May 9, 2016

[Submitted electronically to www.regulations.gov]
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Docket CMS — 1670 — P for "Medicare Program; Part B Drug Payment Model (CMS-1670-P)."

ASHP is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed Part B payment demonstration (the "Model"). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 43,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 70 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP appreciates CMS's ongoing efforts to enhance healthcare quality and value, and we support the Model's goal of reducing Medicare spending, while improving care and maintaining patient access. After careful review and analysis of the Model, we remain concerned that the Model's scope, timeline, and methodology could negatively impact patient access and quality of care. The Model's extremely aggressive timeline alone raises red flags, and CMS's decision not to solicit any input from key stakeholders — including physicians, pharmacists, and patients — prior to proposing a mandatory demonstration program magnifies the issue. Given the Model's potential to disrupt care, coupled with what will surely be costly implementation and oversight, ASHP urges CMS to rethink and restructure the Model with input from stakeholders and patients. A considered, collaborative approach has worked for other demonstration programs; in departing from best practices in this case, CMS will miss an opportunity to engage experts in crafting a demonstration project that can meet our shared goals without undermining care or destabilizing patient access. To assist CMS in this process, we have highlighted risk areas in the Model and proposed alternative approaches to certain elements in the Model.

I. The Model's timeline and scope threaten patient access.

As noted above, while we support the Model's goals, its proposed timeline and scope could disrupt patient access and reduce quality of care. Generally, we question the imposition of a large-scale mandatory demonstration program without first testing its methodology in smaller, more targeted pilot programs.

A. *Timeline of Model*

Although we appreciate the importance of data, the Model presents clear risks for patients, including provider disruption and care delays, which outweigh the value of comprehensive data on pricing of all

Part B medications. Further, due to the randomized nature of Phase I and a rapidly approaching target start date, providers will have minimal time to prepare for changes that can significantly impact their budgets and ability to continue certain patient care services. This issue seems likely to intensify for Phase II, which includes only vague descriptions of potential models, but which is slated to be rolled out only a year after Phase I begins. With no previous opportunity to engage with CMS on the Model and without adequate time to plan for these changes, it will be extremely difficult for providers to implement programs in a way that protects patients from unintended negative consequences. Therefore, as noted above, we advocate for collaborative revision of the Model's scope and timeline.

B. *Scope of Model*

Broad Inclusion of Part B Drugs: ASHP suggests that the Model's broadly inclusive approach fails to target medications appropriately and may create negative consequences for patients. While we understand that CMS seeks to gather data on prescribing practices, the Model is premised on two erroneous assumptions: 1) that prescribing decisions are intrinsically linked to profit margins; and 2) that there are always lower-cost alternatives to higher-cost medications. Regarding the first assumption, due to medication purchasing practices, prescribers are often unaware of the purchase price of medications, which would also make them unaware of any prescribing incentives. Prescribers choose the best therapeutic option for their patients — and the best option may be a higher-cost medication. Further, for some drugs, such as rituximab and CMV immune globulin, the best option is also the only option. Given the time constraints of the comment period, we could not fully survey our members regarding drugs with no lower-cost alternatives, which raises concerns that there are similarly situated medications that have not yet been identified. To safeguard patients, we suggest limiting a demonstration of this type only to medications that have known lower-cost equivalents.

Additionally, while we were pleased that CMS excluded drugs in "short supply," we are concerned that CMS defines this term too narrowly. Relying solely on the FDA shortage list would offer only a piece of the shortage picture.[1] Coupled with CMS's proposal to require that a drug appear on the FDA shortage list at the time the Model's quarterly price report is produced, a narrow definition of shortage could exacerbate access problems. Thus, the FDA list should be supplemented with other recognized lists, including, but not limited to, the ASHP shortage list.[2]

Impact on Existing Models and Demonstrations: ASHP supports expansion of alternative payment models (APMs) linked to quality and value. Although some of the proposed Phase II value-based payment models sound promising, we question how CMS will overlay multiple models on systems

[1] *See, e.g.,* Sheri Fink, "Drug Shortages Forcing Hard Decisions on Rationing Treatments," NY Times (Jan. 29, 2016), *available at* http://www.nytimes.com/2016/01/29/us/drug-shortages-forcing-hard-decisions-on-rationing-treatments.html?_r=0 and ASHP, "Understanding and Managing Drug Shortages" (2002), *available at* http://www.ashp.org/DocLibrary/Policy/DrugShortages/DShort-abbott-drug.aspx.

[2] *See* ASHP Drug Shortages Resource Center, *available at* http://www.ashp.org/shortages and ASHP, "Contrasting the FDA (CDER) and ASHP Drug Shortage Websites: What are the differences?," *available at* http://www.ashp.org/DocLibrary/Policy/DrugShortages/FDA-versus-ASHP.pdf.

with ongoing APMs and demonstrations without interfering with them. ASHP requests that CMS clarify how both phases of the Model will interact with new and existing APMs. Specifically, how will CMS treat the Model under the new MIPS and MACRA proposals? Will the Model be treated as an APM? Will CMS be able to control for Model participation when evaluating providers through other APMs and demonstrations — particularly after Phase II is rolled out? Based on feedback from our members, if the Model is implemented as proposed, it could create a chilling effect on provider participation in other APMs. Members indicated that logistical and administrative burdens created by the Model, particularly for providers with practice sites in different model arms, would make them less likely to participate in other CMMI demonstrations or APMs simultaneously. Absent clear evidence that CMS has considered the Model's impact on, and interaction with, current APMs and demonstrations, we are concerned that it may distort program results and undermine participation in value-based programs/models.

II. The Model may disrupt patient access and care quality, while failing to provide patients with immediate, measurable benefits.

Patient Costs: Optimal, safe, and effective medication use is impossible without actual patient access to medications, and medication costs can hinder patient access to vital medications. ASHP is committed to finding workable solutions to this problem, but CMS provides no evidence that Phase I of the Model will result in concrete patient savings. CMS notes that it "doesn't expect a sizable overall reduction in Part B drug spending associated with phase I of this model, but we do anticipate an incentive to use higher-value drugs."[3] CMS makes no claim that any cost savings in the system will be passed on to beneficiaries in the tangible form of reduced out-of-pocket costs. Further, as discussed below, the Model carries serious unintended negative consequences for patient access — yet these risks are not balanced by reward in the form of unambiguous gains for patient access and outcomes.

Patient Access: Based on discussions with our members and other clinician stakeholders, ASHP anticipates that payment changes in Phase I will likely result in a significant shift of patients from community settings to hospital outpatient departments. The proposed Model test payment (2.5% of ASP + $16.80) does not cover the overhead and handling costs for many medications in the hospital and health-system setting[4] — and it seems likely that this would also be true in community settings. Given the limited comment period, we were unable to survey members regarding drugs that are "under water," but anecdotally our members indicate that there are examples at all price points, including infliximab, a higher-cost biologic. Additionally, members indicate that the reduced payment (particularly when the cost of sequestration is factored in) may result in losses on a number of other drugs, including ipilimumab and melphalan. Reimbursement reduction may limit the ability of providers to offer certain services (e.g., infusions), leaving hospital outpatient departments as the only alternative. The resulting

[3] 81 Fed. Reg. 13239 (Mar. 11, 2016).

[4] ASHP has consistently advocated for a reimbursement rate of ASP + 6% in its comments on CMS's annual Hospital Outpatient Prospective Payment System rules. As noted in these comments, the 6% rate allows hospitals to cover their costs. Factoring in sequestration's impact, hospitals already face reimbursement rates lower than the minimum required to cover the costs of core pharmacy services — and the Model would further reduce reimbursement.

disruption of provider-patient relationships would fragment care, complicate beneficiary access, and increase pressure on hospital outpatient departments.

We commend CMS for addressing patient safety by offering a prior approval process for Model drugs and proposing to implement a "real-time claims monitoring" system to monitor beneficiary access. However, as proposed, neither fully safeguards patient access. Prior approvals come at the cost of increased administrative burden and delays for patients. We believe prior approvals should be a last resort, not a solution for the larger medication access issues that the Model may generate. As noted above, not all medications have acceptable lower-cost equivalents — for providers who prescribe those drugs, prior approvals will be the rule rather than the exception. Similarly, CMS's proposal to implement a "real-time claims monitoring process" to protect patient access lacks sufficient detail. Our understanding is that developing this system would require, at minimum, extensive technology upgrades plus personnel support and oversight. Further, it is unclear how access problems would be identified and resolved. Given how essential effective monitoring is to ensuring patient access, we request that CMS clarify how the monitoring process will work in practice.

Again, we reiterate our support for the Model's underlying goals, and we thank CMS for its efforts to improve care and reduce Medicare spending. However, based on the concerns highlighted above, ASHP advocates for significant revisions to the Model's scope and timeline after comprehensive, meaningful consultation with stakeholders, including physicians, pharmacists, and patients. As CMS continues its work on the Model, ASHP is eager to collaborate with other industry stakeholders and assist CMS in any way possible. Please contact me via email at jschulte@ashp.org or by phone at (301)-664-8698) if you have any questions or wish to discuss our comments further.

Sincerely,

Jillanne M. Schulte, JD
Director, Federal Regulatory Affairs