AMCP | Academy of Managed Care Pharmacy®

December 31, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs; [CMS-5528-ANPRM]

Dear Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to provide comments in response to Centers for Medicare & Medicaid Services' (CMS) Advanced Notice of Proposed Rulemaking (ANPRM) on the *Medicare Program; International Pricing Index Model for Medicare Part B Drugs; [CMS-5528-ANPRM]*. AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP shares CMS's concern with the rising cost of prescription medications in the United States. AMCP is pleased to see a commitment by CMS to evaluate methods to reduce prescription drug spending in Medicare Part B and believes that there is an opportunity for CMS to address this issue by leveraging and improving upon the previous Competitive Acquisition Program (CAP) under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and implementing other market-based solutions for Medicare part B.

Generally, AMCP is supportive of CMS's efforts to lower prescription drug prices. However, we are concerned that some of the elements outlined in the ANPRM need further consideration to ensure that they are sustainable solutions for decreasing medication costs before making substantial changes to existing programs. Before proposing a rule in the Spring, AMCP urges CMS to consider our comments and others' comments.

Distinct Issues in IPI Model Should Be Handled Separately

As written, the ANPRM seeks to address two complex issues that would better be handled in two separate rulemakings. First, CMS suggests the potential to utilize Model Vendors to negotiate drug costs with manufacturers, inspired by Medicare Part D's use of competing private-sector companies. Secondly, CMS

suggests a potential reimbursement model for Part B drugs purchased from manufacturers based on a new International Pricing Index (IPI), phased in over a five-year period using a vendor. While these issues are interconnected in some ways through their impact on the system, they are fundamentally different. Once in practice, the concepts would eventually be interdependent but currently, each is a complex issue and need to be considered on its own merits before brought together into one proposed rule. If considered separately, there is greater chance that the highest impact to lower prescription drug costs could be realized with broad, high quality and focused feedback to CMS from stakeholders.

IPI Model Should Allow for the Use of Utilization Management Tools and Formularies

AMCP is concerned that the ANPRM does not specifically include the use of utilization management tools, such as step therapy or prior authorization under the new purchase and payment system. These tools are elements that have been critical to decreasing costs, improving quality, and increasing value in the Medicare Part D Program and the commercial market. Furthermore, the flexibility to implement well-designed, evidence-based utilization management tools optimizes patient outcomes by ensuring that patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost.

In August 2018, CMS announced that Medicare Advantage Plans would have the choice to implement step therapy and prior authorization for Part B drugs beginning in January 2019.[1] The IPI model would provide for a different interpretation of Medicare Part B that is inconsistent with establishment of utilization tools in other parts of the Medicare program that allow for flexibilities in utilization tool use.. In order to better negotiate drug prices in the IPI model, CMS should align its Programs to allow for the appropriate use of utilization management tools facilitated by Model Vendors. Thus, if CMS moves forward with a proposed rule to implement a new payment system for Medicare Part B, it should specifically outline its allowance for step therapy and utilization management.

Additionally, AMCP supports the use of well-designed and evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs. Generally, a formulary is developed and maintained by a Pharmacy & Therapeutics (P&T) Committee, comprised of physicians, pharmacists, and other health care professionals, that meet regularly to review and evaluate the medical and clinical evidence from literature, relevant patient utilization and experience, economic data, and provider recommendations to determine what drugs are the safest, most effective, and produce the best clinical outcomes. AMCP strongly encourages CMS to consider the inclusion of a drug formulary—in addition to utilization management tools—to support the goals of the IPI Model.

The IPI Model Should Outline Enforcement Mechanisms to Encourage Better Negotiation

The ANPRM outlines how CMS would pay a Model Vendor for Part B drugs based on international prices using an IPI but does not provide any negotiating tools or regulatory authority for the Model Vendor to use in

[1] "Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs." Accessed December 10, 2018. Available at https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.

negotiating with pharmaceutical manufacturers. For example, if the Model Vendor negotiates a better price than the IPI, CMS should specific that it will not interfere with the ability of the Model Vendor's negotiation. If CMS proposes a rule, it should outline the mechanism to encourage better negotiation without unnecessary government interference.

IPI Model Concept Design

AMCP is supportive of innovative models that seek to lower the cost of prescriptions drugs but cautions CMS that the scope of the model in the ANPRM may be too broad. CMS is anticipating that the geographic area selected for the model would include approximately half of all Medicare Part B spending in the United States and thus have an impact on a significant number of Medicare beneficiaries. AMCP is concerned that a model this large would require significant and complex changes that could have negative implications for patients and the health care and distribution systems.

Moreover, we are concerned that this proposal appears to be a departure from a true pilot where CMMI administers focused demonstrations and, if proven to be successful, moves forward with wider nationwide implementation. AMCP strongly encourages CMS to focus on a smaller, but still statistically significant, sample of a geographic area.

Pharmacists as Key Members of the Health Care Team

In the ANPRM, CMS asks for feedback on how to monitor beneficiary outcomes, as well as patient experience, in a way that minimizes burden on included health care providers and beneficiaries. Pharmacists play a critical role as members of the health care team by serving as medication management experts to help patients achieve clinical goals, reduce overall health care costs, and improve patient satisfaction. Furthermore, pharmacists, in collaboration with other health care providers and patients, provide valuable, ongoing, comprehensive assessment of patient-specific clinical outcomes and reduction in overall cost of care.

The team-based approach to health care, to include pharmacists, plays an integral role in the successes demonstrated in Medicare Part D and the commercial market. For these reasons, AMCP strongly suggests that any model proposed by CMS that seeks to achieve better outcomes for beneficiaries in Medicare should include pharmacists as a key member of the health care team.

Quality Measures in IPI Model Should Be Outcomes Based

In the IPI Model, CMS is considering collecting quality measures to help better understand the impact of the IPI Model on beneficiary access and quality of care. AMCP strongly suggests that CMS adequately detail how it will assess the impact of the IPI Model on the quality of care delivered to Medicare beneficiaries. Quality metrics in the IPI Model should be based on existing metrics proven to improve outcomes and not rely on process-based measures. AMCP strongly suggests that detailed quality metrics and patient outcomes that will be used to determine what constitutes ultimate success is critical to outline in advance of a proposed IPI Model.

Thank you for the opportunity to comment on the IPI model. AMCP appreciates your consideration of the concerns outlined above as it further considers development of the IPI model. We look forward to working with the Administration to address the rising cost of prescription drugs in a manner that is attainable, practical, and sustainable. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer