



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

May 9, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016

[Submitted electronically to www.regulations.gov]

Re: Medicare Program; Part B Drug Payment Model (CMS-1670-P)

Dear Acting Administrator Slavitt:

APhA is pleased for the opportunity to provide input to Centers for Medicare & Medicaid Services on the Medicare Program; Part B Drug Payment Model proposed rule (the “Proposed Rule”). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, physician office practices, hospice settings, and the uniformed services.

APhA appreciates the intent of CMS in its Proposed Rule to test alternative drug payment designs that will lead to reduction in Medicare expenditures while preserving or enhancing the quality of care provided to patients. Although APhA supports such efforts to minimize waste and maximize the beneficial impact federal health care resources can have on patients, we have concerns that some of the efforts identified in the Proposed Rule may impact patients negatively, especially with regard to patient access and quality of care.

I. Impact on Patient

In the Proposed Rule, CMS offers two phases for the Part B Drug Payment Model – the first phase implementing a variation of the average sale price (ASP) add-on payment¹ and the

¹ See 81 Fed. Reg. 13229, 13232, Table 1, *Summary of the Proposed Model*, Phase 1 ASP listed at [ASP + 6%(control)] and [ASP + 2.5 % and Flat Fee Drug Payment] and Phase 2 listed as [ASP + 6% (control)], [ASP + 6% with VBP Tools] and [ASP + 2.5% and Flat Fee Drug Payment] and [ASP +2.5% + Flat Fee Drug Payment with VBP Tools].

second phase implementing a value-based purchasing² in addition to the changes in phase I. As stated previously, while APhA is supportive of efforts to use Medicare resources more effectively, we want to make certain the proposed phase I and phase II changes do not negatively impact patients. For example, CMS will need to assess whether patient access is affected. APhA could foresee some providers needing to change their business model by relying on increased patient volume to make up for lower reimbursement, which could result in provider consolidation or relocation to geographical areas that can support increased volume of patients. In addition, the proposed payment models may ultimately incentivize manufacturers to contract with select providers, which could further restrict patient access by creating narrow distribution networks. APhA believes that phase II changes could limit patient access even more, especially through implementation of outcomes-based risk sharing agreements between CMS and manufacturers that link payment for drugs to patient health outcomes. As CMS is aware, patient access is critical to optimizing the impact of medications. Therefore, APhA recommends that when CMS is developing measures to evaluate the impact of the proposed models on patients, it considers and implements access standards, similar to those in Part D, that will be used to assess actual patient access.

II. Role of the Pharmacists

CMS states repeatedly throughout the Proposed Rule its desire to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare beneficiaries. Although CMS's particular focus in the Proposed Rule is on identifying ways to more effectively pay for Part B medications and produce savings in Medicare, there is not one reference to pharmacists, the health care professional with more medication-related education and training than any other member on the patient's health care team. APhA is supportive of CMS continuing to incorporate quality and innovative health care delivery into its payment policies. APhA has also applauded CMS's efforts to advance the Three Part Aim³ of better care for individuals, better health for populations, and lower costs through new value-based care delivery models. Pharmacists help achieve the best possible health outcomes from the use of medications through various types of medication-related services. These services include working collaboratively with physicians and other healthcare providers in recommending specific medications or changes in medications.⁴ The pharmacist's role in optimizing the impact of medications on the patient is critical and government policies should not disincentivize the health care team utilizing the pharmacist in this role. APhA encourages CMS to better include the role of the pharmacist in the effective and efficient delivery of team-based care into policies, like regulations and guidances.

III. Evaluation of New Models

CMS notes in the Proposed Rule that it exercises its authority to test whether proposed alternative drug payment designs will lead to spending dollars more wisely for Part B drugs and

² See 81 Fed. Reg. 13229, 13232, providing examples of value-based tools including value-based pricing and clinical decision support tools.

³ See Centers for Medicare & Medicaid Services, *CMS Grand Rounds: CMS Quality Strategy*, presented June 2, 2014, last accessed May 9, 2016 at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Slides-for-CMS-Grand-Rounds-on-CMS-Quality-Strategy-held-on-06-02-2014.pdf>

⁴ See Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care*. 2010;48(10):923-933.

reduce Medicare expenditures, while preserving or enhancing Medicare beneficiary quality of care. APhA wants to underscore the need for CMS to look comprehensively at Medicare expenditures when evaluating the cost effectiveness of any new payment or delivery model. Because of the fragmentation of the Medicare program (i.e. Part A, Part B, Part C, Part D), in order to truly assess the cost impact of new Part B drug payment models, CMS needs to include the impact these models will have on hospitalizations and/ or Part D drug expenditures. For example, while phase I or phase II drug payment designs may lower drug costs in Part B, changes in provider prescribing or patient access could result in higher hospitalizations or Part D drug utilization. Therefore, unless the cost impact to all parts of the Medicare program are included in the evaluation of these new pricing models, CMS could falsely attribute savings to them.

Furthermore, APhA is concerned that CMS will not be able to assess the impact that these new models will have on patients. While the Proposed Rule acknowledges the need to evaluate the impact on quality of care, access to care, timeliness of care and the patient experience of care, CMS does not provide any detail on how it will measure these patient-related outcomes. Prior to implementation of any model test, CMS needs to make certain that costs and impact to the patient can be adequately and accurately evaluated.

IV. Implementation Timeline

APhA recommends that CMS delay implementation of phase II, value-based purchasing (VBP), until it receives data on the impact of phase I. As mentioned previously, while we are supportive of making changes in the Medicare programs that increase efficiencies and effectiveness of care to patients, we are concerned that patients may be negatively impacted from phase I. Before making additional changes, results from phase I should be evaluated. In addition, the data received from phase I may be useful in developing and refining phase II models. Finally, implementation of phase I or II should not occur until CMS is able to accurately measure the impact these models will have on patients and Medicare costs as a whole.

We appreciate CMS's continued work to spend health care dollars more cost-effectively for the benefit of the Medicare Program and its beneficiaries. As CMS moves forward, we hope you will use APhA as a resource. Thank you again for the opportunity to provide information on this important issue. If you have any questions or require additional information, please contact Stacie Maass, Senior Vice President, Pharmacy Practice and Government Affairs, at smaass@aphanet.org or by phone at (202) 429-7533.

Sincerely,



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Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs