July 28, 2023

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

RE: 340B Bipartisan Request for Information (RFI) issued June 16, 2023
Submitted electronically via Bipartisan340BRFI@mail.senate.gov

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran and Cardin,

UnityPoint Health appreciates this opportunity to provide input on your 340B Drug Pricing Program RFI. UnityPoint Health is one of the nation’s most integrated health care systems. Through more than 32,000 employees and our relationships with over 360 physician clinics, 36 hospitals in urban and rural communities, and 14 home health agencies across our 8 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin.

Within our integrated health care system, we have nine\(^1\) 340B hospitals participating in the 340B Program. Altogether in 2022, these nine 340B hospitals created approximately $116M in value that was reinvested back into the local communities they serve. The programs supported are varied and tailored to meet the needs of their communities: Discounts on prescription medications; extended/24-hour access to outpatient pharmacies; Med-to-Bed programs ensuring patient access to medications at hospital discharge; new clinical pharmacist shifts supporting high-quality care; birthing services support, including lactation consultants and NICU coverage; dental clinic for underserved populations; pediatric infusions in rural areas; mental health programs, services and outreach; and even facilities investments to expand capacity at one of our Child/Adolescent Psychiatric hospitals. In short, the 340B Program makes it possible

\(^1\) This number represents hospitals wholly-owned by UnityPoint Health. In total, UnityPoint Health has 28 affiliated hospitals, including 19 Critical Access Hospitals under management agreements, that are eligible Covered Entities and participate in the 340B Drug Pricing Program.
for our hospitals to maintain, grow and expand services that our communities need. The diversity of the program’s benefits is one of its greatest strengths and should be vigorously defended.

UnityPoint Health is a member of 340B Health and the American Hospital Association and generally supports the formal comments submitted by these organizations. In addition, UnityPoint Health respectfully offers the following input.

1. **What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?**

   **Comment:** For Covered Entity oversight, HRSA appears to have adequate resources. For more than 30 years, HRSA has successfully provided oversight for the 340B Program. Covered Entities must apply to participate in the federal program, and Covered Entities have a long history of abiding by HRSA program parameters, including HRSA rules from 1994\(^2\) and 1996\(^3\). In 2022, HRSA audited more than 200 Covered Entities, although only 6 drug manufacturers were subject to an audit. Whether there is equitable distribution of audit resources and focus between Covered Entities and other stakeholders to ensure appropriate oversight may be a ripe topic for further investigation.

   Aside from enforcement oversight, 340B Program administrative oversight ultimately hinges on the scope of the underlying statutes and regulations. HRSA has the ability to engage in a public notice and comment process to proactively engage stakeholder feedback and message regulatory requirements. Covered Entities appreciate a formal rulemaking process with associated timely agency guidance to permit the implementation of any operational changes. As court challenges seek to revise Congressional intent related to HRSA’s authority, Congress may need to course correct to target these issues.

   When Congress delegates program administration and oversight to an agency, the agency should have authority to enforce that program within statutory parameters. The Administrative Dispute Resolution (ADR) process is one avenue available to HRSA, but the ADR Final Rule\(^4\) has not been released. This process would offer a mechanism for Covered Entities to individually challenge the unlawful actions of 25 drug manufacturers who are imposing additional restrictions on the use of contract pharmacies contrary to HRSA guidance. These restrictions have significantly impacted access to covered outpatient medications by UnityPoint Health patients, oftentimes making those 340B-priced medications inaccessible.

2. **What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?**

   **Comment:** UnityPoint Health 340B hospitals are struggling to manage the current 25 different 340B programs – as each manufacturer is setting their own “rules” in addition to HRSA’s rules, and these manufacturer restrictions change frequently and with varying notice. Managing these restrictions has

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\(^3\) 61 Federal Register 43549 dated August 23, 1996.
\(^4\) HHS Docket No. HRSA-2021-000X
significantly increased the resources needed to operationalize the 340B Program, has increased participation complexity making compliance more challenging, and ultimately has reduced patient access to 340B-priced medications.

Beginning in 2020, drug manufacturers have stepped into the shoes of regulators and are establishing individual policies for contract pharmacy dispensing, including prohibiting contract pharmacy entirely for hospitals that have their own retail pharmacy, allowing only one retail or specialty contract pharmacy if hospitals have no pharmacy of their own, prohibiting exceptions for system-owned pharmacies, and/or placing distance restrictions on where a contract pharmacy is located relative to the hospital. Recent restrictions disproportionately affect the highest cost specialty medicines. For instance, when drug manufacturers limit 340B pricing to single contract pharmacy within 40 miles of the Covered Entity, this effectively eliminates access to limited distribution drugs, may not align with a patient’s pharmacy benefit dictated by health plan coverage, and does not reflect geographic topography or pharmacy locations. At UnityPoint Health, mileage restrictions effectively prevents many UPH facilities from working with our health system-owned specialty pharmacy, which is located more than 40 miles from most of our 340B hospitals.

UnityPoint Health encourages Congress to affirm contract pharmacy arrangements as an essential component of the 340B Program. Our use of contract pharmacies depends upon the 340B hospital and how we can best accommodate access to medications for the convenience of our patients. Contract pharmacies often have extended evening and weekend hours (even 24/7 access in some cases) and greatly reduces patient travel distance and/or time in both rural and urban areas. At UnityPoint Health, we estimate that the contract pharmacy restrictions for our nine 340B hospitals equates to approximately a $10-million reduction in program benefit annually – roughly half our total contract pharmacy value. As the number of manufacturers imposing restrictions increases and the restrictions themselves become more onerous, we anticipate this reduction to grow significantly to nearly wipe out the value of our entire contract pharmacy benefit. This reduction could not come at a worse time as hospitals across the country face a variety of factors creating a financial maelstrom; we are committed to providing the vital community services supported by our 340B savings for as long possible, but not all are sustainable without support from our contract pharmacy networks.

3. What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

Comment: 340B Covered Entities are bestowed with stewardship of spreading scarce federal resources in the promotion of health care access. UnityPoint Health recommends that Congress consider the following:

- **Prohibit PBM Discriminatory 340B Pricing Practices.** To preserve PBM rebate revenue, Pharmacy Benefit Managers (PBMs) have instituted practices that pay 340B hospitals less than non-340B hospitals for covered outpatient drugs. Discriminatory pricing is contrary to the intent of, and syphons funds from, the 340B Program.

- **Establish a 340B Patient Discount Safe Harbor.** This safe harbor would enable Covered Entities to extend the 340B discount to patients without compliance fears. Currently, Covered Entities
wishing to do so must navigate a labyrinth of conflicting laws to prevent unlawful inducement (e.g. Stark Laws, CMS inducement, Civil Monetary Penalties, etc.). Additionally, many Part D and commercial plan contracts create barriers to using the 340B discount to help underinsured patients afford their copays. This is a major obstacle to establishing direct access to 340B pricing for our patients and takes considerable resources to start and manage a discount program.

- **Restrict Limited Distribution Drug and White/Brown Bagging Policies.** Limited distribution drug policies are imposed by drug manufacturers while white/brown bagging restrictions are imposed by health plans and PBMs; but both limit where patients are able to fill their prescriptions. These policies negatively impact the ability of Covered Entities to provide necessary and timely care for patients and create unnecessary barriers for patients to access 340B-priced medications.

- **Preserve the Inflationary Penalty.** Drug manufacturers who raise their prices faster than the rate of inflation must pay additional 340B discounts. Research by the American Medical Association found that the stiff penalties drug manufacturers face in the 340B Program for price increases above the rate of inflation restrain drug price increases for all purchasers. This inflationary penalty is a benefit of the program which curbs costs and helps all patients access lower prices.

4. **What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?**

**Comment:** UnityPoint Health supports the implementation of a retrospective national clearinghouse model to improve duplicate discount prevention based on the Oregon experience and as detailed in the American Hospital Association comment letter. The current practice of using real-time claims modifiers can be very difficult to operationalize. The 340B Program is complex and variables, such as patient status or payor, can change retrospectively altering eligibility. A retrospective clearinghouse would allow these changes to occur before Covered Entities need to submit the claim for duplicate discount prevention and reduce Covered Entity time and effort resources directed to maintain compliance. When establishing a clearinghouse, it should be (1) administered by neutral third party and (2) focused on preventing Medicaid duplicate discounts as defined in the statute, excluding private commercial discounts that drug manufacturers may voluntarily enter into.

5. **What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?**

**Comment:** UnityPoint Health 340B hospitals, like the vast majority of 340B hospitals, dedicates significant resources to ensuring program integrity and operational excellence; however, the program’s complexity

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strokes the deck against Covered Entities who are trying to stay fully compliant. Three specific changes to simplify the program and improve program integrity include:

- **Eliminate the GPO Prohibition.** This restriction on obtaining covered outpatient drugs through a Group Purchasing Organization (GPO) applies to some, but not all, Covered Entity types and results in sites paying a premium (i.e. the full Wholesale Acquisition Cost) on some purchases contrary to the intent of the 340B Program. It also requires all Covered Entities subject to the GPO prohibition to maintain a virtual inventory of not just 340B accumulations, but also of GPO accumulations. As a result, three wholesaler accounts (GPO, 340B, and WAC) are required to maintain compliance, which adds administrative complexity.

- **End the Orphan Drug Exception.** This exception applies to a different subset of Covered Entity types (generally rural providers, such as Critical Access Hospitals and Sole Community Hospitals) and excludes some products from 340B pricing at those locations. Any drug approved as an Orphan Drug is exempt from 340B pricing at these Covered Entities, but drug manufacturers can add additional indications after approval which widen their targeted population. For instance, Humira is one of the top selling drugs of all time but is considered an Orphan Drug in the 340B Program. Orphan Drugs are often some of the highest-priced medications, and rural patients would benefit from improved access.

- **Register Child Sites by Building/Address.** Over time, HRSA has audited for more granular registration of child sites. Historically, Covered Entities could register an offsite clinic as a single building; however, HRSA now requires a separate registration for each service provided in the building. For instance, separate registration is required for Internal Medicine, Family Medicine, and Pediatrics at each of our primary care child sites. This level of granularity makes the Office of Pharmacy Affairs (OPA) database less useful and increases the complexity to maintain an expanding number of line items. It also creates the appearance of immense program growth, despite the fact the statutory eligibly has remained static.

While UnityPoint Health supports simplifying the program to help Covered Entities dedicated to program integrity, we also support disincentives for 340B stakeholders who intentionally disregard established program rules. HRSA has the authority to impose and should pursue civil monetary penalties against participating drug manufacturers or others for intentional disregard of 340B Program agency directives.

6. **What specific policies should be considered to ensure transparency to show how 340B health care providers’ savings are used to support services that benefit patients’ health?**

**Comment:** UnityPoint Health supports transparency and accountability in the 340B Program. Given the program’s complexity, transparency requires thoughtful consideration to accurately reflect the benefits and impact of the program to the patients, hospitals, and communities. 340B hospitals already submit substantial amounts of public data, such as 990s and Community Benefit statements. These existing data points should be leveraged as much as possible to minimize the overhead required to generate them.
Transparency should also reinforce one of the foundational strengths of the program – flexibility for Covered Entities to use the program’s benefits to meet the unique needs of the community and patients they serve. Reporting must not pigeonhole or prescribe the way the benefits should be used.

Transparency must also extend to all program stakeholders, including drug manufacturers. For instance, pricing decisions by drug manufacturers dictate the 340B discount and the impact of these decisions should be calculated and publicly reported. Additionally, in exchange for participating in the 340B Program, drug manufacturers can sell their products to beneficiaries of government programs. Public reporting should also include drug manufacturer profits for participating in those programs compared to the amount of the 340B discounts.

We are pleased to offer feedback on this RFI and its impact on our hospitals, patients and communities. We look forward to working together further on ways to improve this vital program and would be happy to discuss any of these topics in more detail. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Government & External Affairs at Cathy.Simmons@unitypoint.org or 319-361-2336.

Sincerely,

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