American Academy of
Allergy Asthma & Immunology

December 31, 2018

Seema Verma, MPH
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-5528-ANPRM
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

Established in 1943, the AAAAI is a professional organization with more than 7,000 members in the United States, Canada, and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We appreciate the opportunity to provide feedback on the Administration's advance notice soliciting comment on potential options it may consider for testing changes to payment for certain separately payable Part B drugs and biologicals.

Background

Through a recent Advance Notice of Proposed Rulemaking (ANPRM), CMS discussed a model concept design for an "International Pricing Index Model (IPI)" that would initially focus on Part B single source drug and biologics that comprise a high percentage of Part B drug utilization and spending. The five-year model, anticipated to begin in spring 2020, would be tested through CMS' Innovation Center and require participation from physicians, hospitals, and potentially other providers and suppliers in randomly selected geographic areas.

Under the model, private-sector vendors would negotiate prices for drugs with manufacturers, take legal title to drugs, and compete for physician and hospital contracts. Over the five years of the model, CMS would reduce the Medicare payment amount for included drugs to more closely align with international prices. Participants, such as physicians, would be paid a "flat fee" instead of the current percentage-based add-on to Average Sales Price (ASP). CMS would distribute these flat fees from

(more)

a “pot” of money equaling a 6% ASP add-on, i.e., CMS would calculate what the agency would have paid to demo participants absent the model and without sequestration and then redistribute that money as flat fees, based on an as yet unknown distribution formula.

Despite the well-intended effort of the Administration to address the rising cost of pharmaceuticals, we are deeply concerned with the model as described in the ANPRM. This is particularly true given the current use of Part B drugs in allergy/immunology, and anticipated new drug therapies on the horizon.

Mandatory Nature of Model Concept

As we stated in our comments on the Innovation Center’s “New Directions” Request for Information (RFI), AAAAI has significant concerns with models that mandate participation by providers, and thus, their patients. At a minimum, models that auto-enroll participants should provide an opt-out mechanism. Our concern about mandatory participation is exacerbated when the demo is large-scale, as this one will be if the Administration moves forward with its goal of including 50% of Part B drug expenditures.

In addition, we generally support the use of financial incentives to facilitate participation in demonstration projects and funding that assists providers with costs associated with infrastructure, data and analytical capabilities, staffing, and capital to assume downside-risk. However, in the case of this model, more financial and administrative burdens are shifted onto providers, as explained below.

Model Concept Design: Model Vendors

We are deeply concerned about the proposed model vendors and their role in negotiating prices for drugs, which is similar to the role of today’s pharmacy benefit managers (PBMs) in Part D. If CMS’ aim is to demonstrate a new, innovative concept for lowering drug prices, we strongly urge the agency to consider allowing physician practices to work directly with manufacturers to negotiate prices – eliminating middlemen altogether. As we’ve observed in the current market, PBMs have a significant cost, with very little return for any stakeholder they supposedly serve. Now is the time to take a new approach, streamlining the process and distribution channel to eliminate as much wasteful spending as possible. In our experience, every stop in the supply chain provides an opportunity for markup. This adds no value for the ultimate consumer: the patient.

In light of the above, we appreciate the Administration’s suggestion that providers could be vendors. However, we urge the Administration not to unduly complicate the process for providers to take on that role. For example, the idea that a vendor should serve nationwide, as suggested in the ANPRM, will effectively exclude many providers from the vendor role. A smaller scale, voluntary model that experiments with changes to ASP but in which providers could purchase directly from manufacturers to serve the needs of their practice seems more feasible and far less convoluted.

Finally, with regard to vendors, under no circumstances should utilization management become part of these entities’ responsibilities. Again, we have experience with PBMs in other parts of the Medicare program and do not wish to replicate their aggressive utilization management techniques because they compromise patient access to needed treatment. If the demo moves forward, we urge CMS to include a clear prohibition on utilization management by vendors. In Medicare Advantage, the Administration plans to lift a longstanding ban on step therapy for Part B drugs and we are concerned that this is indicative of the agency’s openness to additional utilization management in the Medicare program.

Model Concept Design: Burdens on Providers

We are concerned by the Administration's proposal to make providers bear distribution costs for drugs in the model. That is an added financial burden and it is unclear why providers should be responsible for distribution costs. If the Administration moves forward with the concept of creating third party vendors, then manufacturers or the Administration itself should bear the cost of distribution. Providers should not have to pay third party vendors a fee, especially considering that we do not wish to contract with these entities in the first place.

Furthermore, while providers collect cost-sharing in Part B, this is not the case in Medicare Advantage, where specialty pharmacies act, in many ways, as the vendors the Administration envisions in the demo. The specialty pharmacies collect cost-sharing amounts from beneficiaries or supplemental insurers. If the Administration moves forward with the concept of third party vendors, these entities should be made responsible for cost-sharing collection. It is particularly concerning that the Administration is considering reducing reimbursement to providers for other services to reflect the cost-sharing amounts providers must collect. To cut reimbursement on an unrelated service would be extremely concerning in cases when the provider is unable to collect the cost-sharing amount. Providing demo participants with access to bad debt collection is insufficient to ameliorate this concern, as bad debt payments are usually only a fraction of what is actually owed.

Finally, we urge CMS to provide an opt-out mechanism for practices that are underwater as a result of their participation in the IPI. If a participating practice cannot maintain a positive margin on medicines acquired from the IPI vendor(s), it should be allowed to opt out of the IPI and return to the existing buy-and-bill system, in order to avoid a disruption in Medicare beneficiary access. Such a mechanism should consist of a fast, efficient process that is procedurally transparent.

Model Concept Design: Add-On Payment

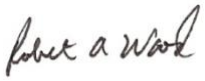
As described above, the Administration wants to move away from a percentage-based add-on payment to ASP. However, the model does not accomplish this. While it manages to delink the add-on from the individual product, the global payment "pot" will be based on ASP plus 6%. The result will be that, when ASPs drop as a result of the model, the funds available for add-on payments will drop as well. Yet, the cost of administration grows like all medical services, regardless of the price of the drug. If the Administration wishes to completely divorce the add-on payment from the ASPs, we urge CMS to conduct a comprehensive, in-depth survey of administration costs and set a flat fee amount based on real-world data. That fee should be grown at the rate of medical inflation each year. This is a more rational and complete way to move away from reimbursement based on ASPs.

While we support the concept of a bonus pool based on evidence-based prescribing, we are dismayed at the concept of bonuses being awarded to providers simply for prescribing the least expensive medicines. This idea is the result of the Administration's continued assertion that payments influence the clinical judgment of prescribers. We do not believe this to be the case but we agree that, if such influence exists, it is negative. Thus, we are disappointed at the fact that the Administration condemns it in the context of the ASP add-on percentage but would endorse it in the case of a bonus pool. Furthermore, such a concept would punish those providers who care for the sickest and costliest Medicare beneficiaries. We urge the Administration to create a bonus pool for physicians who practice evidence-based utilization and follow guidelines developed by their relevant societies.

*****

To discuss these comments further, please contact Renee Vandlik at RVandlik@aaaai.org or 414-272-6071. She will facilitate further communication with AAAAI leadership.

Sincerely,



Robert A. Wood, MD FAAAAI
President