August 21, 2017

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Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Medicare Program; Request for Comments on the Proposed Rule Regarding CY2018 Updates to the Quality Payment Program: Merit-Based Incentive Payment System (MIPS) and the Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Ms. Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding updates to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models. PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

Our comments on the proposed rule, set forth in detail below, can be summarized as follows:

- **MIPS Payment Adjustments**: CMS should announce a policy clarifying that MIPS payment adjustments do not apply to payments for Part B medicines or other items and services that are not paid under the MPFS. The MACRA statute plainly limits the MIPS adjustment to clinician services paid under the PFS, and applying adjustments more broadly would have unintended consequences for providers and patients.

- **MIPS Scoring**: PhRMA supports CMS' proposal to assign a weight of 0 percent to the resource use performance category in PY 2020.

- **MIPS Performance Measures**: PhRMA appreciates CMS' efforts to balance the financial incentives in the MIPS and APM programs with closely aligned, clinically meaningful quality measures. We are encouraged by the incremental steps taken to emphasize the importance of patient-centeredness in care across the performance categories, such as incorporation of shared decision making and patient-reported outcomes.

- **Nominal Financial Risk**: PhRMA encourages CMS to consider a lower threshold for the nominal financial risk criterion in light of the status of APM testing and its findings with respect to care quality and access.

- **Other Payer APMs**: PhRMA supports CMS' proposal to post information about Other Payer Advanced APMs on the CMS website. We recommend that CMS also publish the brief description of the nature of the arrangement to facilitate a broader understanding of the types of models that qualify as Other Payer Advanced APMs.

- **Physician Focused Payment Model Technical Advisory Committee (PTAC)**: CMS should clarify the recommendation categories used by the PTAC so that they do not promote confusion by suggesting that models under SSA §§ 1115A or 1866C can start with anything other than "limited-scale testing".
I. MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS) PAYMENT ADJUSTMENT

CMS seeks to clarify the specific Part B services that are subject to MIPS payment adjustments. While this section of the preamble is unclear, it appears to suggest that Part B drug payments will be subject to MIPS payment adjustments.

Applying MIPS payment adjustments to payments for Part B medicines is inconsistent with MACRA's language and purpose. Further, CMS has not issued a clear proposal for application of the payment adjustment in a notice of proposed rulemaking, so stakeholders cannot provide meaningful comments. If MIPS adjustments were applied to Part B drug reimbursements, this could have unintended consequences for MIPS eligible clinicians, who could now experience significant swings in their reimbursement for Part B medicines. As a result, access to care and quality of care for Medicare patients could begin to suffer in practices that receive negative payment adjustments. For these reasons, CMS should announce a policy clarifying that MIPS payment adjustments do not apply to payments for Part B medicines or other items and services that are not paid under the MPFS.

A. CMS SHOULD ANNOUNCE A PROPOSAL CONCERNING THE CLINICIAN PAYMENTS SUBJECT TO MIPS ADJUSTMENTS, AND LIMIT THESE ADJUSTMENTS TO PHYSICIAN FEE SCHEDULE SERVICES

MIPS has two key parameters: the adjustment factors and the base (the services furnished by the clinician to which the adjustment factor applies). CMS has developed rules on determining adjustment factors, but the base to which the adjustment factor applies is still unclear. In particular, CMS has not yet proposed a rule on whether MIPS adjustments apply to Part B drugs furnished incident to the services of MIPS-eligible clinicians (which are not paid under the Medicare Physician Fee Schedule). It is critical that CMS addresses this question -- and does so consistent with MACRA and consistent with the notice and comment rulemaking requirements of the Administrative Procedure Act and the Medicare statute.

Under MACRA -- specifically, under Social Security Act § 1848(q)(6)(E) -- the MIPS adjustment factor is applied to a base amount that equals "the amount otherwise paid under this part with respect to [items and services furnished by the MIPS eligible clinician during the relevant year]." As explained below, that base should only include professional services furnished by the MIPS-eligible clinician that are paid under the Medicare Physician Fee Schedule (PFS). The brief discussion of this issue in the proposed rule preamble is unclear, but suggests that at least in some cases CMS envisions including Part B drugs in the base. Applying the MIPS adjustments to items and services other than an eligible clinician's professional services would be an unreasonable, noncontextual reading of the statute; depart from all of the payment adjustment policies on which Congress built the MIPS; depart from MACRA's other payment pathway (the 5% bonus for clinicians in advanced APMs); and jeopardize patient access to critical medications, while driving up Medicare spending. Accordingly, we urge CMS to make a clear proposal on this point that MIPS payment adjustments apply only to Physician Fee Schedule services and then allow stakeholders an opportunity to comment on the proposal before adopting a final regulation. Such a proposal would harmonize with MACRA's language and purpose.

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1 Social Security Act (SSA) § 1848(q)(6)(E) ("In the case of items and services furnished by a MIPS eligible professional during a year (beginning with 2019), the amount otherwise paid with respect to such items and services and MIPS eligible professional for such year" shall be multiplied by 1 plus the sum of the MIPS adjustment factor and additional MIPS adjustment factor).

2 The preamble states in part that “[f]or those billed Medicare Part B allowable charges relating to the purchasing and administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations." 82 Fed. Reg. at 30019.
B. CMS MUST ANNOUNCE AND SEEK COMMENT ON A CLEAR PROPOSAL SPECIFYING WHICH ITEMS AND SERVICES ARE SUBJECT TO MIPS ADJUSTMENTS

Under long-standing Administrative Procedure Act case law, an agency can only adopt a final rule that is a logical outgrowth of its proposed rule, so that stakeholders have clear notice of the agency's planned approach and an opportunity to provide comments on it. In the Medicare context, Congress placed such importance on this logical outgrowth requirement that it expressly incorporated it into the Medicare statute.

Social Security Act § 1871 states that "[i]f the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation." In accordance with this provision of the Medicare statute, CMS can only issue a final rule that differs from a proposed rule if the final rule is a logical outgrowth of the proposed rule. A final rule is a "logical outgrowth" only if the policy contained in the final rule is reasonably foreseeable from the proposal contained in the proposed rule.

In the CY 2017 final Quality Payment Program rule, CMS stated that "[o]ne commenter requested that CMS clarify whether Part B drug payments will be affected by MIPS payment adjustments. The commenter observed that in previous programs (PQRS, EHR Incentive Program (Meaningful Use), and Value-based Payment Modifier) the payment adjustments were only made to the services paid under the Medicare PFS, which included administration of Part B drugs, but not the cost of the actual drugs. The commenter would like verification that this policy will continue under the Quality Payment Program." In response, CMS stated that "[w]e did not address this issue in the proposed rule. We will consider this issue and intend to provide clarification in the future."

Despite stating in last year's QPP final rule that it would "consider this issue and provide clarification," CMS did not make a proposal about which items and services would be subject to MIPS adjustments in the proposed rule. Instead, the proposed rule only includes a short and puzzling preamble passage on this issue. Any final policy could not be a "logical outgrowth" of this passage, because it is too confusing to permit meaningful comments:

"We note that when Part B items or services are rendered by suppliers that are also MIPS eligible clinicians, there may be circumstances in which it is not operationally feasible for us to attribute those items or services to a MIPS eligible clinician at an NPI level in order to include them for purposes of applying the MIPS payment adjustment or making eligibility determinations. To further clarify, there are circumstances that involve Part B prescription drugs and durable medical equipment where the supplier may also be a MIPS eligible clinician. In circumstances in which a MIPS eligible clinician furnishes a Part B covered item

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3 See, e.g., Doe v. Rumsfeld, 341 F. Supp.2d 1, 14 (D.D.C. 2004) (while the final rule need not be identical to the proposed rule, if the final rule "deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal") (quoting AFL-CIO v. Donovan, 757 F.2d 330, 338 (D.C. Cir. 1985)); CSX Transportation, Inc. v. Surface Transportation Board, 584 F.3d 1076, 1080 (D.C. Cir. 2009) ("[A] final rule fails the logical outgrowth test and thus violates the APA's notice requirement where interested parties would have had to 'divine [the agency's] unspoken thoughts,' because the final rule was surprisingly distant from the proposed rule.")

4 SSA § 1871(a)(4) (emphasis added).


7 81 Fed. Reg. at 77340 (emphasis added).
or service such as prescribing Part B drugs that are dispensed, administered, and billed by a supplier that is a MIPS eligible clinician, or ordering durable medical equipment that is administered and billed by a supplier that is a MIPS eligible clinician, it is not operationally feasible for us at this time to associate those billed allowable charges with a MIPS eligible clinician at an NPI level in order to include them for purposes of applying the MIPS payment adjustment or making eligibility determinations. For Part B items and services furnished by a MIPS eligible clinician such as purchasing and administering Part B drugs that are billed by the MIPS eligible clinician, such items and services may be subject to MIPS adjustment based on the MIPS eligible clinician’s performance during the applicable performance period or included for eligibility determinations. For those billed Medicare Part B allowable charges relating to the purchasing and administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations.8

This passage lacks the clarity necessary to enable stakeholders to understand when CMS would apply the MIPS adjustment to a Part B drug, and thus to provide meaningful comments on the CMS position. To provide meaningful comments on the circumstances in which CMS would apply the MIPS adjustment to Part B drugs, stakeholders need a clear CMS proposal and an explanation of why the proposal is consistent with MACRA. Among other things, CMS would need to explain how it proposes to define services “furnished by” a physician, especially as CMS has stated previously that services furnished “incident to” physician services are not actually “furnished by” the physician but treated for certain purposes “as if” they are furnished by the physician;8 the preamble passage creates further confusion by suggesting that services “furnished by” the physician must be prescribed by the physician (which is not always the case with incident-to drugs), but without stating that clearly or explaining CMS’ reasoning.10

PhRMA urges CMS to announce a clear proposal regarding the application of the MIPS payment adjustment to Part B drugs in the CY2019 Quality Payment Program Notice of Proposed Rulemaking, and to solicit stakeholder comments on the proposal before it announces a final policy. We also urge CMS to develop a proposal that is consistent with the statute, which -- as explained below -- plainly limits the MIPS adjustment to clinician services paid under the PFS.

C. MACRA LIMITS MIPS ADJUSTMENTS TO PROFESSIONAL SERVICES PAID UNDER THE PHYSICIAN FEE SCHEDULE

The MIPS payment adjustment provisions are part of SSA § 1848, which is entitled “payment for physicians’ services” and pertains to payment under the physician fee schedule. Had Congress meant for MIPS adjustments to apply to items and services outside the PFS, it would have stated that explicitly, or placed the MIPS adjustment provisions in a different section of the Social Security Act to make clear that they apply to items and services going beyond those paid under the fee schedule. Instead, Congress housed this provision -- SSA § 1848(q)(6)(E) -- in the

8 82 Fed. Reg. at 30019.
9 80 Fed. Reg. 70886, 71065 (Nov. 16, 2015) (“incident-to services are treated as if they were furnished by the billing physician or other practitioner for purposes of Medicare billing and payment”).
10 82 Fed. Reg. at 30019 (referring to circumstances “in which a MIPS eligible clinician furnishes a Part B covered item or service such as prescribing Part B drugs that are dispensed, administered, and billed by a supplier that is a MIPS eligible clinician”) (emphasis added).
fee schedule section, with no indication they had a broader application. The provision accordingly must be read in that context.\textsuperscript{11}

Statutory language must be read in context, and a critical part of that context is the placement of a provision in the statute. For example, the Supreme Court recently emphasized that courts must always "bear[] in mind the fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their placement in the overall statutory scheme."\textsuperscript{12} Courts have held that under this canon "the placement of a provision in a particular subchapter, for example, suggests that its terms should be interpreted consistently with its context."\textsuperscript{13} Courts have thus rejected an interpretation as "an unreasonable and untenable construction" when it "clashes with our fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their placement in the overall statutory scheme."\textsuperscript{14}

Applying this fundamental canon of statutory construction here, the MIPS adjustment provision plainly applies to services paid under the PFS, given Congress' decision to place it in SSA § 1848; any other construction would clash with this canon and would be "an unreasonable and untenable construction."

Moreover, as CMS recognized in the 2017 final QPP rule, all the predecessors to the MIPS adjustment provision -- the PQRS, the EHR incentive provision (meaningful use), and the value-based modifier -- only make adjustments to fee schedule services.\textsuperscript{15} MACRA's MIPS provisions were expressly designed to consolidate and streamline those various adjustment provisions\textsuperscript{16} -- but Congress gave no indication that it intended to expand the scope of the adjustments. Therefore MIPS adjustments should apply to the same services as the previous adjustment polices that MIPS subsumed.

\textsuperscript{11} See, e.g., United Sav. Ass'n of Texas v. Timbers of Inwood Forest Assoc., Ltd., 484 U.S. 365, 371 (1988) ("statutory construction ... is a holistic endeavor. A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme"); Green v. Rock Laundry Mach. Co., 490 U.S. 504, 528 (1989) (stating that the "meaning of terms on the statute books ought to be determined, not on the basis of which meaning can be shown to have been understood by a larger handful of the Members of Congress; but rather on the basis of which meaning is (1) most in accord with context and ordinary usage, and thus most likely to have been understood by the whole Congress which voted on the words of the statute (not to mention the citizens subject to it), and (2) most compatible with the surrounding body of law into which the provision must be integrated").


\textsuperscript{13} Northshore Mining Co. v. Secretary of Labor, 709 F.3d 706, 710 (8th Cir. 2013) (citing Davis v. Michigan Dep't of Treasury, 489 U.S. 803, 809 (1989) and Fla. Dept. of Revenue v. Piccadilly Cafeterias, Inc., 554 U.S. 33, 46-52 (2008)). In Piccadilly, 554 U.S. at 47, the Supreme Court stated:

We find it informative that Congress placed § 1146(a) in a subchapter entitled, "POSTCONFIRMATION MATTERS." To be sure, a subchapter heading cannot substitute for the operative test of the statute. Nonetheless, statutory titles and section headings are tools available for the resolution of a doubt about the meaning of a statute. The placement of § 1146(a) within a subchapter expressly limited to postconfirmation matters undermines Piccadilly's view that § 1146(a) covers preconfirmation transfers. (Citations and internal quotations omitted.)

\textsuperscript{14} Colonial Press Int'l v. United States, 788 F.3d 1350, 1357 (Fed. Cir. 2015) (quoting Davis v. Michigan Dept. of Treasury, 489 U.S. at 809)).

\textsuperscript{15} See SSA § 1848(a), (k), (m), (o), (p).

\textsuperscript{16} For example, a February 6, 2014 summary prepared by the House Committees on Energy and Commerce and Ways and Means and the Senate Committee on Finance staff concerning the SGR Repeal and Medicare Provider Payment Modernization Act (which was nearly identical to MACRA) provides that the bill "Consolidates the three existing quality programs into a streamlined and improved program that rewards providers who meet performance thresholds, improves care for seniors, and provides certainty for providers."
Finally, Congress created two payment pathways in MACRA -- the MIPS and the advanced APM pathways -- and never suggested that they should apply to a different set of services, which suggests that CMS should align the MIPS and advanced APM policies involving Part B drugs. Under the advanced APM pathway, qualifying participants receive a bonus “equal to 5 percent of the estimated aggregate payment amounts for . . . covered professional services under [Medicare Part B] for the preceding year.”17 “Covered professional services” are “services for which payment is made under, or is based on, the fee schedule established under [SSA § 1848] and which are furnished by an eligible professional,”18 and CMS has therefore recognized that “drugs, biologics, and devices covered under Medicare Part B . . . are not covered professional services.”19 There is no reason to believe Congress meant for the MIPS adjustment to apply to more services than the advanced APM bonus.

Accordingly, MACRA’s language, structure, and purpose make clear that the MIPS adjustment -- like the PQRS, the EHR incentive programs, the value-based modifier, and the advanced APM bonus -- have no application to Part B drugs. The same is true of other items and services that may be furnished by a MIPS-eligible clinician but that are not paid under the PFS, such as vaccines, devices that are not paid under the PFS such as DMEPOS items, and those preventive items and services that are not paid under the PFS.

D. APPLYING MIPS ADJUSTMENTS TO PART B DRUG PAYMENTS WOULD HAVE UNINTENDED CONSEQUENCES FOR PROVIDERS AND PATIENTS

1. APPLYING THE MIPS PAYMENT ADJUSTMENT TO PART B DRUGS COULD REDUCE ACCESS TO CARE BY MAKING IT DIFFICULT FOR LOW-PERFORMING PRACTICES TO PROVIDE PART B MEDICINES.

Applying MIPS payment adjustments to Part B medicines could have significant unintended consequences for practices that furnish Part B drugs, because it would make it more challenging for practices that receive negative payment adjustments to provide these medicines to patients. Specialties that administer many Part B therapies like oncology/hematology and rheumatology will face higher penalties than they otherwise would if Part B drugs are included in MIPS payment adjustments. In PY2019, negative payment adjustments are entirely driven by failure to meet reporting requirements. Assuming that oncologists/hematologists and rheumatologists participate in MIPS at similar levels as its predecessor programs in the first reporting year, 43 percent of low-performing rheumatologists and 59 percent of low-performing oncologists could face a penalty greater than $20,000 if Part B drug payments are included. If Part B drug payments are excluded, just 4 percent of low-performing rheumatologists and 10 percent of low-performing oncologist/hematologists would receive penalties greater than $20,000.20

These penalties would undercut the reimbursement methodology for Part B medicines established in the Medicare statute. Medicare reimburses for Part B medicines at a rate of average sales price plus 6 percent (ASP + 6%). The ASP payment methodology ensures that Medicare reimbursements reflect nearly all of the rebates and discounts that are privately negotiated in the market. The 6% add-on to the ASP payment helps to cover geographic and provider purchasing variability, complex storage and handling, and other overhead costs (e.g., prompt pay discounts, wholesaler markups, and sales tax, which can create a gap between manufacturers’ reported ASP and the average purchase price across providers)21 for practices that administer these medicines. The reimbursement rate was explicitly set by Congress to establish a balance between patient access and appropriate reimbursement for

17 SSA § 1833(z)(1)(A) (emphasis added).
18 SSA § 1848(k)(3)(A) (SSA § 1833(z)(3)(A), added by MACRA, defines “covered professional services” as “the meaning given that term in [SSA § 1848].”).
medicines. The reimbursement rate was intended to align Medicare reimbursement with the costs that physician practices incur to acquire and maintain an inventory of these medicines.

If Part B drug payments are subject to MIPS adjustments, practices in specialties that administer Part B medicines could be under significantly more financial risk than Congress intended when it set the MIPS adjustment rates. Because providers that administer Part B medicines must cover the costs of acquiring and maintaining an inventory of drugs, applying MIPS adjustments to Part B drug payments reflects a steeper reduction in Medicare payments for practices that administer these drugs. Assuming that providers are able to acquire drugs at ASP (actual purchase price can vary, and small and rural practices are more likely to pay above ASP for their drugs), physician specialties that administer Part B medicines in their practice could face steeper negative adjustments if they are lower performers under MIPS after accounting for their drug acquisition costs. By 2022, nearly one-third of Medicare revenues could be at risk for some specialties. The table below shows the maximum reduction in Medicare revenues for selected specialties after accounting for the cost of purchasing Part B medicines at ASP.22

### Reduction in Medicare Revenues: Selected Specialties

<table>
<thead>
<tr>
<th>Specialty</th>
<th>2019 (4%)</th>
<th>2020 (5%)</th>
<th>2021 (7%)</th>
<th>2022 and beyond (9%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatology</td>
<td>-13%</td>
<td>-16%</td>
<td>-23%</td>
<td>-29%</td>
</tr>
<tr>
<td>Hematology/Oncology</td>
<td>-13%</td>
<td>-16%</td>
<td>-22%</td>
<td>-29%</td>
</tr>
<tr>
<td>Medical Oncology</td>
<td>-13%</td>
<td>-16%</td>
<td>-22%</td>
<td>-29%</td>
</tr>
<tr>
<td>Ophthalmology</td>
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<td>-7%</td>
<td>-10%</td>
<td>-13%</td>
</tr>
<tr>
<td>Neurology</td>
<td>-5%</td>
<td>-6%</td>
<td>-8%</td>
<td>-11%</td>
</tr>
<tr>
<td>Internal Medicine</td>
<td>-4%</td>
<td>-5%</td>
<td>-7%</td>
<td>-9%</td>
</tr>
<tr>
<td>General Surgery</td>
<td>-4%</td>
<td>-5%</td>
<td>-7%</td>
<td>-9%</td>
</tr>
</tbody>
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Low performing practices could be under water on the medicines they purchase, which in turn could create access challenges for patients. Physician groups have repeatedly warned CMS that cuts to Part B drug payments would reduce patient access to those drugs, especially for patients treated by small rural practices and certain specialty practices. For example, just last year the AMA cautioned CMS that

> "[C]uts to Medicare reimbursement rates could lead to more providers (especially physician offices) being unable to administer important Part B drugs -- including drugs to treat cancer -- to their Medicare patients, thus jeopardizing Medicare patients’ access to treatments they need for serious diseases with a disproportionate impact on small rural practices and certain specialties such as oncology.23"

Major changes to Medicare drug reimbursements inflicted in the form of MIPS payment adjustments could force practices to turn away Medicare patients, refer patients to hospital outpatient departments where care can be more expensive for beneficiaries and the Medicare program, or close all together. Cuts to the Medicare Part B drug reimbursement rate imposed by sequestration are already having a negative impact on patient access. Since

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22 Avalere Health LLC. Analysis of Including Part B Drug Payments in MIPS. Conducted for PhRMA, August 2017.

23 Letter from James L. Madara, MD, Executive Vice President and CEO of the American Medical Association, to The Honorable Orrin Hatch, Chairman of the U.S. Senate Committee on Finance, and The Honorable Ron Wyden, Ranking Member of the U.S. Senate Committee on Finance (April 13, 2016), available at [http://www.mag.org/sites/default/files/downloads/madara-letter.pdf](http://www.mag.org/sites/default/files/downloads/madara-letter.pdf).
sequestration went into effect, providers report a greater likelihood of adjusting their payer mix (46 percent), reducing staff (45 percent), struggling financially (44 percent), and turning away patients (30 percent).  

As MIPS requirements become more stringent in future program years, small practices and those serving beneficiaries with social risk factors may be more likely to receive negative payment adjustments, further jeopardizing their ability to provide Part B medicines to their Medicare patients. Though CMS has taken steps to exercise the flexibility that Congress provided for implementation of the QPP in the first two performance years, substantial uncertainty remains about the structure of the QPP for 2021 and beyond. Beginning in 2021, CMS is required to set a performance benchmark that reflects either the national mean or median performance. In a 2016 proposed rule, CMS proposed to set the performance benchmark for the QPP at a level where approximately half of the eligible clinicians would be below the performance threshold and half would be above the performance threshold. CMS’ own estimates of the impact of this proposed policy suggest that over 50% of practices with 1-24 eligible clinicians would have received a negative payment adjustment in 2019 had the policy gone into effect, with a disproportionately large impact on smaller practices. Relatedly, the Assistant Secretary for Planning and Evaluation recently published findings that suggest that providers who disproportionately serve beneficiaries with social risk factors tend to have worse performance and experience higher penalties in value-based purchasing programs than providers who serve fewer of these beneficiaries. Subjecting reimbursement for Part B medicines to MIPS payment adjustments could be detrimental to access to specialty care for such beneficiaries, many of whom already experience access challenges.

Given the potential for low performing practices to see steep cuts in revenue that could impact their ability to continue to provide care to patients who depend on Part B medicines, CMS should clarify that the MIPS adjustment does not apply to Part B drug reimbursements.

2. APPLYING MIPS PAYMENT ADJUSTMENTS TO PART B MEDICINES WOULD IMPACT THE DISTRIBUTION OF PERFORMANCE-BASED BONUSES

Applying the MIPS payment adjustment to Part B drug payments would also have unintended effects on the distribution of positive payment adjustments. This could create a scenario where clinicians are rewarded proportionally more simply because they bill for Part B drugs, irrespective of their performance in the program. In the impact analysis included with the 2017 QPP Final Rule, CMS estimates a 1 percent average bonus including the adjustment for exceptional performance. CMS also estimates that 77 percent of clinicians receiving a positive payment adjustment will qualify for the exceptional performance bonus. Taking this into consideration, we estimate that 25 percent of hematologists/oncologists could receive bonuses of more than $10,000 if Part B drug payments are subject to the adjustment, with over half receiving bonuses of $20,000 or more. Comparatively, only 1 percent of oncologists would receive bonuses of more than $10,000 if Part B drugs were not subject to payment adjustments. Due to budget neutrality requirements, awarding higher bonuses to clinicians based on their Part B drug reimbursements also means that providers who do not prescribe these medicines will experience lower positive payment adjustments than they otherwise would for reasons that are unrelated to their performance under MIPS.

The purpose of the MIPS program is encourage high quality, efficient care by linking payment for Medicare services to performance on quality, resource use, clinical practice improvement, and EHR use. We do not believe

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27 Derived from elements of Table 61: MIPS Estimated Payment Year 2019 Impact on Total Allowed Charges by Specialty, Alternative Participation Assumptions; 2017 QPP Final Rule.
that Congress or CMS intended for bonuses to be disproportionately higher or lower based on Part B drug utilization, and encourage CMS to clarify that MIPS payment adjustments do not apply to Part B drug payments.

E. IT IS NOT OPERATIONALLY FEASIBLE TO APPLY THE MIPS PAYMENT ADJUSTMENT TO PAYMENTS FOR PART B DRUGS OR DURABLE MEDICAL EQUIPMENT AND ATTEMPTING TO APPLY ADJUSTMENTS TO DRUGS COULD DRIVE CARE INTO THE HOSPITAL SETTING

Due to differences between the OPPS and MPFS payment systems and the lack of required field items on the CMS 1450 used for billing in the hospital outpatient department, it may be difficult or impossible to link billed Part B drugs and durable medical equipment to particular NPIs for purposes of determining eligibility for MIPS and applying the payment adjustment. This puts clinicians that utilize the CMS 1500 claim form to bill Medicare for care provided in the office setting at a disadvantage in MIPS.

CMS specifically recognized in the proposed rule that MIPS adjustments would not always apply to Part B drugs furnished in hospital outpatient departments (HOPDs) and paid to the hospital: "If a MIPS eligible clinician furnishes items and services in an ASC, HHA, Hospice, and/or HOPD and the facility bills for those items and services (including prescription drugs) under the facility’s all-inclusive payment methodology or prospective payment system methodology, the MIPS adjustment would not apply to the facility payment itself." CMS also notes that it is often not operationally feasible to associate billed allowable charges for Part B medicines and durable medical equipment with a MIPS eligible clinician at an NPI level. In the case of Part B drugs, CMS 1450 claim form used for hospital outpatient claims does include areas for multiple NPIs for different types of providers such as attending (Form Locator 76), operating (FL 77), and Other (FL 78 and 79). It is expected that the physician that orders the drug would be included in area FL 78 while the physician who administers the drug (if different from the ordering physician) would be included in area FL 79. Form locator 78 and 79 are considered "situational" and not "required" elements, which means they may not be present on an outpatient claim including a Part B drug. The Medicare manual states, "Report when state or federal regulatory requirements call for a combined claim, i.e., a claim that includes both facility and professional fee components (e.g., a Medicaid clinic bill or Critical Access Hospital claim). If not required, do not send."

This puts MIPS eligible clinicians who provide Part B medicines in their offices at a distinct disadvantage. Because CMS will often lack the ability to link HOPD claims for Part B medicines to a TIN/NPI combination, clinicians who provide care in the HOPD setting may be less likely to be eligible for MIPS under CMS' proposed low-volume threshold. Those that are eligible will receive smaller overall payment adjustments because CMS will be unable to apply the adjustment to their Part B drug billings. Clinicians who bill Medicare for Part B medicines in the physician office may also be at a disadvantage as a result of CMS’ proposal to allow clinicians to elect to use the inpatient hospital value-based purchasing score in place of the MIPS score for hospital-based physicians. Hospitals may be more likely to utilize this option if the hospital has received scores qualifying for an inpatient hospital VBP bonus. This may differentially inflate the performance for hospital-based clinicians.

In summary, applying MIPS payment adjustments to Part B drug reimbursements would disproportionately impact clinicians who provide Part B medicines in the office setting. This could have the unintended effect of shifting care to the hospital setting, particularly given the impact on practice revenues described above. Low performing practices may have greater incentives to refer patients to the hospital for care, potentially leading to disruptions in treatment, higher costs, or other access barriers. This policy could also lead to greater practice consolidation, a trend that has been found to increase health care costs overall. One study found that a one percentage point

29 Ibid.
30 Health Care Cost Institute & National Academy for State Health Policy, The Impact of Provider Consolidation on Outpatient Prescription Drug-Based Cancer Care Spending (April 2016).
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.

To avoid disruptions in patient access to essential medicines and other unintended consequences, CMS must comply with MACRA and not apply the MIPS adjustment to Part B drugs – just as Congress wisely required when it placed the MIPS adjustment provisions in SSA § 1848 and thereby limited their scope to services paid under the PFS, consistent with the predecessor payment adjustments now subsumed in the MIPS adjustment. This approach also should be applied to other items and services furnished by MIPS-eligible clinicians that were not part of the predecessors to MIPS and are not paid under the PFS; this includes, for example, vaccines, certain devices not paid under the PFS (which, like Part B drugs, are purchased items that could generate a loss for the clinician if MIPS adjustments reduced the net payment), and those preventive items and services that are paid outside of the PFS.

II. MIPS MEASURES AND SCORING

A. MIPS SCORING

The proposed rule presents the four performance categories of MIPS—Quality, Resource Use, Clinical Practice Improvement Activities, and Advancing Care Information—and requirements and performance scoring rubric for each of the categories. CMS has proposed to revise the performance weights for 2018 as follows:

- Quality: 60%
- Resource Use: 0%
- CPIAs: 15%
- Advancing Care Information: 25%

MACRA provides CMS with the flexibility to adjust the quality and resource use weights in the first two years of the MIPS program. PhRMA appreciates CMS’ responsiveness to clinician concerns and stakeholder recommendations and supports CMS’ decision to exercise its flexibility to down-weight the cost performance category from 10% to 0% for an additional payment year. Reducing the Resource Use weight to 0% will allow CMS and clinicians additional time and experience needed to develop a more sophisticated approach to resource use measurement with clear linkages to quality. This will help ensure that incentives based on these measures are well-aligned with high-quality, individualized care.

While PhRMA supports a continued gradual phase-in of resource use measures, we note that there are still underlying methodological issues related to resource use measures that may take longer to fully address. An example of one such challenge is attributing physician practices for reliable resource use measurement, and this problem is particularly acute for smaller, independent practices. In fact, one study found that relatively few primary care physician practices are large enough to reliably measure 10 percent relative differences in common measures of quality and cost performance among fee-for-service Medicare patients. In addition, we believe that providers would benefit from having some experience with reporting cost measures prior to CMS applying the full weighting of 30 percent in performance period 2019. This presents a steep learning curve and practice changes for which clinicians may not be fully prepared. As described in greater detail below, we continue to have concerns with the reliability and validity of the MSPB and Total Per Capita Cost measures that CMS is proposing to adopt. We recognize that CMS has undertaken a renewed effort to develop and seek input on episode-based cost measures. Given the time needed to develop, validate, and adopt these measures through rulemaking, it is unlikely that providers will have sufficient experience with these measures by the time they might count towards the resource use performance score.

We encourage CMS to carefully consider these challenges and consider additional means of offering reporting flexibility for resource use measures as it continues implementation of the MIPS program.

B. QUALITY PERFORMANCE CATEGORY

1. QUALITY MEASURE REPORTING REQUIREMENTS

CMS is not proposing any changes to the submission criteria for quality measures in the proposed rule. For the second year of the program, MIPS eligible clinicians will be required to report on six quality measures of their choosing, provided that at least one measure is an outcome measure. CMS will not require clinicians to report on a cross-cutting measure.

PhRMA supports the continued requirement for MIPS eligible clinicians to report on at least one outcome measure. In particular, we appreciate CMS' clarification that patient-reported outcome measures are considered outcome measures, while efficiency measures that capture cost of care associated with a specific level of care are not considered as outcome measures. It is important to distinguish the activities and measures of patient health that can be attributed as a result of the health care provided from the cost that care. As the MIPS program continues to progress and clinicians gain familiarity with reporting requirements, we encourage CMS to place a greater emphasis on outcome measure reporting.

CMS also proposes that it will not require MIPS eligible clinicians to report on a cross-cutting measure, but seeks additional comment on this policy. Cross-cutting measures that are applicable across clinical settings, such as medication reconciliation, are important to fostering shared accountability and provide a more holistic perspective of care quality. Additionally, cross-cutting measures can serve as a means to reduce measurement burden because they can be reported on by a broad range of providers and specialties. We urge CMS to consider these factors as it develops future measure reporting requirements for MIPS.

Ideally, quality measure sets for MIPS should include a mix of measure types, i.e., outcomes/intermediate outcomes and processes; disease-specific and cross-cutting; and clinical and patient-reported data sources, to ensure that measure sets provide a complete picture of the quality of patient care. We recommend that CMS encourage development of both clinical outcomes (e.g., survival for patients with cancer and other life-threatening conditions) and patient-reported outcome measures (e.g., quality of life, functional status, and patient experience) to support this aim.

2. CHANGES TO THE CAHPS FOR MIPS SURVEY

CMS is considering several summary survey measures for removal from the CAHPS for MIPS survey, including removal of the summary survey measure (SSM), "Helping You to Take Medication as Directed" due to low reliability. We strongly encourage CMS to identify alternative measures as a supplement in order to continue to capture safe and appropriate medication use as a domain of the CAHPS for MIPS survey. Ensuring the right medication at the right time, for the right patient is an important component of care to avoid medication errors or further health complications. As CMS seeks comments on expanding the patient experience data available for the CAHPS for MIPS survey, we believe patient understanding of the appropriate use of the medications they take is critical to include.

3. MAINTENANCE OF MEASURES IN THE MIPS PROGRAM

Through the continued progression and evolution of the MIPS program, it will be critical to ensure a sound process is in place for ongoing measure maintenance, and a review process for measure inclusion or removal that is evidence-based, and grounded in robust data. As CMS works to maintain the measure set, it is also essential to ensure that measure specifications are kept current in order to ensure that quality of care is properly supported and
correctly evaluated. MIPS measures should be consistent with the latest clinical guidelines and scientific evidence. Coordination among the measure stewards, measure endorser, and CMS is necessary to ensure that the most updated and current measure specifications are in alignment and applied within the Quality Payment Program.

CMS has proposed a timeline for identification and removal of topped out measures. CMS proposes to remove measures that have been topped out for 3 consecutive years through rulemaking for the fourth year. PhRMA supports removal of measures that are topped out, and we agree with CMS’ proposal to base its identification of topped-out measures on multiple years of data. However, the current structure of the MIPS program presents several challenges for accurately determining when measures are topped out.

CMS permits physicians to choose the measures that they will be evaluated on under MIPS. This flexibility to select from the full range of available measures could result in selection of ‘low-bar’ measures with little room for improvement in some cases, or selection of measures that are neither clinically relevant nor representative of providers’ patient populations or the diseases they treat. When clinicians are permitted to choose the measures they report on, it becomes difficult to determine if a measure is truly topped out, or if its consistently high performance rate is a function of the group of providers that have chosen to report on the measure in any given year. Of note, 30 percent of eligible clinicians did not participate in the Physician Quality Reporting System at all in 2015.32 As these providers begin participating in quality reporting over the next several years, scores on some measures that appear to be topped out could shift dramatically. In this case, retiring a measure because it currently appears topped out could be premature.

Additionally, the variability in reporting mechanisms from different data sources (e.g. claims, registry, EHR) as well as rates of reporting can influence data collection, and therefore may not provide an accurate depiction or apples-to-apples comparison of measure performance. We encourage CMS to consider these variables, and continue to take a thoughtful approach in designing a process for identification and removal of topped out measures.

Both measure stewards and National Quality Forum uphold measure maintenance policies that include both a regular measure maintenance cycle and an off-cycle measure update process. The regular maintenance cycle allows for typically review of clinical evidence and update of the measure based on that evidence every three-years. An off-cycle measure update process provides for updates that are necessary during the intervening period to ensure that measures reflect current treatment guidelines and keep pace with an evolving evidence base. While CMS maintains a regular cycle, we recommend the application of a more formal off-cycle measure update process when measures do not reflect current treatment guidelines. Measures that conflict with guidelines could result in physician treatment selection that is not optimal for patients. In order to avoid a situation whereby measures in use do not reflect the current clinical guidelines, we suggest a more flexible feedback process in which CMS remains in close contact with the guideline developers and measure stewards on a more frequent basis, rather than waiting until the next regular open update period. This way measure stewards can notify CMS at the point that measures in use are updated so that they can be appropriately updated for the program in question, and in turn, CMS can make the updates when notified and adjust benchmarking and scoring accordingly.

Finally, we recommend that CMS follow the guidance from the Measures Application Partnership (MAP) on criteria for consideration for measure removal from any program measure set. As mentioned previously, due to provider self-selection of quality measures, there could be incongruent cohorts and utilization of measures, making the evaluation and benchmarking process difficult to ascertain which measures are topped out or present other methodological problems that warrant their removal. The MAP holds substantial expertise that can help guide CMS’ decisions.

C. RESOURCE USE PERFORMANCE CATEGORY

For the 2018 MIPS performance period, CMS proposes to adopt for the Resource Use category the following measures: Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Costs. Episode-based measures will be included in the cost performance category in future years as they are developed. MSPB and Total Per Capita Costs are currently used in the value-based modifier program, however these measures have repeatedly been called into question by stakeholders for their validity – the MSPB Measure has not been endorsed for use at the physician-level, and the Total Per Capita Cost Measures have yet to achieve endorsement. In the case of both measures, many concerns were raised by the members of the NQF Cost and Resource Use Steering Committee charged with their initial review. During the most recent maintenance review for the MSPB-Hospital measure, several commenters continued to express concern that this measure is proposed for use at the physician level without being validated and endorsed.33 For these reasons, we recommend against adoption of this measures.

As resource use measures for the MIPS evolve, we encourage CMS to establish clearer linkages between quality and resource use measures. In particular, any cost measures used should be reported in the context of appropriate quality data as a means of providing a framework for interpretation so that the cost data are not misused or misunderstood. In such a framework, cost measures must be aligned with the reported quality data to make the comparison between quality of care provided at cost expended an apples-to-apples comparison. Application of raw cost measures in the absence of meaningfully linked quality data could result in reduced provision of needed care and decreased adoption of new medically beneficial treatments in an effort to stem costs, especially when applied in an incentive program. This is one of our chief concerns with the current value-based modifier program, which pairs broad, total cost of care measures and quality measures that do not necessarily relate to one another. Well-designed quality measures can help to balance cost measures and ensure that patients are receiving the right types of treatment to achieve desired health outcomes.

D. CLINICAL PRACTICE IMPROVEMENT ACTIVITIES (CPIA) PERFORMANCE CATEGORY

CMS has proposed a number of activities that address health disparities and promote appropriate medication management, the incorporation of evidence-based guidelines into clinical practice, and patient engagement in treatment selection through shared decision-making. PhRMA supports including these types of clinical practice improvement activities because we believe that these activities, including activities that aim to prevent the misuse and abuse of prescription medications and those that promote adherence, have the potential to both improve the quality and reduce cost of care. These include, but are not limited to:

- Appropriate Use of Medications
  - Attestation of consultation of the prescription drug monitoring program to review patient’s controlled substance history prior to issuance of a controlled substance Schedule II opioid prescription (High)
  - Initiation of CDC Training on Antibiotic Stewardship (Medium)
  - Communication of Unscheduled Visit for Adverse Drug Event and Nature of Event (Medium)
  - Participation in a systematic anticoagulation program for practice patients who receive anticoagulation medications (High)
  - Attestation from eligible clinicians prescribing oral Vitamin K antagonist therapy (warfarin) that ambulatory care patients are being managed by certain clinical practice improvement activities (High)
  - Documentation of discussion of an anticoagulation management plan with a patient undergoing a planned invasive procedure or surgery in which interruption in anticoagulation is anticipated (Medium)

- Achieving Health Equity

Clinician leadership in clinical trials, research alliances, or community-based participatory research that identify tools, research or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes (Medium)

- Shared Decision-Making
  - Implementation of practices/processes to develop advance care planning (Medium)
  - Promote Use of Patient-Reported Outcome Tools (Medium)
  - Engagement of patients, family, and caregivers in developing a plan of care and prioritizing goals for action, documented in the EHR technology (Medium)

Better use of medicines is an integral part of the solution to improving outcomes for Medicare beneficiaries. There is strong evidence in the peer-reviewed literature that improving patient adherence offers one of the best opportunities to achieve better results and greater value from our health care system. In fact, the Congressional Budget Office (CBO) announced in 2012 that going forward, it will reflect offsetting savings in medical spending associated with use of prescription drugs. The CBO decision was based on extensive research showing that improved use of recommended medications is associated with improved health and productivity, as well as reduced total health care costs. Non-adherence has been estimated by IMS to cost the US health care system at least $105.4 billion annually.34

PhRMA also supports including activities related to shared-decision-making tools, as well as providing information on clinical trials in the options for the CPIA performance category of MIPS. Shared decision-making is a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as patients' values and preferences. According to one study of more than 1000 office visits in which more than 3500 medical decisions were made, less than 10% of decisions met the minimum standards for informed decision-making.35 Similarly, another study found that only 41% of Medicare patients believed that their treatment reflected their preference for palliative care over more aggressive interventions.36 We commend CMS for including such activities that recognize the time clinicians and community physicians take to provide information about clinical trials, so patients can be more informed and empowered to make health care decisions that best meet their needs.

In considering these activities, it will be important for CMS to ensure that shared-decision making tools are rigorous and patient-centered. The agency should promote transparency in the types of shared-decision making tools being recognized as CPIAs and consider developing criteria to ensure that these tools are focused on helping patients and physicians make an informed, individualized choice from among a range of care options, including clinical trial options. Ensuring transparency in the design of shared-decision making tools will have the added benefit of improving knowledge of the types of tools that are most effective.

Additionally, PhRMA supports the recognition and expansion of patient-reported outcome (PRO) tools as a CPIA, and option for the advancing care information bonus. We appreciate the examples of such tools CMS has provided, and are pleased to see that MIPS eligible clinicians may utilize EHR data to capture this information and incorporate patient generated health data. This is also consistent with CMS' view that PRO performance measures are considered outcomes measures. As health data increasingly becomes available electronically, we also

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encourage CMS to consider the role of digital technologies in improving care, and including related activities as part of continual clinical practice improvement for future consideration.

In the proposed rule, CMS indicates that CPIAs are weighted based on several factors, including alignment with national priorities and programs promoting expanded access, integrated behavioral health, and public health. A higher weighting translates into a higher performance score for clinicians who take on higher-weighted activities. We urge CMS to assign a “High” weighting to use of patient-reported outcome tools in order to encourage broader collection and use of patient-reported data about the quality of care received and outcomes achieved.

E. QUALIFIED CLINICAL DATA REGISTRY (QCDR) REQUIREMENTS

PhRMA recognizes and appreciates the promise of QCDRs as a new source of quality measures and quality data for the MIPS program and APMs. Many QCDRs have advanced capabilities for data collection, physician feedback, and reporting that hold potential to improve the caliber of quality measures that are collected while easing the administrative burden of quality reporting for physicians. Several QCDR entities are also actively developing new measures to fill measure gaps.

As more clinicians elect to use the QCDR reporting option, it will continue to be important to ensure that QCDR measures are methodologically rigorous, evidence-based, and that information on measure specifications is readily available. Although CMS is not proposing any changes to the criteria for data submission in this proposed rule, we appreciate the additional clarifications and expectations CMS is providing to existing criteria and encourage CMS to continue working with QCDRs to improve the transparency of the measure development and evaluation process for measures included in QCDRs. As an initial step to improve the availability of specification information for QCDR measures, CMS could consider including the list of QCDR measures available for current year reporting annual Medicare Physician Fee Schedule or Quality Payment Program Rule. This would provide an opportunity for stakeholders to consider these measures in conjunction with the CMS-proposed measures and offer comments that would inform CMS’ annual review of QCDRs.

CMS also seeks comment for future rulemaking on requiring that QCDRs fully develop and test their measures prior to submitting measures during the self-nomination process. PhRMA supports this additional requirement because it will better align the evidence requirements for QCDR measures with other MIPS measures, which undergo annual review by the MAP. Formal measure endorsement and review processes, such as those operated by NQF and the MAP, ensure that measures have successfully undergone the rigor of careful testing, validation, and scrutiny to ensure that they provide accurate, reliable, and meaningful results.

III. REQUIREMENTS FOR ADVANCED ALTERNATIVE PAYMENT MODELS (APMs)

A. NOMINAL FINANCIAL RISK

CMS proposes to maintain the nominal amount standard for Medicare Advanced APMs at 8 percent of average estimated total Medicare Parts A and B revenue of providers and suppliers in participating APM entities for the 2019 and 2020 performance periods. However, CMS seeks comment on whether or not to consider either a lower or higher nominal amount standard.

Consistent with our June 2016 comments on CMS’ Proposed Rule Regarding the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models\(^\text{37}\) and December 2016 comments on CMS’ Final Rule with Comment

Period, we believe that a lower nominal amount standard, including recognition of the substantial investment and risk that providers assume in one-sided risk models, may be more appropriate for the initial years of the Quality Payment Program.

As stated in our previous comments, many providers have only recently begun to explore two-sided risk models. If CMS were to set the nominal risk standard too high or increase the level of financial risk that an Advanced APM must take on too quickly, it could put a premium on cost-containment and discourage clinicians participating in Advanced APMs from providing high-quality innovative care. Doing so would have unintended effects on beneficiaries that are inconsistent with the overarching goal of the Quality Payment Program.

Most APMs are designed to shift greater care management risk to providers in order to encourage cost reduction through better care coordination, reducing hospital admissions and ER visits, reducing duplicative and unnecessary services, and finding other care efficiencies. If the financial risk required by the model exceeds the opportunity for better care management, APMs could have unintended consequences such as care stinting or cherry-picking of patients. This is also true of models that lack appropriate mechanisms to account for variation in patient risk, strong incentives for care quality, and mechanisms to account for innovative medical advances. In the absence of clear approaches to reduce costs, there is a risk that providers will turn to strategies that could include inappropriately standardizing treatments, steering patients to lower cost providers, reducing beneficiary access to items and services, or turning away more complex cases.

Further, for many of the models that we expect will meet the nominal financial risk criterion established in the Final Rule, it is too early to tell if the impact on program spending and care quality will be positive or negative. These two-sided risk models are in the earliest stages of implementation. For example, nearly 5 years into the Medicare Shared Savings Program, experience with two-sided risk accountable care organizations (ACOs) remains limited. Of the 375 ACOs participating in the Medicare Shared Savings Program in 2016, only 20 ACOs were accepting downside risk. For many of the CMMI models that we expect will meet the Advanced APM criterion, testing remains nascent. Testing for the Oncology Care Model, Next Generation Accountable Care Organization Program, and Comprehensive Care for Joint Replacement model began in 2016, and final requirements for CMS’ now-delayed cardiac bundled payment model have yet to be announced. As a result, CMS has little data available to understand the impact that these models – which are by definition experimental tests with unknown effects – are having on quality and access to care for Medicare beneficiaries.

As CMS makes final determinations for Medicare Advanced APMs, we encourage the agency to carefully consider the status of APM testing and its findings with respect to care quality and access. Consequently, we urge CMS to consider a lower threshold for the nominal financial risk criterion. The ongoing testing and evaluation of two-sided risk models will yield critical information about the best way to calibrate financial incentives to support cost efficiency without harming quality and access to care for patients. Prior to pursuing any increase in the financial risk standard going forward, we encourage CMS to evaluate its standard for nominal financial risk in light of model testing experience in order to ensure that the standard supports the provision of high quality care for Medicare beneficiaries.

B. SUBMISSION REQUIREMENTS FOR OTHER PAYER APMs

CMS proposes that submissions for Other Payer Advanced APMs must include the arrangement name, a brief description of the nature of the arrangement, participant eligibility criteria, locations where the arrangement will be available, evidence that the CEHRT criterion is satisfied, evidence that the quality measure criterion is satisfied, including an outcome measure, evidence that the financial risk criterion is satisfied, and other documentation as

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38 PhRMA Comments on Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models Final Rule with Comment Period. December 19, 2016.
necessary. CMS further proposes that it will post select information about Other Payer Advanced APMs on the CMS website. CMS proposes to include the names of payers with Other Payer Advanced APMs, the locations in which the Other Payer Advanced APMs are available, and the names of the specific Other Payer Advanced APMs.

PhRMA supports CMS’ proposal to post information about Other Payer Advanced APMs on the CMS website. We recommend that CMS also publish the brief description of the nature of the arrangement in addition to posting the names of payers, the locations in which APMs are available, and the names of specific APMs. Publication of this information would facilitate a broader understanding of the types of models that qualify as Other Payer Advanced APMs and aid researchers as they seek to understand implementation of the QPP and its impact on the Medicare program and patient care. Should CMS agree with our recommendation, it would be important for the agency to ensure that public descriptions of Other Payer Advanced APMs do not include commercially sensitive information.

IV. PHYSICIAN FOCUSED PAYMENT MODELS (PFPMs)

Because CMS currently defines a PFPM as a subset of APMs, any PFPM must be authorized by SSA § 1115A, SSA § 1866C, SSA § 1899 (MSSP ACOs), or another federal provision that “requires” a particular demonstration. Under SSA § 1115A and SSA § 1866C, CMS must test any models on a limited scale before implementing the model on a nationwide basis. While SSA § 1899 does not require limited-scale testing, it only applies to “eligible ACOs.” As a practical matter, CMS acknowledged that it “anticipate[s] PFPMs that are recommended by the PTAC and implemented by CMS will be tested under section 1115A authority.” This means that almost any PFPM recommended by the PTAC would have to be tested by CMS before it could be expanded nation-wide.

Current PTAC procedures, however, provide for recommending proposed PFPMs to CMS for “implementation” as well as “limited scale testing.” Specifically, the PTAC’s recommendation categories are as follows:

1. Do not recommend proposed payment model to the Secretary;
2. Recommend proposed payment model to the Secretary for “limited scale testing”;
3. Recommend proposed payment model to the Secretary for “implementation”; or
4. Recommend proposed payment model to the Secretary for “implementation as a high priority.”

These recommendation categories could be clarified so that they do not promote confusion by suggesting that models under SSA § § 1115A or 1866C can start with anything other than “limited-scale testing.” There is no point in the PTAC recommending that CMS “implement the proposed payment model” or “implement the proposed payment model as a high priority” (both of which suggest full-scale implementation, especially in the context of the PTAC’s current classification scheme) in the usual case where the model is authorized by SSA § 1115A and therefore can only begin with limited scale testing. Appropriate changes in the PTAC’s recommendation categories could align them better with the statute’s authorizing PFPMs and avoid creating a disconnect between PTAC recommendations and the CMS actions that result.

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39 SSA § 1115A(b) (requiring Phase I testing); SSA § 1866C(b) (requiring that CMS establish “demonstration program” under which the Secretary shall approve “demonstration projects” that meet certain criteria models can later be expanded using the same process and standards as under SSA § 1115A).
41 These recommendation categories are listed in PTAC’s Request for Proposals (last revised on February 21, 2017) and its Processes for Reviewing and Evaluating Proposed Physician-Focused Payment Models, which went through a comment period that ended on December 9, 2016 and was published on May 5, 2017.
PhRMA appreciates the opportunity to comment on the 2018 Quality Payment Program Rule. Please do not hesitate to contact us if we can provide additional information or answer any questions related to our comments.

Sincerely,

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