates HRSA's efforts to provide manufacturers and covered entities with a fair and efficient process for resolving material disputes that the parties cannot resolve on their own through informal good faith efforts. For reasons discussed above, however, it is critical that HRSA put in place all of the foundations necessary to shape the ADR process before developing the ADR process. Once the overarching threshold issues identified above have been addressed adequately, there will be an appropriate foundation for a new ADR proposal and we hope that in developing that proposal HRSA will find our additional recommendations helpful.

Please do not hesitate to contact Sylvia Yu at syu@phrma.org with any questions, comments or requests for additional information. We would welcome the opportunity to provide any additional information that may be useful to HRSA. Thank you again for this opportunity to comment on the proposed rule.

Sincerely,

/s/

Sylvia Yu
Assistant General Counsel

PRESS RELEASE

New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients

PhRMA | October 8, 2020 | SHARE THIS

WASHINGTON, D.C. (October 8, 2020) – Today, the Berkeley Research Group (BRG) published an analysis of historical trends in 340B contract pharmacy arrangements. The findings conclude that the growth in the number of these arrangements is fueling explosive growth in the program at large and driving the 340B program farther and farther away from its original intended goal of providing discounted medicines to safety-net entities treating uninsured and vulnerable patients.

Congress created the 340B program to help safety-net providers, including certain qualifying hospitals and federally-funded clinics, access discounts on prescription medicines for low-income or uninsured patients. In 2010, a Health Resources and Services Administration (HRSA) policy opened the door to allow all 340B entities to contract with an unlimited number of for-profit retail pharmacies (e.g., CVS, Walgreens) to dispense 340B medicines. While this policy may have been intended to improve patient access to needed medications, it had the misguided effect of creating an opening that allowed for-profit vendors, pharmacies and pharmacy benefit managers to exploit the program and make a profit on 340B sales – sales intended to benefit low-income and vulnerable patients.

“It is clear that contract pharmacies have leveraged market power to drive unprecedented program growth and siphon money out of the program and away from vulnerable patients,” said Stephen J. Ubl, president and chief executive officer of the Pharmaceutical Research and Manufacturers of America (PhRMA). “I urge lawmakers to consider the results of this analysis and pursue policies that ensure the 340B program benefits vulnerable patients rather than just line the pockets of for-profit corporations.”

Key findings from the analysis show that many retail pharmacies and other third parties have taken advantage of and financially benefited from the 340B program’s contract pharmacy arrangements:

- The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72% compared with a margin of 22% for non-340B medicines dispensed through independent pharmacies.
- 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents more than 25% of pharmacies’ and providers’ total profits from dispensing or administering brand medicines.
- Following HRSA’s expansion of the contract pharmacy program in March 2010, contract pharmacy participation grew a staggering 4,228% between April 2010 and April 2020.
- While over 27,000 distinct pharmacies participate in the 340B program today, over half of the 340B profits retained by contract pharmacies are concentrated in just four pharmacy chains – Walgreens, Walmart, CVS Health and Cigna’s Accredo specialty pharmacy.

Analysis after analysis shows there is explosive growth in the program, but there is little to no clear evidence that this growth has benefited low-income and vulnerable patients. Even the New England Journal of Medicine found no evidence that expansion of the 340B program has resulted in improved care or lower mortality among low-income patients.

These new findings build upon a mounting body of evidence from the Government Accountability Office (GAO) and HHS Office of the Inspector General, which show hospitals are taking advantage of contract pharmacy arrangements to generate additional revenue through 340B without ensuring that low-income patients are benefiting from manufacturer discounts. GAO found that more than half of 340B hospitals surveyed reported that they did not share discounts with patients at their contract pharmacies. OIG found similar evidence, noting some 340B hospitals “do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements. … [I]f covered entities do not, their uninsured patients pay the full non-340B price for prescriptions filled at contract pharmacies.”

To learn more about the 340B program and ways to fix the program, visit PhRMA.org/340B.

To read the full report, “For-Profit Pharmacy Participation in the 340B Program” visit: https://www.thinkbrg.com/insights/publications/for-profit-340b/

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