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April 1, 2024

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 Discussion Draft and Request for Information (RFI) issued February 2, 2024

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 discussion draft and supplemental request for information on "Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act" or the "SUSTAIN 340B Act". Thank you for continuing to be champions for this crucial program! UnityPoint Health is one of the nation's most integrated health care systems. Through more than 29,000 employees and our relationships with 375+ physician clinics, 36 hospitals in urban and rural communities, and 13 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 2023, these nine 340B hospitals created approximately $134M 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

[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, which are eligible Covered Entities and participate in the 340B Drug Pricing Program.

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 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.

Section 2. Sense of Congress. This section codifies the intent of the 340B Program.

Comment: Thank you for draft language that memorializes Congressional intent in statute. **UnityPoint Health wholeheartedly supports the inclusion of statutory language to provide Congressional intent for the 340B Program**, which underpins the program and guides overall program direction. Historically, the 340B Program has been intended to help safety net providers maintain, improve, and expand patient access to health care services. This "Sense of Congress" and direction for the program should serve as an operational thread for 340B Covered Entities and participating drug manufacturers and be tied comprehensively to overall governance, including program transparency and reporting requirements.

Section 3. Contract Pharmacy. This section provides that contract pharmacies can be used by Covered Entities in accordance with HRSA's 2010 guidance. The RFI requests additional information on potential limitations to contract pharmacy use.

Comment: **UnityPoint Health cannot overstate the importance of contract pharmacies for patient access to 340B drugs.** Under this arrangement, Covered Entities purchase drugs at 340B prices and contract with pharmacies in the community to dispense the drugs to Covered Entity patients on the Covered Entity's behalf. These arrangements are authorized in the 2010 Health Resources and Services Administration (HRSA) guidance on contract pharmacy arrangements, which requires manufacturers participating in the 340B Program to:

1) offer Covered Entities the 340B price for an outpatient drug regardless of whether the drug is dispensed at a contract pharmacy or an in-house pharmacy;

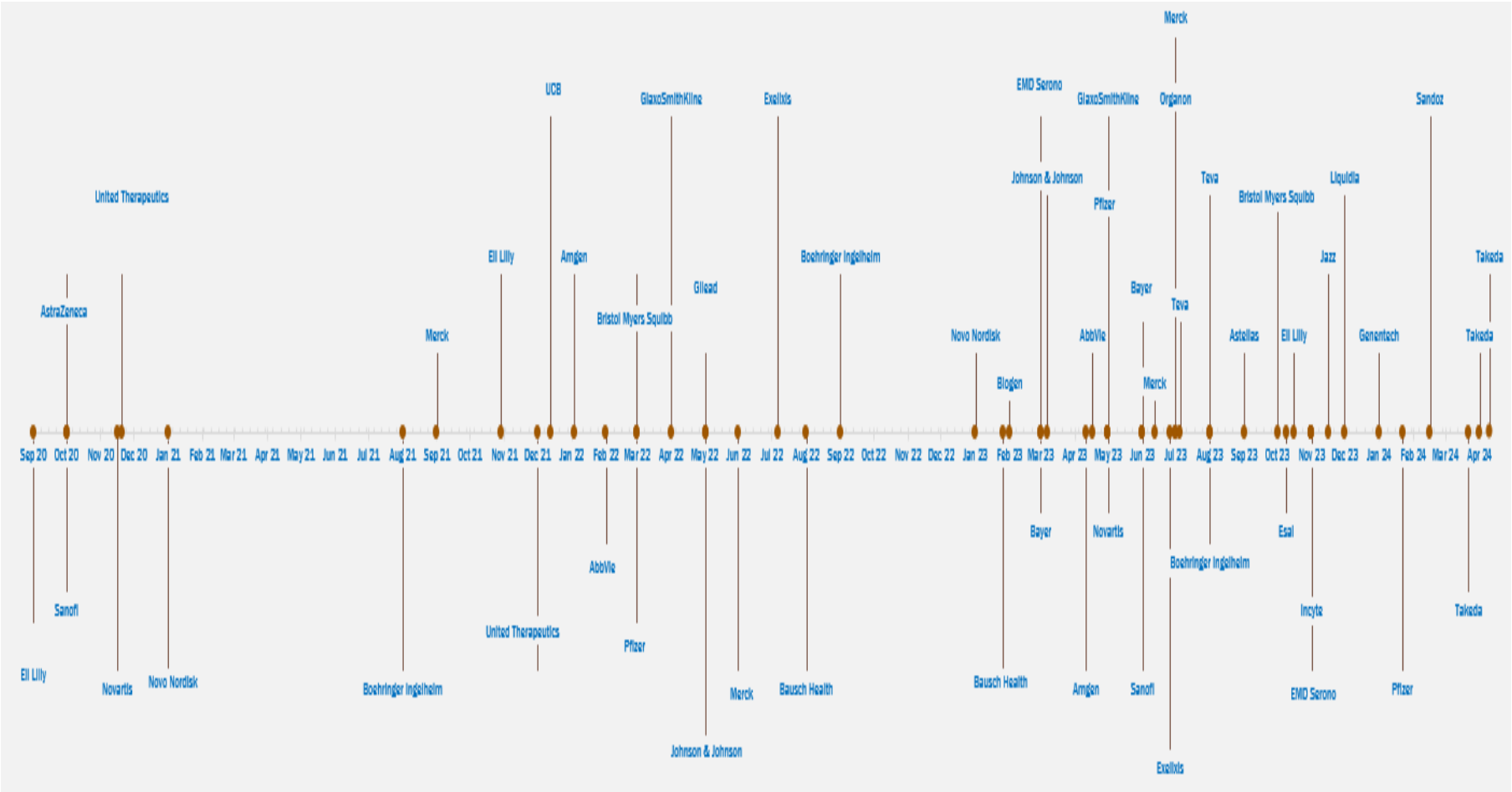
2) deliver covered outpatient drugs purchased by a Covered Entity and their associated sites to pharmacy locations as requested by the Covered Entity; and

3) not place conditions on the ability of a Covered Entity to purchase drugs at the 340B price, including a drug that is dispensed at a contract pharmacy location.

Although this language is presently within HRSA guidance and should have the full force of law, UnityPoint Health encourages Congress to statutorily authorize this practice. These arrangements should be subject to local need and market forces, and we urge any statutory language to mirror the 2010 HRSA guidance.

Since July 2020, 31 drug manufacturers have taken unilateral action to establish or alter 340B Program conditions of participation, which refuse to provide and/or restrict 340B pricing to Covered Entities for

Figure A – 340B Program timeline (9/1/2020 – 4/10/2024)



drugs dispensed through contract pharmacies (see Chart A, page 3). The most recent additions are Liquidia with an effective date of April 1, 2024, and Genentech with an effective date of April 10, 2024. In total, these manufacturers are AbbVie; Amgen; Astellas; AstraZeneca; Bausch Health; Bayer; Biogen; Boehringer Ingelheim; Bristol Myers Squibb; Eli Lilly; EMD Serono; Esai; Exelixis; Genentech; Gilead; GlaxoSmithKline; Incyte; Jazz; Johnson & Johnson; Liquidia; Merck; Novartis; Novo Nordisk; Organon; Pfizer; Sandoz; Sanofi; Takeda; Teva; UCB; and United Therapeutics. *This number keeps growing (see Figure A, page 3) as there is no government reprisal.*

Meanwhile, the impact of these restrictions is devastating. First, as manufacturers step into the shoes of regulators and impose new rules, this increases administrative workload for hospitals just to access the drugs at 340B-acquired drug pricing. Each manufacturer has imposed different restrictions, such as mandating submission of claims data using 340B ESP (a specific vendor) to access 340B pricing for drugs dispensed at contract pharmacies, refusing 340B pricing for drugs dispensed at contract pharmacies unless a limited exception applies, or both claims reporting and limited exceptions. **Effectively, hospitals now have 32 340B Drug Pricing Programs to administer, including the one authorized by Congress and administered by HRSA.** The 31 manufacturer programs are subject to frequent change with little notice, if any, and the frequency of changes is increasing as shown in the timeline above. This results in compliance chasing activities that detract 340B safety-net providers with extra administrative burdens and divert resources away from the program's intent ("to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services") to administrative tasks. Second, **this assault on the 340B Program from manufacturers impacts beneficiaries and access to medications**. These medications are needed to treat and manage chronic conditions and are not luxury items. Contract pharmacies enable outreach to beneficiaries at convenient locations and often with more extended hours. In an era when CMS is doubling down on telehealth to facilitate health care access and beneficiary convenience, the access to 340B-acquired drugs through community pharmacies seems similarly situated.

Furthermore, these restrictions threaten $20 million dollars per year of 340B benefits for UnityPoint Health communities. These dollars provide and maintain the comprehensive safety net services we offer, including those mentioned above. Additionally, our most rural sites have been most impacted by these restrictions, with a larger percentage of their 340B benefit coming from contract pharmacy arrangements.

Geographic Restrictions: **The vital role of contract pharmacies spans all Covered Entities and geographies** – if you have seen one Covered Entity and its patients, you have seen one Covered Entity and its patients. Geographies and communities differ, patient needs differ, the presence of pharmacies and access to specialty pharmacies differs, and health care coverage from payers differs. Generally, these variables do not lend themselves to nationwide restrictions on contract pharmacy networks. At the core of the issue, UnityPoint Health encourages patients to fill prescriptions where they see fit and many fill prescriptions where they have a pre-existing pharmacy relationship close to where they live. The 340B Program should not dictate new pharmacy relationships but should support pre-existing relationships when possible and at the convenience of the patient. **We believe it would be a mistake to legislate with a focus on the location of the Covered Entities or contract pharmacies, as the intent of the program is to maintain,**

improve, and expand patient access. For instance, arbitrary restrictions on mileage (i.e. 35 miles from a Covered Entity), distinctions among Covered Entity locations or types (i.e. rural Covered Entities vs. urban Covered Entities vs. high-need Covered Entities), and/or limitations on overall contract pharmacy numbers (i.e. not more than 10 contract pharmacies) may adversely impact patient access – the degree of impact will vary by Covered Entity.

UnityPoint Health does not support arbitrary mileage restrictions for patients to access 340B pricing, which adversely impacts patients of both rural and urban hospitals.

- ***Rural patients are disproportionately impacted by restricting contract pharmacies to a certain mileage circumference from Covered Entities.*** In rural areas, Covered Entities routinely serve patients that must overcome distance and transportation barriers to receive services. Some rural patients travel in excess of 35 miles to seek care, especially when they require advanced and specialized services. For example, maternal health care and specifically labor and delivery services are offered by fewer hospitals. In Iowa 33.3% of counties are identified as maternity care deserts.[2] Additionally, nearly 22% of babies born in Iowa are born to women in rural communities, while only 9% of maternity care providers practice in those rural communities.[3] For new moms and babies, limiting contract pharmacies within a static mileage radius of a Covered Entity with labor and delivery services may not align to the larger geographies of rural service areas.

- ***Complex and higher-acuity patients are also disproportionately affected by mileage restrictions because specialty and subspeciality care is often centrally located in urban Covered Entities.*** This is particularly true when specialists are in short supply and runs the gambit of services. In Iowa, there are only two Level I trauma centers that serve patients from across the state, including a UnityPoint Health Covered Entity located in the state capital. In Illinois, a UnityPoint Health Covered Entity is located in a regional population center and houses a cancer center serving a 13-county region. In Wisconsin, a UnityPoint Health Covered Entity in the state capital operates the only not-for-profit inpatient child and adolescent psychiatry (CAP) program in south central Wisconsin, serving youth ages 6–18 with behavioral health challenges. Figure B indicates inpatient

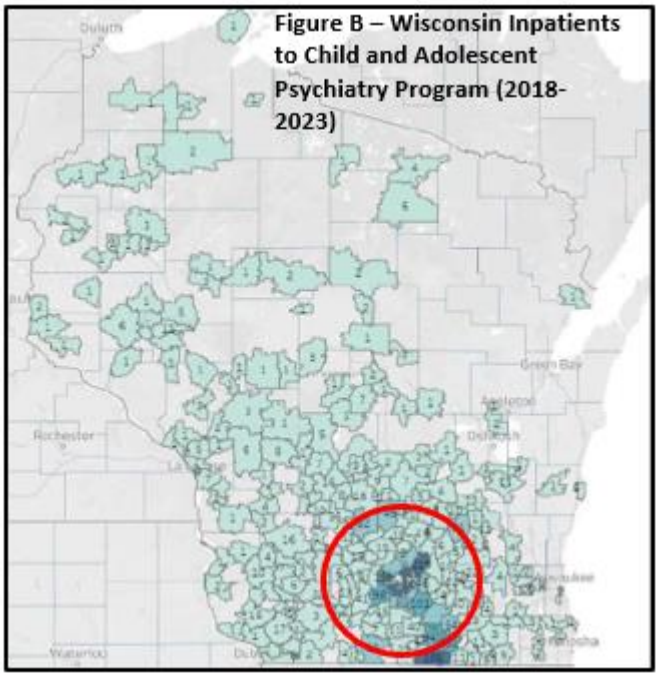


Figure B – Wisconsin Inpatients to Child and Adolescent Psychiatry Program (2018-2023)

[2] Maternal care deserts are defined as having zero hospitals and birthing centers that offer obstetric care and zero obstetric providers.
[3] https://www.marchofdimes.org/peristats/assets/s3/reports/mcd/Maternity-Care-Report-Iowa.pdf

CAP encounters by Wisconsin residents from 2018 to 2023, and the red circle denotes a 40-mile radius.

- ***Patient access to limited distribution drugs and specialty pharmacy drugs will effectively be eliminated for the majority of patients***. In these arrangements, payers and drug manufacturers limit where patients can fill these prescriptions – often to distribution networks of only 5-10 pharmacies nationally. These drugs tend to be the most expensive and access to 340B pricing by patients is crucial for affordability. For example, Revlimid is a cancer drug (generally for multiple myeloma) with limited distribution to 21 pharmacies nationally; and Trikafta is a cystic fibrosis drug with limited distribution to 6 pharmacies nationally. For UnityPoint Health, we have patients that take and benefit from these medications; however, these limited distribution and specialty pharmacies fall outside the geographic footprint of the majority of our Covered Entities. Although the patient number is small, the impact to their health and quality of life is huge.

Caps on Sites/Locations: **UnityPoint Health urges caution in placing arbitrary limitations on the number of contract pharmacies per Covered Entity.** The presence of retail pharmacies in urban areas tends to be more prevalent. It should be no surprise that urban Covered Entities usually contract with a greater number of contract pharmacies. While urban residents may not face overall mileage barriers, there are logistic barriers of accessing convenient pharmacies using public transportation. It may take an individual more time to traverse across the Madison, Wisconsin metroplex than to travel across three Iowa counties. In Waterloo, Iowa, public transportation does not operate during the evening. **Placing caps on contract pharmacy locations will effectively:**

- ***Remove local need/demand and market forces from contract pharmacy arrangements***. Instead of basing the scope of arrangements on patient need, a cap will institute a strawman target. Whereas 10 locations may be suitable for one Covered Entity, another may use 2 contract pharmacies and still another may use 20+ contract pharmacies. The market should control, not legislative or regulatory limits set without regard to local need. In our markets, our individual Covered Entities refine the number of pharmacies – both independent and national chains – on an ongoing basis to meet patient need. In some cases, we eliminate locations from a network for no or very low utilization and, in other cases, we add locations when patient needs present themselves. For instance, over the last 10 years our Madison, WI Covered Entity has enrolled 22 pharmacies, terminated 58 pharmacies, and currently operates a network of 34 pharmacies. These changes were designed to ensure we meet the needs of our communities while balancing the administrative overhead of maintaining each location. Covered Entities should be given the flexibility to determine contract network adequacy and be enabled to police themselves.
- ***Limit the use of chain pharmacies, creating patient confusion and hampering convenience***. Instituting a pharmacy cap may disallow some national chain pharmacies from participating – it is not common and overly burdensome for a national chain pharmacy to enter into contracts for one site. Yet patients often prefer these pharmacies that often have extended pharmacy hours and are located on public transportation routes. Additionally if contracts are limited to a single

grocery store or national chain pharmacy location instead of all locations within a metropolitan area, this creates unnecessary patient confusion when pricing differs.

- ***Eliminate patient access to limited distribution drugs and specialty pharmacy drugs for a majority of patients***. Like geographic restrictions, a cap on pharmacies will also adversely impact our ability to keep these pharmacies within our contracted network. With different distribution networks for specific life-changing medications, these could easily take up all pharmacy slots under a cap. The choice of network partners will pit those serving a majority of patients with low to moderate cost prescriptions against a small number of patients with extremely high-cost medications. This choice is not one that would be envisioned under the "Sense of Congress" to promote access.

Role of Pharmacy Benefit Managers (PBMs): 340B Covered Entities are bestowed with stewardship of spreading scarce federal resources in the promotion of health care access. **UnityPoint Health supports prohibiting PBM discriminatory 340B pricing practices.** To preserve PBM rebate revenue, 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. As for network requirements, PBMs do own specialty pharmacies and establish formularies that drive network participants to those pharmacies for those drugs while excluding other pharmacies. While not all Covered Entities own a specialty pharmacy, our parent entity did establish a specialty pharmacy eight years ago to timely offer medications to coordinate care by administering oversight and clinical benefit for complex and expensive patients under our value-based contracts. It has been difficult if not impossible to negotiate with PBMs for inclusion of our specialty pharmacy within network contracts. **UnityPoint Health requests that Congress consider requiring non-exclusive specialty pharmacy networks for networks that include a PBM-affiliated specialty pharmacy.**

Section 4. Patient Definition. This section provides a definition of patient which is currently omitted from the statute. The RFI seeks additional feedback on how to appropriately structure the definition.

Comment: **UnityPoint Health supports the HRSA 1996 patient definition.** This definition is the lynchpin for Covered Entities to apply 340B-acquired drugs and use 340B pricing. If this definition is to be placed in legislation, we caution against definitional changes that may enable further scrutiny and legal challenges to narrow the scope of the 340B Program.

However well-intentioned a "meaningful relationship" standard is to define the existence of a 340B patient triggering use of 340B pricing, such a standard is more apt to develop bright-line rules that fail to account for diverse patients and disease states resulting in reduced access to 340B drugs.

- Clinical Responsibility for Health Care Services Directly Related to Use of the 340B Drug: We echo 340B Health's concerns that imposing a meaningful relationship standard harkens back to the withdrawn HRSA mega-guidance that proposed to restrict "340B use to only those drugs ordered as part of a service provided by the Covered Entity, determined on a prescription-by-prescription basis, and barred 340B use in many other widely used areas, including for prescriptions written

outside of the hospital pursuant to referrals and discharge prescriptions related to inpatient care."[4] A prescription-level location test (1) creates eligibility complexity with an appearance of inconsistency, (2) reinforces patient confusion and dissatisfaction that erodes trust in their ability to rely on 340B pricing and their providers, and (3) contradicts the "Sense of Congress" under which safety net providers (Covered Entities) are charged with maintaining, improving, and expanding patient access to health care services.

As an example of how a location test could be confusing to patients, consider this example: a patient was admitted to one of our hospitals and received a prescription at discharge. She filled the prescription with us for a few months and, when it ran out of authorized refills, we faxed her provider. The clinician authorized a new prescription in her clinic which is not 340B-eligible. From the patient's perspective this is the same medication, from the same provider, used to treat the same condition. For the past few months, it has been available at the reduced 340B price but that price is no longer available. This scenario would be confusing to any patient, particularly our safety net population who are most dependent on consistent availability of the discounted price.

- Clinics with Clinically Meaningful Range of Services: It is uncertain whether a clinic targeting a particular disease state (cardiology) or specific service (infusion) would meet these requirements. Ultimately, the range of services that are "clinically meaningful" should be within the purview of providers and not regulators as they would need to be assessed against the availability of various services across the community.
- Prescribers as Employees or "Bona Fide Contractors": The relationship of providers / prescribers to Covered Entities is ever-evolving and not limited to employees or "bona fide contractors". Providing a laundry list of approved relationships in statute for 340B prescribers is a slippery slope that will be subject to periodic review and updates. As such, we recommend excluding this provision.

If a 340B patient definition is included in statute and Congress elects to further refine the 1996 definition, UnityPoint Health would support a reasonable limitation on the duration of the patient relationship. At minimum, we would suggest using national standards, such as the American Medical Association (AMA) guidelines that consider an established patient to be an individual who received a health care service from a provider within the last three years.

While it is true that patients may be served by multiple Covered Entities, UnityPoint Health believes that this is an area that is sufficiently addressed through software vendors and the dynamic contract pharmacy market without additional legislative language. Ultimately, Covered Entities are responsible for compliance. The current risk of multiple discounts being paid is minimal – at the end of the day, a pharmacy only collects revenue for the prescription once and it can only pass that along to one Covered Entity. How Covered Entities operationalize this coordination in the market is something we believe is best left to the technology vendors who are experts in this and develop solutions to communicate and coordinate across Covered Entities.

[4] 340B Health Response to the Draft Sustain 340B Act Legislation, dated March 27, 2024, page 5.

Section 5. Child Sites. This section provides for the establishment and use of child sites in the 340B Program emphasizing that child sites should be wholly-owned by and financially and clinically integrated into the Covered Entity. The RFI seeks additional feedback on how to appropriately ensure child sites are aligned with the intent of the 340B Program.

Comment: **Foremost, UnityPoint Health applauds the transition from child sites being on a reimbursable line of the Medicare cost report**. This aligns with the "Sense of Congress," which is vital for a reliable health care safety net and drives access by patients to discounted prices. By focusing on clinical integration over financial integration, Covered Entities are empowered to deliver care in the most cost-efficient manner, and patient access to drugs and services is prioritized over copayments.

Clinical integration should be broadly defined to enable integrated delivery networks and the evolving nature of clinical relationships with child sites that promote coordinated care and value-based arrangements. The 340B Program should not silo care or create barriers for safety net Covered Entities to offer discounted medications or to support health care access. Child site flexibility also keeps patient experience at the forefront, where it should be, and supports continuity of patient care plans. For patients, care among Covered Entity child sites should appear seamless.

In terms of child site oversight, current HRSA registration practice has exponentially inflated this issue to the point where it is nonsensical. 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 (more than 30,000 child sites nationally), despite the fact the statutory eligibility has remained static. For instance, our Des Moines Covered Entity currently shows 65 active child sites located at just 13 different addresses, including 27 child sites at a single street address. **We urge Congress to rein in the child site registration process and require that child sites be registered by address, not at the accounting unit level**.

Section 6. Transparency. This section provides that Covered Entities report detailed information regarding their program savings, policies, patient and prescription information, and that information be publicly available.

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 340B Program to the patients, hospitals, and communities. Congress should consider the following principles:

- Meaningful, Holistic Measures: **Transparency should reinforce the "Sense of Congress"** to enable flexibility for Covered Entities to use 340B Program benefits to meet the unique needs of the community and patients they serve and accurately reflect those benefits. Reporting must not pigeonhole nor overly prescribe the way benefits should be used.
    - *Safety Net Community Benefit*: When 340B benefits are equated solely with charity care, this

vastly underreports community benefit. **Although charity care is a subset of 340B benefits, it is not the totality of safety net community benefit**. Instead, safety net community benefit includes charity care, subsidized services, community health improvement activities, Medicaid underpayments, health professional education and research. 340B hospitals already publicly report this data on Form 990s and Community Benefit statements.

- *Program Savings*: **340B Program savings is accurately measured by the Group Purchasing Organization (GPO) drug price minus the 340B Program drug price**. The use of the Wholesale Acquisition Cost (WAC) drug price minus the 340B Program drug price overstates any program savings as the WAC price is never utilized under the program. As such, WAC is essentially meaningless but the inflated price tag would be a boon to 340B Program critics who could suggest hospitals aren't doing enough to justify the inflated amounts.

- Ease of Administration: Transparency should avoid duplicative or onerous reporting so that the administrative burden does not outweigh the program benefit. Considerations include:
  - *Covered Entity Level Reporting*. Congress should demand transparency at the Covered Entity and drug manufacturer level. These are the primary parties to the 340B Program. While UnityPoint Health supports reporting by Covered Entities, **the administrative burden of reporting per individual child site and/or contract pharmacy location is onerous and, in many cases, not meaningful.**
  - *Leveraging Existing Data*. 340B hospitals already submit substantial amounts of public data, such as Form 990s and Community Benefit statements. These **existing data points should be leveraged as much as possible** to minimize the overhead required to generate them.
  - *Access to Specific Datapoints.* The discussion draft proposes at least 12 discrete categories of data for reporting. Some of this data is not currently collected, and the rationale for its proposed collection is not stated. Instead of simplifying reporting, **this proposal appears to make reporting more complex without underlying justification or ties to Congressional intent**. If Congress seeks to significantly revamp Covered Entity reporting, we recommend that this be studied prior to implementation for collection burden, oversight efficacy, and impact on the health care safety net.

- Equitable Transparency Among 340B Parties: **Both Covered Entities and drug manufacturers should be accountable for 340B Program transparency**. While this RFI and current 340B Program transparency concentrates on Covered Entity reporting, this should be a shared responsibility with drug manufacturers. The 340B Program is a voluntary program for drug manufacturers and their participation is a gateway to selling their medications to Medicare beneficiaries and Medicaid enrollees. Presently, drug manufacturers are not subject to 340B reporting requirements. Congress should consider requiring drug manufacturers to be accountable, and reporting of the benefits and costs of the 340B covered drugs seems like a reasonable starting point.

- Exclude Oversight of Proprietary Contracts: **Covered Entities enter into contract arrangements to operationalize the 340B Program, including proprietary contracts with software vendors and**

contract pharmacies. While Covered Entities may identify those contracts, their terms are proprietary and disclosure would cause unfair competitive advantage. This situation would be similar for drug manufacturers and/or PBM contractual arrangements.

Section 7. Enhancing Program Integrity. This section provides that the Secretary will issue additional guidance regarding audits in the program and provide appropriate consequences if a Covered Entity does not meet compliance requirement.

Comment: 340B Program integrity ultimately hinges on the scope of the underlying statutes and regulations. **To ensure Covered Entity and drug manufacturer compliance, UnityPoint Health urges HRSA to clearly articulate agency standards**. HRSA has the ability to engage in a public notice and comment process to proactively engage stakeholder feedback and message regulatory requirements. While Covered Entities appreciate a formal rulemaking process with associated timely agency guidance to permit the implementation of any operational changes, this has not been HRSA's routine practice. Rather, 340B Program integrity involves a retrospective review of audit findings by Covered Entities to garner trends on areas of oversight focus and concern. HRSA performs 200 audits annually and, for 2023, 60 audit findings are still pending going into the second quarter of calendar year 2024. These pending audit findings will likely yield new areas of oversight emphasis to be identified by Covered Entities, despite the fact that the statutory authority and overarching regulations have not changed.

Section 8. Preventing Duplicate Discounts. This section creates a national third-party clearinghouse.

Comment: **UnityPoint Health supports the implementation of a retrospective national clearinghouse model to improve duplicate discount prevention based on the Oregon experience**. 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 and alter 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 a 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*. UnityPoint Health opposes the collection of claims data from all payers to mitigate duplicate discounts, and clearinghouse data should not be shared with drug manufacturers.

We also appreciate the discussion draft's consideration of a 340B Patient Discount Safe Harbor. A safe harbor enables Covered Entities to extend the 340B discount to patients without compliance fears. Currently, Covered Entities wishing to provide a patient discount face 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.

Despite any safe harbor protections, **UnityPoint Health is concerned with changes to charity care that will require Covered Entity financial assistance policies to be applied at the point of sale to all sites of care**. As charitable tax-exempt organizations under Internal Revenue Code Section 501(c)(3), UnityPoint Health hospitals meet the medically necessary health care needs of all patients who seek care, regardless of their financial abilities to pay for services provided. Pursuant to Internal Revenue Code Section 501(r) and other applicable state laws, each UnityPoint Health hospital has adopted and publicizes its financial assistance policy to provide discounted care to financially needy patients. The proposed safe harbor changes will support our expansion of charity care to improve access to medications; however, requiring this policy at all contract pharmacies may not be as impactful as desired. Some specialty medications continue to have prohibitive costs, even with the 340B discount. For instance, most patients may not see much benefit in only facing $18,000 per month rather than $25,000 per month on some specialty medications. Regardless, ongoing access to these medications at contract pharmacies plays a vital role our ability to provide comprehensive services, and the 340B Program serves to help slow inflation on these exorbitantly priced medications. While contract pharmacy provide needed access points for medication distribution, extending Covered Entity financial assistance policies to contract pharmacies is not only contractually and operationally burdensome but it adds a layer of governmental interference in private contracts for which market forces and business judgment should rule.

Section 9. Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies. This section provides that plans and PBMs cannot place differential terms on Covered Entities or their contract pharmacies and that the benefit accrues to the Covered Entity and not other parties.

Comment: As referenced in our comments under "*Section 3. Contract Pharmacy*," **UnityPoint Health supports prohibiting PBM discriminatory 340B pricing practices**. Due to Congressional inaction, states have started to address this on a piecemeal basis. As a federal program with oversight by HRSA, **Congress should be the legislative body to address nondiscriminatory pricing practices**. This will also avoid compliance complexities that will naturally result from a patchwork of state laws on this issue.

In addition, PBMs routinely include within their contracts provisions that require pharmacies to collect in full patient co-pays. Depending upon the plan, higher priced drugs could result in hefty co-pays, even with the 340B Program. **To drive patient access, Congress could consider permitting 340B revenue from the drug manufacturer or PBM to be used by Covered Entities to offset patient co-payments**.

Additional Comments. Although not specifically addressed in the Discussion Draft or RFI, Congress could consider additional issues within a legislative proposal.

Comment: **UnityPoint Health encourages Congress** to consider memorializing the following in statute in any future legislation:

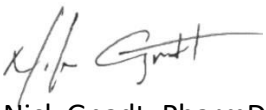
- Preserve the Inflationary Penalty. Drug manufacturers who raise their prices faster than the rate of inflation must pay additional 340B discounts. Research by the American Medical Association found that the stiff penalties drug manufacturers face in the 340B Program for price increases above the

rate of inflation restrain drug price increases for all purchasers.[5] This inflationary penalty is a benefit of the program which curbs costs and helps all patients access lower prices.

- 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.

We are pleased to offer feedback on this Discussion Draft and RFI and the impact of the 340B Program 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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Cathy Simmons, JD, MPP
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[5] Dickson S. Association Between the Percentage of US Drug Sales Subject to Inflations Penalties and the Extent of Drug price Increases. *JAMA Netw Open*. 2020;3(9):e2016388, accessed at https://jamanetowrk.com/journals/jamanetworkopen/fullsrticle/2770540