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January 30, 2023

Carole Johnson, Administrator
Health Resource and Services Administration (HRSA)
Department of Health and Human Services (HHS)
Docket No. 2021-0004
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Docket No. 2021-0004 - 340B Drug Pricing Program; Administrative Dispute Resolution; published at Vol. 87, No. 229 Federal Register 73516-73527 on November 30, 2022.

Submitted electronically via http://www.regulations.gov

Dear Administrator Johnson,

UnityPoint Health appreciates this opportunity to provide comments on this notice of proposed rulemaking (NPRM) related to 340B Drug Pricing Program; Administrative Dispute Resolution. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 32,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health appreciates the time and effort of HRSA in developing this NPRM. As a member of the American Hospital Association (AHA) and 340B Health, UnityPoint Health supports their respective comment letters submitted in response to this NPRM. In addition, UnityPoint Health respectfully offers the following input.

MORE ACCESSIBLE ADMINISTRATIVE DISPUTE RESOLUTION (ADR) PROCESS

HRSA seeks comments on whether to retain the existing minimum threshold, eliminate the minimum threshold altogether, or set a new minimum threshold for submitting a claim to ensure a fair, efficient, and expeditious process.

Comment: Given the diverse group covered entities represent**, UnityPoint Health recommends the elimination of a minimum threshold value necessary to file a petition.** Removing the minimum threshold increases access to the ADR process for covered entities with limited resources and ensures that all can seek relief for material issues given their relative size. The resources required to complete the ADR process

should prevent frivolous petitions.

ADR PANEL STRUCTURE

HRSA seeks comments on the revised structure of the 340B ADR panel, including limiting the panel to the Office of Pharmacy Affairs (OPA) staff only.

Comment: Under current structure, HRSA selects three voting board members (one each from HRSA, Centers for Medicare & Medicaid Services (CMS), and Office of General Counsel (OGC)) to form an ADR panel. Individuals are appointed from the OPA to serve as an ex-officio, non-voting member for each ADR panel. Under the proposed rule, the ADR panels would be limited to OPA staff only. **UnityPoint Health supports of the removal of CMS representation on the ADR panel.** This will subdue any unintentional conflict of interest between CMS and the ADR process. **UnityPoint Health also supports the inclusion of OPA staff as members on the panel but would strongly encourage a more diverse panel structure inclusive of an equal number of covered entities and manufacturer representation.**

ALIGNMENT OF ADR PROCESS TO 340B STATUTE

HRSA seeks comments on whether there may be appropriate claims limitations to ensure that ADR is limited to the specific statutory areas (diversion, duplicate discounts, and overcharges). HRSA also seeks comments on its proposal to suspend ADR review of claims that involve issues pending in federal court.

Comment:

- ADR Process Limited to Specific Statutory Areas – Today, 18 major drug manufacturers have limited access to certain 340B drugs for contract pharmacies. Notifications of federal law violations have been sent to most of the manufacturers with some manufacturers being referred to HHS and the Office of Inspector General (OIG) for consideration of civil monetary penalties (CMPs). To date, no manufacturer has been subject to CMPs or any other penalty. **UnityPoint Health strongly encourages the enforcement of the 340B Drug Pricing Program requirements to stop unilateral action by drug manufacturers to establish or alter conditions of participation.** We continue to urge HHS and OIG to use current statutory authority in imposing civil monetary penalties against all drug manufacturers who have unlawfully overcharged safety net health care providers. These manufacturers' unlawful actions have undermined the ability of covered entities to serve vulnerable communities, particularly in rural areas, where contract pharmacies are vital to providing access to affordable medications.

  UnityPoint Health opposes limiting ADR to specific statutory areas (diversion, duplicate discounts, and overcharges.) Limiting the ADR process allows claims outside of the specified statutory areas to remain unresolved and may result in the continuation of bad actors, such as those referenced above, intentionally disregarding agency guidelines and statutory requirements. It's imperative that the ADR process allows for the resolution of claims to ensure the 340B Drug Pricing Program is utilized as Congress intended.

- Suspending Claims with Issues Pending Federal Court – As noted by 340B Health in their letter to this NPRM, challenges to a government action are not necessarily determined by a single federal

court. Suspending a claim because the issue is before a single federal court prevents covered entities from promptly pursuing claims in their own jurisdictions, pursuit to statute. Since the ADR process is the sole avenue for covered entities to challenge drug manufacturers' unlawful behavior, a significant delay in moving forward with a claim could be devastating for a covered entity and prevent them from making their arguments on how the issue applies to the facts in their specific situation.

In alignment with 340B Health recommendations, UnityPoint Health strongly encourages the revision of this provision to allow suspension of a claim only if requested by the covered entity, similar to the policy currently utilized by the Provider Reimbursement Review Board, an HHS administrative adjudicative body. If HRSA moves forward with the policy to suspend claims, at the very least, UnityPoint Health requests additional clarification on the factors used to determine whether the issues are similar and permit the parties to challenge the decision to suspend a claim.

We are pleased to provide input on this NPRM and its impact on our patients and communities. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director of Government and External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

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Ambulatory Pharmacy Director
UnityPoint Health

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