December 31, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–5528–ANPRM
P.O. Box 8013
Baltimore, MD 21244–1813


Submitted electronically via www.regulations.gov

Dear Administrator Verma,

UnityPoint Health (“UPH”) welcomes this opportunity to provide feedback on the advanced notice of proposed rulemaking. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 38 hospitals in metropolitan and rural communities and 15 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

UPH appreciates the time and effort of CMS in developing this proposal and respectfully offers the following comments.

MODEL CONCEPT DESIGN

The proposed International Pricing Index (IPI) Model is offered to: (1) Reduce expenditures while preserving or enhancing the quality of care for beneficiaries; (2) ensure comparable prices for Part B drugs relative to other countries; (3) reduce out-of-pocket costs for included drugs; (4) maintain relative stability in provider revenue through an alternative drug add-on payment; (5) reduce participating health care providers’ burden and financial risk associated with furnishing included drugs by using private-sector vendors; and (6) introduce greater competition into the acquisition process for separately payable Part B drugs.

The IPI Model test would include the following components:

- Set the Medicare payment amount for selected Part B drugs to be phased down to more closely align with international prices;
- Allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business;
• Increase the drug add-on payment in the model to reflect 6 percent of historical drug costs; and
• Pay physicians and hospitals the add-on based on a set payment amount structure.

Comment: As providers, we are very appreciative that the Administration is considering mechanisms to combat high pharmaceutical costs. We also recognize that the Administration is taking additional steps, through this advance-notice stage of proposed rulemaking, to solicit stakeholder input. **While we generally agree with the goals as set forth, we have concerns with the model’s degree of complexity, use of private-sector vendors, impact on patient access to medications, associated provider duties and costs, payment to providers, interaction with the 340B Drug Pricing Program and ceiling price calculation and scope and impact creep to patients/providers outside the demonstration.** We are also concerned that by targeting a subset of Part B drugs that CMS is eroding its opportunity to leverage the size of the Medicare program in negotiating fair drug prices and lowering patient co-pays overall. Lastly, as an Innovation Center demonstration, we are concerned that that stakeholders may not have further opportunity to vet a more detailed framework before the Innovation Center launches this model. Overall, the proposed model is very complex, contains many unknowns and will require numerous operational changes requiring time and resources requiring a significant go live timeframe.

**In an effort to offer a simpler solution, we would suggest that CMS explore the use of a standard Medicare formulary, like that used by Veterans Affairs and the Department of Defense.** Since this is already in place for select federal agencies, it could be implemented quickly and has yielded cost savings. In addition, CMS could revise the add-on payment for providers to avoid any perception of perverse incentives based on the price of the drug. We would suggest a tiered reimbursement structure based on the type of drug, which could be comprised of a direct cost for drugs and a separate fee to support the indirect costs of labor.

**340B DRUG PRICING PROGRAM IMPLICATIONS**

After the release of this advance notice, HHS has indicated that it is “aware of the complex interaction between the 340B program and Medicare Part B compensation for drugs . . . [and would like] to better understanding how hospitals that invest significant resources into serving vulnerable populations could be impacted by the IPI model.”

Comment: As one of the largest nonprofit, nondenominational health systems in the country, the UPH network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals and Rural Health Clinics provide vital access to health care services. Through 12 hospitals at 33 locations, the 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois and Wisconsin.

As we interpret the IPI Model, the 340B Drug Pricing Program would be superseded / eliminated for included drugs in geographies impacted by this proposed demonstration. In addition, it appears that the IPI Model vendors meet the definition of Group Purchasing Organization (GPO), for which 340B covered entities are prohibited from participation pursuant to HRSA Policy Release 2013-1.2 **We**

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1 https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html
request that CMS preserve the 340B program which has required manufacturer discounts for safety net providers to enable such providers to stretch scarce resources to provide more comprehensive services to vulnerable patients.

Furthermore, the complexity of the IPI Model calls into question our ability to continue to provide free or discounted medications to Medicare recipients who are unable to afford the copay on their Part B medications. As a safety net provider, we often choose to provide access to necessary medications even in cases where we find it unlikely the patient will be able to afford their copay. Under the IPI Model as proposed, it is not clear what discretion a hospital may have in this situation as the copay represents monies owed to the vendor rather than the hospital.

From an operational perspective, the IPI Model may significantly limit our patients’ access to Part B drugs or disrupt their treatment. The proposal adds many unknowns and potential points of delay within the drug distribution system. There is also the potential for an uptake in white/brown bagging practices, which could lead to drug safety and efficacy issues for patients. In addition, the IPI Model adds another layer of administrative monitoring and reporting. 340B covered entities already operate complex management systems to manage 340B and non-340B drug inventories. This model would require covered entities to manage a separate manual process or invest in separate software to track model drugs.

The 340B program has and continues to make a difference by allowing our providers to address the individualized needs of the people we service in meaningful ways – and we do not believe that the substitution of an IPI Model will likewise target vulnerable populations and community need. Recent examples of the diverse community needs targeted through UPH’s participation in the 340B Drug Pricing Program include:

- **Public Emergency Response:** In the spring of 2018, at least 150 people were poisoned in Illinois – more than 83 people in the Peoria area – and four people died. The culprit was tainted synthetic cannabinoid, known as K2 or Spice, that was laced with a long-acting coumarin derivative. Many victims were hospitalized for internal bleeding as well as blood coming from the ears, eyes and mouth associated with brodifacoum. Treatment involves managing and building up the blood clotting function with high-dose vitamin K, at costs exceeding $50,000 for a month’s supply. Once stabilized, uninsured patients were faced with continued hospitalization to maintain the pricey drug regime. The 340B Program enabled UnityPoint Health – Methodist Hospital in Peoria to discharge 47 impacted patients to home with supplies of high-dose vitamin K for $17 per week, instead of $13,000 per week. In a period of two months, more than $1.7 million worth of supplies were provided.

- **Improved Access:** Fort Dodge, Iowa, a community of roughly 24,000 residents, is served by UnityPoint Health – Trinity Regional Medical Center, a Sole Community Hospital and Rural Referral Center. There are no 24-hour pharmacies in Fort Dodge and weekend pharmacy hours are limited. The 340B Program has funded an InstyMeds dispenser, which is an automated system much like a bank ATM, that dispenses prescription medications directly to patients 24 hours per day. Located in the Emergency Department, more than 5,600 prescriptions have been dispensed via InstyMeds over the past two years. Of these prescriptions, more than 800 or 14% were provided to patients at no cost through the Compassion Care Rx program. The 340B program has not only enabled timely community-
wide access to prescriptions in Fort Dodge, but an average of one prescription per day has been delivered to vulnerable individuals under the Compassion Care Rx program.

- **Chronic Care Outreach:** UnityPoint Clinic physicians noticed that high drug costs for patients with chronic conditions often resulted in patients stopping their medications. Ongoing drug regimens are particularly important for managing diabetes, congestive heart failure and pulmonary conditions. Despite understanding the health benefits of taking medications, individuals who are uninsured, lack drug coverage or reach the Medicare "donut hole" are more likely to stop filling their prescriptions. UnityPoint Health – Methodist Hospital in Peoria has established special hospital clinics for patients with large ongoing out-of-pocket medication costs. They have worked with a 340B contract pharmacy to provide virtual insurance that enables them to receive discounted pricing. For diabetic patients, cost savings can be hundreds of dollars per prescription. For example, Le vemir is provided for $16.50 rather than $500. More importantly, patients are remaining on their prescribed medications. Clinics have been piloted with diabetic patients and pulmonary patients using this approach and 340B funds.

*We encourage the Administration to work with 340B hospitals in refining the IPI Model to avoid any unintended consequences that may negatively impact our ability to target 340B resources to serve vulnerable patients and our communities.*

We are pleased to provide comments to this advanced notice and its impact on our patients and integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

Gary Robb, RPh, MBA  
VP, Chief Pharmacy Officer

Sabra Rosener, JD  
VP, Government & External Affairs