

January 26, 2016

The Honorable Orrin Hatch  
Chairman  
Committee on Finance  
United States Senate

The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Johnny Isakson  
Senator  
Committee on Finance  
United States Senate

The Honorable Mark Warner  
Senator  
Committee on Finance  
United States Senate

**VIA ELECTRONIC SUBMISSION TO: [chronic\\_care@finance.senate.gov](mailto:chronic_care@finance.senate.gov)**

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to the Bipartisan Chronic Care Working Group's Policy Options Document, released in December 2015. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Consistent with that mission, PhRMA continues to applaud the Committee for its commitment to the important issue of finding ways to improve outcomes for Medicare beneficiaries with chronic conditions.

Our comments are divided into two sections below. The first provides comment on policy options related to PhRMA's written comments provided to the Committee in June of last year. The second section provides comments on other topics that are addressed in the policy options document. Each section is organized by the order in which the policy appears appear in the document.

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### **Policy Options Related to PhRMA's June 2015 Comments**

#### [Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees](#) (p. 13)

PhRMA appreciates that the Chronic Care Working Group is considering a Value-Based Insurance Design (VBID) policy option to give plans greater flexibility in benefit design to improve the quality of care for Medicare beneficiaries with chronic conditions. PhRMA also suggested this policy idea in our June comments to the Working Group and we are pleased to see its inclusion in the Policy Options Document.

The Working Group is soliciting feedback on more detailed questions related to this policy option. Specifically, the Working Group asks about other types of requirements MA plans should be required to meet in order to improve care for beneficiaries with chronic conditions without disrupting care for other Medicare beneficiaries. Consistent with comments submitted to the Committee previously and to CMMI on the VBID model test announcement,<sup>1</sup> PhRMA believes it is critical that plan sponsors are not permitted to propose reductions in benefits or increased cost-sharing amounts as VBID interventions, whether for beneficiaries with chronic conditions who are targeted for these interventions, or for other beneficiaries who are not targeted interventions. Further, it will also be imperative to operationalize VBID interventions in the Part C and Part D bid submission process in a way that maintains the integrity of the existing bidding structures. Doing so will help ensure that VBID interventions do not result in increased costs (whether premiums or cost-sharing) or reduced benefits for any Medicare beneficiaries, whether or not they are targeted for VBID interventions.

Expanding Supplemental Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees (p. 15)

PhRMA supports the Committee's consideration of a policy to allow MA plans to offer a wider array of supplemental benefits than they do today. We suggest that the Committee consider clarifying that adherence support services are among the services that plans can offer as a supplemental benefit. Adherence support services can include a range of primarily non-medical services, such as reminders or tools that help patients take their medications as prescribed. As described previously, improvements in medication adherence have been shown to lead to reduced medical spending for many chronic conditions.<sup>2</sup> In addition, improvements in adherence are linked to improvements in patient health for many chronic conditions including hypertension and diabetes.<sup>3</sup> For these reasons, it would be beneficial to clarify that plans can provide adherence support services as a supplemental benefit.

Developing Quality Measures for Chronic Conditions (p. 22)

PhRMA supports the proposal for CMS to include the development of measures that focus on health outcomes for individuals with chronic disease in its measure development plan. Currently, patients with chronic disease (especially those with multiple chronic conditions) are not well represented in care guidelines, and this has resulted in a dearth of quality measures to assess care provided to these patients. We appreciate the Working Group's attention to measures of patient and family engagement and shared decision making in particular. Measures of both general and disease specific patient-reported outcomes are needed to assess quality of care from the patient perspective. Similarly, measures to promote shared

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<sup>1</sup> Submitted as attachments to these comments, for your reference.

<sup>2</sup> Ibid.

<sup>3</sup> Cutler DM, Long G, Berndt ER, et al. The value of antihypertensive drugs: a perspective on medical innovation. *Health Affairs*. 2007;26(1):97-110; and Gibson TB, Song X, Alimayehu B, et al. Cost sharing, adherence, and health outcomes in patients with diabetes. *Am J Manag Care*. 2010;16(8):589-600.

decision making and robust standards for shared decision making tools will support efforts to ensure that patients with chronic disease are receiving high quality patient-centered care that aligns with their values and preferences. In addition, we recommend that the development plan include measures of medication adherence, as medication adherence is correlated with improved patient outcomes and an important aspect of managing many chronic conditions.

Increasing Transparency at the Center for Medicare & Medicaid Innovation (p. 28)

PhRMA supports the Working Group's consideration of policies to improve transparency at the Center for Medicare & Medicaid Innovation (CMMI). Currently, CMMI is not required to issue notice and comment rulemaking for Phase I (testing) models, though they are required to do so for Phase II (expansion) models. As the Working Group notes, many of the concepts that CMMI is testing are complex and large in scope, and collecting robust public input is essential to ensuring the success of these demonstrations.

The Working Group seeks comment on which types of CMMI models should be subject to notice and comment rulemaking and when rulemaking should occur. PhRMA supports the proposal to require notice and comment rulemaking for all mandatory Phase I models and those models that will make fundamental changes to the Medicare program benefit. We also support requiring a minimum 30-day public comment period for all other types of Phase I models.

Rulemaking and public comment should occur prior to the issuance of a Request for Applications (RFA) for the Phase I model, and should address the key features of the model, including: the details of the payment methodology that will be tested, the quality measures that will be used, features of the model that will help to protect patient access; any waivers of federal law that will apply, and the methodology that CMMI will use to evaluate the model. CMMI should also describe in the rulemaking/public comment opportunity the mechanisms that will be used to account for new tests and treatments in the model. This is particularly important for models that rely on historical spending benchmarks, as these models are based on the current, not the future, standard of care and safeguards are needed to ensure that patients maintain access to new medical advances.

Requiring rulemaking and public comment prior to the issuance of an RFA for a Phase I model will ensure that the public is aware of new models and has the opportunity to offer comments and refinements prior to implementation of the model test. We recognize that rulemaking requirements must be balanced with the flexibility to innovate and make modifications to models during Phase I testing. Accordingly, we do not believe it is necessary for CMMI to issue rulemaking each time a model is modified. However, details of any modifications made should be posted on the designated page of the CMMI website to ensure that the public is aware of these changes.

## Study on Medication Synchronization (p. 29)

PhRMA appreciates the Committee's consideration of a study to identify potential obstacles to medication synchronization under Medicare Part D. Medication synchronization is a process of consolidating a patient's refills for multiple medications to reduce the number of trips he or she has to make the pharmacy. Medication synchronization can support adherence and also has potential to support better medication management by allowing the dispensing pharmacist to review all of the patient's medications at one time, identify any missing or duplicate therapies, and provide counseling as needed. Synchronizing medications can also enable use of compliance-based packaging at the pharmacy, which packages together medications to be taken at a particular time each day.

Initial evidence about the effect of medication synchronization suggests that it can improve adherence.<sup>4</sup> Improved adherence has been shown to lead to reductions in medical spending for patients with many chronic conditions.<sup>5</sup> A study exploring current barriers to medication synchronization under Part D could help identify changes that have potential to yield savings for the Medicare program.

We also support legislation to test medication synchronization interventions that has been introduced in the House of Representatives. The Synchronization & Nonadherence Correction (SYNC) Act of 2015 (H.R.4292) would require a demonstration testing three approaches to medication synchronization – synchronization, synchronization with compliance-based packaging, and synchronization with ongoing pharmacist counseling. This demo would offer an opportunity to formally evaluate the impact that medication synchronization interventions have on adherence – evidence that is currently lacking in the literature due to limited adoption of this promising intervention. The SYNC Act would also test 90-day fills at retail pharmacies, an intervention which shows great promise in improving adherence. Because current evidence around the effect of medication synchronization is so limited, there is need for a study testing the effectiveness of these interventions in the real world.

## **Other Issues in the Chronic Care Working Group Policy Options Document**

### Providing Continued Access to Medicare Advantage Special Needs Plans for Vulnerable Populations (p. 10)

PhRMA supports the Chronic Care Working Group's consideration of a long-term extension or permanent authorization of special needs plans (SNPs). Specifically, PhRMA supports the Working Group's consideration to require SNPs that enroll beneficiaries eligible for both Medicare and Medicaid (D-SNPs) to offer fully integrated services. Achieving better care for dual eligibles is important, and efforts to better

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<sup>4</sup> D. Holdford and T Inocencio. Appointment-Based Model (ABM) Data Analysis Report. Prepared for Thrifty White Pharmacy. Virginia Commonwealth University.

<sup>5</sup> Roebuck MC, Liberman JN, Gemmill-Toyama M, et al. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health Affairs*. 2011;30(1):91-99.

integrate services across Medicare and Medicaid preserves what works well in both programs and minimizes disruptions in coverage and care.

Highly integrated D-SNPs can serve as a vehicle for more coordinated, quality care, and provide critical protections to beneficiaries that are available in Medicare but not always available to low-income Medicaid beneficiaries. Since its inception in 1965, Medicare has included all beneficiaries in the same program. This has been an essential protection for vulnerable, low-income beneficiaries. States' primary focus of care for dual eligibles centers on long-term supports and services, not acute medical care. Medicare is innately qualified and experienced to serve the medical needs of the dual eligible population, and it is better suited to lead the integrated care needed by these vulnerable beneficiaries. In their March 2013 report, MedPAC found that requiring D-SNPs to simply enter into contracts with state Medicaid agencies had not resulted in desired clinical and financial integration between Medicare and Medicaid.<sup>6</sup> As such, a long term extension or permanent authorization of D-SNPs should explore requirements for plans to provide both clinical and financial responsibility for all Medicare beneficiaries while also providing fully integrated Medicaid services. For example, in their research on D-SNPs in 2013, MedPAC gave examples of two models of D-SNPs for which an incentive existed to clinically and financially integrate Medicaid benefits.<sup>7</sup> Examples such as the ones provided by MedPAC could be further explored as the criteria for D-SNPs are evaluated and a long-term extension or permanent authorization is considered. D-SNPs should also exhibit success in care coordination, including high levels of performance on relevant quality measures.

Additionally, centering integrated care for dual eligibles at the federal level not only prevents disruptions in care, such as dis-enrolling beneficiaries from their current Part D plans, it also protects the competitive bidding architecture in Part D. Winning low-income subsidy recipients/dual eligibles' enrollment is a key feature of the bid process that encourages Part D plans to bid low; preventing the removal of the dual eligible population from Part D protects against the potential of higher premiums or reduced benefits for other, non-low-income beneficiaries. High performing D-SNPs could not only provide better ways to coordinate coverage, they can help avoid market disruption and triggering new and unintended problems in other parts of Medicare.

#### Providing Accountable Care Organizations the Ability to Expand the Use of Telehealth (p. 17)

PhRMA supports the appropriate use of telehealth services and recognizes the potential benefits of modifying telehealth payment requirements for two-sided risk Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program (MSSP). However, while expanded telehealth has potential to improve patient access, care coordination, and efficiency, we are concerned that it could also add to the risk of abuse already well-documented in the Federal 340B prescription drug discount program administered by the Health Resources Services Administration (HRSA). Specifically, the broad definition of a "patient" under HRSA's current guidance could be stretched even further in an environment in which

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<sup>6</sup> Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy." March 2013, p. 325-326.

<sup>7</sup> Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy." March 2013, p. 326.

telehealth reimbursement requirements were loosened. We are concerned that this could threaten the quality of patient care by allowing for Medicare payment in cases where a provider lacks a bona fide relationship with the patient. This would undercut one of the ACO program's primary goals: to "promote accountability for a patient population."<sup>8</sup>

Because of these concerns, we recommend that the Committee consider delaying legislative action until Congress can evaluate the agency's experience with a telehealth waiver in the CMMI Next Generation ACO Model, set to begin in 2016. This would give time for both CMS and HRSA to work together to ensure that a waiver of telehealth requirements does not result in an expansion of the patient definition in the 340B program –precisely the type of "unintended consequences" CMS attempted to avoid when choosing not to finalize its proposed telehealth waiver in last year's final ACO rule. In the rule's preamble CMS stated it was not finalizing its proposed telehealth waiver (as well as other payment waivers) but instead would take a phased-in approach:

"[W]e continue to have concerns with immediately adopting untested or unproven waivers with which we have little experience on a national scale and could lead to unintended consequences for the FFS beneficiaries we serve or for the health care system more broadly...We intend to offer [a telehealth] waiver starting as early as in 2017, with specific requirements to be determined based on CMS' experience implementing such a waiver in the Next Generation ACO Model."<sup>9</sup>

If the Committee decides to move forward with its proposal we urge the inclusion of strong program integrity safeguards to ensure that the potential for abuse in the 340B program is reduced to the greatest extent possible.

#### Ensuring Accurate Payment for Chronically Ill Individuals (p. 19)

The Working Group is considering policy options to change the CMS-Hierarchical Conditions Category (HCC) Risk Adjustment Model and requests feedback on other potential changes to the model that should also be considered. One area the Working Group could consider exploring further is the addition of pharmacy claims to the risk adjustment model in order to improve the predictive accuracy of the model. In particular, the addition of pharmacy claims to the risk adjustment model could help improve risk adjustment accuracy for conditions where pharmacy data is more predictive of severity level. Additionally, it could help identify beneficiaries with chronic conditions whose care is currently being managed through the pharmacy benefit but may not currently require frequent physician visits. PhRMA would welcome the opportunity to discuss this topic further with the Working Group.

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<sup>8</sup> 79 Fed. Reg. at 72763. *Id.*

<sup>9</sup> 110 Fed. Reg. 32692, 32806 (June 9, 2015).

Providing Flexibility for Beneficiaries to be Part of an Accountable Care Organization (p. 21)

The Chronic Care Working Group is considering a policy that would allow for prospective assignment of beneficiaries to ACOs participating in Track 1 of the Medicare Shared Savings Program. Currently, prospective assignment is only an option for ACOs participating in Track 3.

PhRMA recognizes that prospective assignment makes it easier for ACOs to prepare for the risk they will assume in a given performance year, and plan for coordination of care. In order for ACOs to work, patients ideally would seek care with the ACO as often as appropriate. At the same time, allowing prospective assignment could result in unintended consequences, such as ACOs discouraging higher risk beneficiaries from seeking care within the ACO to avoid having these more costly beneficiaries assigned to the ACO; or ACOs creating inducements for assigned beneficiaries to only receive services within the ACO. For example, some commercial ACOs have already established incentives for patients to seek specialty care inside their organization, such as preferred referral lists (which may only include specialists within the ACO) or lower cost-sharing.<sup>10</sup> It is important that patients do not feel undue pressure from their healthcare providers or the ACO to seek treatment within the ACO. This is particularly true for ACOs that do not include a broad range of specialists; as this could impede patient access to specialist care that is appropriate for their clinical needs.

We encourage the Working Group to proceed carefully, and with attention to these potential unintended consequences. It will be particularly important to ensure that CMS has mechanisms, such as robust quality measures, in place to monitor for potential patient steering or other access issues.

The Working Group is also considering a recommendation that Medicare beneficiaries have the ability to voluntarily elect to be assigned to the ACO in which their primary provider is participating. PhRMA supports allowing beneficiaries to attest to their participation in ACOs. Implementing beneficiary attestation is a positive step towards allowing beneficiaries to actively enroll in the ACO of their choice, and would also address many of the patient selection issues raised above. It would also reduce concerns about inappropriately encouraging patients to receive care within the ACO by allowing for greater beneficiary choice of ACO. Beneficiary attestation would also reduce the issue of patient churn in ACOs, which under the current attribution methodology averages 24%.<sup>11</sup>

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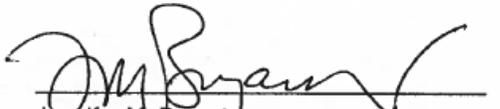
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<sup>10</sup> DeCamp, M. and Soleymani Lehmann, L. "Guiding Choice — Ethically Influencing Referrals in ACOs." *New England Journal of Medicine*. Jan 15, 2015

<sup>11</sup> M. McClellan, et al. "What the New MSSP Proposed Rule Means for ACOs." *The Brookings Institution*. Dec 2014.

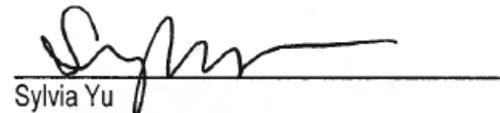
PhRMA appreciates the opportunity to submit comments in response to the Bipartisan Chronic Care Working Group's Policy Options Document. PhRMA remains committed to working with you on these important issues and welcomes the opportunity to discuss our comments in greater detail.

Sincerely,



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Jennifer M. Bryant  
Senior Vice President, Policy and Research



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Sylvia Yu  
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