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December 31, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Response to International Pricing Index Model for Medicare Part B Drugs
(CMS-5528-ANPRM)**

Dear Administrator Verma:

On behalf of the Healthcare Distribution Alliance (HDA), we appreciate the opportunity to provide comments to the Advance Notice of Proposed Rule Making regarding the International Pricing Index (IPI) Model for Medicare Part B Drugs (IPI Model). We share CMS' interest in testing innovative pathways to reduce patient costs while improving outcomes for Medicare patients. We recommend that CMS continue to work with all stakeholders, including patient advocacy groups, to explore voluntary models that focus on improving care delivery holistically and incentivize use of clinically effective, lower cost treatment alternatives. However, our past experience with a Competitive Acquisition Program (CAP) suggests that it will not succeed at lowering Medicare Part B drug costs and could negatively impact patient access to necessary medicines. As a result, we, along with all of our member companies, cannot support the IPI Model.

HDA is the national trade organization representing primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Our primary function in the pharmaceutical supply chain is to ensure the safe and efficient distribution of prescription medicines to healthcare providers and the patients they serve and care for.

While we cannot support the IPI Model, we are committed to working with you and Secretary Azar to help improve access to lower cost, high quality medicines for Medicare beneficiaries.

Role in the Supply Chain

By way of background, it may be helpful to describe the current role of distributors in the U.S. healthcare supply chain. While it is an extremely complex system with multiple players, it is also one of the most sophisticated and efficient distribution systems in the world.

On a daily basis, pharmacies, hospitals and other healthcare providers place orders with HDA distributor members for the medicines, supplies and equipment they need to serve their patients. In turn, distributors maintain distribution centers that are stocked with every potential medicine, supply and piece of equipment their provider customers may need. This includes carrying a full line of products from almost all pharmaceutical manufacturers as well as many over-the-counter drugs and consumer goods.

HDA distributor members purchase drugs directly from manufacturers of FDA-approved medicines. Unlike third party logistics providers, primary pharmaceutical distributors actually take title to (own) all of the products that enter their warehouses. They inventory all products in secure and controlled facilities. Cold chain products are kept in refrigeration units. Controlled drugs are kept in secure vaults and cages. All products are entered into sophisticated inventory management systems (IMS) that track inventory levels and are used to pick, pack and ship products when they are ordered by provider customers. All of this occurs on a 24 hour-a-day cycle and is why HDA members are able to provide next-day service to all of their downstream customers.

In addition to being full-line, full-service distributors, HDA members provide valuable services to their customers, including the health systems and physicians treating Medicare patients. By working with full-line distributors these healthcare providers can maintain just-in-time inventories, saving the expense and staff necessary to carry extensive inventories or having large, secure storage facilities, both of which would add significantly to their cost of operations. In addition, distributors often provide financial services to their provider customers, particularly smaller physician-run offices in rural areas.

While HDA members are primarily supply chain logistics and operations experts, our industry does much more than move products from point A to point B. Pharmaceutical distributors provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely, delivering significant value to manufacturers and healthcare providers — and ultimately to patients.

Proposed Competitive Acquisition Program (CAP)

We understand that the Administration wants to reduce drug prices and lower patient out-of-pocket costs. However, we are concerned that the IPI Model relies heavily on an unproven Competitive Acquisition Program (CAP) vendor concept. Inserting another entity into the existing pharmaceutical supply chain, just for the Medicare Part B program, will likely result in delays or limits on access to needed medicines for Medicare patients and could actually lead to higher costs. In fact, a report just released by Avalere titled, *International Price Index*

*Model's Impact on Patients and Providers*¹, found that Medicare Part B beneficiaries would see little or no savings under the IPI Model.

Chief among our concerns is the fact that the CAP model does not correspond to any existing or viable supply chain economic model. That is, the model seeks to have CAP vendors provide the same if not better services than the current distribution system at much lower costs while adding another entity to the existing supply chain that would take title to Medicare Part B drugs but not necessarily possession of such drugs. We do not see any way that a qualified CAP vendor could possibly provide the same levels of service, even under current reimbursement levels, that existing supply chain entities provide today. For instance, if CAP vendors were required to purchase and take title to product, these entities would likely want to maintain minimal inventories since CAP vendors would only receive reimbursement for such products when a provider ordered a drug, the drug was administered to a patient and the CAP vendor billed Medicare for the product. Due to the inevitable lag period between distribution and reimbursement, we surmise CAP vendors would not want to maintain robust inventories, particularly for high-cost biologic medicines. We feel this would invariably lead to delays in delivering product to ordering physicians, which would lead to corresponding delays in treatment for Medicare patients.

An additional concern is the fact that providers assigned to a CAP vendor under the IPI Model will have to maintain two separate distribution systems and inventory—one for Medicare Part B patients through the CAP vendor and the other for all other patients, including those with commercial insurance that continues to reimburse under a “buy and bill” model. CAP vendors would be required to implement systems to bill Medicare Administrative Contractors (MACs) for the Medicare Part B drugs shipped to health care providers for patient administration. These systems do not currently exist. Furthermore, CAP vendors would have incomplete information for MACs to adjudicate Medicare Part B claims in accordance with federal law as CAP vendors do not diagnose or treat patients and would not be privy to patients’ diagnosis codes. Systems would need to be put in place to flow such patient diagnoses from treating providers to CAP vendors and/or MACs. Again, such systems do not exist today in any context.

Ultimately, we have concerns that additional layers of administrative gatekeeping by designated CAP vendors for the Medicare Part B program could result in limiting access and potentially driving up costs for patients, particularly without incentives or options for Medicare Part B practitioners to participate. Likewise, we are concerned that manufacturers will elect not to negotiate discounted pricing for Medicare Part B drugs with the CAP vendors because such discounts or price concessions are not currently excluded from Medicaid Best Price or Medicare Part B ASP calculations. Without such exclusions, manufacturers may not offer the CAP vendor discounts or concessions beyond those offered to other customers currently despite any preference that a CAP vendor might be able to offer a manufacturer for

¹ International Price Index Model's Impact on Patients and Providers, available at <https://avalere.com/insights/international-price-index-models-impact-on-patients-and-providers>

its products. Essentially, CAP vendors will have very limited negotiating power without such government pricing exclusions.

Mandatory Participation in Demonstration

We understand that the IPI Model will vary significantly from the previous Centers for Medicare & Medicaid Innovation (CMMI) demonstration model that was proposed in 2016. However, it appears that the mechanics of implementing the model will be similar if not identical to the proposed 2016 Medicare Part B demonstration – essentially half of the physicians treating Medicare Part B patients would be required to obtain drugs for Medicare Part B patients through a CAP vendor and receive reimbursement for drug administration and an add-on payment. The other half of the provider cohort would continue to buy and bill for Medicare Part B drugs and be reimbursed under the current ASP model. After five years, CMS would assess the cost savings and impact on patient care and make a determination about how to proceed.

Like the previous proposed demonstration, providers will likely be assigned to either the control arm or the alternative reimbursement arm based on some type of demographic algorithm. In 2016 it was Primary Care Service Areas (PCSAs), which are defined by aggregating zip codes reflecting Medicare patient travel to primary care providers.

As we stated when we responded to the proposed CMMI Part B demonstration in 2016, HDA is concerned that the process for assigning providers to the control or alternative reimbursement arms based solely on provider location will lead to differentials in quality of care for Medicare beneficiaries. In addition, since the assignment of providers to control and alternative reimbursement arms of the study will be transparent, patients and providers are likely to change their behaviors to adapt to the arbitrary assignments, particularly if there are access restrictions or delays in the CAP. Specifically, providers that are part of large multi-location practices will have the ability to shift site of care locations for patients in the event that some office locations are in the control group and others in the alternative reimbursement group.

CMMI acknowledged this possibility in 2016, stating that, “there could be situations during the model test in which those large practices are exposed to multiple arms, and thus to different payment methods simultaneously.” In addition, patients may select treating providers based upon their exclusion from the test/control group. For oncology care in particular, we may continue to see more patients shifted from physicians’ offices to hospital outpatient departments for chemotherapy and other cancer treatments, as has been a growing trend.

Furthermore, we are concerned that requiring providers to obtain Medicare Part B drugs from CAP vendors with limited formularies might impede patient access to needed medications. The IPI Model is mandatory in nature—not allowing time to assess the impact of such a CAP on patient access, quality and cost-effectiveness. We feel a true

demonstration should be voluntary and done on a small scale to ensure that it is scalable and does not disrupt access to care.

Conclusion

We appreciate the importance of containing costs and driving health care reimbursement towards payment systems that focus on quality of care and value. We feel the IPI Model focuses too heavily and primarily on reducing program expenditures, possibly at the expense of patient access to critical medications and quality of care. Ultimately, we feel strongly that the IPI Model, including the CAP, would drastically disrupt a supply chain that is working well today and could impede access and/or delay care for Medicare patients.

While HDA and all of our member companies cannot support the IPI Model, we are committed to continuing to work with you and Secretary Azar to explore voluntary models that could reduce program expenditures and lower out-of-pocket costs, while improving access to high quality care and treatments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Patrick M. Kelly".

Patrick M. Kelly
Executive Vice President
Government Affairs

cc: John O'Brien, Special Advisor to the Secretary