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Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Department of Health & Human Services
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1859

RE: Draft Guidance on the Medicare Drug Price Negotiation Program

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov

Dear CMS Deputy Administrator and Director of the Center for Medicare Seshamani,

UnityPoint Health appreciates this opportunity to provide comments on CMS' draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price provisions released May 3, 2024. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 29,000 employees and our relationships with 370+ physician clinics, 36 hospitals in urban and rural communities, and 13 home care areas of service throughout our 8 markets, UnityPoint Health provides care throughout Iowa, west-central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health is responsible for a service area of over 2.3 million people and has generated $344.6 million in community impact.

As a nonprofit, integrated healthcare system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals, and Rural Health Clinics provides vital access to healthcare services. 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. *Not including our affiliated 18 critical access hospitals, we have 12 hospitals (9 covered entities) under the 340B Drug Pricing Program*. **We respectfully offer the following input limited to the impact of the draft guidance on the 340B Drug Pricing Program.**

IRA'S MAXIMUM FAIR PRICE (MFP) IMPACT ON 340B CEILING PRICE

The IRA requires the Primary Manufacturer to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug. CMS acknowledges the intersection between the IRA requirement under the Negotiation Program for manufacturers to provide access to the MFP and Health Resources and Services Administration (HRSA) requirements for manufacturers to make the 340B ceiling price available to 340B covered entities.

Comment: **While UnityPoint Health agrees that covered entities should not receive duplicate**

discounts, the draft guidance proposes to address this through an arduous process that places unreasonable burdens upon 340B covered entities and ultimately adversely impacts Medicare beneficiaries. As proposed the draft guidance would impermissibly interfere with hospitals' ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on 340B hospitals, would recommend that 340B hospitals share their claims data directly with manufacturers, and would force hospitals to float greater drug costs pending manufacturer refunds in instances where a drug's MFP is lower than its 340B ceiling price. CMS has failed to meet its statutory obligation to ensure that 340B covered entities (CEs) receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP.

We urge CMS to abandon its current proposal to make the MFP available in a nonduplicated amount to the 340B ceiling price and instead work with 340B CEs to develop a workable means for CEs to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP. Challenges created by this proposal include:

Default Payment Methodology: CMS' proposal requires providers to purchase drugs at prices significantly higher than MFP and wait weeks to receive a payment from the manufacturer to net the purchase cost to MFP ("default payment"). This essentially requires providers to float revenue to manufacturers. Applying this to 340B CEs, CMS proposes that when the 340B ceiling price is lower than MFP, 340B CEs voluntarily append a modifier on the claim to identify the claim as 340B. This modifier would allow manufacturers to avoid making the default payment for those claims. Yet, CMS acknowledges that most CEs use a virtual inventory system in which 340B claims cannot be tagged until after the claim is submitted. The virtual inventory model has been in use since the 340B Drug Pricing Program was enacted more than 30 years ago, and it is the model used by our CE hospitals. It would be unworkable to expect our CE hospitals to use a separate physical inventory of 340B drugs. Instead, **we recommend that CMS develop a methodology to enable CEs to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF) and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer**. This process has been used successfully by Oregon Medicaid for more than a decade.

Claims Submission to Manufacturers: Recognizing the issues with point-of-sale identification, CMS urges that CEs submit their 340B claims data directly to the manufacturers for drugs subject to the MFP. This would involve individual CEs separately submitting data to individual manufacturers, each of which could have its own separate data requirements and processes. While CMS does not mandate that CEs share data, the draft guidance sets up processes for manufacturers to use such data. **We strongly oppose CMS allowing manufacturers to mandate 340B claims data submission through their own deduplication policies**. Ceding this responsibility to numerous drug manufacturers:

- ***Conflicts with CMS' explicit authority*** in section 1193(d)(1) of the Social Security Act to develop a process in which manufacturers do not provide the MFP for drugs sold at the 340B price and, per sections 1193(a)(5) and 1196(b), that process be one that CMS can "administer" and for which CMS can ensure compliance. CMS can neither administer nor ensure compliance with unclear and vague statements about what the parties should agree to outside of, and separate from, the

government's stated process, especially when there could be numerous different policies.

- ***Creates significant barriers to CEs*** accessing the lower of the 340B ceiling price or MFP for numerous manufacturers and will be tremendously burdensome for CEs to manage. We are especially concerned because CMS provides no guidelines for the plans or criteria for how the agency will evaluate these plans, including manufacturers responsibilities. Absent evaluation guidelines and criteria for the manufacturers' nonduplication plans, manufacturers plans and processes will likely vary. There is no govern on manufacturers as to scope of claims data, reporting methodology, or additional restrictions (e.g., CE assurance of 340B compliance). For example, a manufacturer could (1) assume all outpatient claims attributed to a CE's NPI are 340B eligible; or alternatively, (2) require CEs to submit large volumes of data to receive the 340B ceiling price or MFP as a refund. Either would be at odds with the longstanding practice of CEs accessing the 340B discount as a purchase price and would be highly disruptive to how hospitals manage their 340B programs. It is also not difficult to imagine that numerous and varying requirements will increase operational burdens for CEs (especially small CEs), add to oversight complexity for CMS and HRSA, and insert unnecessary delays in receiving 340B payments.

  These assertions are based on the experiences and frustrations of our CE hospitals who currently share 340B claims data with drug manufacturers through the vendor ESP in connection with 340B contract pharmacy restrictions. The process of obtaining and preparing 340B claims data for submission to ESP imposes a significant administrative burden. CEs must download claims data reports from the portals of every 340B third-party administrator (TPA) with which they contract and for every contract pharmacy arrangement administered by each TPA. There is wide variation around reinstatement of 340B pricing at hospitals' contract pharmacies after they have submitted claims data to ESP. It has been our experience that 340B pricing is made available for only some NDCs, but not all, and only at some contract pharmacy locations, but not all. Our CE hospitals have devoted extensive time and staff resources to follow up on notifications in ESP's portal that claims submissions are incomplete to ensure 340B pricing is preserved. It is commonplace to send multiple emails to ESP in support of issues and fixes in the portal. To add to the frustration, manufacturers can and do change restrictions/rules at will and sometimes without notice, yet CE hospitals may only change their single contract designation once every 12 months.

MFP Relationship to 340B Ceiling Price: **We also oppose the draft guidance's proposed implementation of MFP when it is lower than the 340B ceiling price**. The draft guidance effectively prohibits use of the 340B benefit in those instances, expecting CEs to purchase drugs for 340B-eligible patients at a non-340B price. This requires safety-net hospitals participating in the 340B Drug Pricing Program to float more upfront drug costs. This would substantially disrupt our CE hospitals' longstanding practice of purchasing and using 340B drugs for patients and will impact our virtual inventory systems. CEs should be able to use the 340B benefit for all 340B-eligible patients, as permitted under the 340B statute, and not amended by the IRA. **Additionally, we suggest that CMS establish a clear process for manufacturers to make CEs whole by providing the difference between the two price points**.

As a 340B stakeholder, we appreciate this opportunity to offer input on this draft guidance and its impact on our hospitals and health system, our beneficiaries, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

Cathy Simmons, JD, MPP
Executive Director Government & External Affairs