PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

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Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-9944-P

RIN: 0938-AS19: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016

Dear Ms. Tavenner:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" (the Proposed Rule), published in the Federal Register on November 26, 2014. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP) and administer drug plans for many individuals who obtain health insurance through the Exchanges established by the Affordable Care Act (ACA).

PCMA remains committed to helping HHS assure the ongoing successful implementation of ACA and its goals of expanding high quality, affordable, stable care to the uninsured. Some of the proposals in the Proposed Rule, such as the movement towards reliance on Pharmacy and Therapeutic committees (P&T committees) to assure appropriate drug coverage, are important steps in that direction. However, we are concerned that many of the provisions in the Proposed Rule could have significant negative implications for achieving these goals. We provide below an Executive Summary of our comments and recommendations, which are then addressed in detail in the eleven sections that follow:

1. P&T Committee Requirements – §156.122(a)
2. Drug Count System and Options – § 156.122(a)
3. Mandatory Access to Retail Pharmacies – § 156.122(e)
4. Specialty Pharmacy – § 156.122(d)
5. Exceptions Procedures – § 156.122(c)(1)

6. Temporary or Transition Fill – No Regulatory Language Provided
7. Essential Health Benefits – § 156.110, § 156.120
8. Formulary Transparency – § 156.122(d)
9. Prohibition on Discrimination – § 156.125
10. Good Faith Compliance – § 156.800
11. Regulatory Construct/Timeframe

EXECUTIVE SUMMARY

PCMA supports the goals of the ACA and its successful implementation. PCMA believes some aspects of the Proposed Rule, such as greater reliance on P&T committees to assure appropriate drug coverage, are important steps toward meeting those goals. However, many provisions of the Proposed Rule, such as mandating potentially open-ended transition coverage and restricting issuer ability to determine clinically appropriate use of specialty pharmacies could undermine achieving the ACA goal of expanding access to affordable and high-quality health care for the uninsured. These and other proposals would impose unnecessary, potentially clinically inappropriate, and costly restrictions on enrollee access to service delivery options and establish federal requirements that duplicate, or even contradict, existing state regulations. Further, policies advanced by certain provisions seem to work against others (e.g., improvements to formulary transparency that help assure that consumers understand their coverage, in contrast to sweeping transition fill mandates that could undermine incentives to pick a plan best suited to an individual's needs). PCMA's concerns and suggestions regarding specific provisions in the Proposed Rule are summarized below.

1. P&T Committee Requirements – §156.122(a)

PCMA supports the proposal to use the independent P&T committee structure to establish the requirement to meet the EHB standard for prescription drugs, with two key changes: (a) P&T conflict of interest and other standards should be based on the standards used by accrediting bodies of PBMs such as NCQA and URAC; and (b) clinical recommendations made by P&T committees should be based on scientific evidence such as peer-reviewed medical literature, standards of practice such as evidence-based treatment guidelines, and other sources of appropriate information.

2. Drug Count System and Options – § 156.122(a)

Consistent with the recommendation to use the independent P&T committee structure, PCMA supports dropping the mandatory use of the benchmark plan/USP framework drug counting standard in favor of giving issuers the discretion whether or not to employ a counting benchmark or a combination of benchmarks (including but not limited to USP and AHFS) should the P&T committee determine it is clinically appropriate. The independent P&T committee should not be constrained by rigid counting requirements

but rather should be permitted to consider a wide range of information and evidence from several sources.

3. Mandatory Access to Retail Pharmacies – § 156.122(e)

HHS should not regulate use of mail service pharmacies. Instead, HHS should maintain the current regulatory construct, which provides individual consumers with flexibility to select from among various pharmacy network designs for the desired balance of access versus cost in a manner consistent with applicable state law. If HHS proceeds with regulation of access to mail service pharmacies, it should retain the proposed 2017 effective date and conduct a robust rulemaking process that takes into account the model guidance being drafted by NAIC on network adequacy and allows for a thorough assessment of the clinical, cost and consumer choice implications of mail order.

4. Specialty Pharmacy – § 156.122(d)

HHS should recognize and take into account the important role of specialty pharmacies in improving clinical outcomes while controlling costs, by not proceeding with the unnecessary, clinically inappropriate, and costly proposed pharmacy access requirements impacting specialty pharmacy. If HHS proceeds with the new access requirements, PCMA urges HHS to substantially broaden the proposed narrow specialty exceptions to the pharmacy access requirements, and adopt language that allows issuers greater flexibility in their use of specialty pharmacies to enhance quality, manage utilization of high-cost and often high-risk medications, and improve clinical outcomes.

5. Exceptions Procedures – § 156.122(c)(1)

We fully support exceptions processes but believe these should be in the purview of state regulators, not HHS. We are very concerned about the confusion, duplication and cost if the current proposal is retained. If HHS proceeds to mandate this, it should address the wide range of questions we have posed, and any such mandate should not take effect until 2017. The exceptions language should be changed to (a) clarify that the timeframes toll until "all information necessary to process the request has been received," and (b) provide that the issuer should be required to inform the enrollee as to the length of time of the approved exceptions, relying on best practice as developed by the P&T committee.

6. Temporary or Transition Fill – No Regulatory Language Provided

PCMA strongly opposes the adoption by HHS of a temporary or transition fills mandate in the pharmacy benefit. Mandatory transition fills are not part of commercial programs, and are counter-intuitive to formulary transparency, achieving affordable health care, and maintaining stable premiums. Instead, issuers should continue to use best practices for when transition coverage is appropriate. These practices, along with member protections including an expedited exceptions process (as currently required by HHS) and a transparent formulary structure, obviate the need for the proposed transition/temporary

fills. If HHS decides to proceed with such a mandate, we urge HHS to propose actual regulatory language, with an effective date no earlier than 2017, so that stakeholders can have a meaningful chance to comment and assure that any such mandate is as limited as possible to reduce the significant negative consequences of such a mandate.

7. Essential Health Benefits – § 156.110, § 156.120

HHS should not use the 2014 plans as a new benchmark, unless it drops the drug counting policy and allows P&T committees to determine appropriate drugs to include in the plan's formulary. If HHS proceeds with the 2014 benchmark option, in addition to coverage increases, it should allow coverage deletions (i.e., in some classes the benchmark number could be reduced) to address developments in therapies and side effect profiles. In addition, given the administrative effort required to adapt to a new benchmark plan, HHS should not require its use until plan year 2017 at the earliest. PCMA strongly recommends continued efforts to ensure that proprietary bidding, pricing and payment information be kept highly confidential.

8. Formulary Transparency – § 156.122(d)

While we support formulary transparency, we are concerned that the "update at all times" standard is not realistic, and in fact is infeasible. Rather, the formulary drug list should be required to be updated on an "at least a quarterly basis," as is the standard in the commercial arena. PCMA does not think that cost sharing information should be required but instead HHS should adopt the standard practice in commercial markets, where tiering information on the formulary can be combined with cost sharing information in the required coverage documents. HHS should make the requirement effective in 2016 only if HHS develops and releases the technical requirements in sufficient time for issuers reasonably to test and implement the standards for 2016. Otherwise, the effective date should be 2017.

9. Prohibition on Discrimination – § 156.125

HHS should refrain from requiring or otherwise making unfounded statements regarding coverage of specific dosage forms or delivery modes for prescription drugs under the EHB such as with respect to extended release drug formulations. We also think that it would be very helpful if HHS would provide clarification on overall compliance with non-discrimination rules and regulations enforced by HHS, specifically addressing how compliance with § 156.125 fits into the full range of enforcement.

10. Good Faith Compliance – § 156.800

The good faith compliance standard should apply for as long as the 2015 benefit year obligations are outstanding and should be extended to 2016 benefit year obligations. Moreover, we think that the good faith standard should apply not only to compliance with the rules but also to efforts to develop workarounds where an applicable standard is not

achievable due to lack of infrastructure. HHS should establish a 2016 good faith compliance standard now so that the regulation is in place before the beginning of 2016.

11. Regulatory Construct/Timeframe

We question whether HHS provided a meaningful opportunity for the public to comment on this Proposed Rule. In any event, we urge HHS to assure the public a meaningful opportunity to comment in the future. This can be accomplished by publishing future draft Notices of Benefit and Payment Parameters sufficiently early to permit the full sixty-day comment period and to allow HHS to publish a final Notice of Benefit and Payment Parameters by January. Furthermore, in this and future proposed rules, HHS should delay the applicability date of substantive, difficult-to-implement regulations, beyond the next benefit year. Many of the prescription drug benefit rule changes discussed in our comments, if finalized, will involve very significant operational and technical changes and require close coordination between QHP issuers, PBMs, Exchanges, and others. They should apply no earlier than 2017.

SECTION-BY-SECTION COMMENTS

1. P&T Committee Requirements – §156.122(a)

HHS Proposal: For the 2017 plan year, HHS is proposing, "to replace the drug count standard with a requirement in § 156.122(a)(2) that plans adopt a pharmacy and therapeutics (P&T) committee and use that committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs. We are proposing P&T committee standards that must be met for the prescription drug coverage to be considered EHB." Under this proposal, HHS sets out a long list of requirements for P&T committees, including provisions on membership, conflict of interest, and evidence consideration, among many others. HHS specifically solicits comments on:

a. Make-up of P&T committees, including whether "other practicing health care professionals" should be limited to those who can prescribe.
b. Requiring members who have a conflict of interest from voting on issues related to their conflict.
c. Percent of committee members who should have zero conflicts.
d. What should be the standard of conflict of interest and how should it be implemented?
e. What should constitute a permissible relationship with insurer or manufacturer?
f. Should HHS look to Part D and/or NAIC standards for P&T committees?

Discussion: PCMA strongly supports moving to a P&T committee standard from the current drug count standard, which is the greater of one drug in every US Pharmacopeia ("USP") category and class, or the same number of prescription drugs in each category and class as the EHB–benchmark plan. In short, this is because a formulary is a tool for treatment of disease and preservation of health, whose primary purpose is to encourage the use of the safe, effective and most affordable medications. By contrast, the purpose of any category/class framework or other counting standard—no matter how thoughtfully or skillfully constructed—is merely to classify drugs along one or several chosen dimensions as a tool for a variety of uses by a variety of entities.

P&T committees have worked well for many years in determining the range of covered drugs in both public- and private-sector health plans and will work well for EHB plans. Rather than look at existing classes of drugs and asking which drugs should be covered from each class, P&T committees look at the various disease states and consider what the optimal treatments are for each disease or condition. Using this approach, a P&T committee could recommend multiple drugs in a given class and no drugs in another, if the evidence and guidelines indicated that the first class's drugs were a superior treatment.

HHS lays out a long list of potential requirements for P&T committees in the Proposed Rule and solicits comments in several areas. However, we believe compiling and promulgating such a list of requirements is unnecessary, because respected, independent accrediting bodies, such as URAC and NCQA, employ dozens of experts who have worked for many years to set accrediting standards for formularies and countless other health services. These accrediting bodies set standards for P&T committees in every area mentioned in the Proposed Rule and more, including:

- Committee membership;
- Conflict of interest;
- Timely consideration of new drugs;
- Committee policies and procedures;
- Committee meeting administration;
- Quality improvement functions; and,
- Review functions.

Additional, prescriptive regulation on P&T committees is likely to create confusion and burdensome new requirements, especially because many standards suggested in the Proposed Rule differ significantly from adopted regulatory standards in the Medicare Part D prescription drug program.

If HHS does not adopt P&T committee governance standards from accrediting bodies such as URAC or NCQA, standards for P&T committee composition should align with existing Medicare Part D standards in order to allow for a single, unified P&T committee across the different lines of business, capitalizing on the experience of these P&T

committees and fostering consistency and efficiency, while noting the population differences of the two programs.

With respect to specific proposals for P&T committees made in the Proposed Rule, we support the suggestion that members of the P&T committee who "have a serious conflict of interest with respect to the issuer or a pharmaceutical manufacturer would be permitted to sit on the P&T committee, but would be prohibited from voting on matters for which the conflict exists." However, we question the provenance of the proposal that "at least 20 percent of the P&T committee's membership must have no conflict of interest with respect to either the issuer or to any pharmaceutical manufacturer." We agree that the P&T committee members should be obligated to identify all potential conflicts of interest on an annual basis, but it is unclear why this specific number was chosen.

We also support having practicing physicians, pharmacists, and other health professionals on the committee and requiring that a majority of them should be practicing professionals. The term "practicing" professionals should not, however, be interpreted to include only full-time practitioners. Many individuals practice part-time because they also participate in clinical research or other professional activities.

Additionally, we note that the Proposed Rule suggests that formularies provide access to drugs that are referenced by "broadly accepted treatment guidelines and general best practices." We believe this term is inadequate because it does not require any standard of evidence, and we fear it could lead to confusion if adopted in a final regulation. We suggest a standard that P&T committees' clinical recommendations always be based on scientific evidence (e.g., peer-reviewed medical literature), standards of practice (e.g., evidence-based treatment guidelines) and other sources of appropriate information.

Finally, beyond the clear clinical superiority of the P&T committee standard over the current category/class or benchmark plan drug counting standard, there are practical advantages to moving to P&T committee standard without requiring it to operate under the aegis of a sole, newly chosen counting standard such as AHFS. Requiring the use of a P&T committee to operate simultaneously with a changed drug count standard for formulary development would impose significant and administratively burdensome challenges on health plans and would be extremely difficult, if not impossible, to do in a timely manner and on an ongoing basis. Rather than developing the formulary based on the clinical recommendations of a robust P&T committee, the health plan would need to constantly match the committee's clinical recommendations with the newly chosen reference system and then return to the committee for further input and deliberation if there are any inconsistencies.

<u>PCMA Recommendation</u>: PCMA supports utilizing the independent P&T committee structure under the Proposed Rule to establish the requirement to meet EHB with the following changes. P&T conflict of interest and other standards should be based on the standards used by accrediting bodies of PBMs, such as NCQA and URAC. Clinical recommendations made by P&T committees should be based on scientific evidence

such as peer-reviewed medical literature, standards of practice such as evidence-based treatment guidelines, and other sources of appropriate information.

2. Drug Count System and Options – § 156.122(a)

HHS Proposal: The preamble states, "[w]e are proposing to replace the drug count standard with a requirement in § 156.122(a)(2) that plans adopt a pharmacy and therapeutics (P&T) committee and use that committee to ensure that the plan's formulary drug list covers a sufficient number and type of prescription drugs. We are proposing P&T committee standards that must be met for the prescription drug coverage to be considered EHB."

The preamble also states that "[a]s an alternative to, or in combination with, the above-proposed P&T committee requirements, we are also considering whether to replace the USP standard with a standard based on the American Hospital Formulary Service (AHFS)."

Discussion: Taken together, we understand the language in the preamble to mean that HHS is proposing to do one of the following:

a. Drop the USP/benchmark plan standard for counting drugs in categories or classes altogether, in favor of allowing individual plan P&T committees to determine formularies, subject to certain proposed requirements of the P&T committee, or;

b. Adopt the individual plan P&T committee standard, to be used in combination with either the current USP standard, or the AHFS standard; or,

c. Not adopt a P&T committee standard, but replace the current USP category/class framework with the AHFS framework.

We strongly support the option to drop the current mandatory use of the USP or benchmark plan drug counting standard altogether, in favor of allowing individual plan P&T committees to determine formularies. Reliance on any particular drug counting standard is less effective in developing an appropriate formulary than reliance on a plan's own robust and active P&T committee, which considers category and class frameworks such as USP's, in addition to myriad additional information and evidence. P&T committee recommendations are flexible in the face of constant change in the clinical evidence and other industry considerations, such as drug shortages. As the Proposed Rule states with respect to the USP standard, "[n]ewly approved drugs were not counted; some drugs were counted in multiple USP classes; discontinued drugs had to be manually removed from the counting tool; and issuers had to submit justifications to explain their inability to meet the benchmark count due to system issues."[1] These shortcomings

[1] 79 Fed. Reg. at 70718.

sharply illustrate the advantages of using a P&T committee over any drug counting standard. In addition to USP, other drug counting methodologies are likely to share these shortcomings.

Additionally, a new standard allowing a sponsor's own independent, robust, and active P&T committee to recommend its own plan formulary is superior to the current standard that also mandatorily links formularies to a state's chosen benchmark plan. Plans across a state will have a variety of enrollees, exhibiting diverse health needs across populations, potentially leaving gaps in a formulary for some enrollees. Tying all formularies to a state benchmark plan could result in plans excluding drugs that best evidence shows should be covered or including drugs that are obsolete, and could result in coverage that lags far behind evolving standards of care in the commercial marketplace.

Any drug counting standard, whether a category/class framework or a benchmark plan framework, is at best a blunt instrument for determining a formulary. For example, evidence might show that a particular newly approved drug renders an entire existing class (or the rest of an existing class) of drugs obsolete. While an independent P&T committee could quickly add the new drug and remove the existing drugs from the formulary, a counting standard takes longer to update—some go multiple years between successive editions—and could still result in mandatory listing of unnecessary drugs. Additionally, a P&T committee considers relevant information and evidence from not only available counting methodologies, but across multiple platforms, including current and up-to-date medical literature, CMS-approved compendia, and widely-recognized national, evidence-based guidelines. Thus, we believe that reliance on an independent, robust, and active P&T committee rather than one particular counting standard alone will lead to better clinical decision making.

Should HHS not adopt the independent P&T committee standard described in these comments and tie formularies to a category/class framework such as the proposed AHFS or the existing USP standard, we urge HHS not to require the use of one particular standard over all others. We believe that both the USP and the AHFS standards have their strengths and weaknesses and that one is not clearly preferable to another across all aspects of the classification systems. Indeed, the USP describes its own Medicare Model Guidelines as a tool to "convey categories and classes for medicines that prescription drug plans may use when developing their own formularies," clearly recognizing its proper role as one tool for building a formulary, rather than being a formulary unto itself.

Thus, should HHS not adopt the independent P&T committee standard, we urge the agency to afford flexibility for P&T committees to use a combination of counting benchmarks (including but not limited to USP and AHFS), in addition to other appropriate sources of evidence and information. Current best practices for P&T committees use all available information and evidence—including both USP and AHFS—to make clinically sound formulary recommendations. We believe it is counterproductive and unnecessarily limiting to force P&T committees to determine formularies using only one such methodology.

PCMA Recommendation: ***Consistent with the above recommendation to use the independent P&T committee structure to determine the EHB standard for prescription drugs, PCMA supports dropping the mandatory use of the benchmark plan/USP framework counting standard in favor of giving plan sponsors the flexibility to employ any combination of counting benchmarks, including but not limited to USP and AHFS, in conjunction with the independent P&T committee structure, which considers a wide range of information and evidence from several sources.***

3. Mandatory Access to Retail Pharmacies – § 156.122(e)

HHS Proposal: HHS notes that currently issuers have flexibility to use only mail order pharmacies while it notes that there are circumstances where obtaining mail order drugs may not be viable. Thus, it is proposing to add new rules that require that enrollees have the option to access their prescription drug benefits through retail (brick-and-mortar or non-mail order) pharmacies. In other words, any health plan required to cover EHB "cannot have a mail order only prescription drug benefit." While a plan could still charge a higher cost sharing amount for a drug at an in-network retail pharmacy, this additional cost sharing would count towards the annual limit on cost sharing and would need to be taken into account for the AV calculation of the plan. HHS recognizes that certain drugs have limited access requirements and cannot always be accessed through in-network retail pharmacies. Thus, it also proposes that access to a particular drug can be limited only when (1) the FDA has restricted distribution to certain facilities or practitioners, or (2) appropriate dispensing of the drug requires extraordinary special handling, provider coordination or patient education that cannot be met by a retail pharmacy. However, additional education or counseling alone would not qualify a drug for limited distribution. Further, if access to a drug is to be restricted for either of the two permissible reasons, this must be listed on the formulary drug list that the plan must make publicly available under the proposed formulary transparency rules.

HHS is soliciting comments on all of the proposed requirements including "whether additional standards should be adopted to ensure enrollee access to the EHB prescription drug benefit or whether additional exemptions to accessing drugs at in-network retail pharmacies should be permitted." While HHS is proposing these to be in effect as of 2017, it seeks comment on whether the effective date should be 2016.

Discussion: PCMA has a number of issues with this proposal and strongly objects to its inclusion. Initially, we thought it would be useful to include some basic background on how mandatory mail programs for maintenance mediations are structured. We then turn to a general overview of our concerns, followed by a more detailed review of the concerns we have with this proposal.

Background on Mandatory Mail for Maintenance Medication

Some employers and health plans elect to require the use of mail order for their employees or members who are already stable on maintenance medications for

chronic conditions. Normally, when an employer or health plan elects to require the use of mail order for maintenance medications, the patient first goes to a bricks-and-mortar pharmacy to make sure the prescribed regimen is effective. Then the patient transitions to a mail order system. Local drugstores are used for new therapy starts and acute-care prescriptions like antibiotics. In other words, consumers use mail service pharmacies once they are stabilized on a medication, typically after having finished several 30-day prescriptions from their local drugstores. Under mandatory mail programs, mail service pharmacies typically provide 90-day prescriptions for medications that consumers need on an ongoing basis. Restrictions on these kinds of mandatory mail medication offerings would (a) prevent consumers from receiving the benefit of lower co-payments on their maintenance medications; (b) limit the choice of a safe, cost effective option for employers and health plans; and (c) raise costs for consumers by prohibiting an employer or health plan from opting to utilize mail order pharmacies for long-term prescriptions in a cost-effective way.

Overview of PCMA Concerns

- It is not clear why HHS is seeking to regulate access to mail service pharmacies. While mandatory mail order programs in the commercial market are not common, they represent a viable and important choice for consumers and employers. HHS identifies only speculative concerns and does not cite any real world problems.

- Consumers should not be precluded from the opportunity to consider health insurance coverage designs that reduce premiums and improve clinical outcomes by requiring mail service pharmacies for maintenance medications once an individual is stabilized on the medication. Consumers will still always have the option to choose plans that do not require use of mail for their maintenance medications and pay the extra premium and cost sharing to get these medications at retail pharmacies. However, HHS should not preclude the option for individuals to select a plan with mandatory mail for maintenance medications (and receive the benefit of the related reduced premium and cost sharing).

- If HHS has concerns on network adequacy, those should be addressed in network adequacy regulatory efforts.

- The rule would be contrary to and undermine the use of clinically effective, appropriate cost-saving mail order programs like those in effect for TRICARE and many union-sponsored plans, among others.

- The concerns that HHS has expressed over the impact of mandatory mail order requirements on transient population are unfounded. Moreover, federal and state privacy laws already address HHS' generalized concern regarding the confidentiality of a mail-service pharmacy delivery.

- If HHS proceeds to regulate mail order, the proposed exceptions to mandatory mail are extremely narrow and would significantly harm the ability of plans to provide appropriate access to a range of specialty drugs. In light of the significance of this issue, we address specialty drugs and specialty pharmacies separately in the next section below.

- A 2016 effective date is not acceptable. If HHS is going to regulate mail order, it should conduct a detailed review of use of mail order and allow for public stakeholder process.

Network Adequacy

As HHS acknowledges in the preamble to the Proposed Rule, NAIC is currently developing a model network adequacy rule based on input from industry stakeholders. PCMA urges HHS not to short-circuit this valuable effort. HHS' proposal interferes with the traditional role of state legislatures and state insurance departments as the regulators of provider networks. The states have made and continue to make reasoned policy judgments as to the adequacy of networks through their network adequacy requirements, balancing the competing factors of access versus cost at the macro level for their jurisdictions. HHS' proposal interferes with and arguably supersedes state governance by imposing on all issuers standards that HHS has selected, regardless of states' prior consideration of the issues. HHS should defer to states to make decisions regarding network adequacy and access to benefits that are appropriate for and tailored to their populations.

Moreover, HHS is wrongly including network adequacy issues under the rubric of EHB. To be consistent with the ACA, EHB should rather be focused on the scope of benefits and their limitations. The ACA's EHB requirement addresses the items and services that must be covered by health insurance coverage offered in the individual and small group commercial market. The ACA EHB provision authorizes HHS to set the covered benefits in the EHB package, but does not give HHS any authority to regulate the adequacy of networks through which those benefits are provided. ACA § 1302(b). That HHS is not authorized to set network adequacy standards as part of the EHB definition is demonstrated by the fact that a separate provision of the ACA authorizes HHS to set network adequacy standards solely for qualified health plans (QHPs), ACA § 1311(c)(1)(B), which would be unnecessary if HHS already had that authority under the EHB provision. We have doubts whether HHS has authority to prohibit mandatory mail order even under § 1311(c)(1)(B), but, in any case, that authority would apply only to QHPs and is not the authority HHS relies on in the Proposed Rule.

Value of Mail Service – Clinical

Mail service pharmacies deliver improved clinical outcomes. Medication adherence contributes significantly to reducing the chances of adverse outcomes and lowering overall medical costs through avoidance of acute episodes arising from inconsistent

treatment of conditions. Studies demonstrate that patients receiving medications through mail service pharmacies have higher medication adherence rates as compared to patients obtaining medications through retail pharmacies. Studies also indicate that fewer clinical errors are associated with prescriptions dispensed by mail service pharmacies. Allowing consumers to choose plans in which members are directed to mail service pharmacies for maintenance medications fosters better outcomes and lower costs, all of which generate better quality of care and lower premiums.

1. A 2014 presentation to the Academy of Managed Care Pharmacy described a study finding higher medication adherence in patients who continuously used mail service pharmacies as compared to members who switched between mail and retail pharmacies. The study found a similar pattern across multiple therapeutic classes of chronic medications and across different member populations.[2]

2. Another study more specifically reviewed adherence with oral anti-diabetic medications among Medicare Part D beneficiaries, found that beneficiaries using mail service pharmacies had better adherence to oral anti-diabetic medications than those who used retail pharmacies.[3]

3. Patients with diabetes who received prescribed heart medications by mail were less likely to visit the emergency room than those patients who picked up prescriptions in person, according to a 2013 Kaiser Permanente study funded by the CDC and published in the American Journal of Managed Care. Although the study did not analyze why mail service pharmacies were associated with fewer emergency room visits, a logical explanation is that automated prescription refill-and-shipment programs helped to eliminate gaps in medication due to a failure to refill a prescription.[4]

4. A 2011 study on the comparative effectiveness of mail service pharmacy use versus local retail pharmacy use for new statin users found that "new statin users who primarily refilled by mail were more likely to be in control of their LDL-C levels within 3-15 months after medication initiation than patients who used" retail pharmacies. This positive association was consistent across patient gender and race/ethnicity.[5]

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[2] Tran, J, et al., "Adherence to Chronic Therapeutic Classes of Medications in Mail Service Users."
[3] Zhang, L, et al., "Mail-order pharmacy use and medication adherence among Medicare Part D beneficiaries with diabetes," J. Med. Econ. 14(5):562-7 (2011); see also, Duru, O, et al., "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications," Am. J. Manag. Care 16(1): 33-40 (Jan. 2010).
[4] Am. J. Manag. Care, 2013;19(11):882-887, available at: http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n11/Safety-and-Effectiveness-of-Mail-Order-Pharmacy-Use-in-Diabetes.
[5] Schmittdiel, J, et al. "The Comparative Effectiveness of Mail-Order Pharmacy Use vs. Local Pharmacy Use on LDL-C Control in New Statin Users," J Gen Intern Med 26(12): 1396-402.

Value of Mail Service – Cost

In addition to improved clinical outcomes, mail service pharmacies are proven to save money for consumers and plan sponsors. Consumers should be able to choose plans with lower premiums to take advantage of these savings. Numerous studies demonstrate that maintenance medications dispensed through mail service pharmacies cost less overall than when dispensed by retail pharmacies. Below are some examples of the growing body of research supporting this conclusion:

1. A 2013 study conducted for the TRICARE program showed that the prescription mail service program cost 16.7 percent less than prescriptions obtained through retail pharmacies.[6]

2. A recent study by Visante for PCMA estimated that mail service pharmacies would save consumers, employers, and other payers an estimated $5.1 billion over retail pharmacies in 2015 alone, or $59.6 billion from 2015-2024.[7]

3. In 2006, the CBO analyzed estimated average pharmacy prices and determined that retail pharmacies pay more for single-source brand-name drugs than mail service pharmacies. In particular, CBO estimated that retail pharmacies paid about 83 percent of the average wholesale price for single-source drugs, while mail service pharmacies paid no more than 78 percent. One of the cited reasons is mail service pharmacies' ability to negotiate greater rebates due to larger volume and their ability to influence drug market shares,[8] as well as mail service pharmacies' lower administrative and dispensing costs.[9]

Concerns with Transient Population Unfounded

HHS references in the preamble its concern that "making drugs available only by mail order would discourage enrollment by, and thus discriminate against, transient individuals and certain individuals who have conditions that they wish to keep confidential." (p. 70722). To the extent HHS is concerned about access to drugs for those who do "not have a stable living environment" or "a permanent address," then it has other options to assure their access to drugs. (For example, plans already utilize exceptions processes to the use of mail service pharmacies to ensure that consumers

[6] U.S. Department of Defense, Inspector General, The TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place, p. 3, July 24, 2013, available at http://www.dodig.mil/pubs/documents/DODIG-2013-108.pdf.

[7] Pharmaceutical Care Management Association, New Research: Mail-Service and Specialty Pharmacies to Save Consumers, Employers, Unions and Public Programs $311 Billion, Sept. 2014, available at http://www.pcmanet.org/images/stories/uploads/2014/visante-pcma%20mail%20and%20specialty%20savings.pdf.

[8] Congressional Budget Office, Prescription Drug Pricing in the Private Sector, p. 3, Jan. 2007, available at http://www.dol.gov/ebsa/pdf/cbo010711.pdf.

[9] See generally, The Health Strategies Consultancy LLC, "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain" (prepared for the Kaiser Family Foundation, March 2005), p. 13.

can obtain prescriptions from network retail pharmacies where mail delivery is not a viable option (e.g., for those with irregular access to mail)). This proposal to prohibit mandatory mail order for all plans and populations is so poorly tailored to the alleged harm – which could be remedied through a significantly less restrictive alternative, such as an exceptions process – that it is hard to see how there is a rational basis for the proposal.

Moreover, HHS' statement overlooks the fact that mail service pharmacies are already "covered entities" under the HIPAA privacy and security rules and, therefore, are required to implement policies and procedures to maintain the privacy and security of individuals' protected health information, including prescription drug utilization. For mail service pharmacies, these privacy policies and procedures often include concealing the fact that a shipment contains prescription medications, such as by omitting the pharmacy's name from the return address. Indeed, in today's world, delivery of packages to an individual's home or office has become commonplace and unremarkable. With the prevalence of Amazon and other retailer shippers, confidentiality concerns regarding delivery of a non-descript package – even on a routine basis – do not justify a broad policy decision that interferes with the opportunity of consumers to select health insurance coverage designs that meet their needs and priorities, both in terms of access to benefits and premiums and related cost sharing obligations.

Finally, HHS' statement overlooks the confidentiality considerations that arise in a retail pharmacy setting. Individuals often use their "local" retail pharmacy, meaning a pharmacy located in their home or work neighborhood. These patients are thus susceptible to encounters at the pharmacy with neighbors, colleagues, and acquaintances. The lack of true privacy at retail pharmacies reduces the likelihood that an individual will ask the pharmacist questions regarding the individual's prescription or health status. On the other hand, mail service pharmacists are available by telephone on a 24/7 basis and thus can be contacted at the individual's convenience. HHS' concerns about the confidentiality of deliveries are unwarranted, as these privacy concerns already are addressed by existing law, and HHS' reliance upon these confidentiality concerns as a justification for benefit access limits is misplaced.

PCMA Recommendation: HHS should not regulate use of mail service pharmacies. Instead, HHS should maintain the current regulatory construct, which provides individual consumers with flexibility to select from among various pharmacy network designs for the desired balance of access versus cost in a manner consistent with applicable state law. If HHS proceeds with regulation of access to mail service pharmacies, it should retain the proposed 2017 effective date and conduct a robust rulemaking process that takes into account the model guidance being drafted by the NAIC on network adequacy and allows for a thorough assessment of the clinical, cost and consumer choice implications of mail order.

4. Specialty Pharmacy – § 156.122(d)

HHS Proposal: As part of the proposed EHB prescription drug definitions requiring that enrollees be provided with access to their drug benefit through retail pharmacies, HHS recognizes that certain drugs have limited access requirements and cannot be accessed always through network retail pharmacies. HHS is proposing that the health plan may restrict access to a particular drug or require use of mail pharmacies only when (1) the FDA has restricted distribution of the drug to certain facilities or practitioners (e.g., Elements to Assure Safe Use in Risk Evaluation and Mitigation Strategies), or (2) appropriate dispensing of the drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a retail pharmacy. HHS also proposes that additional education or counseling alone would not be enough to qualify a drug to be restricted to a non-retail pharmacy. If a health plan requires mail-only access to a drug, it must indicate that such requirements apply on the formulary drug list that HHS is proposing plans must make publicly available. HHS specifically solicits comments on:

a. Whether additional standards should be adopted to ensure enrollee access to the EHB prescription drug benefit?

b. Whether additional exemptions to accessing drugs at in-network retail pharmacies should be permitted?

c. Timing for implementation of these requirements (i.e., the 2017 plan year as proposed or the 2016 plan year?).

Discussion: In addition to our strong reservations noted above about the proposed restrictions on mail service pharmacies, we are very concerned that the language allowing exceptions to the proposed retail pharmacy access requirement is inappropriately narrow and, if adopted, would unduly restrict access to specialty pharmacies, including those uniquely equipped to provide critical clinical services for patients. PCMA is also concerned that HHS' proposal stating additional education or counseling alone would not be enough to qualify a drug for distribution by a specialty pharmacy is too narrow. Currently, issuers in commercial markets may recommend or require an enrollee to use a specialty pharmacy for a very high cost drug (e.g., new Hepatitis C drugs) because distribution of that drug must be tightly controlled to ensure proper adherence, avoid potential diversion, and eliminate waste: all these factors are important for maximizing favorable clinical outcomes and holding down drug costs.

a. Specialty pharmacies play a significant role in improving health outcomes and this has been documented by numerous published studies.[10] Patients taking

[10] "Managing Medicaid Pharmacy Benefits: Current Issues and Options", Kaiser Commission on Medicaid and the Uninsured, September 2011; Tschida, et al., "Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications", Am. J. Pharm. Benefits, 2012, 4(4), 165-174; Barlow, et al.,

specialty drugs usually have complex health conditions and comorbidities, and need the continued involvement, monitoring, and clinical oversight provided by the highly trained health professionals who staff specialty pharmacies. Specialty drugs, which include a significant number of biologic products, often require special environments for preparation and handling, often are difficult to titrate and administer, and may generate side effects significant enough to require ongoing clinical management. The Proposed Rule does not take into account the unique clinical benefits and improved outcomes provided to enrollees when their specialty drugs are dispensed by specialty pharmacies.

b. Specialty medications and the patients who take them pose unique and extraordinary challenges for the delivery and management of health services. Specialty patients are a small percentage of enrollees who use pharmacy benefits (about 1 percent), but their drug use has a disproportionate impact on drug spending in many plans (25 to 40 percent). In 2013, 19 of the 28 new drug products approved by FDA were specialty medications. Issuers need to retain their ability to direct enrollees to specialty pharmacies that offer cost-saving strategies and favorable pricing on specialty drugs in order to manage their overall drug spending. Moreover, the Proposed Rule does not take into consideration that sometimes it is the pharmaceutical manufacturer, not the FDA, which imposes limits on distribution channels utilized by plans.

c. In commercial insurance markets, issuers commonly require specialty pharmacies that participate in their specialty networks to meet national accreditation standards, such as URAC accreditation. Pharmacies that meet these standards must demonstrate the highest levels of capability and service by providing, among other things, 24/7 patient access to pharmacists and the availability of health professionals qualified for disease-specific consultation. If HHS adopts the proposed retail pharmacy access requirements, which would shift the dispensing of many specialty drugs to retail pharmacies, the quality standards and controls that plans have adopted for specialty drugs would be weakened and enrollees put at risk.

d. Congress instructed HHS to set EHB requirements so that they are "equal to the scope of benefits provided under a typical employer plan." Employer plans currently are not subject to requirements like those proposed by HHS that limit where and when certain medications can be dispensed. Instead, employer plans can make site of service decisions based on available clinical evidence and applicable state law. PCMA urges HHS not to establish an EHB standard for

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"Impact of Specialty Pharmacy on Treatment Costs for Rheumatoid Arthritis, Am. J. Pharm. Benefits, 2012, 4 (Special Issue), SP49-SP56; IMS Health, "Understanding and Improving Adherence for Specialty Products", available at http://adherforhealth.org/wp-content/uploads/pdf/Understanding_Improving_Adherence_Specialty_Products_IMS_Health.pdf.

prescription drugs that would place individual and small group health insurance coverage at odds with existing employer coverage.

e. The 2003 NAIC Carrier Prescription Drug Benefit Management Model Act contains no restrictions pertaining to when a prescription must be made available through an in-network retail pharmacy or the use of specialty pharmacies.

PCMA Recommendation: ***PCMA recommends that HHS recognize and take into account the important role of specialty pharmacies in improving clinical outcomes while controlling costs, by not proceeding with the unnecessary, clinically inappropriate, and costly proposed pharmacy access requirements impacting specialty pharmacy. If HHS proceeds with the new access requirements, PCMA urges HHS to substantially broaden the proposed narrow specialty exceptions to the pharmacy access requirements, and adopt language that allows issuers greater flexibility in their use of specialty pharmacies to enhance quality, manage utilization of high-cost and often high-risk medications, and improve clinical outcomes.***

5. Exceptions Procedures – § 156.122(c)(1)

HHS Proposal: HHS proposes to build on the current expedited exception process for non-formulary drugs that is in place for 2015 by proposing to adopt (a) similar standards for the standard exception process, and (b) standards for a secondary external review process if the first exception request is denied by the plan (which would apply regardless of whether the exception was requested under the standard or the expedited process).

a. For the standard exceptions process, the enrollee would need to be notified within 72 hours of the request and if an exception were granted, coverage of the non-formulary drug would need to be for "the duration of the prescription, including refills." The excepted drug would be considered EHB for all purposes, including counting towards the annual limit on cost sharing.

b. For the external exception process, HHS is proposing that the timing be the same as applied to the initial review. Thus, if the request was denied under the standard exception review process, the independent review organization (IRO) would have to make its decision and the plan would have to notify the enrollee within 72 hours after it gets the external exception review request.

c. HHS is also proposing that the IRO would have to be accredited by a nationally recognized private accrediting organization and also that the issuer could use the same IRO for the drug exception process as it uses under the final external review decision under § 147.136 (which relates to adverse benefit determinations for formulary drugs).

HHS solicits comments on all of the proposed requirements, and whether any additional standards are needed for the exceptions process. HHS is proposing to apply the revisions to the 2016 plan year, and asks for comments on the proposed timing.

PCMA Discussion: PCMA supports the standard that all plans should have a robust exceptions process for non-formulary drugs. However, virtually all states require such a process. This kind of consumer protection is in the scope of responsibility for states. If a state has such a requirement, it should be utilized. Otherwise, this duplicative regulation may unnecessarily place a heavier burden on the process for plans as well as consumers. As noted, there are already standards in place to protect consumers; it is unclear to us what problem HHS is trying to solve with this proposal where a process already exists.

To the extent HHS proceeds to establish new standards for exceptions requests, there are a number of issues that need to be addressed.

a. It is unclear to us how these new exceptions standards will interact with existing state laws in this area. We would ask that HHS clarify how the federal and state laws will interact and what would prevail in the case of a conflict. For example, in most states, external reviews by IROs are triggered only after there have been denials at both the first and the second internal request levels. Yet, the HHS proposal appears to require the option to request external review by an IRO after the initial internal exception review. This will create significant uncertainty. Does the consumer now have the right to request external review of adverse internal decisions twice (i.e., after both the initial and any subsequent internal decision)? Does the issuer now have to incur the expense of paying for the external decision twice? Who decides? Further, is the answer to these questions the same in a FFE state as it is in a state where there is a state Exchange?

b. There is a significant issue pending from the most recent HHS rulemaking which requires that the expedited exceptions request be made within 24 hours *of the request*.[11] PCMA had discussions with HHS, including on the pharmacy stakeholder call with several other stakeholders, where it was stated in response to a question from a representative of another government agency that this meant within 24 hours *of receipt of necessary information*. HHS noted that while it expected that plans would not require unnecessary information, it understood that plans could not reasonably be expected to make decisions on exceptions requests without all critical information. It would seem that this pending rule is an appropriate vehicle to make that change. Thus, we would propose that the phrase "following receipt of the request" be changed to "following receipt of all information necessary to process the request" in every place under § 156.122(c)(1) where it appears.

[11] Section 156.122 (c)(2), as finalized on May 27, 2014 for 2015 in the final rule entitled, "Patient Protection and Affordable Care Act Exchange and Insurance Market Standards for 2015 and Beyond."

c. Another aspect that will be important for a proposal to address is, if the exceptions request is granted, for how long is the enrollee entitled to receive the drug? For coverage approved under an expedited request, the non-formulary drug must be covered "during the duration of the exigency." (§ 156.122(a)(2)(iv)). Yet, the proposed language for the standard exception requires coverage for "the duration of the prescription, including refills." This could be very open-ended; it is not clear why there should be a different standard for the two processes. An open-ended standard "including refills" could result in provision of drugs in perpetuity, as "refills" is plural. This would be contrary to best practices. Instead, our recommendation is that the issuer should be required to let the enrollee know, at the time the exceptions request is granted, the period of coverage approved. As is common in the commercial arena, issuers use best practices in making the assessment (e.g., shorter periods if drug is potential subject to drug abuse issues, longer if it is a chronic drug with limited likelihood of adverse side effects).

d. For the IRO, we believe it is reasonable to require accreditation by a nationally recognized private accrediting organization. Further, we think it is appropriate and efficient for a plan to be able to utilize the same IRO for external appeals for formulary and non-formulary drugs. Indeed, we are not aware of any reason not to allow this.

e. Finally, any expedited exceptions request process must make it clear whether the request must come from the member or the physician/prescriber, or both. We would support flexibility in who can file the request, but would expect all requests to include the prescribing physician's supporting documentation.

PCMA Recommendation*: *We fully support exceptions processes but believe these should be in the purview of state regulators, not HHS. We are very concerned about the confusion, duplication and cost if the current proposal is retained. If HHS proceeds to mandate this, it should address the wide range of questions noted above and any such mandate should not take effect until 2017. The language should be changed to clarify that the timeframes toll until "all information necessary to process the request has been received." The language should also be changed to delete the requirement for coverage for "the duration of the prescription, including refills" and instead provide that the issuer should be required to inform the enrollee as to the length of time of the approved exceptions, relying on best practice as developed by the P&T committee.

6. Temporary or Transition Fill – No Regulatory Language Provided

HHS Proposal: HHS notes in the preamble that some new enrollees may not know what is on the formulary or how to use the exceptions process, or may need to obtain prior authorization (PA) or go through step therapy (ST) to obtain coverage for a drug. "Since new enrollees may need more immediate coverage for drugs that they have been prescribed and are currently taking, we urge issuers to temporarily cover non-formulary

drugs (including drugs that are on an issuer's formulary but that require PA or ST) as if they were on formulary (or without imposing PA or ST requirements) during the first 30 days of coverage." p. 70722. HHS states that it is considering whether to adopt requirements in this regard.

Discussion: HHS has raised the issue of "temporary" or "transition" fills in several regulatory or subregulatory issuances over the last two years. PCMA has previously commented on its deep concerns with these statements from HHS,[12] including noting that (a) such coverage would undermine efforts to have consumers elect plans that best meet their needs, (b) there is a lot of uncertainty about what the term "have been prescribed" means, and (c) it is not clear how HHS' "expectation" relates to the exceptions process already available to enrollees who are on "a current course of treatment." In other words, all of HHS' statements about temporary or transition fills considered together could end up "grandfathering" in virtually all the prescriptions of anyone already taking a drug or drugs regardless of the robustness of the formulary drug listing of the plan in which they are now enrolled and the availability of an exceptions process. As discussed below, this proposal is bad policy and is not a sustainable mandate.

For the convenience of HHS, we provide some quotes below from our prior comments.

"Similarly, PCMA has all the concerns raised previously as well as additional significant concerns with the temporary non-formulary drug coverage proposed in the Issuer Letter, such as:

- *Lack of clarity whether CMS is proposing an exceptions policy or a transition policy;*
- *Lack of clarity about who is and isn't eligible for temporary coverage (e.g., as proposed, it appears that an individual with no prior insurance coverage but with current prescriptions for chronic conditions would not be eligible for temporary coverage);*
- *Lack of clarity about what constitutes "non-QHP" coverage;*
- *CMS does not address safety or clinical appropriateness overrides, or adherence to best medical practices, without which an issuer would be unable to protect enrollees from potentially harmful drug interactions or death; and*

[12] PCMA has previously commented on this topic in detail with respect to (1) the interim final ACA rule published on Dec. 1, 2013 (comments filed December 20, 2013), and (2) the draft 2015 letter to QHP Issuers in the Federally Facilitated Marketplace, released February 14, 2014 (comments filed February 24, 2014). Both letters are included in Attachment A.

- *CMS does not address the potential adverse impact on the issuer's ability to pursue fraud, waste and abuse situations, such as interventions to prevent opioid overuse.*

PCMA believes CMS' proposed temporary drug coverage policy is totally inappropriate for the population served by the Marketplaces, and is not typical of transition policies employed by plans in the commercial insurance market. The common industry best practice is to make appropriate clinical assessments on a drug-by-drug basis as to whether a drug should be transitioned on a temporary basis, and not to mandate such coverage across-the-board. The clear Congressional intent of the ACA is that policies offered in the Marketplaces are required to be benchmarked against commercial policies offered by employers, and the coverage policies adopted by CMS must be aligned with those policies. This proposed temporary coverage policy clearly does not meet that test.

Further, as discussed above, CMS proposes to require issuers to provide easier access to formulary information so that potential enrollees can compare coverage among plans for the drugs they are currently prescribed, or may be prescribed, and use such information to make an informed choice of which plan best suits their drug coverage needs prior to enrollment. The whole point of requiring greater transparency of formulary information should be to encourage enrollees to shop wisely and match their drug coverage needs with the plan in which they enroll.

The proposed temporary coverage policy basically conveys a contrary message to consumers: the policy seems to say "don't waste your time checking the formulary of the plan you choose because it will be required initially to cover all your current medications, even those not on the plan formulary, and after that you can use the exceptions and appeals process to continue that initial coverage for several months, perhaps for the entire year."

We are very concerned that the proposed temporary drug coverage will confuse enrollees and have unintended adverse consequences. If coverage for all medications that an enrollee has been prescribed is mandated, with no exceptions, during the first 30 days after enrollment, many enrollees may believe that all their drugs are fully covered for the entire plan year even though they do not appear on the formulary. Then, when the temporary coverage period ends, the enrollee could be in for a rude awakening at the pharmacy counter when she attempts to refill and is denied. In some instances, enrollees who misunderstand the temporary nature of their non-formulary drug coverage may lose their opportunity for an appeal if they wait too long to file an appeal. Any rulemaking for the proposed temporary non-formulary coverage requirements would have to address all of the concerns we raise above.

<u>PCMA Recommendation</u>: PCMA urges CMS to reconsider whether to issue this proposal and carefully review the policies currently used by commercial plans regarding coverage of non-formulary drugs on a temporary basis for new enrollees. CMS also should conduct an actuarial cost analysis of this proposal and make it publicly available. If,

after careful review and consideration, CMS should decide to proceed with a robust notice and comment rulemaking on this proposal, we strongly urge CMS to address in such issuances all of the issues noted above and delay implementation until the 2016 plan year." [13]

Simply put, mandating transition coverage of non-formulary medications and not allowing plans to utilize effective PA/ST requirements for all new enrollees runs counter to HHS' emphasis on increased formulary transparency and will lead to widespread enrollee confusion and dissatisfaction (once enrollees learn that their transition coverage is only temporary). It also undermines the ability of issuers to manage appropriately their enrollee's drug benefits. This will increase costs significantly and will ultimately be charged back to the entire enrollment through higher premiums. This type of mandate is not found in the commercial market. This is not a sustainable mandate under health reform where affordability is a critical factor in achieving higher levels of enrollment and access to health care.

Finally, as we have also previously noted, if HHS chooses to ignore our legitimate concerns and proceeds with implementing a mandate for coverage of a temporary/transition supply, HHS still needs to address the wide range of issues noted above and in our prior comments. It is not sufficient for HHS to note in a preamble that it is considering the adoption of a significant new mandate, while not proposing any specific operative language, and then finalize such a provision without providing any opportunity for stakeholder comment. If HHS chooses to proceed – and setting aside, for the moment, whether HHS even has the authority to adopt such a sweeping mandate without a meaningful opportunity to comment – a policy change of this magnitude would take considerable time to implement. Staff must be trained, systems need to be reprogrammed and members and providers need to be informed. Thus, if HHS is serious about mandating a temporary/transition fill, it will need to issue a granular proposal that addresses the myriad issues raised by stakeholders and also will need to allow issuers sufficient time to include this substantial expansion of benefits and significantly increased administrative and cost burdens into actuarial projections and the establishment of rates.

PCMA Recommendation*: *PCMA strongly opposes and recommends against HHS proceeding to adopt a temporary or transition fills mandate in the pharmacy benefit. Such fills are counter-intuitive to formulary transparency, achieving affordable health care, and maintaining stable premiums. Instead, as discussed above, we support issuers continuing to use best practices for transition coverage, an expedited exceptions process (as in current requirements) and a transparent formulary structure (without including cost sharing). These member protections obviate the need for the proposed transition/temporary fills.

[13] February 24, 2014 letter from PCMA to Gary Cohen, CCIIO Director, commenting on the draft 2015 letter to issuers in the federally facilitated marketplace. We include the full text as Attachment A hereto, so HHS may review the complete list of questions and concerns we have previously expressed with this potential change.

7. Essential Health Benefits – § 156.110, § 156.120

HHS Proposal: HHS is proposing to allow each State to select a new base benchmark plan for the 2017 plan year. States have the option to choose a 2014 plan as the new base benchmark plan for the 2017 plan year. HHS believes the base benchmark plan update based on 2014 plans will minimize confusion, because virtually all the base benchmark plans will by definition now already meet the requirements of § 156.110 and other market reform requirements, such as the prohibition on no life time dollar limits and mental health parity. Section 156.110 lays out the various categories of goods and services (e.g., ambulatory services, hospitalization, prescription drugs) that must be covered. Under § 156.120, HHS also proposes to require the issuer of the state benchmark plan to provide data on the plan including administrative data and all information on the plan's health benefits, treatment limitations, drug coverage, and exclusions, which it believes are already on the forms filed with state insurance commissioners. HHS seeks comment on alternative ways of addressing situations in which a state has few potential base benchmark plans meeting the requirements from which to choose. HHS also solicits comment on the plan data submission requirement.

Discussion: While PCMA is sympathetic to the concept of using a benchmark already substantially in compliance with ACA requirements to reduce confusion, PCMA believes that with respect to drug coverage, the requirement will have deleterious consequences, at least insofar as HHS retains the one-drug-per-class requirement as under the current rule. When P&T committees and PBMs consider options with respect to appropriate therapies for a given disease or condition, they approach the task by considering the optimal treatments, consulting with evidence, including peer-reviewed journals, compendia, and professional treatment guidelines. Given this approach, requiring coverage of specific numbers of drugs is arbitrary, does not improve health care, and adds costs. Thus, moving to a 2014 benchmark merely prolongs a policy that not only does not improve patient access to needed prescription drugs, but also perpetuates coverage of treatments that may be outmoded by or less effective than others.

If this benchmark plan proposal is adopted with no change to the requirement that a plan cover a given number of drugs in a class, then HHS will be codifying the notion that simply adding drugs to be covered is always better. PCMA objects to this notion. As research and development progresses, some drugs may make others obsolete. Others approved under fast-track authority may prove to have a side-effect profile considerably more challenging than another drug. Locking these drugs into a coverage requirement simply because a benchmark plan happened to cover them, and thus cover a specific number of drugs in a class, whether in 2012 or 2014, will provide neither optimal coverage nor optimal cost-effectiveness.

If HHS proceeds with this option, it should allow coverage deletions (i.e., in some classes the benchmark number could be reduced) as well as additions based on the benchmark changes. In addition, given the administrative effort required to adapt to a new benchmark plan, HHS should not require its use until plan year 2017 at the earliest.

With respect to the requirements to submit data to HHS, PCMA urges caution with respect to proprietary information. HHS to-date has safeguarded proprietary bidding and pricing information appropriately to lessen the opportunity for tacit collusion among competitors. PCMA strongly recommends continued efforts to ensure that proprietary bidding, pricing and payment information be kept highly confidential.

***PCMA Recommendation*: PCMA recommends that HHS not use the 2014 plans as a new benchmark, unless it drops the drug counting policy and allows P&T committees to determine appropriate drugs to include in the plan's formulary. If HHS proceeds with the 2014 benchmark option, in addition to coverage increases, it should allow coverage deletions (i.e., in some classes the benchmark number could be reduced) to address developments in therapies and side effect profiles. In addition, given the administrative effort required to adapt to a new benchmark plan, HHS should not require its use until plan year 2017 at the earliest. PCMA strongly recommends continued efforts to ensure that proprietary bidding, pricing and payment information be kept highly confidential.**

8. Formulary Transparency – § 156.122(d)

HHS Proposal: For 2016, HHS is proposing that plans must publish up-to-date, accurate, easily accessible and complete list of covered drugs on its formulary drug list, including any tiering structure and any restrictions on the manner in which a drug can be obtained. HHS specifically solicits comments on:

a. Should tiering information include cost sharing?
b. While up-to-date means up-to-date at all times, HHS solicits comments on this requirement.
c. Should the formulary transparency rule also mean that plans must make the information publicly available in a machine-readable file and format specified by HHS?
d. What about the option instead for formulary drug list information to be submitted to HHS through HHS-designated standardized template?
e. What should the technical requirements be for developing a machine-readable file and for how the information can be updated?
f. What additional types of information should be included in the formulary drug listings?

Discussion: Conceptually, PCMA supports facilitating consumer access to formulary information. However, we also think that HHS should make sure that the requirements it is considering to achieve such transparency are realistic. Specifically, the timing of the updates and the development of the related technical aspects become paramount.

a. The "up-to-date at all times" proposal is not achievable. We are not aware of any health care program, whether government sponsored or private sector, that requires that publicly posted formularies be up-to-date at all times. Indeed, this suggests real time updates which would require enrollee and prospective enrollee logins and substantial technical developments. The standard for commercial plans is for formularies to be updated at least quarterly, and we think that standard should be utilized here as well. P&T committees generally meet quarterly and indeed HHS has proposed in § 156.122(a) that such committees meet at least quarterly.

b. We believe there are other less restrictive alternatives than the "up-to-date" at all times standard for assuring that individuals have access to as current a formulary as possible. For example, plans have toll-free call center numbers where an enrollee or a prospective enrollee can call to find out the status of a drug on the formulary.

c. We also seek clarification on what is meant by the term "complete." Previous terminology referenced "abridged" and "comprehensive." What is the definition of complete as intended by HHS? We suggest HHS stick with the phrase "comprehensive" as the word "complete" could be seen as covering every dosage form and strength and every possible brand name, which is not viable.

d. We would be pleased to provide input on acceptable technical specifications for a "machine-readable file and format." However, in light of the short comment period provided for these rules, we suggest that HHS provide an industry work group or other stakeholder vehicle to obtain this type of technical input.

e. With respect to the inclusion of cost sharing information, we are concerned that providing specific cost sharing on printable formulary PDFs will create significant confusion as individuals consider plans. This is due to the expanded permutations of formularies that would have to be provided on the URL to accommodate differing cost sharing designs based on metallic status of a plan. For example, the formulary that is applicable to four different metallic plans (with the only difference being the applicable cost sharing for each tier) would result in three different formularies to accommodate the differing cost sharing. Extrapolating this exercise across all issuers, each with multiple plan designs, would result in an overwhelming amount of formulary information a consumer would have to digest prior to making a purchasing decision. In addition, issuers would have to manage and update up to four times as many formularies creating an arduous administrative burden that delivers little consumer value.

For your convenience, we quote below from the comments we filed earlier this year on the wide range of issues posed by requiring disclosure of cost sharing information in a formulary.

"• Requiring the formulary to include cost sharing is not consistent with existing employer-sponsored health insurance market practices or the Medicare Part D program. For example, if an issuer has 50 plan offerings that use three different formulary designs and three different cost sharing structures, the issuer has three formularies to manage. Under the proposed requirement, issuers would have to create a separate formulary for each of their QHPs, which would exponentially increase the issuer's administrative costs without providing any meaningful transparency or additional information of value to consumers.

It is not clear how the cost sharing should be displayed. For example, would the actual copayments need to be displayed or would general tier pricing with definitions of high cost and low cost be sufficient?

• It is not clear that CMS has considered less burdensome alternatives such as requiring clear and transparent tiering information in formularies that may be cross-referenced to cost sharing information already provided to consumers in plan coverage information included on the Marketplace websites. Before making a change with this level of burden, we suggest that CMS conduct consumer research testing different models for presenting formulary information to determine what current and prospective enrollees might find most useful.

• We encourage CMS to permit issuers to utilize basic information input fields or drop down boxes on the URL page – such as state, zip code and plan name – which would assure that issuers could create drug search engines tools that allow consumers easy access to specific drug coverage information. If the URL link does not include this information, consumers could waste considerable time reviewing formularies for plans that are not available for purchase in their geographic area.

• We strongly urge CMS not to require use of static link, such as a PDF, because updating and maintaining such a link would be costly and burdensome.

• In general, CMS needs to provide much more granular guidance about the formulary link."[14]

Instead, PCMA recommends that HHS require issuers to provide tiering information on the formulary so that a consumer can use it, in conjunction with the SBC or other coverage documents, to determine the applicable cost sharing. This is the standard practice in the commercial market as well as consistent with

[14] February 24, 2014 letter from PCMA to Gary Cohen, CCIIO Director, commenting on draft 2015 letter to issuers in the federally facilitated marketplace (included in Attachment A hereto).

requirements in Medicare Part D. In addition, HHS could permit issuers the flexibility to develop or utilize existing technology solutions that allow a consumer to search drug coverage and cost sharing information on the formulary URL.

f. We are not aware of any other information that should be required to be included in the formulary drug listings. If there is going to be additional information that will be required, HHS should propose that content and allow the industry an opportunity to comment on the viability of providing such additional information.

PCMA Recommendation: PCMA recommends that the formulary drug list should be required to be updated on an "at least a quarterly" basis, as is the standard in the commercial arena. PCMA does not think that cost sharing information should be required but instead HHS should adopt the standard practice in commercial markets, where tiering information on the formulary can be combined with cost sharing information in the required coverage documents. PCMA further recommends that HHS make the requirement effective in 2016 ONLY if HHS develops and releases the technical requirements in sufficient time for issuers reasonably to implement the standards for 2016. Otherwise, the effective date should be 2017.

9. Prohibition on Discrimination – § 156.125

HHS Proposal: HHS has interpreted § 1302(b)(4) of the ACA as a prohibition on discrimination by issuers providing EHB and finalized in the EHB rule that an issuer does not provide EHB if its benefit design (or its implementation) discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. HHS does not include specific regulatory changes in the Proposed Rule but provides the following observations and statements:

- HHS cautions issuers to avoid discouraging enrollment of individuals with chronic health needs with the following examples:
    - Refusal to cover a single-tablet regimen or extended-release product customarily prescribed and as effective as a multi-tablet regimen;
    - Discourages enrollment by individuals who would benefit from such innovative therapeutic options; or
    - Places most or all drugs that treat a specific condition on the high cost tiers.

- HHS will notify and examine issuers whenever an EHB plan reduces benefits for subsets of individuals in a manner that is not based on "clinically indicated, reasonable medical management practices."

- Compliance with § 156.125 is not determinative of compliance with any other applicable non-discrimination and civil rights laws.

- All non-grandfathered health insurance plans in the individual and small group market that are subject to EHB requirements are also subject to guaranteed renewability requirements which limit product modifications to the time of coverage renewal. HHS notes that an EHB plan may not change cost sharing for a particular benefit midyear.

Discussion: The preamble language in the Proposed Rule described above raises several concerns for PCMA:

a. PCMA strongly objects to HHS' use of examples of benefit design and formulary decisions affecting coverage of single-tablet regimens or extended-release products as potential violations of the prohibition on discrimination. As discussed above, issuers rely on P&T committees to review all medications included on their formularies, and these decisions are derived from evidence-based clinical literature and best medical practices. There are numerous examples of extended release drug formulations that have entered the market with an increased cost without increasing efficacy or outcomes. Namenda XR, which is currently the subject of litigation in the state of New York,[15] Astagraf XL, Lamictal XR, Qudexy XR, Quillivant XR, and Copaxone 40mg are all examples of extended-release formulations where consumers are charged a premium price for convenience without any improvement in efficacy. Similarly, single-tablet regimens, which are combination therapies of existing therapies, have entered the market to extend manufacturers' patent protection, but do not actually improve outcomes or provide increased efficacy over the individual agents. Examples of these combination drug therapies include Anoro Ellipta, Combigan, Cosopt, Simbrinza, Breo Ellipta, Janumet XR/Kombiglyze XR/Jentadueto/Oseni (all combinations of new products with metformin), Akynzeo, and Diclegis (a combination of OTC products for the treatment of morning sickness during pregnancy). All issuers have extensive procedures in place for appeals and exceptions to coverage policies and determinations in cases of medical necessity. We urge HHS to refrain from appearing to make blanket pronouncements or to endorse or require coverage of specific dosage forms or drug delivery modes in its role of implementing EHB policy.

[15] On September 14, 2014, the New York State Attorney General filed an antitrust lawsuit seeking to stop a pharmaceutical company from forcing patients with Alzheimer's disease to switch to a new version of a widely used drug. Forest Laboratories had announced that it would stop selling the existing tablet form of the drug, Namenda, in favor of new extended-release capsules called Namenda XR that can be taken once a day instead of twice. The lawsuit argues that the benefit of switching is minimal and that the company decided to force the switch because it feared that not enough patients would switch voluntarily. See State of New York v. Actavis PLC and Forest Laboratories LLC, U. S. District Court, Southern District of New York 14-cv-7473.

b. PCMA believes that HHS' statement about compliance with § 156.125 not being determinative of compliance with any other applicable non-discrimination requirements raises more issues than it resolves. Indeed, HHS has not proposed non-discrimination rules under § 1557 of the ACA (often referred to as the ACA non-discrimination statute). The HHS Office for Civil Rights issued an RFI on this provision in August 2013, to which PCMA responded, but no NPRM or any other follow-up has appeared. We suggest that HHS provide clarification about overall compliance with non-discrimination requirements under the purview of HHS and indicate how compliance with § 156.125 fits into the larger picture.

c. PCMA members seek better guidance from HHS about its enforcement policy regarding all the various non-discrimination rules and requirements that may be imposed by HHS. The absence of coordination among the various parts of HHS with authority to enforce non-discrimination rules can be highly disruptive for issuers and PBMs as they strive to develop products and services that are compliant, as evidenced by the recent spate of EEOC lawsuits against wellness programs that plans implemented on the assumption that the programs were fully compliant with the ACA.

d. It is not clear how the statement that "an EHB may not change cost sharing for a particular benefit mid-year" applies to formulary changes during a plan year. For example, we understand that it is permissible for a non-grandfathered plan to substitute a new brand drug for an existing brand on the formulary midyear. Indeed, on March 31, 2014, HHS issued a FAQ (Number 1368 on REGTAP) that stated, "HHS understands that drug lists can change during the year," and indicated that issuers are not required to submit updated lists to HHS throughout the year but are advised to comply with their state department of insurance to understand the state's rules for updating such lists. Unfortunately, the language of the preamble suggests that midyear changes might not be permissible. PCMA suggests that HHS clarify how the Proposed Rule interacts with the previously issued FAQ 1368 and reaffirm that drug lists can change during the course of the year, which in fact is one of the reasons that we support the effort to make formularies as transparent as possible.

PCMA Recommendation: PCMA urges HHS to refrain from requiring or otherwise making unfounded statements regarding coverage of specific dosage forms or delivery modes for prescription drugs under the EHB. PCMA requests clarification on overall compliance with non-discrimination rules and regulations enforced by HHS, specifically addressing how compliance with § 156.125 fits into the full range of enforcement. PCMA also requests that HHS reaffirm that the policy articulated in FAQ 1368 regarding drug lists changing during the year.

10. Good Faith Compliance – § 156.800

HHS Proposal: HHS proposes to extend the good faith compliance standard for QHPs from the end of the 2014 calendar year to the end of the 2015 calendar year.

Discussion: PCMA welcomes HHS' proposal to extend its good faith compliance standard through at least the 2015 calendar year. While PCMA expects that HHS would generally not take enforcement action against a QHP issuer that is making a good faith effort to comply with applicable requirements, given the significant disruption and uncertainty caused by implementation of the Exchanges and the frequent regulatory and operational changes HHS has made, it is appropriate for HHS to codify this enforcement policy in regulation. Nevertheless, the proposed scope of the good faith compliance standard is inadequate to address the ongoing challenges QHP issuers and their PBMs face in implementing HHS requirements. In particular, HHS should modify the good faith compliance standard as follows:

a. HHS' good faith compliance standard should apply to all obligations that arise from a particular benefit year,[16] not solely those that fall within a designated calendar year. Because many reporting, financial, and other obligations that relate to a particular benefit year are due in the following calendar year, it does not provide meaningful relief to apply a good faith compliance standard for a calendar year only, when many of the QHP issuer's regulatory obligations associated with the benefits provided in that year do not occur until the following calendar year. For example, cost sharing reduction (CSR) reconciliation and medical loss ratio (MLR) reporting occur in the year following the applicable benefit year. For both CSR and MLR obligations, HHS has not yet published the 2014 benefit year reporting instructions, and it is possible that, due to the confusion of the early years of Exchange implementation, this reporting will be particularly difficult. In addition, HHS continues to revise its guidance on the acceptable methodology for CSR reconciliation, most recently in a November 17, 2014, memo to QHP issuers. This is precisely the type of regulatory change that HHS recognizes necessitates the good faith compliance standard, but this standard is not meaningful if it is limited to compliance within a calendar year, as opposed to obligations associated with the benefit year, irrespective of when the obligation is due.

b. HHS should clarify that good faith compliance includes a QHP issuer's efforts to work with HHS to implement appropriate standards, even if the QHP issuer is not able to comply with the currently applicable standards. In at least one major instance in which PCMA has engaged with HHS, the issue has been that issuers/PBMs cannot come into compliance, as the standards for compliance are not achievable under current infrastructure. This specific instance relates to the lack of system ability to perform retroactive adjustments on pharmacy claims, as

[16] "Benefit year" is defined as "a calendar year for which a health plan provides coverage for health benefits." 45 C.F.R. § 155.20.

required in 45 C.F.R. § 155.430(d)(6), where an enrollee has exercised a special enrollment period (SEP) and switches issuers on a retroactive basis. The industry is still interacting with HHS and other stakeholders on a possible workaround. In this case, it would be futile for QHP issuers or their PBMs to attempt to make a good faith effort to achieve the requirements described in the regulations. HHS should affirm that meaningful efforts to work with regulators to implement achievable standards should be recognized as good faith compliance.

c. Because this Proposed Rule is designed to establish rules for the 2016 benefit year, HHS should consider applying the good faith compliance standard to obligations arising from both the 2015 and 2016 benefit years. Just as much as the 2014 and 2015 benefit years, the 2016 benefit year will be a transitional period. It will be the last year of the transitional reinsurance and temporary risk corridors programs and it will be the last year that non-ACA compliant, non-grandfathered individual and small group policies may be renewed under HHS' transitional policy. It will also be the first benefit year in which premium rates can meaningfully incorporate ACA experience and risk adjustment results.

d. Finally, as discussed in greater detail below (see "Regulatory Construct/Timeframe"), in order to ensure ACA implementation is more seamless than it was in 2014, it is important that HHS give more adequate notice of regulatory changes. Because the Proposed Rule will not be finalized for at least several weeks, if not several months, into 2015, it is an inappropriate vehicle to promulgate rules applicable to the ***2015*** benefit year, because this will result in QHP issuers operating at the beginning of 2015 without the benefit of a currently effective good faith compliance standard. While this is now unavoidable for 2015, HHS can prevent this situation from recurring in 2016 by establishing a 2016 good faith compliance standard now. HHS should not view the 2017 Notice of Benefit and Payment Parameters as a further opportunity to establish ***2016*** rules. At minimum, rules should be promulgated prior to the period in which they are intended to apply. Further, as we discuss below, HHS should generally be taking more time in implementing substantive rules, such as postponing applicability of proposals in the Proposed Rule, if they are finalized at all, to at least 2017.

PCMA Recommendation: PCMA recommends that the good faith compliance standard apply for as long as the 2015 benefit year obligations are outstanding and that it should be extended to 2016 benefit year obligations. PCMA also recommends that the good faith standard should apply not only to compliance with the rules but also to efforts to develop workarounds where an applicable standard is not achievable due to lack of infrastructure. HHS should establish a 2016 good faith compliance standard now so that the regulation is in place before the beginning of 2016.

11. Regulatory Construct/Timeframe

HHS Proposal: As it has in previous years, HHS has given stakeholders less than thirty days to comment on this draft Proposed Rule from the date it was published in the *Federal Register*, because HHS allowed only thirty days to comment from the date the rule was put on public display at the Office of the Federal Register. Some of the provisions in the Proposed Rule are proposed to be applicable in 2016 and some in 2017, with HHS soliciting comment on what an appropriate date is to apply these changes.

Discussion: Apart from the substantive changes proposed in the Proposed Rule, HHS could significantly improve the ACA experience for consumers and others by regularizing its rulemaking process. Specifically, HHS should give stakeholders more notice of proposed changes and more time between when regulatory changes are effective and applicable, and make changes on a more stable and uniform schedule. These changes would improve the likelihood that implementation concerns with regulatory changes become apparent before the changes are applicable, while improvements can still be made, enhancing the experience for consumers and the public at large.

a. In a prior regulation, HHS said that the annual Notice of Benefit and Payment Parameters would be proposed in draft form in the middle of each October and finalized in mid-January for the following year. 77 Fed. Reg. 17220, 17223 (Mar. 23, 2012). We urge HHS to stick to that schedule so that there is at least almost a year between when the changes are finalized and when they apply. When HHS established this schedule in 2012, HHS quite sensibly recognized that finalizing benefit and payment parameters for the following year in March or later does not give QHP issuers adequate time to make infrastructure changes, establish their benefit packages and implement other policy changes. This concern is made all the more pressing by HHS' proposal to begin open enrollment on October 1 each year. In order for QHPs to be certified prior to October 1, issuers will need to submit plan certification applications to state and federal regulators early in the spring. This timeline is impossible if the Notice of Benefit and Payment Parameters is not published in final form until March, as has been the case the past two years and will likely occur this year, given the late-November publication of the draft Proposed Rule.

b. Finalizing the Notice of Benefit and Parameters in January still leaves QHP issuers only a few weeks to implement changes applicable for the following year. As HHS has recognized in suggesting that most of its proposed changes to the EHB requirements be first applicable for the 2017 benefit year, many regulatory changes cannot be implemented in so brief a period. HHS should therefore regularly consider whether each change finalized in the Notice of Benefit and Payment Parameters may be effectively operationalized for the subsequent benefit year or if implementation should be delayed for the *next* subsequent benefit year. While January is the latest month that publication of the final Notice of Benefit and Payment Parameters is appropriate, for many, if not most, policy changes,

this will still not be early enough and applicability of those rule changes should be delayed a year.

c. HHS should be clear when QHP issuers are expected to be in compliance. HHS should clearly state in each rulemaking that even though the rule changes may be "effective" soon after publication, QHP issuers will be required to comply no sooner than the beginning of the next benefit year.

d. With respect to the applicability of the EHB rule changes set forth in the Proposed Rule for 2016, HHS has already proposed that most of these changes not be applicable until 2017. ***We suggest that all EHB changes be applicable no earlier than 2017***. Given that the EHB requirements are interrelated, it is difficult to implement these changes on a timeline in which some are applicable in 2016 and some in 2017, and it is unrealistic for these changes to be made any sooner than 2017 given the considerable change that is represented by these proposals (as discussed in our prior comments on the substance of these proposals).

e. In the same light, HHS should generally not publish additional regulations intended to be applicable for the upcoming benefit year after publication of the final Notice of Benefit and Payment Parameters. QHP issuers need a clear understanding of when rules are final and can be used as a basis to design benefit packages. Publication of the final Notice of Benefit and Payment Parameters should be that point.

f. Executive Order 12866 instructs agencies to offer a "meaningful" opportunity to comment on proposed regulations, "which in most cases should include a comment period of not less than 60 days." Furthermore, the Administrative Procedure Act and federal court decisions require that agencies provide the public an adequate opportunity to comment on proposed regulations. In contrast, HHS published the draft Notice of Benefit and Payment Parameters for 2016 on November 26—the day before Thanksgiving—and required comment be submitted by December 22, merely twenty-six days later. This brief comment period is, in effect, further shortened by the fact that it spans the Thanksgiving holiday, limiting the time stakeholders have to consult with constituents and experts and draft well-considered comments on the draft Proposed Rule, which contains many proposals, several of which are very substantial.[17] *Indeed, we ran a word search in the Proposed Rule for "we seek comment" and the results found 98 instances where HHS sought comment*. This finding further underscores our concern that we and other shareholders have not been provided a meaningful opportunity to comment on the wide range of important proposals in the Proposed Rule. HHS has provided no explanation for why it cannot provide the full sixty-day comment period recommended by Executive Order 12866. In future years,

[17] That the comment period arguably began a few days earlier, when the notice was put on public display at the Office of the Federal Register, does not alter the fact that the comment period was unusually short and spanned the Thanksgiving holiday.

the draft notice should be published sufficiently early to allow a sixty-day comment period and publication of the final notice in January. This may require that the draft notice be published in early October. Even if HHS were to provide only a thirty-day comment period, by adhering to its original schedule of publishing the draft Notice of Benefit and Payment Parameters in mid-October, the comment period could occur before Thanksgiving, permitting stakeholders a more meaningful opportunity to comment.

***PCMA Recommendation*: PCMA recommends that HHS assure the public a meaningful opportunity to comment in the future. This can be accomplished by publishing future draft Notices of Benefit and Payment Parameters sufficiently early to permit the full sixty-day comment period and to allow HHS to publish a final Notice of Benefit and Payment Parameters by January. Furthermore, in this and future Notices of Benefit and Payment Parameters, HHS should delay the applicability date of substantive, difficult to implement regulations, beyond the next benefit year. In particular, the prescription drug benefit rule changes discussed in this comment letter, if finalized, will involve very significant operational and technical changes and require close coordination between QHP issuers, PBMs, Exchanges, and others. They should apply no earlier than 2017.**

As always, we appreciate your consideration of our comments and look forward to continuing to work with HHS.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President – Regulatory Affairs

Attachment A