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

Re: [CMS-5528-ANPRM; RIN 0938-AT91] Medicare Program; International Pricing Index Model for Medicare Part B Drugs; Federal Register / Vol. 83, No. 110 / October 30, 2018 / Advance Notice of Proposed Rulemaking With Comment.

Dear Administrator Verma:

On behalf of the more than 145 voluntary and public hospitals that make up the acute care membership of Greater New York Hospital Association (GNYHA), I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) advanced notice of proposed rulemaking (ANPRM) on the International Pricing Index (IPI) Model for Medicare Part B Drugs. Our members are non-profit and public hospitals located in New York, Connecticut, New Jersey, and Rhode Island.

We greatly appreciate and support the Administration's focus on rising drug costs. Drugs are one of the fastest growing categories of health care expenses, crowding out resources available for other services, and impeding access and affordability for patients. Absent interventions, this problem will continue to grow given the number of expensive biologics and biosimilars in the pipeline.

GNYHA is concerned however, that the IPI model, as currently structured, will add significant administrative complexity for providers and negatively impact hospitals participating in the 340B Drug Pricing program. Our comment letter focuses on these concerns, as well as issues that should be addressed/clarified as part of any formal proposed rule. Finally, we highlight other actions the Administration could take to reduce drug prices by promoting competition and accelerating market entry for lower-cost biosimilars.

Comments on the IPI Model

The IPI model seeks to address the impact of rising drug costs on Medicare Part B spending and beneficiary out-of-pocket costs through a mandatory initiative covering 50 percent of the Part B drug spending. Participating providers (physicians and hospitals in designated regions) would be required to acquire their drugs through new contracted vendor(s) that would be responsible for negotiating discounts with manufacturers for selected drugs, managing distribution, and billing Medicare. CMS would replace the current average sales price (ASP) +6% reimbursement for Part B drugs with a pricing model based on a newly constructed IPI phased in over five years. In addition, the aggregate value of the current ASP add-on (i.e., the +6%) would be restructured as a flat add-on paid to providers.

Administrative Burden

The IPI model would disrupt providers' current supply chain process for purchasing and billing for Part B drugs, replacing the current "buy and bill" system and introducing many complexities. Rather than reducing administrative burden on providers, as claimed in the ANPRM, the IPI model will impose *increased* administrative burdens and costs. Specifically, providers would need to implement new systems/processes to acquire drugs from an approved vendor while maintaining their current systems/processes for non-Medicare fee-for-service (FFS) patients, as well as for Part B drugs not included in the IPI model. As a result, providers would be required to:

- Negotiate new contracts with model vendor(s) for IPI model Part B drugs and the new vendor "distribution fee"
- Modify contracts with distributers, as applicable
- Implement new processes/information systems to:
    - Communicate beneficiary information and dosage to vendor(s) to order drugs and for vendor billing purposes
    - Establish and monitor drug inventory by patient insurance
    - Submit "informational" claims for Part B administered drugs
    - Submit claims for the new drug add-on payment

We are also concerned about potential compliance risks if the beneficiary does not receive their treatment, as intended. While hospitals could be required to communicate any treatment changes to the vendor, it would not be appropriate to hold them accountable for any billing errors made by the vendor.

Given these new burdens and complexities, rather than requiring a full-scale duplication of providers' current drug acquisition and inventory management systems, we strongly urge CMS to modify the IPI model to retain the current buy and bill system.

In addition, we believe CMS's proposed model start date of spring 2020 is too aggressive and unrealistic for a successful implementation for all parties involved. Following release of the final rule, CMS would need to select vendors, vendors and providers would need to initiate new contracts, and providers and vendors would need time to implement new systems and processes described above. **Therefore, CMS should allow at least one year following the release of the final rule for implementation.**

Impact on 340B Providers

GNYHA's most significant concern is the potential financial impact of the IPI model on 340B providers. Since its inception, the 340B Drug Pricing program has helped safety net hospitals manage rising drug costs by requiring drug manufacturers that participate in Medicaid to sell covered outpatient drugs at discounted prices to safety net hospitals and other eligible entities. Participants use their 340B "savings" to reinvest in their communities, ensuring access to essential services for vulnerable populations. The 340B program was structured around the current buy and bill system in which 340B providers acquire eligible drugs at or below the 340B ceiling price set by the Health Resources and Services Administration (HRSA).

By replacing the buy and bill system, the IPI model would significantly curtail the benefits of the 340B Drug Pricing program to participants, undermining the program's intent and potentially putting participants at risk for non-compliance with the group purchasing organization (GPO) prohibition. The GPO prohibition prohibits certain 340B hospitals (i.e., disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals) from using GPOs to purchase or obtain outpatient covered drugs, and hospitals found to be non-compliant are terminated from the 340B program. Therefore, if the model vendors are determined to meet the legal definition of a GPO, 340B hospitals participating in the model would lose their 340B program benefit *entirely*. This would unnecessarily put safety net hospitals at great financial risk by inadvertently *raising* their drug prices and would harm access to care for the patients they serve. **The structure of the IPI model must hold hospitals harmless from any 340B impact.**

We believe this could be accomplished through a couple of different approaches, including by making the IPI model voluntary, not mandatory, or by permitting the vendor to act as an agent for purposes of purchasing 340B drugs under the model. **Regardless, it is critical that the agency work with HRSA to ensure that the vendors are not classified as GPOs so that hospitals participating in the model can continue to benefit from the 340B program.** In addition, we note that GNYHA has long called for HRSA to rescind its 2013 GPO Prohibition Guidance Notice—guidance that unnecessarily requires them to purchase non-340B outpatient drugs at a less competitive wholesale acquisition cost—an action that we continue to urge the Administration to take.

Other Comments and Concerns

GNYHA has identified several other areas that it encourages CMS to consider as it develops the IPI model.

- Calculation of ASP: Under the ANPRM, IPI model drug sales would be included in the ASP. We believe it would be inappropriate because this would essentially make what CMS has labeled as a demonstration program national in scope, impacting ASP-based payment rates for non-participants. In addition, this could be a factor that drug manufacturers consider as they determine the level of negotiated discount.

- Medicare beneficiary access to care: GNYHA is concerned that the IPI model could inadvertently create significant access issues for Medicare beneficiaries. As it develops the proposed rule, CMS should develop the policies to address the following concerns:

  - How would participants access drugs if no vendors elected to provide certain drugs included under the model?
  - What remedies would providers have in cases of drug shortages if the vendor is unable to provide adequate supply?
  - What is the role of the vendor (if any) in determining medical necessity and/or conducting utilization review? What appeal rights will beneficiaries and providers have?
  - Would the model encourage shifts in the site of care to either Part A (inpatient) or Part D? If so, what would be the impact on cost and quality?
  - Would the model encourage certain physicians to drop out of the Medicare program, reducing beneficiary access to certain specialties?

- Impact of drug wastage: Patients often have changes in treatment protocols and/or modifications in scheduling that result in excess drug inventory or wastage. Under the buy and bill process, hospitals maintain drug inventories for all patients (regardless of payer) and are at-risk for any unused drugs. How would drug wastage be handled under the IPI model? If CMS finalizes an approach where the vendor is responsible for purchasing and billing drugs under the IPI, we believe it would be appropriate for the vendor to assume the financial risk for any drug wastage.

- Cost shifting: How would CMS prevent drug manufacturers from increasing their prices for drugs that are not included in the IPI model to offset their losses? How would CMS monitor and track the impact outside of the demonstration?

- Collection of coinsurance/Medicare bad debt: Under the IPI model, hospitals would continue to be responsible for billing and collecting the coinsurance from the beneficiary and/or supplemental insurer and remitting it to the vendor. It is unclear which entity (the provider or the vendor) would take the financial risk if a beneficiary does not pay their cost sharing. If it is the hospital, presumably this would be considered an eligible Medicare bad debt?

- Interaction with other programs: CMS should carefully consider the impact of the IPI model on other programs such as Medicaid best price/drug rebate program, average manufacturer price, and the 340B ceiling price. As it evaluates these issues, the agency should seek to minimize and address any unintended impacts.

- Impact on Medicare Advantage (MA): In the ANPRM, CMS states that MA spending would be reduced proportionately to the reduction in Medicare FFS spending in the IPI model, with nearly $10 billion of estimated Federal savings over five years. Would CMS achieve these savings through premium reductions to MA plans? If so, how would MA plans maintain a competitive advantage in the market if they are not model participants? What would be the financial impact on providers and beneficiaries?

Other Potential Reforms to Reduce Drug Costs

GNYHA strongly supports proposals that will increase competition in the generic drug and biosimilar space as the research clearly demonstrates that the more manufacturers available to produce products, the lower

the prices and the less likely that drug shortages will occur. Many high-cost drugs lack lower-cost alternatives in the U.S., even though a biosimilar may already be available in Europe and despite having received Food and Drug Administration (FDA) approval (only five of the 15 FDA-approved biosimilars have launched due to patent litigation and other delays). Addressing the high cost of drugs will require a multi-pronged strategy, and we encourage the Administration to adopt reforms that address the FDA-approval process, market exclusivity and intellectual property issues, and barriers to commercialization (e.g., tactics used by the manufacturer of the reference product to minimize competition from a biosimilar before launching).

We applaud the Administration for the actions that it has already taken to improve the FDA approval processes, such as streamlining review of generic drug applications, encouraging biosimilar development, and creating new approval pathways, which resulted in a record number of generic drug approvals in 2017. However, significant challenges remain beyond the FDA approval process. GNYHA encourages the Administration to continue fighting anti-competitive practices with the goal of encouraging a sustainable, multi-source specialty market.

Simplifying the process for an interchangeable product designation could help address this problem. Specifically, the FDA could allow for the simultaneous submission of the interchangeability data and the biosimilar application. The FDA could also allow the use of real-world evidence from switching studies in the European Union (where they have existed longer) and harmonize U.S. and international regulations by allowing the use of non-U.S. comparators in these studies (the FDA's 2017 guidance on interchangeability states that the reference product must be a U.S.-approved product). GNYHA is encouraged by HHS's initial guidance on demonstrating the interchangeability of biosimilars and hopes to see some of these issues addressed in a revised draft or final guidance.

We appreciate the opportunity to comment on the ANPRM for the IPI model. If you have questions about our comments or would like further information, please contact Rebecca Ryan (212-506-5594/rryan@gnyha.org).

Sincerely,

Kenneth E. Raske
President