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Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1677-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; CMS-1695-P

Dear Administrator Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) concerning revisions to the hospital outpatient prospective payment system (OPPS) for 2019 (2019 OPPS proposed rule).

PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

Our comments fall into four key themes:

- 1) **Ensure that any new demonstration developed by CMS is structured in a way that supports the strengths of the Medicare Part B system for reimbursing medicines.** The strengths of the Part B system include broad patient access to treatments appropriate for patients with the life threatening, high-comorbidity diseases that require Part B medicines, low cost sharing, and a market-based system for balancing costs and access. CMS has sufficient flexibility to achieve its goal of reintroducing competitive bidding for Part B medicines within the Part B competitive acquisition program's statute; however, if CMS chooses to go beyond the statute and utilize its

authority under the CMS Innovation Center (CMMI), we urge the agency to first establish in regulations key safeguards – including that models be voluntary, small scale, and of limited duration– to govern CMMI's activity and provide greater transparency to stakeholders considering whether to participate in any model.

- 2) **Implement, through appropriate processes, policies to reduce costs associated with provider consolidation.** PhRMA supports several of CMS's proposals in support of this aim, including common-sense updates to Medicare Part B reimbursement for 340B prescriptions to limit market distortions caused by the 340B program as a first step toward broader changes to the 340B program, requiring hospitals to share clinical information with community physicians, requiring disclosure of standard charges and administration's aim of site neutral payment, and exploring ways hospitals can help prevent surprise medical bills for patients. At the same time, we are concerned that CMS has not gone through the appropriate process in developing its proposed use of its authority under Social Security Act (SSA) § 1833(t)(2)(F) and urge CMS to address outstanding issues related to this authority before using it to implement volume control options.

- 3) **Establishing sufficient reimbursement for medicines.** PhRMA supports CMS's proposal to pay separately for non-opioid pain management drugs used in Ambulatory Surgery Centers and encourages CMS to continue analyzing utilization data to examine whether its packaging policies are restricting patient access. We also support CMS' proposed change to payment for biosimilars without pass-through status acquired under the 340B program, to avoid inappropriately reducing payment of biosimilar medicines. At the same time, we are concerned with CMS' proposal to cut reimbursement for innovative new medicines administered in physician offices to 103 percent of the Wholesale Acquisition Cost (WAC) and urge the agency not to finalize the change.

- 4) **Maintaining a robust performance measurement to provide an accurate, comprehensive picture of care quality.** PhRMA shares CMS' goals of identifying the highest priority areas for quality improvement that will result in efforts and measures that are focused on achieving meaningful outcomes to patients. However, we would encourage CMS to carefully consider removal of measures to ensure that there is an appropriate balance between provider reporting burden and the benefits of providing both patients and providers with data to inform care decisions. PhRMA also urges caution against the removal of measures from quality reporting programs that address high impact public health areas and present an opportunity for improvement.

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I. REQUEST FOR INFORMATION LEVERAGING THE AUTHORITY FOR THE COMPETITIVE ACQUISITION PROGRAM (CAP) FOR PART B DRUGS AND BIOLOGICALS FOR A POTENTIAL CMS INNOVATION CENTER MODEL

PhRMA is concerned that the CMS Innovation Center (CMMI) is considering establishing a new CMMI model testing competitive bidding for Part B medicines, building upon the existing CAP authority. The complex nature of these medicines, and the fact that many patients who rely on them have serious and life-threatening diseases and multiple comorbidities, makes the risk of unintended negative consequences particularly significant.

As discussed in our comments on the Administration's Blueprint for Drug Pricing, it is essential for any competitive bidding demonstration to be carefully constructed in order to avoid unintended consequences such as reduced beneficiary access to care, lower care quality, and disruptions in care delivery. Important design considerations include: operational improvements to address flaws in implementation of the original Competitive Acquisition Program; and protections to avoid disruptions or delays in delivery of medically beneficial care in the optimal treatment setting and to prevent increases in patient costs that can lead to treatment abandonment.

As CMS describes in the RFI, MedPAC has proposed an alternative to the ASP payment system, called the Drug Value Program (DVP), which would be accompanied by changes to the reimbursement in the existing payment program, as a way to encourage provider participation in the DVP. MedPAC's proposal would severely limit access to treatment for Medicare beneficiaries via restrictive formularies, prior authorization, and step therapy. It would also undermine Part B's market-based reimbursement system by imposing a binding arbitration process to set prices for innovative new medicines. Finally, by using changes to the ASP reimbursement system to drive physicians into the program, it could threaten the viability of community practices and encourage costly provider consolidation. We urge CMS to avoid implementing a competitive bidding program based on MedPAC's DVP.

While PhRMA has significant concerns about the potential risks of any competitive bidding program for Part B medicines, we believe the soundest approach to testing it would be to do so within CMS' existing Competitive Acquisition Program authority, while making key operational improvements to address flaws in the original implementation of the program and encourage vendor and physician participation. Doing so provides CMS a carefully constructed legislative framework that includes some core protections for patients and physicians (e.g., voluntary physician participation), while avoiding some of the constraints of CMMI authority.

In our comments below we offer key priorities that CMS should adopt if it chooses to proceed with developing a new competitive bidding program. While these elements are important regardless of the agency's approach to pursuing a competitive bidding demonstration, they will be especially important if it chooses to pursue a model that diverges from the CAP statute and therefore relies on CMMI authority as proposed in the RFI. Additionally, as discussed below, any use of CMMI authority for a significant change in

policy like competitive bidding should be preceded by codification of core safeguards and operating principles for the Innovation Center consistent with the Guiding Principles articulated in the agency's New Direction RFI. Other key considerations in structuring any competitive bidding program should include:

- keep any demonstration voluntary, small scale and of limited duration;
- adhere closely to the CAP statute, while making necessary operational improvements;
- support continued patient access to the range of available medicines;
- preserve a market-based system to establish reimbursement rates;
- maintain clear lines between public programs and avoid overlap between CMMI models;
- give participating providers a choice between vendors;
- avoid misaligned incentives through introduction of new purchasers in the supply chain;
- create an advisory group to inform program design;
- support community physician practices and avoid further increasing market consolidation;
- ensure value-based arrangements in Medicare are voluntary and market-based.

A. CMMI Demonstrations Should Be Voluntary, Small Scale and Limited Duration

If CMS chooses to implement competitive bidding in Part B using CMMI authority, this proposal should be preceded by codifying in rulemaking the CMMI Guiding Principles laid out in the CMMI New Direction RFI and the additional protections recommended by PhRMA and other stakeholders. These principles included prioritizing voluntary models and small-scale testing.¹ Consistent with these principles, any new model should allow stakeholders the option of whether or not to participate.

It is important to recognize that there is a long track record of changes to payment, including but not limited to those initiated by CMMI, not having the intended effect and generating surprising results. For example, despite the expectation that these models would lead to savings, the financial results from payment reforms run by CMMI have been mixed. The Comprehensive Joint Replacement Model and the Medicare Shared Savings Program (MSSP) both increased cost.² The MSSP is particularly notable because it has increased net costs in each of the first four years of the program, rather than achieving the savings estimated by CBO. In 2016, the program increased costs by \$39 million versus CBO's projection that the program would save \$700 million³ Similarly, United Healthcare implemented a pilot changing physician payments for oncology treatment to a flat fee and implementing an episode-based payment. While the study reduced overall spending on cancer treatment, spending on cancer medicines increased. The changes in drug spending were the opposite of what the study authors intended.⁴ The fact that a renewed

¹ Centers for Medicare & Medicaid Services: Innovation Center New Direction. September 2017. Available at: <https://innovation.cms.gov/initiatives/direction/>.

² Avalere Health. MSSP & CMMI Financial and Quality Performance Results. April 23, 2018. Available at: <http://avalere.com/expertise/managed-care/insights/financial-results-of-mssp-and-cmmi-demos-are-mixed>.

³ Ibid.

⁴ LN Newcomer et al. Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model. *Journal of Oncology Practice* 10, no. 5 (September 1, 2014) 322-326.

competitive bidding initiative would affect some of the sickest seniors and disabled persons, including those who may not have a second chance to get the most clinically appropriate care, reinforces the need for voluntary, small-scale testing, along with other appropriate safeguards.

It is also important to recognize the concerns stakeholders have raised about previous large, mandatory CMMI models. Several proposed models (i.e., the Comprehensive Care for Joint Replacement model, Episode Payment Model, and Part B Drug Payment Model) prompted concern from stakeholders and Members of Congress about their impact on Medicare beneficiaries and their compliance with the requirements of CMMI's authorizing statute. These concerns centered on the large scale of these models, the requirement for mandatory participation, the lack of stakeholder engagement in the model development process, and, as a result, the heightened risk for negative consequences for patients, providers and taxpayers. In addition, several policymakers have raised the concern that CMMI was exceeding its authority by proposing to make permanent, structural changes to the Medicare program.⁵ CMS should learn from this experience that patients and providers' concerns are heightened for mandatory models, due to the increased potential for unintended consequences. This prompted CMMI to stipulate in the New Direction RFI that initial tests should be small scale and preferably voluntary, to withdraw the Part B Drug Payment Model,⁶ to cancel the mandatory episode payment model,⁷ to limit the Comprehensive Care for Joint Replacement (CJR) model to the minimum size needed to achieve scientifically valid results,⁸ and to seek input on future model concepts through the New Direction RFI.

Participation Should be Voluntary

Participation in a competitive bidding program should be voluntary for all stakeholders. This is essential to ensure the program works not just for taxpayers or vendors, but for patients and providers as well. Mandating participation in Phase I models could increase the risk that beneficiaries will experience problems with access to or quality of care, and that providers will be forced to abide by requirements that are unworkable from a clinical or operational standpoint. Voluntary models, by contrast, will ensure vendors work with providers to develop approaches that fit with the clinical needs of patients and provider work flow. A voluntary model also increases the likelihood of success because the participants will be highly engaged, supportive of the demonstration concept, and motivated to help CMMI improve its design and achieve its goals. Approaches that would encourage provider participation in a model by changing reimbursement for non-participating providers are not voluntary – because they non-participating providers did not choose the reimbursement change – and thus should also be avoided.

⁵ "These most basic tenets of our government, intended by our Founding Fathers to preserve and maintain balance of power, have clearly been neglected. CMMI interprets their authority to 'test' innovative models on a limited basis as means to substantially alter both the delivery and reimbursement of care without any input or approval from Congress and the constituents we represent." Letter to Acting Administrator Slavitt and Deputy Administrator Conway from members of the House of Representatives. September 29, 2016.

⁶ 82 Fed. Reg. 46182.

⁷ 82 Fed. Reg. 57066.

⁸ 82 Fed. Reg. 57066.

Providers may choose to opt out of a model because they do not believe that there are opportunities to drive cost savings without harming the quality of care. For example, some providers may choose to opt out of a competitive bidding model that seeks to lower costs by shifting patients from a higher-cost medicine to a lower-cost medicine by rewarding providers that choose lower cost medicines even though clinical results would not be equivalent. Providers opting out of such a model may already be treating their patients with the optimal medicines, given clinical and cost considerations, and so would not have opportunity to achieve rewards associated with the proposed model without shifting their patients to clinically inappropriate medicines. Moreover, mandating provider participation, depending on how providers are designated to participate, could effectively leave patients without the choice of whether to be treated in this experimental setting, with its unknown effects on their care. Requiring participation may also force many providers into a model that is not economically viable. This could lead to increased provider consolidation and increased healthcare costs, undermining CMMI's goals.

Requiring a manufacturer to participate in a CMMI model would also be inappropriate and inconsistent with the idea of a CMMI test. A test is defined as “the procedure of submitting a statement to such conditions or operations as will lead to its proof or disproof or to its acceptance or rejection.”⁹ Policy changes where the outcome is known up front do not need to be proven or disproven, and therefore would not meet the definition of a test.

A model that intervenes in the market by requiring participation would undermine market-based competition and negotiation – two of the four strategies outlined in the Administration's Drug Pricing Blueprint. Instead of pursuing mandatory demonstrations, which as described above, has previously garnered significant opposition from stakeholders, CMS should work to ensure any model it develops is one that a range of stakeholders can support. This type of model will attract sufficient provider and manufacturer participation, ensuring adequate volume for a meaningful test. In addition, many improvements can be made within the existing CAP statute that will make that program more attractive to stakeholders and drive participation without necessitating a CMMI model, and certainly without requiring a mandatory model. These suggested improvements are listed in subsection B, below.

Establish CMMI Safeguards in Rulemaking

If CMS pursues a new competitive bidding model via CMMI, we urge the agency first to codify the Guiding Principles established in the New Direction RFI through formal notice and comment rulemaking, including the principle that CMMI models should start as small, voluntary tests in Phase I.¹⁰ It should also expand on these principles by describing the role of and process by which CMMI will engage with Congress as it seeks to expand successful demonstrations. Codifying principles for CMMI in rulemaking would facilitate more effective collaboration with stakeholders across the health care industry by clearly communicating

⁹ Merriam Webster Dictionary. Available at: <https://www.merriam-webster.com/dictionary/test>.

¹⁰ Centers for Medicare & Medicaid Services: Innovation Center New Direction. September 2017. Available at: <https://innovation.cms.gov/initiatives/direction/>.

requirements for CMMI model tests. It would also reduce regulatory burdens by providing greater predictability in future payment policy. Most importantly, these guidelines will help to minimize potential unintended consequences for beneficiaries.

This will improve the likelihood of success by giving providers and patients confidence in CMMI's process, which may increase model participation, and lead to better model results. In addition, CMS should establish a process to ensure that model design is guided by expert input (as was done for the Oncology Care Model through establishment of a Technical Expert Panel) and should be issued as a proposed rule for broad public input. The changes contemplated by the RFI would be a major new policy test and thus would warrant inclusion of these basic elements.

B. Adhere Closely to the CAP Statute, While Making Key Operational Improvements

As it considers developing a competitive bidding model, we urge CMMI to adhere to the existing CAP statute. Many of the challenges associated with the CAP statute were addressed in rulemaking after the program had ended. We suggest that reviving CAP with these changes (which are consistent with the CAP statute) could be enough to meet CMMI's stated goals to "test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending."¹¹

There are several ways that CAP could be improved under the existing statutory authority, without the need for CMMI waivers.

Make the program more attractive to vendors (and physicians) by targeting drug classes most likely to yield savings and avoid problems with distribution.

The original CAP program required vendors to be able to distribute all 182 products regardless of cost and required vendors to be able to service all 50 states and territories. These requirements may have deterred many potential vendors from bidding (e.g. those lacking the capability to meet the CAP requirements in the U.S. territories at a reasonable cost, or those that could have met the CAP requirements on a regional but not national basis). In addition, the program spanned many physician specialties, making it difficult to communicate about the program and to get the necessary buy-in and volume to make it effective.

A revised CAP could be more attractive to physicians and vendors if it targeted the specialties and drug categories where CAP made the most sense financially and clinically. CMS has the statutory flexibility to identify the specific drug categories included in the program, and to limit the program to products likely to result in significant savings.¹² Targeting specific drug categories would give vendors time to develop infrastructure and work out operational issues on a narrow set of medicines, potentially expanding later.

¹¹ 83 Fed. Reg. 37046 at 37212.

¹² Social Security Act § 1847B(a)(1)(D).

This targeting should be based on total cost of care, not narrowly on the drug line-item. This will maximize the potential for savings, given that drugs are only 11 percent of Medicare Part B spending.¹³

In addition, the statute provides the Secretary with the flexibility to establish “appropriate geographic regions” for the program.¹⁴ CMS could provide vendors geographic flexibility, requiring them to cover specific regions or states and the District of Columbia but not U.S. territories. Vendors could potentially start in specific regions and build out to larger areas as they gained customers and experience as permitted by the statute.¹⁵

Increase physician flexibility and align with clinical and administrative needs.

The prior CAP program required physicians to enroll for an entire year (with the ability to leave CAP mid-year only in limited circumstances¹⁶) and to rely on CAP vendors for all drugs included in the CAP program (i.e., there was only one “category” of competitively biddable drug). As a result, physicians were generally locked into the program even when it wasn’t appropriate for them or their patients.

In targeting the CAP program, CMS should include as a criterion whether the clinical area has predictable utilization and a more stable, less acute patient population. Ideally the initial phase of a new CAP implementation would be with a therapeutic area that has relatively stable use of Part B drugs from physician visit to physician visit or involves Part B drug treatments that are not time critical (e.g., because oncology medicine dosage varies and treatment time critical, these medicines may be less appropriate for a CAP program).

CMS should also seek to identify other opportunities to give physicians more flexibility under existing CAP authority, which would make them more likely to participate. For example, CMS could give physicians more flexibility to enter or exit the program during the year rather than making a single decision each year to be “in” or “out.” The statute requires that a physician be “given the opportunity annually to elect to” participate in CAP and those physicians also make an “annual selection” of the CAP vendor.¹⁷ The statute does not, however, include a requirement that a physician’s annual decision to enroll in CAP also requires that the physician commit to participating in CAP for the duration of a full year. CMS recognizes that, as the CAP regulations allow physicians to leave the program mid-year, but only in relatively narrow circumstances.¹⁸ We believe that there is greater flexibility here that CMS could use to encourage greater physician participation in CAP because more physicians with an interest in CAP might enroll if the conditions for exiting the program were less stringent, revising the regulations to make it somewhat easier for a physician

¹³ N Longo. “Guess what? Part B drug spending remains stable share of Medicare spending.” The Catalyst. January 23, 2018. Available at: <https://catalyst.phrma.org/guess-what-part-b-drug-spending-remains-stable-share-of-medicare-spending>.

¹⁴ Social Security Act § 1847B(a)(2)(C).

¹⁵ Social Security Act § 1847B(c)(3) (“Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.”).

¹⁶ 42 C.F.R. §§ 414.908(a)(2); 414.917(d).

¹⁷ Social Security Act § 1847B(a)(1)(A)(ii) and (iii).

¹⁸ 42 C.F.R. §§ 414.908(a)(2); 414.917(d).

for whom CAP is not working out to leave could increase CAP participation and potentially could make the program more attractive for vendors as well.

Reward physicians for participating in the CAP program

CMS could consider steps to incentivize physician participation by providing extra reimbursement for patient care-related services associated with participating in the program. For example, the agency could consider linking CAP participation to payment incentives under the Quality Payment Program (QPP). For example, participation could be factored into the Merit-Based Incentive Payment System (MIPS) cost score.

Consider additional steps to provide greater efficiency and flexibility for vendors and physicians under CAP.

Under the original CAP program, CMS sought to implement a number of additional policy changes to improve the functioning of the program for vendors and clinicians. However, many of these changes came too late to benefit the program before it was ended. A new CAP program could be re-launched with many of these changes already incorporated. For example, as the CAP program was initially implemented, physicians participating in CAP could not maintain a stock of a CAP vendor's drug in their inventories.¹⁹ This led to product wastage and cost that the vendor had to bear because the physician did not have alternative medicines or doses available should a patient's needs change (e.g., if an expensive cancer treatment was shipped, but the patient's blood count wasn't "in range" when he or she arrived for treatment). It also led physicians to utilize an emergency stocking provision built into the original CAP model. After the benefit of time and experience administering the program, CMS sought to provide greater flexibility to physicians by providing "a framework under which certain quantities of vendor-owned CAP drug stock may be located in a participating CAP physician's office and delivered in conjunction with electronic transactions and charge capture."²⁰ However, CMS suspended the CAP program before this policy could be operationalized.

CMS also provided some flexibility to permit physicians to transport drugs to multiple locations²¹, but these changes were made too late to benefit the CAP program.²² Incorporating these changes from the outset would reduce physician burden and address concerns with delay in initiating treatment.

C. Patients Should Continue to Have Access to the Full Range of Medicines

PhRMA opposes approaches that would establish third-party vendors which negotiate prices for Part B drugs using formularies and utilization management requirements such as prior authorization and step therapy. These tools would make it more challenging for Part B patients, many of whom have life-threatening, high morbidity, and/or clinically complex conditions, to access the medications they need.

¹⁹ See 74 Fed. Reg. at 61913

²⁰ 74 Fed. Reg. at 61913-61914.

²¹ 74 Fed. Reg. at 61918.

²² 74 Fed. Reg. at 61918.

Part B's current structure ensures the availability of a range of treatment options. Due to the personalized nature of many medicines in Part B and the diseases that they treat, physicians and patients need maximum flexibility to tailor (including quickly changing) treatments to meet patients' needs, consistent with clinical evidence and the physician's expertise and knowledge of individual patients' needs and preferences. For this reason, imposing conventional, cost-driven formularies or other utilization management tools would put patient access to treatment at risk. As discussed above, prescribing flexibility is essential to the management of complex conditions like cancer, RA, rare diseases and other conditions treated with Part B medicines. For example:

- Comorbid conditions can impact a patient's tolerance for the toxicity of certain cancer medications. Patients with heart disease and congestive heart failure may require different medications than patients without these comorbid conditions to avoid serious and life-threatening complications.
- Patients with RA respond differently to biologic Disease-Modifying Anti-Rheumatic Drugs (DMARDs), making choice of treatments critically important. While some patients may respond best to one DMARD, another medicine may work better for other patients. In addition, RA patients often stop responding to one treatment over time, requiring them to shift to a different option.²³
- Many patients with multiple sclerosis who are receiving an infused Part B medication may be on their second or third line of treatment. Step therapy or other utilization management requirements could force these patients to revisit therapies their physician has already determined are ineffective in managing their disease.
- Congress specifically recognized the need for cancer patients to have access to a wide range of treatments, including medically accepted off-label uses of these medicines, given the life-threatening nature of this condition.²⁴ If cancer patients are included in a demonstration, they should continue to have robust access to the full range of medicines covered by Medicare.

A recent survey of physicians underscores these concerns. Eighty-eight percent of oncologists and rheumatologists believe a CAP or DVP program would take care decisions away from the person in the best position to make that decision; more than 87 percent believe it would limit their ability to provide the best care to patients; and 75 percent of providers believe it would increase the administrative burden for their practices.²⁵

²³ American College of Rheumatology. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2012;64(5):632.

²⁴ See Social Security Act § 1861(t)(2).

²⁵ Community Oncology Alliance. COA Physician Survey: Medicare Part B Proposals Will Harm Patients, Increase Costs and Bureaucracy. May 2018. Available at: <https://www.communityoncology.org/portfolio-items/coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/?portfolioCats=64%2C60%2C67%2C70%2C59%2C69%2C66%2C65%2C63%2C61%2C68%2C51%2C58>

By excluding use of traditional UM tools from a competitive bidding demonstration, CMS also will avoid the risk that any demonstration is found to limit beneficiary access to care and therefore is ineligible for expansion. In particular, CMMI's statute states that the agency can only expand initial Phase I testing models in instances where, among other things, "the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable subchapter for applicable individuals."²⁶

As reflected in the RFI's question about formulary and/or utilization management strategies such as step therapy, we recognize the agency is clearly interested in implementing these types of tools more broadly. PhRMA believes that incorporation of any utilization management tool in the Part B context creates an undue risk of policies that are misaligned with high-quality care and impede access to the individualized care that patients need, and therefore we oppose use of UM in competitive bidding. It will also be important for CMS to observe for at least one year how recent changes which gave Medicare Advantage Plans more flexibility to implement step therapy are implemented, and the effect on patient outcomes, before further expanding utilization management.²⁷ However, to the extent CMS moves forward to consider reforms that include UM tools, it will be essential to establish basic standards and process requirements to move beyond conventional, cost-driven UM and promote alternative approaches to protect patient access, support high-quality, individualized care, and fit into physician workflow in ways that reduce, rather than increase, administrative burden. To ensure this, it will be important to build in the following protections:

- Ensure that utilization management does not lead to denial of coverage of medically necessary services, as required under the Medicare Statute by ensuring utilization management
 - Is aligned with evidence-based clinical practice guidelines and appropriate clinical evidence,
 - Is based on medical appropriateness and not cost-effectiveness,
 - Is not discriminatory,
 - Provides coverage based on an assessment of need by the beneficiary's provider.

- Ensure development and management of clinically appropriate UM tools is led by organizations representing relevant clinical specialists, practicing physicians and affected patients. As noted above, beneficiaries who need treatment with physician-administered medicines often have multiple, complex diseases and conditions and variable needs and preferences. As a result, it will be essential that any decision-support or UM be led by physicians with relevant expertise, as well as patients with conditions that would be affected by the utilization management policy. This will help to ensure the policies are aligned with good clinical practice and are consistent with the statutory requirements for Medicare Advantage plans.²⁸

²⁶ See Social Security Act § 1861(t)(2).

²⁷ CMS. HPMS memo to Medicare Advantage Organizations. "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage." August 7, 2018.

²⁸ Social Security Act § 1852(j)(2).

- Ensure meaningful, timely process for exceptions and appeals. Any CMS demonstration that uses incentives to influence physician prescribing decisions must include a strong, timely process for beneficiary exceptions and appeals. This is particularly important for physician-administered drugs under Medicare Part B, which frequently are relied on by vulnerable patients with serious, complex diseases like cancer, multiple sclerosis, autoimmune disorders and rare diseases. Any utilization management or decision-support should be accompanied by clear exceptions for patients for whom the utilization management protocol is clearly inappropriate, such as patients who are already stable on another medicine, or who have already tried and failed on a related medicine. If an exception is rejected and a patient or provider needs to appeal to the organization administering the utilization management, the appeals process should be clear and have a short deadlines – such as the 72-hour expedited review process under Medicare Part D.²⁹ If appeals are not responded to in a timely manner, there should be a presumption of coverage that allows patients to access their medicine. It is also important that any exceptions and appeals processes further the Administration’s “Patients Over Paperwork” initiative by decreasing administrative burden on physicians as much as possible.

D. Preserve A Market-Based System for Establishing Reimbursement Rates

The competitive market is uniquely well-designed to make complex determinations about the value of medicines as many heterogeneous purchasers are best able to assess their own needs in light of the available evidence. In contrast, policies that would impose a centralized government determination of value should be rejected because they would reduce choice, lead to suboptimal outcomes, and undermine continued innovation.

One example of the successful market-based system can be understood by looking at Average Sales Price (ASP), which works to moderate price growth for Medicare Part B medicines. If CMS moves forward with a competitive bidding demonstration, it will be important to exclude discounts provided to the competitive bidding vendor from ASP to preserve the integrity of the ASP system, as was done in the original CAP program. Excluding vendor discounts from ASP will ensure that providers who choose to remain in buy-and-bill are adequately reimbursed if new vendors are able to secure deeper discounts for Part B medicines. It will also ensure an effective test of the competitive bidding program relative to the current system. Finally, this ensures that the competitive bidding program would truly be voluntary for practices.

Reimbursement for Part B drugs is generally based on ASP, which reflects the weighted average of discounts and rebates given to providers and payers, subject to certain exceptions. This means that the Medicare program and beneficiaries benefit from the discounts health plans and providers negotiate on these drugs. Due to this market-based competition, ASP prices are often substantially lower than list prices. Looking at discounts for the 25 medicines with the highest spending under Part B, the ASP

²⁹ Medicare Prescription Drug Manual, Chapter 13 Sec. 70.8.1.

represents a weighted average discount of 21.2 percent off the list price.³⁰ Over time, the inclusion of these discounts in ASP has worked to moderate price growth for Part B medicines. The volume weighted ASP for Part B medicines has remained steady year over year, and price growth for Medicare Part B drugs is below overall medical inflation.³¹ In addition, CMS analysis found that, in the third quarter of 2018, the ASP-based Part B payment amount for 11 of the top 50 drugs decreased; and, for most of the higher volume drugs, ASP changed 2 percent or less.³²

In contrast to a market-based system, experience in several European countries has shown the dangers of the government price setting based on centralized, one-size-fits-all judgments of value. Restrictions imposed by the U.K.'s NICE have created substantial barriers between patients and life-saving treatments—recent analysis shows that from 2013 to 2017, nearly 92 percent of oncology treatments were subject to some kind of access restriction.³³ Patients who live in countries that impose centralized value judgements also have access to fewer treatment options—recent data shows that nearly 90 percent of newly launched medicines were available in the U.S., compared to just two-thirds in the U.K., half in Canada and France, and one-third in Australia.³⁴ Ensuring reforms are market based is essential to preserving access to a range of treatment options that patients identify as high value.

E. Maintain Clear Lines Between Public Programs and Avoid Overlap Between CMMI Models

PhRMA is concerned that CMS is considering how a potential competitive bidding model could include other payers including Medicare Advantage organizations, State Medicaid agencies, as well as Medicaid Managed Care Organizations (MCOs). Each of the programs CMS is considering has different requirements for manufacturers as well as the health plan or state that the manufacturer may contract with. Allowing vendors to work across programs raises a host of compliance questions for manufacturers as well as health plans. These questions could make any program extremely difficult to administer and subject to conflicting standards and pressures. Medicaid best price, which the Administration has acknowledged distorts markets,³⁵ is one example. Discounts provided to a State Medicaid agency under a CMS-approved supplemental rebate agreement are excluded from best price, while discounts to Medicaid Managed Care Organizations are not. These government rules create significantly different incentives for manufacturers

³⁰ Estimates based on analysis by PhRMA using the July 2018 ASP Pricing File, 2018 Medispan files, and 2018 Medicare Part B Drug Spending Dashboard.

³¹ The Moran Company. Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2015. December 2016.

³² CMS, 2018. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2018ASPFiles.html>

³³ Hughes K and N Jeswani. HTAs Recommendations for Oncology Have Grown More Restrictive Over Time. Avalere Health. June 2018. Available at: <http://avalere.com/expertise/life-sciences/insights/htas-recommendations-for-oncology-have-grown-more-restrictive-over-time>

³⁴ Haninger K. New analysis shows that more medicines worldwide are available to U.S. patients. PhRMA. The Catalyst Blog. June 2018. Available at: <https://catalyst.phrma.org/new-analysis-shows-that-more-medicines-worldwide-are-available-to-u.s.-patients>

³⁵ HHS, American Patients First.

as they engage with different market sectors, an example of why allowing discounts to be shared across programs may not yield the results that CMS is hoping to achieve, such as additional supplemental rebates for state Medicaid programs.

CMMI should also work to avoid overlap with existing models, including the Oncology Care Model (OCM) and the various Accountable Care Organization (ACO) programs. These are significantly changing payment for medicines and the role of ASP in Medicare fee for service on a large-scale basis. OCM encompasses roughly 3,200 oncologists and roughly 155,000 of fee for service oncology patients;³⁶ ACOs are responsible for the care of over ten million Medicare beneficiaries, or well over one-fifth of all Medicare fee for service beneficiaries.³⁷

CMMI should seek to leverage and improve the existing Oncology Care Model, rather than set up a competitive bidding program for oncology drugs. While the Oncology Care Model would benefit from refinements, developing a new payment model to improve quality and/or reduce costs in a complex clinical area like oncology poses substantial challenges, and CMS would likely have more success in achieving its aims by working to reform the current program, rather than developing a new competitive bidding program for oncology drugs. Improving the Oncology Care Model could encourage more providers to participate in this model, which is aligned with CMS' aims by using tools available in the commercial market to drive competition. OCM could have a greater ability to encourage reductions in cancer care costs if it were not so narrowly focused on cancer medicines, and instead allowed episodes to start earlier and incorporate more of the high cost hospitalizations that tend to occur earlier in a patient's treatment. Despite the model's limitations, the narrowly targeted episodes in OCM do encompass the full range of oncology costs, rather than being restricted to the roughly 18% of costs attributable to the medicine line item for Medicare cancer patients.³⁸ We suggested in our New Direction RFI comments several refinements to the program that would make the model more successful, specifically: strengthening the adjustment for novel therapies, broadening the episode to provide greater opportunities for care coordination and savings, and improving incentives for care quality by utilizing cross-cutting indicators of clinical and patient reported outcomes, such as measures focused on disease outcomes and quality of life.³⁹

The Medicare Shared Savings Program, and other ACO programs give providers incentives to manage medical spending cost, including the cost of medicines. In addition, CMS recently released a proposed rule considering updated participation requirements for the MSSP program. Allowing ACOs to participate in a competitive bidding program would confuse the findings of both the ACO program changes and the

³⁶ HHS Announces Oncology Care Model Participants. IndustryEDGE: A Press Ganey Publication. July 2016. <http://www.pressganey.com/docs/default-source/industry-edge/issue-6---july/hhs-announces-oncology-care-model-participants.pdf?sfvrsn=2>

³⁷ CMS. Medicare Shared Savings Program Fast facts. January 2018. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf>.

³⁸ K. Fitch, *et al.* Milliman, "Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014," April 2016, <http://www.milliman.com/uploadedFiles/insight/2016/trends-in-cancer-care.pdf>.

³⁹ PhRMA Comments to CMMI New Direction RFI. Available at: <https://catalyst.phrma.org/medicare-monday-phrmas-comments-on-new-direction-for-cmmi>.

competitive bidding program, because it would not be clear which program drove any cost savings or quality changes. Allowing OCM practices to participate would raise similar concerns. Challenges associated with evaluating groups that are participating in multiple models has been raised as a concern by stakeholders.⁴⁰ For this reason, we urge CMMI to exclude ACOs and OCM practices and patients from any competitive bidding program.

F. Give Participating Providers A Choice Between Vendors and Avoid Disruptions or Delays in Treatment

It would be important to ensure that a competitive bidding program has multiple vendors for providers to choose among. The original CAP model had many operational challenges which reduced vendor interest, such as requiring physician to place an order with the CAP vendor in advance of the patient visit. This created potential for physicians not to have the appropriate medicine available to patients, if a last-minute change in therapy or timing of treatment was required. While CMMI suggests that it is considering approaches to prevent this type of challenge, capabilities and implementation approaches may vary by vendors and physicians choosing to participate in a competitive bidding program should have a choice of vendors they believe will best allow them to meet their patients' needs. Having multiple vendors may also encourage vendors to compete based on their ability to distribute medicines in a timely fashion, because providers are likely to prioritize this capability in selecting a vendor. Allowing providers to choose between multiple vendors – and opt out of vendors that do not meet their needs – would serve as a test of whether vendors are doing a good job. It would also allow providers to stay in the competitive bidding program even if they have an underperforming vendor in their region, by selecting an alternative vendor.

As noted above, physicians participating in the original CAP program utilized the program's emergency restocking provision in some cases in order to provide their patients timely access to medicines. After the program was paused, CMS updated the regulations to create additional flexibility for participating physicians to administer their own stock of medicines, if needed. Any new competitive bidding model should maintain this flexibility to ensure that a new vendor does not lead to delays in treatment for patients with the serious illnesses treated by Medicare Part B medicines. It will also be important to ensure that medicines can be provided in the appropriate setting and does not lead to additional travel or clinic visits for patients.

An additional issue that will be important to boost vendor interest in a new competitive bidding program and thus enhance the likelihood of physicians having a choice of vendors is assuring prospective vendors that CMS will maintain the confidentiality of trade secret and other proprietary information they submit. To that end, CMS should make clear that it will adhere to the confidentiality provisions in the CAP statute. Under these provisions, CMS must follow the provisions of the Federal Acquisition Regulation relating to

⁴⁰ RA Berenson and N Cafarella. The Center for Medicare and Medicaid Innovation: Activity on Many Fronts. Urban Institute. February 2012.

confidentiality of information in carrying out the bidding process,⁴¹ and must also follow the confidentiality provisions in the Medicaid rebate statute (SSA § 1927(b)(3)(D)), as modified to apply to CAP bids, during periods in which a bid is submitted.⁴² It will be important for CMS to maintain confidentiality of prices paid to competitive bidding vendors to maintain confidentiality of net drug prices and avoid increasing prices. Claims should only be released in an aggregated form subject to a research protocol. As an example of the concern regarding lack of confidentiality leading to higher prices, the Congressional Budget Office (CBO) has stated that publishing product-level rebate information would result in slightly lower rebates and therefore higher costs to the government and patients.⁴³

G. Avoid Creating Misaligned Incentives Through Introduction of New Purchasers in the Supply Chain

Establishing a new vendor in Medicare Part B risks creating some of the perverse incentives that exist for medicines sold at pharmacies. While robust negotiation between PBMs and manufacturers has helped constrain overall spending on medicines in the U.S., middlemen can retain a significant share of rebates and price concessions. HHS Secretary Alex Azar has raised concerns that this creates incentives for middlemen to favor drugs with high list prices.⁴⁴

A key concern is that patients face higher costs as a result of misaligned vendor incentives for retail medicines. Unlike care received at an in-network hospital or physician's office, PDPs typically base cost sharing for prescriptions filled with coinsurance on undiscounted list prices, rather than on prices that reflect negotiated rebates and discounts. Use of coinsurance for prescription medicines has grown sharply in recent years, increasingly exposing patients to high out-of-pocket costs based on undiscounted prices, creating scenarios in which medicines appear to be more costly than other health care services. High cost sharing is a cause for concern, as a substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.⁴⁵ For this reason, it will be important not to create a new middleman vendor that negotiates discounts that do not benefit patients through lower cost sharing, and instead ensure that any vendor negotiated discounts are shared with patients.

⁴¹ SSA § 1847B(a)(1)(C).

⁴² SSA § 1847B(c)(5).

⁴³ Orzag P. Letter to Joe Barton and Jim McCrery. March 12, 2007.

⁴⁴ Alex Azar, HHS, Testimony Before the United States Senate Committee on Finance: Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market, June 26, 2018.; Alex Azar, HHS, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Full Committee Hearing: The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices, June 12, 2018

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

To avoid creating perverse incentives that increase patient and provider costs, we encourage CMS to ensure that any competitive bidding vendor is not paid based on a percentage of the list price, e.g., by requiring vendors to be paid a fixed fee.

The challenge has been seen as smaller employers and health plans may not benefit from the price concessions negotiated by PBMs, particularly if the PBM decides not to classify certain fees or other concessions as 'rebates.' For example, one benefits consultant has observed that PBMs are increasingly changing the contractual definition of rebates to exclude certain administrative fees, allowing the PBM to retain these payments rather than passing them back to the plan sponsor. These administrative fees can be as high as 25 to 30 percent of the total amount paid in rebates and fees by the manufacturer to the PBM and in some cases may not be reported to the plan sponsor by the PBM.⁴⁶ Small providers may face a similar challenge as they seek to work with a large competitive bidding vendor – discounts and rebates negotiated from manufacturers may be retained by the vendor, not shared with the provider.

H. Create an Advisory Group to Inform Program Design

Developing a bidding program that would fundamentally change the system of reimbursing Part B medicines will require many implementation decisions with substantial ramifications based on the complex nature of the drug supply and distribution system. It is important that CMS engage stakeholders with relevant expertise as it analyzes the implications of changes that it is making, to avoid the types of operational and technical challenges faced by the original CAP program. To maximize the potential for a new program to be successful and more importantly, to avoid creating distortions that would undermine the successful Part B system, we suggest that CMS develop an advisory group that will help CMS understand and weigh the ramifications of program design decisions. This group should include broad stakeholder representation, including patients most affected by the model, community-based physicians, manufacturers, payers and other providers.

One operational challenge the advisory group should address is setting up the competitive bidding system to prevent medicines purchased through the program from being diverted for use in other programs. Physicians purchase medicines for use in both commercial and Medicare patients. To the extent that medicines sold to a competitive bidding vendor reflect additional discounts beyond those typically provided to physicians, it will be important that those medicines be used only for patients of physicians participating in the competitive bidding program and not diverted to patients who are not covered by Medicare Part B.

⁴⁶ Dross D. Will Point-of-Sale Rebates Disrupt the PBM Business? *Mercer*. July 31, 2017. Available at: <https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.htm>

I. Support Community Practices to Avoid Further Increasing Provider Consolidation

Any new competitive bidding program should be developed recognizing the cost of increased provider consolidation and structured in a way that reduces rather than increases this consolidation. Payment differentials, and differences in the acquisition cost of goods (e.g. the 340B program), incentivize hospital systems to acquire physician practices.⁴⁷ Consolidation leads to increased market power, which allows hospitals to charge more for the same care, driving up costs of care for patients with both public and private insurance.⁴⁸

One way to help ensure that a new competitive bidding program does not increase consolidation is to avoid inadvertently expanding 340B eligibility by disallowing hospital-owned pharmacies from acting as competitive bidding vendors and prohibiting 340B entities from accessing these vendors' discounts. The 340B program has been demonstrated to increase provider consolidation across a range of specialties, so preventing its expansion can help mitigate further costly consolidation.⁴⁹ CMS should also consider whether to structure a competitive bidding demo around small community practices that may not have the resources to keep certain higher investment medicines in stock. Allowing a vendor to carry the capital costs associated with purchasing and stocking these medicines may support small practices in making a broader range of medicines available to patients. Utilizing vendors that are closely aligned with the clinical and financial needs of community physicians could also help push back on pressures driving provider consolidation.

J. Value-Based Arrangements in Medicare Must Be Voluntary and Market-Based

PhRMA appreciates CMS's continued interest in value-based arrangements, but we urge CMS not to limit its consideration of value-based arrangements to a competitive bidding program. Value-based arrangements are a promising tool for injecting new types of competition into the competitive market and HHS can support development of these arrangements by addressing policy barriers that can inhibit these beneficial, innovative contracting approaches. Specifically, CMS can support development of value-based arrangements by clarifying federal price reporting requirements that can serve as an obstacle. In addition, the HHS OIG can facilitate these arrangements by establishing a new safe harbor to the Anti-Kickback Statute. PhRMA has submitted recommendations to the HHS OIG in both 2017 and earlier this year in support of creating a new safe harbor for value-based arrangements under the Anti-Kickback Statute.⁵⁰ We also detailed our recommendations for price reporting changes in our comments on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.⁵¹

⁴⁷ Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Affairs*. 2014;33(5):756-63.

⁴⁸ Bai G, Anderson GF. A more detailed understanding of factors associated with hospital profitability. *Health Affairs*. 2016;35(5):889-97.

⁴⁹ Desai S and JM McWilliams. Consequences of the 340B Drug Pricing Program. *NEJM*. 2018; 378:539-548.

⁵⁰ PhRMA comments to OIG-125-N. Solicitation of New Safe Harbors and Special Fraud Alerts. February 2017, and to OIG-127-N. Solicitation of New Safe Harbors and Special Fraud Alerts. February 2018.

⁵¹ Cite to docket.

Value based arrangements have led to cost savings for private payers. A recent Avalere survey found that 74 percent of health plans report costs savings as a result of their value-based contracts, a significant increase compared with the 33 percent reporting savings in the prior year.⁵² At the same time, the number of value-based arrangements continues to increase. PhRMA identified 43 publicly announced contracts from 2009 – Q2 2018,⁵³ and data from the Academy of Managed Care Pharmacy and PwC's survey confirm that only a portion of value-based arrangements are publicly announced.⁵⁴

Value-based arrangements have also helped patients afford and obtain innovative medicines. Recent studies have shown that value-based arrangements support better access to medicines⁵⁵ and may have reduced patient copays by 28 percent.⁵⁶ CMS should work to ensure that value-based arrangements continue to support broader patient access to medicines.

To the extent that CMS wishes to encourage value-based arrangements in Medicare, it should do so in a way that allows the market to determine value, not the government or any other centralized organization attempting to make one-size-fits-all assessments. As noted in subsection D above, European experience has shown how government attempts at value determinations can reduce patient access to important medicines.

As CMS considers ways to encourage value-based arrangements in Medicare, it should adopt certain principles that will help to ensure that these arrangements support rather than restrict patient access to innovative medicines:

- Value-based arrangements rely on the market to define value, not government dictates, and therefore are voluntary agreements between manufacturers and payers or providers intended to tie payment for medicines more closely to value or improve predictability for purchasers;
- Value-based arrangements should improve, rather than harm patient affordability and access to medicines;
- Value-based arrangements are diverse and adaptable. There is no one-size-fits-all VBA. The design of sound, beneficial VBAs will vary considerably depending on the disease area, the type of treatment, the outcomes of importance to patients and payers, and data available.

⁵² Avalere Health. Outcomes-Based Contracts: Payer Perspectives. Avalere Policy 360. July 19, 2018.

⁵³ Cite to forthcoming blog.

⁵⁴ Duhig AM, S Saha, S Smith et al. The Current Status of Outcomes-Based Contracting for Manufacturers and Payers: An AMCP Membership Survey. *J Manag Care Spec Pharm*. 2018;24(5):410-415; and PwC. Launching Into Value: Pharma's Quest to Align Drug Prices with Outcomes. September 2017. Available at: <https://www.pwc.com/us/en/health-industries/health-research-institute/publications/value-based-drug-pricing.html>.

⁵⁵ See, e.g., description of Entresto and Repatha contracts in: Seely E and Kesselheim A. Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" Commonwealth Fund. September 2017.

⁵⁶ PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018.

- Value-based arrangements can help reduce uncertainty about treatment value, but generally will not, on their own, determine which treatments are of greatest clinical value for individual patients or subgroups.

II. PROPOSALS RELATED TO THE 340B PROGRAM

A. The 340B Program Needs to Build on Reimbursement Change and Make Key Reforms to Address Market Distortions

PhRMA and its member companies have long supported the goal of the 340B program, which was created to help make outpatient prescription drugs more accessible to safety net facilities serving low-income uninsured and other vulnerable patients. Since the program's inception in 1992, we have supported efforts to ensure that the 340B program is strong, sustainable, and operating in accordance with the language and purpose of its authorizing statute. PhRMA shares CMS' continued interest in ensuring that Medicare patients benefit from the significant discounts manufacturers provide under the 340B program.⁵⁷ Targeting the program's benefits to vulnerable patients is especially important today, when hospitals (which are not obliged to share 340B discounts with patients) account for about 85% of all 340B sales.⁵⁸

PhRMA has long been concerned that as the 340B program has grown it has increasingly departed from its purpose and statutory boundaries. The size of the 340B program creates market-distorting incentives that affect consumer prices for medicines, shift care to more expensive hospital settings, and accelerates provider market consolidation. A growing body of evidence from nonpartisan, independent sources, including *The New England Journal of Medicine*, *Journal of the American Medical Association (JAMA)*, the GAO, and others, points to data showing that the 340B program is driving up costs for everyone. Last year the Administration took an important first step to try to address some of these market distortions. Citing analysis from the GAO⁵⁹ and MedPAC⁶⁰ regarding the discrepancy between hospitals' discounted acquisition costs and their full reimbursements for 340B medicines, CMS' 2018 HOPPS final rule took important, initial steps to address the 340B program's misaligned incentives by reducing the reimbursement for Medicare Part B drugs for a subset of 340B hospitals. While more still needs to be done to address the program's perverse incentives to prescribe more medicines and more expensive medicines, PhRMA and its member companies support CMS' decision to maintain the reimbursement policy and urge HHS to take other reforms to address other areas of the program that lead to growth and distort the market that are discussed below.

⁵⁷ 82 Fed. Reg. at 33633.

⁵⁸ Importantly, 340B grantees already have grant-related obligations to establish sliding fee scales and to use income from 340B drugs for grant-related objectives (generally, providing healthcare services generally or specific services to low-income people with low income or special needs). But hospitals, which currently do not have comparable obligations, account for about 85% of total 340B sales. Adam J. Fein, Exclusive: The 340B Program Hits \$16.2 Billion in 2016, Now 5% of U.S. Drug Market, Drug Channels (May 2017).

⁵⁹ GAO. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015.

⁶⁰ MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.

While the reimbursement policy change for 2018 is an important first step, it is critical that the Administration take this policy as a springboard from which key stakeholders—including CMS, HRSA, State Medicaid agencies and managed care plans, covered entities, and manufacturers—may continue a critically important dialogue on how to modernize the 340B program. The key changes needed to ensure the 340B program is sustainable and that would help address the distortions to the pharmaceutical marketplace the program creates are listed below:

1. Program Growth – 340B program growth must be checked to contain the unintended consequences and distortions the program is now causing for patients, payers, and non-340B healthcare providers (including community physician practices that have difficulty competing with 340B hospitals outpatient facilities and maintaining their independence) and to keep the 340B program sustainable.
2. Patient Definition – HHS should issue final guidance that provides a stronger “patient” definition that is consistent with the statute and that eliminates current loopholes such as allowing providers with no legitimate relationship to the 340B patient to have access to 340B discounts.
3. Hospital Child Sites - HHS should revisit its 1994 guidance given the rampant growth in the number of child sites, the lack of any requirements that these clinics serve a safety-net role, and the evidence that they are leading to higher costs for many patients. Reforms are needed to align HRSA’s guidance with the 340B law’s text and its goal of improving eligible patients’ access to medications, including tightening the eligibility criteria to assess when these outpatient facilities are considered part of a covered entity hospital for 340B program purposes. We note that CMS has stated repeatedly that “in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 C.F.R. 413.65,”⁶¹ yet HRSA’s standards for hospital “child site” status do not require adherence to Medicare’s provider-based criteria even though HRSA has stated that the 340B law incorporates Medicare’s definition of a hospital and therefore the 340B program should follow Medicare rules in determining whether an outpatient facility is part of a hospital.⁶²
4. Contract Pharmacies - HHS should use its authority and revisit its current unlimited contract pharmacy policy, which has caused rampant program growth, particularly as it applies to how contract pharmacies are used by DSH hospitals.
5. Hospital Eligibility – HHS should better enforce private hospital eligibility for the 340B program to hold private hospitals more accountable to 340B statutory requirements to participate in the program.

⁶¹ See, e.g., 83 Fed. Reg. at 37138, 37141.

⁶² 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994)(current 340B guidance on when hospital outpatient facilities may be considered part of a 340B hospital and therefore may participate in the 340B program).

6. Duplicate Discount Prevention - CMS and HRSA policies must be recalibrated to better prevent violations of the statutory prohibition on 340B/Medicaid duplicate discounts, as recently highlighted by the Government Accountability Office.⁶³
7. Patient Benefit - the program must be structured to ensure that the benefits of its deeply discounted pricing are traceable and flow to patients.

B. CMS Should Finalize Its Proposal to Expand the 340B Payment Adjustment to Non-Excepted Hospital Outpatient Departments

Under section 603 of the Bipartisan Budget Act of 2015 (BBA), certain hospital outpatient departments (what CMS calls “non-excepted” departments) may not bill under OPSS starting in 2017. Hospital outpatient departments (HOPDs) generally are “non-excepted” if they: (1) are “off-campus” (as defined in BBA § 603); (2) were not billing under OPSS when the BBA was enacted in November 2015; and (3) are not emergency departments.⁶⁴ In its first rulemaking on BBA § 603 CMS decided that the non-excepted HOPDs that cannot bill under OPSS would instead bill most items and services under a newly-created, site-specific variant of the Medicare Physician Fee Schedule (MPFS); currently, under this variant of the MPFS, non-excepted HOPDs are generally paid 40% of OPSS rates. However, CMS decided that separately paid drugs provided in non-excepted HOPDs would be paid 106% of ASP in 2017 (because their payment rate generally does not vary between the HOPD and physician office settings) and continued paying 106% of ASP for Part B drugs furnished in non-excepted HOPDs – including 340B drugs -- for 2018, without extending the ASP minus 22.5% payment rate for 340B drugs furnished in excepted HOPDs to non-excepted HOPDs. This discrepancy in reimbursement policy caused a 28.5% of ASP payment differential between 340B drugs furnished in non-excepted vs. excepted HOPDs.

For CY 2019, CMS is proposing to expand the ASP minus 22.5% payment policy to all provider-based hospital outpatient departments. PhRMA and its members support this proposal to eliminate the payment discrepancy for 340B drugs between excepted and non-excepted HOPDs and apply a uniform ASP-22.5% 340B reimbursement policy to all HOPDs. Treating these two types of facilities differently undercuts the site neutrality goals of BBA § 603. We agree with CMS that the payment discrepancy CMS permitted for 2018 could over time create opportunities for hospital gaming. As we noted last year in our OPSS comment letter, permitting different payment rates for 340B drugs in excepted and non-excepted HOPDs, a 340B hospital with multiple HOPDs in a geographic area (including excepted and non-excepted HOPDs) could reallocate the services performed in the different HOPDs so that (1) a non-excepted HOPD performed all or

⁶³ GAO, Drug Discount Program: Federal Oversight of Compliance of 340B Pharmacies Needs Improvement (June 2018)(“HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement for the majority of Medicaid prescriptions, which occur under managed care”)(emphasis added).

⁶⁴ The 21st Century Cures Act expanded the group of excepted facilities to include: (1) off-campus outpatient facilities of the PPS-exempt cancer hospitals (provided they comply with certain requirements); and (2) certain off-campus HOPDs that were “mid-build” when BBA § 603 was enacted or meet similar requirements.

most of the drug-related services (and received payment for 340B drugs at 106% of ASP); and (2) an excepted HOPD performed all or most of the other, non-drug-related services (and received ordinary OPSS payment rates for those items and services). For example, a 340B hospital could potentially try to centralize drug administration in a non-excepted HOPD that functioned as an infusion center and thus receive 106% of ASP payments on all or most of its 340B drugs.

Equalizing the payment rates for 340B drugs across excepted and non-excepted HOPDs helps ensure that CMS does not create incentives for 340B hospitals to reallocate services between excepted and non-excepted HOPDs so as to shift each type of service to the site paying the most for it -- which would increase Medicare spending, while undermining the site neutrality goals of BBA § 603. Eliminating the payment differential between 340B drugs furnished at excepted and non-excepted HOPDs could help eliminate the incentive for 340B hospitals to continue to purchase independent physician practices and convert them to HOPDs (non-excepted HOPDs, in this case), which Congress sought to prevent in enacting BBA § 603.⁶⁵ Accordingly, we urge CMS to finalize its proposal to apply a uniform payment policy for 340B drugs whether furnished in excepted or non-excepted HOPDs. However, we note that the proposed policy further expands the types of sites where there is a difference in reimbursement formulas for therapies that qualify for pass-through status as compared to therapies that are reimbursed under the ASP-22.5% formula. We recommend that CMS assess whether this difference in reimbursement formulas changes prescribing practices and costs.

C. CMS Should Finalize Its Proposal to Expand Site-Neutral Payment Rates to “New Clinical Families of Services” at Excepted Hospital Outpatient Departments

In its first rulemaking on BBA §603, CMS proposed that excepted HOPDs that develop new service lines could not spread their excepted status to these new services, but did not finalize this proposal. Under the proposed rule, however, CMS would no longer allow excepted HOPDs to spread their excepted status to new “clinical families of services,” chiefly due to concerns that otherwise hospitals “may be able to purchase additional physician practices and add the additional physicians to existing excepted off-campus PDBs [provider-based departments],” and that the existing policy is encouraging shifts in site of service from non-excepted to excepted HOPDs.⁶⁶ or expanded volume (but keep monitoring whether excepted HOPDs start providing new lines of service and/or increase their volume of business significantly).⁶⁷ As indicated in previous PhRMA comments, we share these concerns. Accordingly, we support CMS’ proposed policy change and urge CMS to finalize this proposal.

⁶⁵ See, e.g., 81 Fed. Reg. 79562, 79706 (Nov. 14, 2016) (expressing concern that under a policy allowing excepted HOPDs to expand their excepted status to new service lines, “hospitals may be able to purchase additional physician practices” and be paid OPSS rates, which BBA § 603 was intended to address).

⁶⁶ 63 Fed. Reg. at 37148-49.

⁶⁷ 82 Fed. Reg. at 33558-48.

D. CMS Should Expand its Modifier to Identify 340B Drugs to Medicaid

CMS established a claims modifier that hospital outpatient departments use to report separately payable drugs that were acquired under the 340B program, effective January 1, 2018.⁶⁸ PhRMA again recommends that CMS expand the modifier to the Medicaid program, which urgently needs an effective system to identify claims filled with a 340B drug in order to prevent and detect illegal duplicate discounts (where a manufacturer provides both a Medicaid rebate and a 340B discount on the same drug). Despite the statutory prohibitions on duplicate discounts,⁶⁹ today manufacturers frequently pay duplicate discounts because there is a lack of adequate mechanisms for identifying and preventing them. The most egregious example of this problem is that HRSA announced in 2014 that its only duplicate discount prevention mechanism does not apply to Medicaid managed care claims (which account for over half of Medicaid prescriptions, according to the GAO) and has subsequently failed to establish any other mechanism to prevent duplicate discounts.⁷⁰ Especially in these circumstances, expanding CMS' modifier to Medicaid could greatly improve compliance with the duplicate discount prohibition. Hospitals could be instructed to use the JG modifier on 340B claims (just as it is used under OPSS), and Medicaid fee-for-service programs and managed care plans could automatically exclude all drugs billed with this modifier from the data used in preparing Medicaid rebate invoices. We urge CMS to adopt such a policy, which would be an important and urgently-needed step in improving program integrity.

E. CMS Should Provide Guidance for Hospitals on When an Outpatient Facility Can Properly Be Considered Part of a Hospital, Including Emphasizing its Rule that an Off-Campus Outpatient Department is Not Part of the Hospital Unless It Meets Medicare's Provider-Based Criteria

While the proposed rule has an extensive discussion of CMS' concerns about OPSS spending growth we urge CMS to consider other efforts to curb Medicare spending and ensure hospital outpatient departments are entitled to OPSS payments. Throughout this rule CMS takes note of OPSS growth: citing that "the OPSS has been the fastest growing sector of Medicare payments out of all payment systems under Medicare parts A and B;"⁷¹ that MedPAC has concluded that "[a] large source of growth in spending on services furnished in [HOPDs] appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs;"⁷² that the site neutrality requirements of BBA section 603 "address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, [but] the majority of hospital off-campus outpatient departments continue to receive full

⁶⁸ The modifier is "JG." A separate modifier ("TB") is used to report 340B drugs, for informational purposes, by those HOPDs that are exempt from the 340B payment adjustment (certain rural hospitals, critical access hospitals, and PPS-exempt cancer hospitals).

⁶⁹ 42 U.S.C. § 256b(a)(5)(A); 42 U.S.C. §§ 1396r-8(j)(1), 1903(m)(2)(xiii).

⁷⁰ See, e.g., GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Pharmacies Needs Improvement (June 2018); HHS Office of Inspector General, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (June 6, 2016).

⁷¹ 83 Fed. Reg. at 37139.

⁷² 83 Fed. Reg. at 37140 (quoting MedPAC's March 2018 report to Congress on Medicare Payment Policy).

OPPS payment;⁷³ and that “[w]e have heard that many off-campus departments converted from physician offices to hospital outpatient departments, without a change in either the physical location or a change in the acuity of the patients seen.”⁷⁴

As CMS has previously noted, the 340B program has been a contributing factor in the site of service shift and the conversion of physician offices to “HOPDs.”⁷⁵ Because 340B discounted pricing applies to certain hospitals and (under current HRSA policy) certain outpatient facilities considered “child sites” of 340B hospitals but not to physician offices, the 340B program has long created incentives for 340B hospitals to acquire physicians’ offices and declare them “HOPDs.” As part of its efforts to curb OPPS spending growth, CMS could emphasize its rule on when an off-campus outpatient facility may properly be considered part of a “hospital” – *i.e.*, that “in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 C.F.R. 413.65”⁷⁶ -- and boost enforcement of this requirement, since off-campus outpatient facilities that do not even qualify as part of a hospital may not bill under OPPS.

Medicare’s provider-based requirements, set out at 42 CFR § 413.65, are designed to ensure that a facility is genuinely integrated with a “main provider” such as a hospital before the facility can be treated as part of the hospital (or other main provider) for Medicare purposes. The HHS Office of Inspector General (OIG) has found that many outpatient facilities billing under OPPS do not meet Medicare’s provider-based standards (and while we assume this problem is not limited to outpatient facilities associated with 340B hospitals, it may be more prevalent there for reasons discussed below). In a 2016 report on enforcement of the provider-based regulation, the OIG found that:

... CMS does not determine whether all provider-based facilities meet requirements for receiving higher provider-based payment. Moreover, because the attestation process [a process for verifying that a facility is provider-based, which requires CMS review and concurrence that the facility meets all of the criteria 42 C.F.R. § 413.65] is voluntary, not all hospitals attest for all of their facilities. CMS is taking steps to improve its monitoring of provider-based billing; however, vulnerabilities associated with provider-based billing remain.

Whether or not hospitals voluntarily attest, provider-based facilities must meet specific requirements to receive higher provider-based payment. However, more than three-quarters of the 50 hospitals we reviewed that had not voluntarily attested for all of their off-campus provider-based facilities owned off-campus facilities that did not meet at least one requirement. Examples of requirements not met include demonstrating that an off-campus facility was operating under the control of the main provider and that beneficiaries were notified of potential cost increases for

⁷³ 83 Fed. Reg. at 37141.

⁷⁴ 83 Fed. Reg. at 37142.

⁷⁵ See, GAO, Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform, 12 n. 21 (Dec. 2015) (“In commenting on this report, CMS officials stated that [in addition to Medicare payment rates] the 340B Drug Pricing Program could also provide an incentive for hospitals to acquire physician practices”).

⁷⁶ 83 Fed. Reg. at 37138, 37141.

services at the provider-based facility. **These facilities may be billing Medicare improperly and may be receiving overpayments. Further, beneficiaries may be overpaying for services in these facilities.** ⁷⁷ (emphasis added)

Given these findings, the OIG recommended that CMS take several steps to enforce the provider-based standards and stop hospitals from improperly billing under OPSS for facilities that do not meet these standards, including “establish[ing] a deadline after which it would deny claims for services in provider-based facilities that do not have an attestation on file with CMS.”⁷⁸ CMS did not agree with this recommendation but stated that “after implementing [the BBA section 603 site-neutrality requirements], CMS will consider whether additional activities are needed to ensure that only those facilities that qualify as provider-based departments are being paid at the OPSS rate.”⁷⁹ CMS has now had several years’ experience implementing the BBA 603 requirements and concluded that they “address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, [but] the majority of hospital off-campus outpatient departments continue to receive full OPSS payment.”⁸⁰ If CMS is committed to restraining OPSS spending growth, as the proposed rule suggests, the time has come to ensure that only those facilities that qualify as provider-based departments are being paid at the OPSS rate; we urge CMS to do so.

Stopping outpatient facilities that do not qualify as provider-based from billing under OPSS is important -- and will advance CMS’ goals of saving Medicare money and reining in OPSS spending, as the OIG’s findings illustrate -- irrespective of whether the hospital in question is a 340B hospital. However, it may be that the problem of hospitals treating outpatient facilities that do not meet the provider-based criteria as nonetheless being part of the hospital and entitled to bill Medicare under OPSS could be more acute among 340B facilities. This is because HRSA “child site” guidance does not require that an outpatient facility meet the provider-based criteria to be considered part of a 340B hospital and thus allowed to participate in the 340B program as a “child site.” HRSA’s current child site guidance was released in 1994 (before Medicare’s provider-based regulation was issued) and requires that the outpatient facility be included as reimbursable on the Medicare cost report (discussed in more detail below).⁸¹ HRSA proposed but never finalized a 2007 proposal to require that hospital child sites meet the provider-based criteria. In its 2015 “megaguidance” HRSA stated the following:

⁷⁷ HHS OIG, CMS Is Taking Steps to Improve Oversight of Provider-based Facilities, but Vulnerabilities Remain (June 2016)(emphasis added). The OIG found that 61% of hospitals that owned facilities they reported to be provider-based had not attested to their status as provider-based (a process that requires CMS review and concurrence that the facility meets all of the provider-based criteria in 42 CFR § 413.65). *Id.* at 10. The exact percentage of non-attesting facilities that had at least facility they treated as provider-based that did not meet the provider-based criteria was 78% (39 out of 50). *Id.* at 13. Therefore, OIG’s findings indicate that roughly half (61 percent times 78 percent, or 47.58 percent) of hospitals with “provider-based” off-campus facilities had at least one such facility that did not actually meet the provider-based criteria.

⁷⁸ HHS OIG, CMS Is Taking Steps to Improve Oversight of Provider-Based Facilities, but Vulnerabilities Remain, at 17.

⁷⁹ HHS OIG, CMS Is Taking Steps to Improve Oversight of Provider-Based Facilities, but Vulnerabilities Remain, at 35 (CMS comments on OIG report).

⁸⁰ 83 Fed. Reg. at 37141.

⁸¹ 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994)(current 340B guidance on when hospital outpatient facilities may be considered part of a 340B hospital and therefore may participate in the 340B program).

HHS is actively seeking comments on alternatives [to the cost report test] In considering alternatives, HHS has explored use of provider-based standards (42 CFR 413.65); however, many hospitals choose not to seek provider-based designation for their departments or facilities for unrelated reasons even though these facilities may qualify for the designation. Comments on previously proposed guidance at 72 FR 1543 (January 12, 2007), highlighted the difficulty in verifying whether outpatient facilities and clinics meet provider-based standards.⁸²

Particularly given that HRSA has previously indicated that its “child site” guidance follows Medicare principles since the 340B law’s “hospital” definition comes from the Medicare statute,⁸³ it is important for CMS to emphasize that an off-campus facility that does not comply fully with the provider-based criteria in 42 C.F.R. § 413.65 may not be treated as part of the hospital, and thus may not bill under OPPS. Whether or not the hospital seeks CMS concurrence in this conclusion through the attestation process in the provider-based regulation, the hospital still must verify that an outpatient facility meets the provider-based criteria or it may not bill Medicare under OPPS—“difficulties in verifying whether outpatient facilities and clinics meet provider-based standards” will not excuse noncompliance with those standards or giving up on determining whether the facility is compliant. This message is important both for 340B and non-340B hospitals (and it may be useful to HRSA as well, to clarify that without incorporating Medicare’s provider-based criteria, HRSA’s child site guidance is not aligned with Medicare).

Similarly, we encourage CMS to address the idea that an outpatient facility could properly be included as reimbursable on a hospital’s Medicare cost report—HRSA’s current 340B hospital “child site” test – and yet not meet Medicare’s provider-based criteria. Before the Medicare provider-based regulation was revised to make the attestation process voluntary, it stated that “[a] main provider or a facility or organization must contact CMS and the facility or organization must be determined by CMS to be provider-based before the main provider bills for services of the facility or organization as if the facility or organization were provider-based or before it includes costs of those services on its cost report.”⁸⁴ There is no indication in CMS’ regulatory history that in revising the regulation to make the attestation process voluntary, CMS meant to change the principle that only costs of provider-based facilities may be included in a hospital’s cost report. Therefore, to promote proper Medicare cost reporting and help 340B stakeholders understand the implications of the “cost report test,” CMS should clarify what the precise requirements are for a facility to be included on a reimbursable line of a hospital’s Medicare cost report – and specifically address whether an outpatient facility must meet the provider-based criteria. We urge CMS to issue explicit guidance on this point, which we believe would make clear that even under the current “cost report test,” an outpatient

⁸² 80 Fed. Reg. 52300, 52302 (Aug. 28, 2015)(proposed 340B megaguidance)(emphasis added).

⁸³ 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994)(“Congress referred to section 1886 of the Social Security Act (Medicare inpatient hospital payment) for the definition of a DSH; therefore it is reasonable to utilize existing Medicare rules to determine eligibility for PHS discount pricing. The proposed cost report test was developed by Medicare officials and used, in part, to determine whether a facility is a component of a hospital”).

⁸⁴ 42 CFR § 413.65(b)(2)(2001, westlaw historical CFR database).

facility of a hospital must comply with Medicare's provider-based criteria. Reduced OPPS spending would be a key byproduct of such guidance.

III. REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY AND ELECTRONIC HEALTHCARE INFORMATION EXCHANGE THROUGH POSSIBLE REVISIONS TO THE CMS PATIENT HEALTH AND SAFETY REQUIREMENTS FOR HOSPITALS AND OTHER MEDICARE- AND MEDICAID-PARTICIPATING PROVIDERS AND SUPPLIERS

CMS is considering revising current Conditions of Participation (CoPs) for hospitals to include requirements such as: the transfer of medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

PhRMA commends CMS on its efforts to prioritize patient-centered care and reduce the burden on health care providers through initiatives such as Patients over Paperwork and Meaningful Measures, so providers can focus their attention, time and resources on improving health outcomes patients. We believe a key component of that effort must include promoting interoperable systems and health data exchange beyond the four walls of a health system and into the community to promote more coordinated, efficient care and reduce provider burden. PhRMA supports adding to hospital conditions of participation a requirement for hospitals to share clinical information, including notice of patient discharge, with community physicians.

Many community providers, overwhelmed by reporting requirements and the financial resources required to constantly upgrade their health technology operating systems, have succumbed to consolidation or acquisition by larger health systems. This consolidation, among other factors, leads to decreased competition and access for patients, and only serves to drive up health care costs. Research confirms that a one percentage point increase in the proportion of medical providers affiliated with hospitals and/or health systems was associated with a 34% increase in average annual costs per person and a 23% increase in average per person price of treatment.⁸⁵ Yet, from 2004 to 2011, hospital ownership of physician practices doubled from 24% to 49%.⁸⁶ As a result, insurers pay higher prices for equivalent services that previously were delivered in less-expensive independent physician offices. Physician-administered chemotherapy medicines are an example of how the shift from the community to hospitals contributes to higher spending. From 2004 to 2014, chemotherapy infusions in hospital outpatient departments increased dramatically - from 6% to 46% for commercial patients and from 16% to 46% for Medicare patients. Drug spending was more than twice as high in the hospital setting.⁸⁷ Had this consolidation not occurred, spending would

⁸⁵ Conti RM, Landrum MB, Jacobson M. The impact of provider consolidation on outpatient prescription drug-based cancer care spending. Health Care Cost Institute & National Academy for State Health Policy (2016).

⁸⁶ Cutler DM, Morton FS. Hospitals, market share, and consolidation. JAMA. 2013 Nov 13;310(18):1964-70.

⁸⁷ Winn AN, Keating NL, Trogon JG, Basch EM, Dusetzina SB. Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA Oncology. 2018 Apr 1;4(4):580-1.

have been 7.5% and 5.8% lower for Medicare and commercial infused chemotherapy patients, respectively.⁸⁸

IV. REQUEST FOR INFORMATION ON PRICE TRANSPARENCY: IMPROVING BENEFICIARY ACCESS TO PROVIDER AND SUPPLIER CHARGE INFORMATION

When structured to support patient and consumer decision making, providing useful information about the costs and benefits of health care is critical to improving the functioning of the United States health care system. Combined with the power of the competitive marketplace, the right information will drive more efficient and higher quality care. Patients need accurate and easily understood data that supports well-informed decisions and allows them to pursue their goals for their health and health care. At the same time, transparency proposals that would disclose sensitive or proprietary information could undermine the competitive market, which ultimately would be detrimental to patients and consumers.

For these reasons, we appreciate CMS's objective of "encouraging all providers and suppliers of healthcare care services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services,"⁸⁹ and request for comment on this topic. We commend CMS for steps taken in the FY 2019 Hospital Inpatient Prospective Payment System (IPPS) final rule that require hospitals to make their current list of standard charges available annually via the Internet, in machine readable format.⁹⁰ We offer the following recommendations with the goal of helping patients – both Medicare and others – access useful and easy to understand information about the expected costs of medicines administered in the hospital setting.

A. Patient Out-Of-Pocket Costs

CMS asks whether health care providers and suppliers should "play any role in helping to inform patients of what their out-of-pocket obligations will be."⁹¹ Providers *absolutely* have a role in helping inform patients about their expected out-of-pocket costs for medicines. Such information, as well as other information about the benefits and risks of potential treatment, is critical to allowing patients to make well informed choices among treatment options, consistent with their personal priorities for their care.

To help with patient decisions, CMS should require hospitals to give patients information about expected total costs for a medicine, as well as information that could help to estimate the patient's expected out-of-pocket costs, prior to any non-emergent encounter. At a minimum, hospitals should provide an estimate of out-of-pocket cost information for Medicare patients without supplemental insurance and for patients with

⁸⁸ Pelizzari PM, Bruce Pyenson FS. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman (2016).

⁸⁹ Federal Register Vol 83, No 147, pg. 37211.

⁹⁰ Federal Register Vol 83, No 160, pg. 41686.

⁹¹ Federal Register Vol 83, No 147, pg. 37212.

standard Medigap plans. Ideally, hospitals would go farther to support patients with other forms of insurance by making a good faith estimate of the patient's expected costs for any planned encounter.

To help patients understand both their estimated out-of-pocket costs, and to interpret whether their bill is accurate, hospitals should provide both cost estimates and bills in plain English, at or below a 5th grade reading level. This reading level would be consistent with the Joint Commission recommendation for readability of patient education materials.⁹² Patients should not need a master's degree in coding or health care administration to understand the costs associated with a hospital encounter.

One approach worth consideration as CMS develops policies for hospitals is the development of real-time benefit check in electronic prescribing systems.⁹³ Through these systems, prescribers are able to get drug formulary information at the point of prescribing, based on a patient's individual insurance benefit and where they are in their benefit. The challenges associated with providing retail drug benefit information to physicians at the point of prescribing are substantial, yet health care stakeholders have worked together to develop a tool that can achieve this goal. It should be comparatively straightforward for hospitals to determine and share with patients their out-of-pocket costs for medicines administered in the hospital setting. A similar approach, in which providers share estimated out-of-pocket cost information for patients with planned hospital encounters would help patients plan for their costs, and compare costs between providers, supporting patient-centered treatment decisions and empowering patient-physician decision-making.

B. Standard Charges and Hospital Payments for Medicines

PhRMA supports CMS's work to make hospital charge information more easily available to patients. While CMS does not pay hospitals a percentage of charges, it is the most common payment methodology in the commercial market for single source, brand specialty medicines, where more than half (51%) of payers pay a percent of charges.⁹⁴ Charges information is also important for uninsured patients who must pay full hospital charges, unless they are able to negotiate an alternative payment arrangement. Payers that do not have provider networks, such as worker compensation and automobile insurance, generally pay based on charges, so high hospital charges can also raise premiums for these payers.⁹⁵ Hospital mark-ups can be incredibly high in some cases. A recent analysis by the Moran Company found that hospital charge five times their acquisition cost for medicines, on average, and nearly one in five hospitals marks up medicine prices 700 percent or more, so that a \$150 medicine purchased by a hospital would cost a patient \$1,050.

⁹² LM Stossel, N Segar, P Gliatto, et al. "Readability of Patient Education Materials Available at the Point of Care. *J Gen Intern Med.* 2012 Sep; 27(9): 1165–1170.

⁹³ See, e.g. https://surescripts.com/docs/default-source/products-and-services/real_time_benefit_check_overview_december_2013_surescripts.pdf

⁹⁴ *Managed Care Strategies for Specialty Pharmaceuticals, The EMD Serono Specialty Digest 14th Edition (2018).*

⁹⁵ Bai G, Anderson GF. US hospitals are still using chargemaster markups to maximize revenues. *Health Affairs.* 2016 Sep 1;35(9):1658-64.

One out of every twelve hospitals (8%) has average charge markups greater than 1000% - meaning they are charging at least 10 times their acquisition cost for medicines, on average.⁹⁶

PhRMA also supports CMS's work to share Medicare payment information for hospitals. Because Medicare payments to hospitals are set by the government, they are not commercially confidential and are appropriate to make available to patients and the public. Payment information can help Medicare patients without Medigap or other supplemental insurance who, after a deductible, are required to pay 20 percent cost sharing for any outpatient hospital care, calculate their out-of-pocket cost. Providing information about Medicare payments would also help uninsured patients who are faced with hospital charges by giving them an important point of reference as they seeking to negotiate a lower payment from the hospital.

Currently, CMS shares a wealth of information on hospital cost and quality via the Hospital Compare tool⁹⁷ CMS also makes payment and hospital-specific charges, at the DRG-level, available in a public use file.⁹⁸ Payment amounts for medicines covered under Medicare Part B are publicly available in Average Sales Price (ASP) Drug Pricing Files.⁹⁹ In addition, the average community pharmacy purchase prices of all Medicaid-covered outpatient medicines is publicly available in National Average Drug Acquisition Cost (NADAC) files.¹⁰⁰ Building on this information by providing charge and average Medicare payment at the hospital-level alongside ASP and NADAC for medicines administered in the hospital outpatient department, would help patients compare the cost of receiving medicines from different providers. Data show that hospital outpatient departments are often paid twice as much by commercial payors as physician offices for administering the same medicines to patients with cancer or autoimmune disorders, so comparison shopping could lead to substantial cost savings.¹⁰¹

In addition to adding data to Hospital Compare, CMS could update the Hospital Compare tool to make it more accessible to patients (e.g., by reducing the number of "not available" results) and encourage hospitals to link to their hospital's Hospital Compare data from hospital websites. This could help patient make more informed decisions regarding their choice of provider while minimizing administrative burden. For pharmaceuticals, tools like GoodRx allow patients to compare the cash price of their medicines at different pharmacies.¹⁰² Supporting development of similar tools for patients paying cash, Medicare patients with no supplemental coverage, Medicare patients with standard Medigap plans, or patients paying a percentage of charges would help support decision making.

⁹⁶ The Moran Company. Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to-Charge Ratios. September 2018. Available at: www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf.

⁹⁷ <https://www.medicare.gov/hospitalcompare/>; Data included in the Hospital Compare tool includes measures of: patient experience, timeliness and effectiveness of care, complication and death rates, readmissions, use of medical imagine, and procedure rates relative to national averages.

⁹⁸ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient.html>

⁹⁹ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>

¹⁰⁰ <https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html>

¹⁰¹ Medical Pharmacy Trend Report: 2016 Seventh Edition. Magellan RX Management. 2017.

¹⁰² <https://www.goodrx.com/>

We applaud CMS for providing charge and reimbursement information in a standard format, with an OpenAPI, which makes it easier for third party application developers and others to more easily combine charge information from a range of sources into a single dataset. We note that the *Developers' Center* organized by HHS that provides freely available data in a format that developers can utilize in the creation of innovative products and services.¹⁰³ If CMS does add additional data about medicine charges, payments and costs to hospital compare, it should provide an OpenAPI for the data.

C. Out-of-network bills

According to a 2015 Consumers Union poll, nearly one-third of privately insured Americans have received a surprise medical bill.¹⁰⁴ Most often, this occurs when a patient chooses to have a medical procedure performed at a facility that is in-network with the patient's health carrier, but certain providers at the facility are not in-network. In many cases, a patient will have performed due diligence to find an in-network facility, and not be told by the facility that there is a possibility that its providers do not participate in the same networks (e.g. anesthesiologists or pathologists).¹⁰⁵ In some instances, a patient may have even taken steps to confirm that the physician she has chosen to perform a service is in-network, but consulting physicians whom are not known to the patient are present during the procedure and bill the patient. These scenarios can result in the patient receiving a much larger, out-of-network bill from one or more providers than the patient expects, because the patient rightfully assumed that by choosing an in-network facility all charges would be based on in-network rates.

Visits to the emergency room leave insured patients particularly vulnerable to out-of-network bills. Nearly one in four privately-insured patients (22%) treated at in-network hospital emergency departments were treated by out-of-network emergency department physicians.¹⁰⁶ This out of network care translates directly into unexpected bills; 20 percent of hospital inpatient admissions that originated in the emergency department and 14 percent of outpatient visits to the emergency department likely led to a surprise medical bill.¹⁰⁷

To address concerns with out-of-network bills, PhRMA supports requiring facilities to provide patients with disclosures of provider network status prior to the provision of medical services. For planned encounters, CMS should consider requiring that hospitals share information about providers at their facility who are not

¹⁰³ <https://www.hhs.gov/developer.html>

¹⁰⁴ Consumer Reports National Research Center. "Consumer Reports survey finds nearly one third of privately insured Americans hit with surprise medical bills." Available at: <http://consumersunion.org/research/surprise-bills-survey/>

¹⁰⁵ Bai G, Anderson GF. Variation in the ratio of physician charges to Medicare payments by specialty and region. *JAMA*. 2017 Jan 17;317(3):315-8.; <https://www.compassphs.com/blog/pathologists-what-consumers-need-to-know/>

¹⁰⁶ Cooper Z, Morton FS. Out-of-network emergency-physician bills—an unwelcome surprise. *N Engl J Med*. 2016 Nov 17;375(20):1915-8.

¹⁰⁷ Garmon C, Chartock B. One in five inpatient emergency department cases may lead to surprise bills. *Health Affairs*. 2016 Dec 14;36(1):177-81.

in the patient's network, and the share of similar encounters that were with out-of-network physicians. Providing easier access to this type of information can help patients prevent surprise out-of-network bills.

V. PROPOSAL TO REDUCE THE OPPTS PAYMENT RATE FOR CLINIC VISITS

CMS is concerned that higher Medicare payment in the hospital outpatient department (HOPD) setting is a significant factor in the shift of services from physician offices to HOPDs.¹⁰⁸ To curb the incentive for unnecessary HOPD services, CMS proposes to use its authority under Social Security Act (SSA) § 1833(t)(2)(F) to pay for clinic visits at off-campus HOPDs that are excepted from the site neutrality cuts¹⁰⁹ at the lower PFS-equivalent rate that applies to non-excepted HOPDs. SSA § 1833(t)(2)(F) provides that CMS “shall develop a method for controlling unnecessary increases in the volume of covered OPD services.”¹¹⁰

CMS seeks comments on this proposal, and on other methods that may be authorized under § 1833(t)(2)(F) to control unnecessary increases in OPPTS volume. Among other things, CMS asks whether § 1833(t)(2)(F) permits prior authorization.¹¹¹ Recognizing “the importance of not impeding development [of] or beneficiary access to new innovations,” CMS seeks input on “how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.”¹¹² PhRMA understands CMS’ concern about unnecessary HOPD utilization and we strongly support site neutrality. At the same time, we hope CMS will proceed cautiously in developing a volume control method under SSA § 1833(t)(2)(F). CMS¹¹³ last addressed this issue 18 years ago, at which time it stated that “[g]iven the complexities of developing an appropriate volume control mechanism for hospital outpatient services, we believe[] further study is necessary.”¹¹⁴ CMS decided not to finalize a volume control method it had proposed for 2000 (which would have reduced the conversion factor update if OPPTS volume targets were exceeded in the previous year) and explained that additional analysis of this issue was underway:

This delay . . . gives us additional time to study appropriate methods of controlling outpatient volume over the long term. We are currently working with a contractor to study options for volume control measures for outpatient services. In the future, before we make any final decision, we will publish a notice in which we will discuss our proposal and will provide a public comment period.¹¹⁵

¹⁰⁸ 83 Fed. Reg. 37046, 37142 (July 31, 2018).

¹⁰⁹ See section 603 of the Bipartisan Budget Act of 2015.

¹¹⁰ A related provision in SSA § 1833(t)(9)(C) provides that “if the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under [OPPTS] increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.”

¹¹¹ 83 Fed. Reg. at 37143.

¹¹² 83 Fed. Reg. at 37143.

¹¹³ Although the agency was HCFA at the time, for simplicity we will refer to CMS and HCFA consistently as CMS.

¹¹⁴ 65 Fed. Reg. 18434, 18502 (April 27, 2000).

¹¹⁵ 65 Fed. Reg. at 18503 (emphasis added).

The proposed rule does not mention this previous work to evaluate appropriate volume control methods or the complexities CMS identified in previous analyses of this issue. Therefore, it is unclear what volume control methods CMS has previously studied, what the contractor studies of volume control methods CMS mentioned in 2000 had concluded, and what further studies might be needed to develop a method for controlling unnecessary HOPD volume without reducing access to innovation. In the period leading up to and following enactment of § 1833(t)(2)(F),¹¹⁶ CMS evaluated potential methods to control volume under a hospital outpatient PPS and described them in its 1995 report to Congress and in preambles to IPPS rules. To provide informed comments on volume control options, it is important for stakeholders to understand relevant background information, including findings from past studies of potential volume control options and research questions CMS has identified that remain outstanding. Therefore, we recommend that CMS provide this information to stakeholders and then solicit stakeholder input on potential volume control methods in its next OPSS rulemaking cycle.

We also have particular concerns about using prior authorization to control the volume of unnecessary increases in HOPD services. There is nothing in the history of the OPSS statute to suggest that CMS had identified prior authorization as a potential volume control measure when that law was enacted (and nothing in the legislative history about any specific volume control methods). Importantly, CMS' March 1995 report to Congress had specifically discussed particular volume control methods, but never mentioned prior authorization as a possibility. Instead, the report focused on the applying volume performance standards on physicians' services or directly on OPD payments.¹¹⁷ In June 1995, CMS again addressed possible volume control methods under a hospital outpatient PPS without mentioning prior authorization, explaining it would investigate various methods of volume control including "bundling, ancillary packaging, multiple-procedure discounting, and expenditure targets (volume performance standards)."¹¹⁸ Given this history, it is highly unlikely that Congress enacted SSA §1833(t)(2)(F) expecting it might potentially lead to prior authorization.

In addition, a prior authorization system would create a number of operational complexities, patient care concerns, and extra burdens for providers, CMS, and Medicare Administrative Contractors (MACs). CMS would have to design and implement a prior authorization process that would take place before a beneficiary could receive OPSS services (including establishing whether hospitals or physicians would be responsible for obtaining prior authorization), and MACs would have to make the decisions about whether to grant prior authorization for beneficiaries' requested OPSS services. This would create a substantial increase in MAC workloads (depending partly on which OPSS services were subject to prior authorization) that would drive up Medicare's administrative costs and divert MACs from other responsibilities. Most

¹¹⁶ The history of the OPSS statute (in brief) is that 1990 legislation directed CMS to submit a proposal for a hospital outpatient PPS to Congress, which CMS submitted on March 17, 1995. Shalala, D. E. (1995), March 17) Report to Congress: Medicare Hospital Outpatient Prospective Payment. Wash., D.C., Department of Health and Human Services. The BBA of 1997 (which contained SSA § 1833(t)) then directed CMS to establish a hospital outpatient PPS with certain features (including the volume control method referenced in § 1833(t)(2)(F)).

¹¹⁷ Shalala, D.E. (1995), March 17) Report to Congress: Medicare Hospital Outpatient Prospective Payment at 22-23.

¹¹⁸ 60 Fed Reg. 20202, 29247 (June 2, 1995).

importantly, beneficiaries' access to OPPTS services would be delayed and treatment regimens sometimes disrupted, potentially with adverse health consequences; and a hospital outpatient prior authorization process would increase the administrative burden on physicians and hospitals, thereby increasing an already substantial administrative burden on healthcare providers.¹¹⁹ Such an approach would undercut the "Patients Over Paperwork" initiative — which CMS launched last year to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience¹²⁰ — and President Trump's Executive Order 13771 on Regulatory Reform.

Further, the MACs that would be making decisions on prior authorization requests would have to make these decisions in compliance with Medicare's existing coverage policies.¹²¹ Medicare currently does not have coverage policies that limit coverage to cases where an item or service is furnished in a lower-cost setting than an HOPD (such as a physician's office) when appropriate.¹²² Yet the proposed rule suggests that CMS' goal is shifting services that can safely be performed in physician offices to that setting instead of OPPTS (or reducing OPPTS payments to PFS-equivalent levels)—but not denying beneficiaries coverage for the services in question altogether. A prior authorization system aimed at steering services to appropriate lower-cost settings would require MACs to develop a whole new set of LCDs differentiating between services furnished under OPPTS and in physician offices (or in HOPDs that are paid PFS-equivalent rates under BBA 603, or in ambulatory surgical centers). This would entail a major effort to develop new Medicare coverage policies based on site of service: an undertaking that Congress would have addressed specifically had it meant to authorize this. But SSA § 1833(t)(2)(F)—requiring a "method for controlling unnecessary increases in the volume of covered OPD services"—plainly does not authorize a major shift in Medicare coverage policies coupled with the development and implementation of a hospital outpatient prior authorization system that could delay and disrupt patient care and increase providers' paperwork burdens.

VI. PAYMENT FOR NON-OPIOID PAIN MANAGEMENT THERAPY

Over the past several years, PhRMA has consistently expressed concerns about CMS sharply increasing outpatient packaging, as packaging payments for drugs and related procedures can create an incentive to

¹¹⁹ For example, in an AMA physician survey released in March 2018, 84% of responding physicians reported that prior authorization imposed a "high or extremely high" burden on their practice; 86% reported that prior authorization burdens have increased over the past five years, and 14.6 hours per physician per week was the average reported time spent by physicians and staff to process the physician's prior authorization workload. Regarding patient impact, 75% of physicians reported that PA sometimes, often, or always leads to treatment abandonment and 61% reported that prior authorization can negatively affect patient outcomes. 2017 AMA Prior Authorization Physician Survey, <https://www.ama-assn.org/sites/default/files/media-browser/.../prior-auth-2017.pdf>.

¹²⁰ CMS, Patients Over Paperwork, [http://www.cms.gov.Outreach and Education> Partner Resources](http://www.cms.gov.Outreach%20and%20Education%20Partner%20Resources).

¹²¹ As CMS has stated previously, prior authorization does not change Medicare coverage rules: "Prior authorization helps make sure that all relevant coverage, coding, and clinical documentation requirements are met before the item is furnished to the beneficiary and before the claim is submitted for payment. Prior authorization requires the same information necessary to support Medicare payment today, just earlier in the process." December 19, 2016 Fact Sheet, CMS Announces First Two Items of Durable Medical Equipment Subject to Prior Authorization Under the National Program.

¹²² Instead, current coverage guidance states that "MACs should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting." Medicare Benefit Policy Manual, chap. 15 section 50.2.K.

skimp on drugs that are clinically important and could thus restrict beneficiaries' access to care in the hospital outpatient and ambulatory surgical center (ASC) settings. The risks of compromising the quality of patient care are heightened where the packaged payment level does not adequately reflect the cost of the drug and the other components of care, where there is patient heterogeneity that is not distinguishable from claims data, and where a drug that is not always part of the procedure in question is packaged and the Medicare payment is the same whether the drug is used or not.

In response to last year's proposed rule (which included a broad request for comments specifically about its packaging policy), PhRMA recommended that CMS avoid any expansion in drug packaging and evaluate its current packaging policies in a rigorous, analytically sound way. We asked that CMS assess and revisit:

- Packaging of certain drugs with costs above the packaging threshold (*i.e.*, diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, and drugs that function as "supplies" in surgical or diagnostic procedures).
- Packaging of certain drugs that are not always part of the procedure in question and making the same payment whether the drug is used or not.

We encouraged particular attention to the following:

1. Whether particular packaging policies are changing the care patients receive (compared to the care they otherwise would have received or to guideline-recommended care);
2. If so, whether the packaging-driven changes in care patterns are adversely affecting patient health outcomes and other relevant quality metrics;
3. Whether other mechanisms (*e.g.*, use of quality metrics or other incentives to follow clinical guidelines) would be better suited to advancing CMS' stated goal of encouraging use of "the most cost-efficient item that meets the patient's needs;" and
4. Whether packaging is needed in light of new episode-based care models that seek to reward provision of high quality efficient care.

Additionally, a 2017 report by the President's Commission on Combatting Drug Addiction and the Opioid Crisis stated that "the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for post-surgical pain instead of administering non-opioid medications"¹²³ As a result of these concerns, CMS recently evaluated the impact of its policy on packaging drugs that function as "supplies" in surgical procedures on utilization of these drugs in the hospital outpatient and ASC settings. CMS found that the number of units used of Exparel (a non-opioid drug for post-surgical analgesia, which was the only non-opioid pain management drug CMS

¹²³ President's Commission on Combatting Drug Addiction and the Opioid Crisis, Report (2017).

identified that is packaged as a “surgical supply”) had decreased by 70% in 2015-2017 (after its pass-through status expired at the end of 2014) in the ASC setting. In contrast, Exparel utilization had increased by 238% in ASCs in 2013 and 2014.¹²⁴ In hospital outpatient departments, CMS found that Exparel use had increased by 229% between 2013 and 2017, as opposed to 18% in the 2015 to 2017 period following expiration of pass-through status.¹²⁵ Based on the post-pass-through drop in Exparel utilization in ASCs, CMS now proposes to pay separately for non-opioid pain management drugs used in surgery in this setting, stating that such a change will “incentive the use of non-opioid pain management drugs and is responsive to the Commission’s recommendation to examine payment policies for non-opioid pain management drugs.”¹²⁶

PhRMA supports this proposal, and we support CMS analyzing utilization data to examine whether its packaging policies are restricting patient access. We encourage CMS to evaluate its packaging policies more broadly to help ensure patient access to appropriate therapies,¹²⁷ and we hope CMS will give serious consideration to the recommendations noted above that PhRMA made in last year’s comment letter. As we emphasized last year, to gain a good understanding of how packaging may be affecting patient care in hospital outpatient departments and ASCs, CMS should evaluate how packaging affects the utilization of a medicine compared to what utilization would have been without packaging and compared to guideline-recommended care; therefore we encourage CMS to go beyond examining whether a drug’s utilization has increased or decreased following expiration of pass-through status, as it is possible that packaging is suppressing the use of a drug even if its use has increased since its pass-through status expired. We additionally applaud CMS’ efforts to eliminate barriers for patients in accessing non-opioid pain management options used in this setting. Addressing the range of hurdles that patients face in accessing appropriate treatment options are a critical component of a comprehensive approach to combatting the opioid crisis. We encourage CMS to consider other areas and settings where patients may face challenges in accessing non-opioid treatment options as well as other non-pharmacological interventions for the treatment of pain. In the years ahead, the tools available to treat acute and chronic pain will continue to expand and continued efforts to ensure patients can access these tools will be critical to having a meaningful impact on this public health crisis.

¹²⁴ 83 Reg. Reg. 37046, 37069 (July 31, 2018).

¹²⁵ 83 Fed. Reg. at 37069.

¹²⁶ 83 Fed. Reg. at 37070.

¹²⁷ We note that in its recent analysis CMS “did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the [packaged surgical] drugs included in our analysis.” 83 Fed. Reg. at 37068 (emphasis added). However, the proposed rule does not discuss CMS’ findings for any of the remaining drugs (other than Exparel), which apparently had significant post-pass-through declines in utilization in the OPPS. We encourage CMS to share these findings with stakeholders and to analyze them to see if the “surgical supply” packaging policy is inappropriately reducing utilization of these drugs.

VII. PAYMENT POLICY FOR BIOSIMILAR BIOLOGICAL PRODUCTS WITHOUT PASS-THROUGH STATUS THAT ARE ACQUIRED UNDER THE 340B PROGRAM

PhRMA supports CMS's proposed change to payment for biosimilars without pass-through status acquired under the 340B program from ASP (of the biosimilar) minus 22.5 percent of the reference product to ASP (of the biosimilar) minus 22.5 percent of the biosimilar's ASP. This payment change will help to avoid inappropriately reducing payment of biosimilar medicines with a lower ASP than their reference product. It is important to ensure adequate reimbursement for biosimilar medicines to support their uptake by providers, when clinically appropriate. Recent studies project that biosimilars could reduce spending on biologics by between \$25 billion to \$150 billion over the next 10 years.¹²⁸ This is on top of cost savings from lower-cost generics which now represent 90 percent of all medicines given to patients.¹²⁹

VIII. PAYMENT OF DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS IF AVERAGE SALES PRICE DATA ARE NOT AVAILABLE

PhRMA is concerned about the potential for unintended, negative consequences as a result of CMS' proposal to cut reimbursement for innovative new medicines administered in physician offices to 103 percent of the Wholesale Acquisition Cost (WAC), and urge the agency not to finalize this change. Currently, Medicare generally reimburses physician offices at 106 percent of WAC for new drugs that lack an ASP-based payment rate under Social Security Act (SSA) § 1847A(c)(4), which permits payment for these drugs "based on" WAC or payment methodologies in effect on November 1, 2003. WAC-based payment provides a mechanism to ensure that providers receive adequate reimbursement for physician-administered drugs when they are newly introduced, for example, and have not yet generated the data needed to set an ASP.

This proposed payment cut is not supported by the data and could have the effect of leaving some physicians "under water" with payment rates that are below their acquisition costs for these treatments. We are particularly concerned that this cut would be targeted to the most innovative medicines for patients with serious diseases such as cancer and immune disorders.

PhRMA is also very concerned by an additional, related proposal that would contravene the statute by permitting Medicare contractors to reduce reimbursement below WAC + 3% for certain drugs. The proposed rule states that, for new drugs that are "not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File," CMS would "permit MACs [Medicare Administrative Contractors] to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs."¹³⁰

¹²⁸ AW Mulchy, JP Hlavka, SR Case. "Biosimilar Cost Savings in the United States: Initial Experience and Future Potential." RAND Corporation. 2017. Available at: <https://www.rand.org/pubs/perspectives/PE264.html>

¹²⁹ IQVIA. "2017 Medicine Use and Spending." Published April 2018.

¹³⁰ 83 Fed. Reg. at 35855.

This suggests that payments for new drugs not listed in CMS' pricing files could be below 103 percent of WAC.¹³¹

We have serious additional concerns about this proposal. CMS states that it would revise the Claims Processing Manual to "permit MACs to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs," and that "MACs have longstanding authority to make payment determinations when we do not publish a payment limit in our national Part B drug payment files and when a new drug becomes available."¹³² The statute does not include special provisions on drugs that are not listed in CMS' ASP or NOC files (the statute never even mentions these files).¹³³ Therefore, drugs that are not listed in these pricing files must be paid at the same payment rate that would apply if they were listed in the CMS pricing files, in accordance with SSA § 1847A.

Although CMS lacks a published policy on when it excludes drugs from its quarterly pricing files, our understanding is that CMS may even exclude drugs with ASP-based payment rates from these files (e.g., if CMS considers the drug low volume).¹³⁴ Therefore, it appears that CMS would authorize MACs to pay "up to" 103 percent of WAC for an undefined but potentially broad group of drugs -- not only new drugs lacking an ASP-based payment rate that fall under SSA § 1847A(c)(4), but also drugs that by law must be paid 106 percent of ASP under § 1847A(b)(1). Nothing in the statute permits this, and accordingly we ask that in the final rule CMS clarify that MACs must pay for drugs at the applicable rate specified in § 1847A. The statement that MACs have "longstanding authority to make payment determinations when we do not publish a payment rate in our national Part B drug pricing files and when a new drug becomes available" is incorrect if it is intended to suggest that MACs may depart from the payment rates specified in the statute.

Additional discussion of our concerns with changes to reduced WAC-based reimbursement was provided in our comments to the Medicare Physician Fee Schedule.¹³⁵

¹³¹ This is particularly concerning because cutting new drug payments to 103% of WAC results in a 101.35% of WAC payment after sequestration cuts.

¹³² 83 Fed. Reg. at 35855 (emphasis added).

¹³³ Specifically, payment for Part B drugs is generally the lesser of 106% of ASP or 106% of WAC (or, for multiple source drugs, 106% of a blended ASP for the multiple source HCPCS code). SSA § 1847A(b)(1)(3). Payment for a new drug for which ASP data is not yet sufficiently available is based on WAC or methodologies in effect on November 1, 2003. SSA § 1847A(c)(4). Payment for biosimilars is 100% of the biosimilar ASP plus 6% of the reference biological's ASP. SSA § 1847A(b)(8). Payments for certain DME inhalation drugs described in SSA § 1847A(b)(7) are determined under that provision. Payments for drugs with an ASP exceeding Average Manufacturer Price by a threshold percentage may be determined under § 1847A(d). Finally, under § 1847A(e) CMS may use WAC or other reasonable measures of the drug's price to pay for drugs in certain public health emergencies.

¹³⁴ Manufacturers that have previously asked CMS why certain drugs are excluded from the ASP and NOC pricing files have been told the following:

CMS evaluates the program need for publishing a national price before adding (or removing) a drug from the ASP "NOC" file. This decision considers a number of factors, including but not limited to the setting in which the drug is used, the volume of use in Medicare Part B, and access issues.

¹³⁵ PhRMA comments to CMS-1693-P. Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program.

IX. REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM AND THE AMBULATORY SURGERY CENTER QUALITY REPORTING (ASCQR) PROGRAM

A. Meaningful Measures Framework

PhRMA commends CMS on the steps the Agency is taking to enhance the measures framework through the Meaningful Measures Initiative. We share the goals of the initiative, to identify the highest priority areas for quality improvement and measurement that will result in efforts and measures that are focused on achieving meaningful outcomes to patients. We also appreciate CMS' attention and responsiveness to the reporting burden of providers and other stakeholders, which can be a barrier to clinicians providing the high-quality patient care they desire. As CMS continues to engage with stakeholders on the Meaningful Measures Initiative, PhRMA looks forward to providing additional feedback on the framework.

PhRMA supports the use of measures, whether structural, process, or outcome, that are well-grounded in evidence, have successfully undergone rigorous evaluation and validation to ensure they provide accurate, reliable, and meaningful results, and have been subjected to an external review and public comment process. While we understand that CMS has shared and developed the Meaningful Measures framework with several stakeholders including the Measures Application Partnership (MAP), similar to our views on measure development, we encourage CMS to provide additional opportunities for public comment on the framework itself to gain consensus and make continual improvements through an iterative process. We also strongly encourage CMS to work in close collaboration with the MAP, which has an established process to provide an additional mechanism for multi-stakeholder review, public comment, recommendations (including identification of measure gaps, and prioritization of measures (including identification of relating and competing measures) for inclusion in select federal programs.

As CMS evaluates measures for removal or future inclusion, PhRMA encourages the Agency, the MAP and measure stewards to prioritize and focus on the framework's 19 meaningful measures areas that represent the most important issues around achieving high-quality care and improving patient outcomes including the development of patient-centered measures. The addition of more granular, outcomes-focused measure types such as quality of life and patient outcomes that are aligned to current clinical guidelines can help advance the current standard of care in ways that would meaningfully improve patient health and reduce overall health costs. Measuring the quality and outcomes of care delivery that take into consideration social determinants of health and incorporate the patient's perspective is particularly essential to ensure that appropriate care is being provided, and patient access to essential treatments is not hindered.

While we support the move towards a more harmonized set of measures that provide greater impact, PhRMA believes quality measure sets should include both population-based measures and measures that would be valuable at a personalized level to inform care decisions. These measure sets should include a mix of measure types (i.e. outcomes and processes), that are both disease-specific and cross-cutting and

include data from clinical and patient-reported data sources to ensure that measure sets provide a complete picture of the quality of patient care. We caution against removing measures that capture individual preferences and experiences of care, such as patient-reported outcomes, measures of shared decision making, or measures that address public health priorities, like immunizations, due to burdensome reporting.

B. New Measure Removal Factor

CMS is proposing to adopt an additional factor when evaluating measures for removal from both the Hospital OQR and ASCQR measure sets: the costs associated with a measure outweigh the benefit of its continued use in the program. The Agency also discussed measure removal criteria with the MAP and asked for input on which factors CMS should consider when removing measures from quality reporting and value-based purchasing programs. The MAP had thoughtful feedback that PhRMA strongly encourages CMS to take under consideration.¹³⁶ These suggestions for CMS include paying special attention to the unintended consequences of implemented measures, balancing provider burden with meaningful information for consumers, and ensuring proper risk adjustment.

PhRMA recognizes the burdens associated with measure reporting and supports the removal of measures that are not enhancing patient care experience or improving outcomes. Aside from measure removal due to immediate patient safety concerns, evaluating measures for removal should be carefully conducted through a holistic perspective. As the MAP noted, focusing too heavily on any one criterion could have negative unintended consequences. One suggestion for CMS to consider would be for the Agency and the MAP to jointly develop an evaluation rubric with all eight (if finalized) measure removal factors. This could promote better alignment with the work of the MAP committees and provide greater transparency into the rationale behind measure changes. Working from a consistent set of mutually agreed-upon set of criteria could help stakeholders more easily understand and compare the MAP's recommendations for measures inclusion or removal to CMS' proposals.

We would encourage CMS not to solely consider cost reductions, or generating greater efficiencies, when evaluating whether to remove measures, but rather to ensure that there is an appropriate balance between reporting burden and the benefits of providing both patients with data to inform care decisions and hospitals and physicians receive actionable feedback to improve the quality of patient care they provide. Additionally, care should be given to ensure that measure removals do not result in stinting on care, greater gaps in care quality, or reduced access for patients.

¹³⁶ National Quality Forum Measures Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. February 2018.

C. Proposed Removal of Quality Measures from the Hospital OQR and the ASCQR Programs

Beginning with the CY 2020 payment determination and subsequent years, CMS is proposing to remove the Centers for Disease Control developed measure, Influenza Vaccination Coverage Among Healthcare Personnel measure (OP-27, ASC-8, NQF #0031) from both the Hospital OQR and ASCQR programs, respectively. CMS is proposing to remove this measure in tandem with the proposed new criteria for measure removal, that the costs associated with the measure outweigh the benefit of continued use in the program. CMS notes that although the collection burden for healthcare personnel for this particular measure is less than chart-abstracted immunization measures, there is still a burden on facilities to identify and document the influenza immunization status among all staff. Furthermore, the Agency anticipates that a portion of MIPS eligible clinicians will report on the Preventative Care and Screening: Influenza Immunization measure through the QPP.

PhRMA appreciates that hospitals and ambulatory surgery centers will ensure that their health care personnel continue to receive their annual influenza vaccine, and we recognize the burdens associated measure reporting. However, we are more principally concerned about adequately addressing the fundamental and significant public health benefits of vaccinations. Regardless of care setting, health care personnel should be leading and setting an example for patients to receive routine, guideline recommended vaccinations.^{137,138}

Immunizations have long been a part of the CMS strategic goals, National Quality Strategy, and the HHS 2018-2022 Strategic Plan, which includes components that address prevention of communicable and chronic diseases.¹³⁹ Routine, guideline-recommend immunizations align with CMS' quality priority of "Promote Effective Prevention and Treatment of Chronic Disease" in the meaningful measure area of "Preventive Care". CMS should also strive to create consistency across multiple payment and reporting programs, especially with such a cross-cutting measure that could impact patient outcomes such as hospitalizations given the frequency with which health care personnel come into contact with patients in these care settings.

We are concerned that this measure is being proposed for removal when it addresses a high impact public health issue and there is still great opportunity for improvement. Although trending in a positive direction, the overall percentage of health care personnel 18 years and older vaccinated against seasonal influenza remains well below the Healthy People 2020 goal of 90 percent.¹⁴⁰ Additionally, our concern with measure

¹³⁷ Centers for Disease Control. Immunization of health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2011;60(No. RR-7):1-45.

¹³⁸ Grohskopf LA, Sokolow LZ, Broder RK, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2018 – 2019 Influenza Season. MMWR Recomm Rep 2018;67(No. RR-3):1-20.

¹³⁹ HHS 2018-2022 Strategic Plan: <https://www.hhs.gov/about/strategic-plan/strategic-goal-2/index.html>

¹⁴⁰ Healthy People 2020 Midcourse Review: Immunization and Infectious Disease. <https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C23-IID.pdf>

removal from a reporting program is the lack of accountability mechanisms to ensure health care personnel will receive their influenza vaccinations. If the collection and reporting requirement is removed, our concern is that this could lead to facilities and health care personnel to inaccurately conclude that the measure is “topped out, adopt a false sense of complacency, or become more lenient in their policies.

Given the many existing employer requirements for health care personnel to be vaccinated against influenza, we do not believe the tracking and reporting requirements would be as burdensome as CMS estimates. More importantly, we firmly believe that the benefits of a fully vaccinated health care workforce on patient care and outcomes outweigh any recording or reporting burdens. Therefore, we strongly urge CMS to retain this measure in both reporting programs, regardless of what MIPS clinicians may choose to report on. Provider behavior can be tied to accountability, and the quality measures reported in MIPS are self-selected as opposed to required. Removing this measure from reporting programs could inadvertently result in a decline in provider and facility performance when certain accountability metrics are removed.¹⁴¹

Moving forward, PhRMA encourages CMS to carefully consider its evaluation approach and broad application of measure removal criteria that could inadvertently lead to unintended consequences in patient care and reversing the progress and improvements yet to be made in achieving public health goals. Required reporting of quality measures is one way to ensure continued accountability and improve care quality.

X. HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM POLICIES

A. Proposed updates to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey measure (NQF #0166) for the FY2024 payment determination and subsequent years

Effective with the January 2022 discharges, CMS is proposing to remove the recently modified Communication about Pain questions from the HCAHPS Survey for the FY 2024 payment determination and subsequent years. In support of the proposal, CMS cites the final report of the President’s Commission on Combating Drug Addiction and the Opioid Crisis which recommended the removal of the survey questions out of concern that they may incentivize providers to prescribe opioids to raise their HCAHPS Survey Score.

We share CMS’ commitment to addressing the opioid crisis and support policies that promote the appropriate use of medicines and encourage CMS to ensure a balanced approach to pain management that reduces the potential for misuse and abuse. Accordingly, we applaud continued efforts to avoid any unintended consequences of the HCAHPS survey while also ensuring quality care is delivered to patients. We additionally appreciate CMS’ efforts to collect evidence to determine if prior or current iterations of the

¹⁴¹ Lester, Helen, et al. "The impact of removing financial incentives from clinical quality indicators: longitudinal analysis of four Kaiser Permanente indicators." *Bmj* 340 (2010): c1898.

Communication About Pain questions are potentially associated with inappropriate opioid prescribing practices. As CMS moves forward and considers additional measures, we support a continued evidence-based approach to ensure that survey questions do not inappropriately influence prescribing practices. Likewise, we urge CMS to ensure that removing these questions does not impede legitimate patient access to needed medicines.

As pain management is an important dimension of patient-centered care it is critical that alternative measures to replace the Communication about Pain questions in the HCAHPS Survey assess the degree to which patients are appropriately engaged in the delivery of their care. Changes to survey questions should also adequately reflect clinical guidelines and include considerations regarding discharge planning, such as management of patient expectations and necessary follow-up. Additionally, we urge the consideration of alternate questions that seek to ensure adequate patient awareness of the range of treatment options available to manage pain—including non-opioid analgesics and other non-pharmacological modalities of care. In the years ahead, the tools available to treat acute and chronic pain will continue to expand and patient engagement on these treatment options will remain of critical importance.

* * *

PhRMA appreciates the opportunity to comment on this proposed rule, and we hope our comments will be useful to CMS as it develops the final OPPI rule for 2019. Please feel free to contact us if there is any further information we can provide or if you have any questions about our comments.

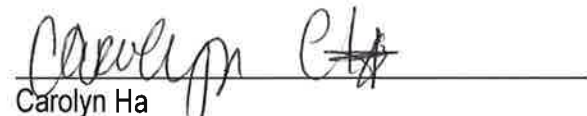
Sincerely,



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