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June 28, 2013

**VIA E-MAIL (Krista.Pedley@hrsa.hhs.gov)**

Commander Krista Pedley
Director, HRSA Office of Pharmacy Affairs
Room 10C-03 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: 340B "Patient" Definition and Hospital Outpatient Facility Status

Dear Commander Pedley:

The Health Resources and Services Administration (HRSA) recently announced that it is developing a comprehensive proposed regulation for the 340B drug discount program that, among other things, would address the definition of a 340B covered entity's "patients." The Pharmaceutical Research and Manufacturers of America (PhRMA) and its members applaud HRSA's efforts to provide more detailed guidance on the program. As a key stakeholder in the program, PhRMA submits this letter to share our views and suggestions on factors that HRSA should consider as it crafts the proposed regulation.

PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

The 340B statute was originally enacted to help make prescription drugs more accessible to uninsured indigent patients. PhRMA and its members support this important goal. However, it is increasingly clear that that the program has deviated significantly from its mission as the program has become increasingly unmoored from the statute and Congressional intent. At the same time, the program has expanded exponentially without the necessary guardrails to ensure that the program fulfills its purpose. As a result, the program likely will continue to generate significant controversy and pressure.

The origin of the program's problems can be traced to three primary factors. The first is a failure to target the program sufficiently to uninsured indigent patients who regularly receive care from a 340B covered entity. Instead, the current system incentivizes covered entities to maximize these arbitrage opportunities for the profit covered entities may receive from the difference between the 340B discounted price and the price they charge insurers for drugs dispensed to insured patients. The program may have unintended consequences for non340B providers to the detriment of patients, which stems from an unclear definition of the term "patient" that has led some covered entities to pursue opportunities to use the program for drugs that are dispensed to insured patients at a profit, with no guarantee that the discount will

flow to uninsured patients. The program is expected continue its rapid expansion, driven in part by the abundant opportunities for arbitrage and changes beginning in 2014 – even as the number of uninsured patients is expected to drop.

The second is HRSA's creation and the proliferation of contract pharmacy arrangements which have exacerbated the program's distortions and deviations. Notably, no mention of these arrangements is found in the statute. Yet, since the program's inception, the number of contract pharmacies has increased dramatically and is expected to increase exponentially, with no evidence that the benefits of these arrangements flow chiefly to uninsured patients. For example, the number of contract pharmacy arrangements grew almost 700% between just 2010 and 2013. As of March 2013, there were almost 30,000 contract pharmacy arrangements. Moreover, there were over 1,500 entities with multiple contract pharmacy networks as of the end of 2012. Some networks have well over 50 pharmacies and a few have more than 200 contract pharmacies According to estimates from the Berkley Research Group, the advent of multiple contract pharmacy networks will drive over half of the future growth in the 340B program. Despite the program's goals, there are no explicit HRSA rules that require contract pharmacies to direct these arrangements to uninsured indigent patients, or to pass discounts on to uninsured patients.[1] And in some cases, these arrangements may incentivize covered entities and contract pharmacies to focus on insured over uninsured patients and to expand the program beyond any meaningful limits as covered entities and contract pharmacies try to maximize the arbitrage opportunities associated with insured patients.

The third is that there is a fundamental flaw in the criteria used to qualify participating hospitals and their "child sites" for the 340B program. Under current law, the statute allows certain hospitals to qualify based on a metric, the disproportionate share hospital share adjustment (DSH) percentage, which bears no relation to whether or not the entity provides care to a large number of uninsured indigent patients. As a result, several hospitals participate in the program even though they serve very few uninsured patients. Moreover, in some cases, these hospitals may displace non-eligible health care providers that serve relatively larger percentages of uninsured patients to the detriment of patients. These problems also are compounded by some 340B hospitals' attempts to attach their eligibility status to other facilities that have little connection with the hospital or the provision of care to uninsured indigent patients. Notably, the program's distortions likely will spread even more rapidly after 2014 as more hospitals become eligible due to the metric used to qualify certain hospitals for 340B status, even as the number of uninsured patients declines.

The significant cracks in the program's foundation will continue to spread and exert additional pressure on the program if it continues to grow untethered from its original mission. Thus, we hope that all stakeholders will join in the effort to realign the program with its goal - helping uninsured indigent patients gain better access to prescription drugs. To that end, this letter addresses two of the three key issues that shape the 340B program: (1) the "patient" definition; and (2) whether a hospital outpatient facility qualifies as an "integral part" of a 340B hospital such that it may participate in the 340B program. In addition, it also

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[1] Although some 340B eligible HRSA grantees must agree to certain conditions to improve care for the indigent or underserved, hospitals generally maintain that they are not required to pass on 340B discounts to patients.

addresses the need for covered entities to maintain compliance policies to prevent drug diversion. We hope these comments will be useful to HRSA as it works to develop a proposed rule.

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## A. The 340B "Patient" Definition

Under the 340B law, a covered entity may only claim a 340B discount under the program if the drug is used for the covered entity's own "patients."[2] The 340B law does not explicitly define the term "patient." However, the law's legislative history makes clear that Congress intended the program to benefit low-income uninsured individuals who are patients of a covered entity.[3] Based on HRSA"s guidance to date, covered entities have not limited their use of the program to drugs that are used on low income individuals without insurance.[4] Rather, these entities have claimed 340B discounts for drugs that are used on patients that have insurance allowing the covered entity to make a profit where the patients insurance will reimburse the covered entity at rates that exceed the 340B discounted price. Currently the program includes no express requirements that the covered entity pass any discount directly to such patients or that they account for the use of revenue that facilities may generate from the program. As a result, no certainty exists that benefits are flowing chiefly to uninsured, indigent patients.

Moreover, the opportunities for 'arbitrage' from the profit covered entities may receive from the difference between the 340B price and the price they charge insurers for drugs sold to patients who have insurance, also creates perverse disincentives that may not serve the program's purpose as intended.[5] With ACA's full implementation, the number of uninsured Americans will drop dramatically and the landscape will be far different than when the 340B program was created. Yet the 340B program is expected to continue expanding rapidly - especially starting in 2014, precisely when the number of uninsured people is projected to drop. In fact, the formula used to define certain facilities' eligibility to

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2 42 U.S.C. § 256b(a)(5)(b).

3 For example, the legislative history provides: "The [bill] provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-284(II), at 13 (1992) (emphasis added).

4 See 61 Fed. Reg. 55156 (Oct. 24, 1996). Under HRSA's current guidance, the patient definition requires that: (1) the covered entity have a relationship with the individual "such that the covered entity maintains records of the individual's health care"; (2) the individual receives health care services from a health care professional who is an employee of the entity or provides care under contract or other arrangements with the 340B entity, "such that responsibility for the care provided remains with the covered entity"; and (3) the individual receives care from the covered entity that is consistent with the service or range of services for which the entity receives federal grant funding or FQHC look-alike status (this requirement does not apply to DSH hospitals). An individual is not considered a patient of a covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug for subsequent self-administration or for administration in the home setting. Different criteria for defining "patients" apply to AIDS Drug Assistance Programs.

5 At least one PBM is actively distributing publicly available materials that illustrate the amount of profit covered entities can make by purchasing products at 340B prices and then billing insurers for drugs sold to insured patients.

participate in the 340B program does not correlate well with those facilities' levels of uncompensated care or number of uninsured patients, and will have the perverse outcomes of increasing the number of eligible facilities just as the number of uninsured persons declines and the number of insured persons increases. Specifically, the flaw in the current DSH adjustment percentage is that the DSH adjustment percentage calculation is based solely on the inpatient population mix at the facility, whereas the 340B program is limited to *outpatient* only, and there is no direct correlation between inpatient DSH factors and uninsured/uncompensated outpatient care provided. These factors undermine confidence in, and therefore the integrity of, the 340B program.

Given these factors, the revised definition should specify that a "patient" is an uninsured individual who receives ongoing medical care from the 340B covered entity (at the covered entity's facilities, through an employee or independent contractor of the covered entity) as described below.

***HRSA Should Clarify That The Program Is Intended For Uninsured Indigent Patients:***

To have the greatest impact on individuals' health and well-being and reflect Congressional intent, covered entities should incorporate insurance status into the definition of a "patient" eligible to receive 340B drugs from a covered entity, since access to care depends largely on whether a person has health insurance. Thus, the patient definition should only encompass people who are uninsured [or under-insured]. [An "underinsured" person might be defined as someone lacking insurance with outpatient drug benefits or, starting in 2014, lacking insurance that covers "essential health benefits" (as defined in ACA § 1302) or lacking "minimum essential coverage" (as defined in ACA § 1501).[6]]

The legislative history of the 340B law makes clear that Congress intended the program to benefit the uninsured. For example, the legislative history of the 340B law provides:

> The [bill] provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.[7]

Similarly, Congress repeatedly stated in the legislative history of the 340B law that the law was intended to counteract the drug price increases experienced by safety net healthcare providers — which care for the uninsured — following the enactment of the Medicaid drug rebate program.[8] The legislative history provides:

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[6] ACA's "minimum essential coverage" standard is used to determine whether health insurance is sufficient to avoid the individual mandate (the penalty for not having insurance).

[7] H.R. Rep. No. 102-384(II), at 12 (1992) (emphasis added).

[8] Congress created the Medicaid drug rebate program in 1990 as part of the Omnibus Budget Reconciliation Act of 1990, or "OBRA 90" requiring a manufacturer of "covered outpatient drugs" to pay rebates to States based on Medicaid utilization of these drugs, or lose Medicaid coverage for its drugs. Id. at 10.

> The Director of an Association which represents the 28 community and migrant health centers in Texas that serve 270,000 low-income and uninsured patients testified that, since the enactment of [the Medicaid Rebate provisions in] OBRA 90, drug prices to the centers . . . have risen "dramatically." . . . Testimony presented by the Chief Operating Officer of the Parkland Memorial Hospital in Dallas, Texas, describes the adverse impact of drug price increases on public hospitals which serve large numbers of low-income and uninsured patients.[9]

Likewise, the 340B law's legislative history notes that the 340B program was meant to allow participation by a private non-profit hospital that contracts to care for "low-income individuals who are not eligible for Medicaid or Medicare" — i.e., who are uninsured — but not a private nonprofit hospital with "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues."[10]

When the 340B law was enacted, the majority of pharmaceutical costs were paid out of pocket, which presented a challenge to both indigent patients and the facilities where they sought care. However, as pharmaceutical therapies have become more central to the health care system, private coverage for prescription drugs has increased and the Medicare Modernization Act extended private prescription drug coverage to Medicare beneficiaries. These changes led the percent of total prescription drug costs paid out of pocket to decrease from 48% in 1992 to 18% in 2010 and it is expected to continue to decrease to 14% in 2021 due to the ACA. (See Appendix A)

Before the enactment of the ACA, which will dramatically expand health insurance coverage, the issue of whether 340B "patients" should be limited to the uninsured simply had relatively little practical significance, because traditionally the people who received their healthcare from covered entities frequently lacked health insurance coverage. However, the ACA will drastically shrink the number of uninsured and will also likely bring more insured patients to community health centers. The Congressional Budget Office (CBO) has estimated that the ACA will expand Medicaid and Children's Health Insurance Program enrollment by 13 million people by 2023,[11] and that a new individual health insurance mandate and new health insurance marketplaces, which will begin in 2014, will further reduce the uninsured. In total, the CBO estimates that the ACA will reduce the number of uninsured Americans by about 25 million people.[12] At the same time, the ACA required that Qualified Health Plans include Essential Community Providers,

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9 Id. (emphasis added).

10 Id. at 14.

11 Letter from Douglas Elmendorf, Director, CBO, to the Honorable Harry Reed, 8-9 & Table 3 (Nov. 18, 2009).

12 Id. Updated to reflect more recent estimates. http://www.cbo.gov/sites/default/files/cbofiles/attachments/44190_EffectsAffordableCareActHealthInsuranceCoverage_2.pdf

which are defined explicitly as providers that qualify for the 340B program.[13] Under this provision, all Exchange enrollees will have in-network access to providers who qualify for 340B. This will likely increase the number of privately insured individuals seen at 340B facilities. Under the Essential Health Benefits requirements in the ACA[14], all these individuals will have prescription drug coverage and many will qualify for premium and cost-sharing subsidies.

In its recent proposed rule on Medicaid Disproportionate Share Hospital (DSH) allotment reductions, CMS described the dramatic impact that ACA will have on our uninsured population, and the related reduction in uncompensated care costs for hospitals:

> As a result of the Affordable Care Act, millions of Americans will have access to health insurance coverage through qualified health plans offered through Health Insurance Exchanges (also called marketplaces) or through the Medicaid program. This increase in the number of individuals having access to health insurance is expected to significantly reduce levels of uncompensated care provided by hospitals. On the assumption that the number of uninsured people will fall sharply beginning in 2014, the statute reforms an existing initiative under the Medicaid program to address the situation of hospitals which serve a disproportionate share of low income patients and therefore may have uncompensated care costs. ... This reform of the DSH payment authority is consistent with the reduction of uncompensated care costs (particularly those associated with the uninsured) expected to result from the expansion of coverage under the statute.[15]

Due to these historic changes and the increased coverage for prescription drugs that we have already seen for those with private health insurance and Medicaid (See Appendix B), the question of whether 340B "patients" can include people with health insurance that includes drug benefits (i.e., the question of whether covered entities can buy price-controlled drugs and then bill them to insurers) has become important, because — for the first time — the vast majority of people treated by 340B entities will have insurance to cover their drug costs. For these newly insured individuals, access to needed medicines no longer will depend on their healthcare provider acquiring drugs with statutorily mandated discounts to treat them. This is a major step forward — and a step that calls for a closer examination of the 340B "patient" definition.

To date, HRSA has not systematically addressed whether 340B "patients" should be limited to uninsured individuals who regularly receive care from a covered entity. Instead, HRSA has focused on the front and center question (crafting a definition that captures people who regularly receive care from a 340B entity), but indirectly addressed the insurance issue in two fact-specific circumstances.[16] However, HRSA

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13 45 C.F.R. § 156.235

14 Sec. 1302 of the Affordable Care Act.

15 78 Fed. Reg. 28551, 28552 (May 15, 2013)(emphasis added).

16 For example, HRSA 2007 proposed guidance on the definition of "patient" noted that a covered entity that provided self-insured coverage to its employees did not automatically qualify the employees as its "patients"; instead,

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never squarely framed and answered the question of whether a person with insurance could be a 340B "patient".

We urge HRSA to take a closer look at this issue and clarify its earlier statements, because providing 340B drugs to individuals who have healthcare coverage simply does not fit Congress' limited goal of helping the uninsured under the 340B program. In light of this Congressional intent — as reflected in the 340B law's legislative history — and the ACA's vast expansion of health insurance coverage, HRSA should recognize that the definition of "patient" should only include uninsured people who rely on a 340B entity for their medical care.[17]

***The Patient Definition Should Ensure That The Program Is Used for Individuals Who Are True "Patients" of the 340B Provider***

The patient definition should also ensure that the individual is a true "patient" of the 340B provider in the traditional sense: someone who relies on that provider for ongoing medical care. Otherwise, the 340B law's prohibition on diverting drugs to non-patients would have little meaning (because even those with little connection to a covered entity could be deemed its "patients").

Accordingly, a patient of a covered entity must receive outpatient medical care from the covered entity, at its facilities, on an ongoing basis. This outpatient medical care must entail ongoing treatment and

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the employees could only qualify as patients of the covered entity to the extent they met generally applicable requirements. 72 Fed. Reg. 1543, 1546 (Jan. 12, 2007). Although HRSA did not explicitly address the issue, this proposed notice implies that insurance coverage would not disqualify these people from being patients of a covered entity (otherwise an examination of generally applicable patient criteria would not have been necessary). Similarly, in other subregulatory guidance, HRSA has instructed 340B covered entity AIDS Drug Assistance Programs (ADAPs) that they may subsidize the health insurance cost-sharing of their "patients" and receive 340B discounts on those individuals' drug purchases, which implies that insurance coverage in that circumstance did not prevent an individual from being a "patient" of the ADAP. HRSA, Attachment B, Questions and Answers About the State AIDS Drug Assistance Program Section 340B Rebate Option, available at http://hab.hrsa.gov/tools/adap/adapSecVIIChap2attachmentB.htm ("Title II/ADAP grantees that participate in the 340B drug pricing program can claim full rebates on partial pay claims under one of the following circumstances: The ADAP grantee must pay the deductible for the patient's medication under the insurance policy, whether or not the program also pays the health insurance premium; or The ADAP grantee must pay the co-pay for the patient's medication under the insurance policy, whether or not the program also pays the health insurance premium.").

[17] This conclusion is also required by the 340B law's diversion provision, which provides that covered entities may not "resell or otherwise transfer" 340B drugs to non-patients. HRSA should specify that this prohibition on "resell[ing] or otherwise transfer[ing]" 340B drugs to non-patients precludes 340B entities from billing insurers for 340B drugs, because this would be a resale of the drug. This would be consistent with the government's interpretation of similar language in the Prescription Drug Marketing Act (PDMA). The PDMA has a prohibition against the "sale" of drug samples ("no person may sell, purchase, or trade. . . any drug sample") that the government interprets as prohibiting billing insurers for samples. The principle that billing an insurer entails a "sale" is equally applicable in the 340B context.

(as HRSA previously has recognized) cannot involve merely dispensing drugs to an individual.[18] Similarly, case management services are not medical care and therefore cannot create a covered entity-patient relationship: a point HRSA recognized in a 2007 proposal to clarify the patient definition.[19]

While a 340B covered entity must provide ongoing medical care to an individual to make that individual a patient, covered entities are institutions (e.g., hospitals or clinics) that can only provide care through individual healthcare professionals. Therefore, the "patient" definition must also address what relationships between healthcare professionals and a covered entity can make the healthcare professional's patients the patients of the covered entity. Only an employee or independent contractor of the covered entity should suffice.[20] Only in these circumstances are healthcare professionals treating a patient on behalf of the covered entity. A physician connected to a covered entity through a more loose affiliation is not the covered entity's representative, and that physician's patients are not the covered entity's patients.[21]

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[18] 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007). ("An individual will not be considered a 'patient' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting").

[19] HRSA stated: "[S]ome covered entities may be using case management arrangements that inappropriately expand their 'patient' populations, diverting 340B drugs to individuals who are not eligible patients of the 340B covered entity. . . . . An individual whose sole relationship with a covered entity is through case management services or other administrative measures, not accompanied by actual medical services from a health care provider . . . , would not be considered a patient of the covered entity eligible to receive 340B drugs." 72 Fed. Reg. at 1546 (emphasis added).

[20] "Independent contractor" is used here to refer to the kind of independent contractor relationship that permits reassigning the right to Medicare payments. A physician who treats a Medicare patient can only reassign his or her right to bill and collect from Medicare in limited circumstances, including a reassignment to an entity for which the physician serves as an independent contractor. Under the independent contractor exception, the parties must have a contractual arrangement whereby the entity bills for the services of the physician; in addition, the entity and the physician-independent contractor must be jointly and severally liable for any Medicare overpayment, and the physician must have unrestricted access to claims submitted by the entity for services furnished by the physician (which is intended to encourage monitoring by the physician). 42 C.F.R. § 424.80(d); Medicare Claims Processing Manual, Chap. 1 § 30.2.7. Thus, this type of independent contractor relationship differs from a situation where a 340B entity simply makes a referral to another provider and is not responsible for that provider's conduct in any significant way (which is what HRSA's current "patient" guidance might be read as permitting). The current guidance permits the use of 340B drugs when an individual receives care from a health care professional who provides services "under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity." The Government Accountability Office (GAO) has reported that HRSA itself is concerned that this language is not sufficiently specific. GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept. 2011), at 23 ("[HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals. . . . seen by providers who are only loosely affiliated with a covered entity and thus . . . for whom the covered entity does not actually have the responsibility for care.") HRSA should limit covered entity representatives who can establish "patient relationships on the entity's behalf and it also should require that the covered entity itself be the party that bills 340B drugs.

[21] As HRSA observed in its 2007 proposal:

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Similarly, even if a covered entity provides ongoing medical care to a patient, the covered entity cannot make an outside (non-employee, non-independent contractor) physician a representative of the covered entity by referring the patient to that outside physician.[22] Because there is no employment or independent contractor relationship - and no ability for the covered entity to exercise oversight or control over the outside physician in such a referral - the medical care provided by the outside physician cannot be attributed to the covered entity. The referred individual is a patient of the outside physician with respect to the care provided by that physician, so any drugs prescribed by the outside physician are not eligible for 340B discounts.

The revised definition also should make clear that a "patient" must receive outpatient care at a covered entity's facilities. It cannot, for example, as HRSA has recognized, entail only dispensing discounted drugs to an individual for subsequent self-administration.[23] The treatment must be administered at the applicable covered entity's facilities. If a covered entity were to administer care on a traveling basis or through professional service agreements with physician offices not otherwise affiliated with the covered entity, they would be providing care to individuals that are patients of other entities. This would threaten to undermine the carefully crafted eligibility criteria of the 340B statute which a defined in great detail. This could result in 340B covered outpatient drugs being dispensed to individuals who are not eligible "patients" under the 340B program.

Finally, the revised definition should make clear that the covered entity's care must be provided on an ongoing basis. HRSA has correctly recognized that an "individual's health care relationship with the covered entity is the most important factor in determining" whether an individual is a patient of a 340B

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> Some DSHs have been contracting with health care providers to create a loose affiliation model for outpatient health care services. The individuals, receiving services from affiliated health care providers, have been filling prescriptions written by these health care providers with 340B drugs. The "contracts" are often simple, one-page documents that do not create contractually enforceable duties or obligations for either the health care provider or covered entity. .... 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, or prescription for, 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. [72 Fed. Reg. at 1546-47 (emphasis added).]

[22] A referral would include, for example, a physician sending an individual to a specialist who works at an outside facility for treatment of a specific medical condition.

[23] 72 Fed. Reg. at 1544 ("An individual will not be considered a 'patient' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting.").

covered entity.[24] We believe this health care relationship factor can be simply stated as follows: to make an uninsured individual its patient, a covered entity must provide ongoing medical care at its facilities to the individual. This medical care must entail the ongoing treatment of illness or injury. As described above, HRSA has previously stated that merely dispensing a drug for "subsequent self administration" does not entail services being provided on an ongoing basis.[25] We agree.

In summary, the following patient definition should be adopted under the 340B program. A 340B covered entity's "patients" are: (1) uninsured individuals, (2) who receive outpatient medical care on an ongoing basis at the covered entity's facilities from a physician who is an employee or independent contractor who is subject to oversight or control by the covered entity. For example, a "patient" would not include an individual who only receives case management services from the 340B entity, who is prescribed a drug by someone who is not an employee or independent contractor of the covered entity, or who visits the covered entity once and then is referred to another provider for subsequent care. Together, these elements of the patient definition would advance Congress' goal of creating a drug discount program to help safety net providers treat uninsured individuals who rely on them for medical care in the outpatient setting.

### B. Refine the Tests for Determining Whether an Outpatient Facility of a 340B Hospital Can Participate in 340B as an "Integral Part" of the Hospital

While the scope of the covered entity - patient relationship is critical to ensure appropriate use and sustainability of the program, the scope of the facilities that can be considered part of a hospital covered entity is also critical. Set forth below is a discussion that addresses the circumstances under which an outpatient facility of a covered entity hospital is an "integral part" of the hospital, such that it may share the hospital's 340B status (and access to discounted drugs). HRSA addressed this issue with respect to DSH covered entities in its 2007 proposed notice, stating that:

> [F]or an outpatient facility of a DSH [covered entity] to be eligible for the 340B program, it must be demonstrated that the outpatient facility is an integral part of the DSH. HRSA has chosen to rely on the category of provider-based facilities as set forth by [CMS] under [Medicare]. This decision has been made because HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 C.F.R. § 413.65, the regulation on when a facility is "provider-based," is appropriate for facilities eligible under the 340B program. Compliance with the rule for provider-

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[24] 72 Fed. Reg. at 1544.

[25] 72 Fed. Reg. at 1544.

> based facilities would . . . ensure that the individuals [served by a DSH hospital's outpatient facilities] are truly patients of the DSH.[26]

PhRMA urges HRSA to finalize this proposal. Because the new categories of hospitals that the ACA made eligible for 340B discounts all raise similar issues to DSHs, HRSA should require that any outpatient facility of any covered entity hospital must, at a minimum, meet the "provider-based" criteria in 42 C.F.R. § 413.65 in order to participate in 340B.[27] This regulation sets out specific, concrete standards to help ensure that, for a facility to be considered part of a "main provider" (hospital), the facility must be clinically, administratively, and financially integrated with the hospital. As stated by CMS, the regulation on provider-based entities is designed to "provide a high level of assurance that a facility complying with [the regulation], is, in fact, an integral and subordinate part of the facility with which it is based, and do[es] not accord provider-based status to facilities that . . . have only a nominal relationship with [the main] provider."[28]

This issue is important because the 340B law has carefully-drawn provisions defining the categories of entities eligible to participate in the 340B program — but these detailed eligibility provisions would become meaningless if 340B hospitals could share their eligibility status with other facilities having little connection with the hospital. Consequently, it is essential to have clear, objective standards that identify those facilities that are truly "integral parts" of a 340B hospital.

Requiring adherence to the provider-based regulation (and requiring a 340B hospital to certify to HRSA that all of the facilities it claims are eligible for 340B discounts meet the regulation's requirements) will give 340B hospitals a clearer understanding of what facilities qualify as "integral parts" of the hospital than HRSA's current guidance on this subject (which HRSA adopted in 1994, but did not discuss in its 2007 proposal). The 1994 guidance requires that an appropriate hospital official certify that he or she is "familiar with the [CMS] guidelines concerning Medicare certification of hospital components as one cost center," and that "the facilities [the hospital wishes to add to the 340B database] are correctly included on the [hospital's] Medicare cost report.[29] However, the HRSA notice cites CMS guidance (Section 2024 of the

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[26] Id. at 1545 (emphasis added).

[27] HRSA also should explicitly renounce the "Morford letter" (Jan. 26, 2001 letter to SNHPA from former HRSA Deputy Administrator Thomas Morford), which suggested that a facility associated with a 340B hospital in some manner that did not meet the "integral part" test in HRSA's published Federal Register guidance could nevertheless obtain access to 340B drugs in certain cases. This position is entirely contrary to the 340B law. Moreover, it was issued in a private letter that was not made available to all 340B stakeholders; never went through notice and comment procedures; and directly contradicts HRSA's published Federal Register guidance. Although this private letter is not an authorized interpretation of the 340B law, HRSA should explicitly renounce this position to ensure no covered entities rely on it. Notably, for example, even the November 2012 update of SNHPA's "Principles to Help 340B Hospitals Comply with Prohibition Against Diversion" lists the Morford letter as one of its sources. www.snhpa.org/public/documents/.../SNHPA_Principles_on_Diversion.

[28] 67 Fed. Reg. 49981, 50088 (Aug. 1, 2002).

[29] 59 Fed. Reg. 47884, 47886 (Sept. 19, 1994).

State Operations Manual) that was revised in 2004 and no longer includes the standards HRSA discussed.[30] Although the tests discussed by HRSA no longer appear in § 2024 of the State Operations Manual, section 2024 does provide that: "When two or more previously separate hospitals merge, all locations of the surviving hospital must meet the criteria found in [State Operations Manual] § 2004. In addition, all non-hospital providers of service under Medicare 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." Section 2004, provider-based designation, references the provider-based regulation (42 C.F.R. § 413.65), which has standards requiring integration of the main hospital and the outpatient facility that are very similar to those emphasized in HRSA's 1994 notice. Thus, the provider-based regulation is an updated version of the standards that HRSA discussed in 1994 as being appropriate tests to determine whether a particular outpatient facility is an "integral part" of a 340B hospital. This provider-based standard should be added to the requirement that the facility must be listed as reimbursable on the hospital's filed Medicare cost report. The provider-based regulation (42 C.F.R. § 413.65) has specific standards designed to ensure clinical, financial, and administrative integration of the main hospital and the provider-based facility, as well as requiring that the facility hold itself out to patients as part of the main hospital and that patients understand that they are entering the hospital when they enter the outpatient facility. The provider-based regulation is therefore more appropriate than the cost report standard alone to determine whether a particular outpatient facility is an "integral part" of a 340B hospital.

Updating HRSA's guidance to reference the provider-based regulation would thus require hospitals to evaluate whether associated facilities qualify as integral parts of the hospital (such that they can properly participate in the 340B program) by reference to easily-identified standards listed in a current Medicare regulation. Therefore, HRSA should finalize its 2007 proposal to use the provider-based regulation to decide whether outpatient facilities of a hospital are "integral parts" of the hospital assuming that they also meet the cost report standard. This issue is fundamental to the integrity of the 340B program, because any vagueness in the criteria that govern this issue could result in an expansion of 340B-participating facilities that Congress never authorized.

Finally, as illuminated in an October 2011 HRSA letter to Senator Grassley, reimbursable clinic costs may be "bundled" on a cost report and the names of individual clinics will not be listed on the cost report; yet, HRSA may still consider individual facilities to be reimbursable on the cost report based on unspecified "supplemental documentation" submitted by the hospital.[31] Further, apparently HRSA may consider a facility reimbursable on a cost report even though the name of the facility is not the same as the name on the cost report.[32] Accordingly, the way in which HRSA checks whether a certain outpatient facility is "included" as reimbursable on a 340B's cost report is not a transparent or objective procedure

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30 59 Fed. Reg. at 47885.

31 HRSA October 21, 2011 HRSA letter to Senator Grassley (HRSA states that there are cases where "clinics are bundled on the [cost report] (i.e., not individually listed by name), the entity must provide supplemental documentation").

32 HRSA October 21, 2011 HRSA letter to Senator Grassley (stating that HRSA reviews additional documentation in situations "where the name of the clinic is not the same as the cost reporting listing").

based solely on looking at the cost report. HRSA should reform this procedure and require that the outpatient facility be explicitly listed by its name on the cost report.

### C. Require that Covered Entities Maintain Written Copies of Compliance Program Policies to Prevent Drug Diversion

We hope that HRSA's rulemaking will be helpful in reducing risks of 340B drug diversion, by clarifying potential ambiguities in the patient definition and expressly addressing some of the practices that have emerged since the patient guidelines were issued. At the same time, we urge HRSA to also make clear that covered entities must maintain written copies of their policies and procedures for identifying "patients" who qualify for discounted drugs in accordance with HRSA guidelines. Many covered entities may already maintain written policies and procedures for identifying 340B "patients." However, an express requirement for covered entities to maintain written policies and procedures on determining individuals' eligibility for 340B drugs would help to ensure that all covered entities carefully evaluate and document how HRSA's patient guidelines apply in their specific circumstances. It also would create a mechanism that will facilitate quicker identification and resolution of questions about the proper interpretation of HRSA's patient guidelines.

In addition, HRSA can help to ensure that questions and ambiguities in this area are addressed expeditiously by providing that covered entities share these policies and procedures in this area with HRSA or manufacturers upon request. Currently, HRSA only allows manufacturers to audit covered entities if they have reasonable cause to believe that the prohibitions on diversion (or duplicate discounts) have been violated. The audit procedure may be underutilized because it may be difficult for manufacturers to obtain enough evidence to meet the reasonable cause standard without performing an audit (which is prohibited unless reasonable cause has already been established). If a covered entity were required to provide copies of its policies for identifying 340B patients upon request, a covered entity's failure to provide these policies (or its use of policies that are clearly inadequate or improper) could provide a reasonable basis for audit. (Conversely, review of the entity's policies and procedures for identifying "patients" could also convince a manufacturer that it is not necessary to pursue an audit.) Likewise, the review of an entity's policies could alert a manufacturer to practices that raise questions and that might benefit from further HRSA guidance.

We believe these simple transparency measures could significantly improve compliance with 340B Program guidelines, as well as facilitate dialogue between program stakeholders on new questions that may arise. Accordingly, we encourage HRSA to incorporate these measures in the final version of the patient guidelines.

* * *

PhRMA hopes that these comments will be useful to HRSA. We would be glad to provide any further information on these issues that may be helpful to you. Please do not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Maya J. Bermingham
Senior Assistant General Counsel

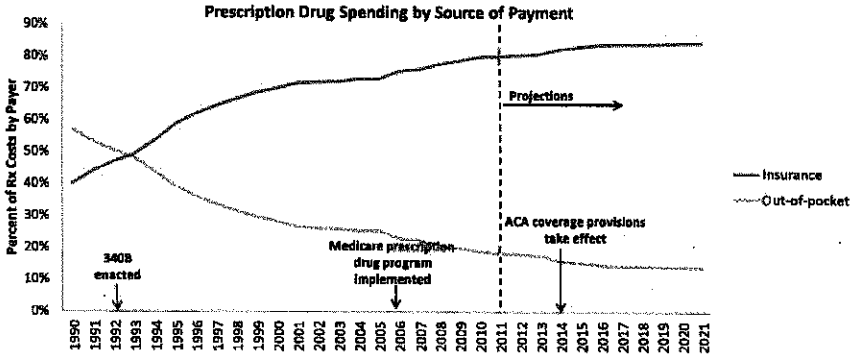
Lori M. Reilly
Executive Vice President, Policy and Research

[enclosure(s) / attachments(s)]

Appendix A

# Percent of prescription drug costs paid out-of-pocket, 1990-2021

- Due to expansion of insurance coverage for medicines, share of spending on medicines paid out of pocket has dropped by more than half since 340B was enacted.

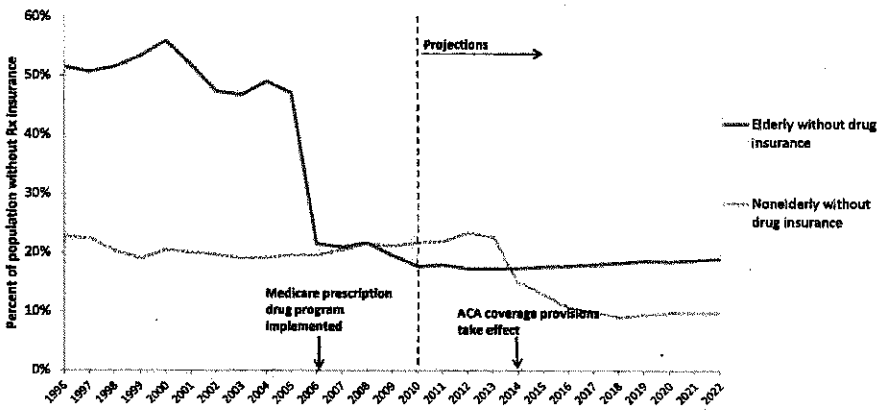



Source: National Health Expenditure data; projections include impacts of the ACA

Appendix B

## Trends in Coverage of Prescription Drugs, 1996-2022

- The share of the nonelderly population without prescription drug coverage is projected to decline due to the ACA, mirroring the declines for the elderly after the implementation of Medicare's prescription drug program.




Source: Historic data is from Avalere analysis of the Medical Expenditure Panel Survey. Projections are from Avalere analysis of CBO, Census and Medicare Trustees report data. Projections were calculated in October 2012 and account for the Supreme Court's ruling on the Affordable Care Act.