August 25, 2023

The Honorable Cathy McMorris Rogers
Chair
House Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

RE: Stop Drug Shortages Act Discussion Draft issued July 28, 2023
Submitted electronically via drugshortages@mail.house.gov

Dear Chair McMorris Rogers,

UnityPoint Health appreciates this opportunity to provide input on Stop Drug Shortages Act Discussion Draft. 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 13 home health agencies across our 8 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin.

UnityPoint Health is pleased that the Committee tackling this important issue and providing an opportunity for stakeholders to comment. UnityPoint Health is a member of the American Hospital Association, has reviewed their formal comments and is generally supportive of their feedback. In addition, UnityPoint Health respectfully offers the following input on select topics.

**Title I. MEDICAID**

*The Stop Drug Shortages Discussion Draft includes provisions to exempt certain specified drugs from certain increases in rebates under the Medicaid program and prohibit a rebate cap for certain drugs.*

**Comment:** As the Committee considers this topic, we caution the creation of financial incentives that are triggered when drugs are in short supply, such as the suspension of Medicaid rebates for these drugs. When crafting drug shortage policies, consideration should be given to whether these actions create perverse incentives and should prioritize preventive strategies rather than those that are reactive to an ongoing shortage. **Alternatively, the Committee could also consider an approach to incentivize manufacturers to build additional capacity, improve redundancy, and maintain an adequate supply of product to meet market fluctuations.**
Title II. 340B Drug Discount Program

The Stop Drug Shortages Discussion Draft includes provisions to exempt generic, sterile injectable drugs from the 340B Drug Discount Program; initiate a Government Accountability Office study on Penny Pricing and Other Price Setting Policies; and task Health Resources and Services Administration to issue guidance on authorize drug diversions during shortage periods.

Comment: We appreciate the Committee’s interest in examining the 340B Drug Pricing Program and its interaction with drug shortages. The 340B Drug Pricing Program is vital to funding the safety net providers and seems ill-equipped as a mechanism to resolve drug shortage issues. UnityPoint Health has not observed, nor do we believe there is, a correlation between 340B prices and drug supply shortages; however, inclusion in the 340B program does not necessarily shield drugs from supply shortages but this does not equate to a cause-and-effect relationship. It is our observation that brand name products tend to be the drugs with the largest 340B discounts, yet these drugs are less likely to be in short supply. Conversely, generic drugs, including some in short supply, have a smaller discount than brand name products under the 340B statute – discounts average 13% versus 23.1% respectively; however, the discount for any drug can be increased if its price increases faster than the rate of inflation.

Sec. 201. UnityPoint Health does not support the elimination of 340B discounts for generic injectables. There is no evidence that the 340B program itself results in supply chain shortages, an overreliance on overseas production, or the consolidation of generic manufacturers. Section 201 creates a slippery slope and will provide an avenue for manufacturers to seek exceptions to avoid supporting 340B safety net providers simply based on delivery methodology. As written, this exception is overly broad based on disease condition and drug delivery without indicating supply chain adversity. Additionally, this exception appears to apply to drugs with multiple approved manufacturers and is not limited to generics. For instance, Leqembi is the newest sterile injectable Alzheimer’s drug, developed by Eisai along with Biogen. The discussion draft would allow each manufacturer to come to market with similar products and avoid paying 340B discounts.

Sec. 202. Addressing the underlying causes of drug shortages is vital to assure that necessary and affordable medications are available. The narrow focus of the proposed GAO study (‘penny priced’ or drugs with costs equal to or less than $1) suggests a misguided causal relationship. For instance, penny priced drugs are only triggered after years of price increases outpacing inflation, and this is an important tool to promote affordability. The Committee should consider tasking GAO to examine top tier causes of drug shortages or for artificially keeping the costs of generic drugs low involves supply chain issues, intellectual property laws, and manufacturer behaviors. Should GAO examine this important root cause, we would recommend that the scope be increased to consider drug pricing generally and overall drug supply chain.

Sec. 203. We welcome HRSA providing explicit guidance on permissible ways to manage through drug shortages. In the development of this guidance, we encourage HRSA to work with stakeholders and gather input prior to releasing its guidance.
Title III. MEDICARE

The Stop Drug Shortages Discussion Draft includes provisions to reduce inflation rebate amounts for certain shortage drugs subject to rebate waivers under the Medicare program; establish a model on alternative payment for generic sterile injectable drugs under CMMI; require hospital reporting of group purchasing organization remuneration under Medicare; clarify Medicare average sales price payment methodology; and authorize studies on (1) market-based pricing for shortage drugs under Medicare Part B, (2) Medicare coding for drugs in shortage or in danger of shortage, and (3) flat fee payment.

Comment: Blank Children’s Hospital is a UnityPoint Health affiliate located on Des Moines, Iowa. This hospital serves acute and chronically ill pediatric patients.

Sec. 503. As a member of the Children’s Hospital Association, we echo their comments related to importance of pharmacy compounding flexibility when facing drug shortages:

503B compounding facilities can play a vital role in preventing the impact of pediatric drug shortages. For example, earlier this year, children’s hospitals across the country started to see a shortage in albuterol, which prompted hospital/supplier collaboration. Just when the manufacturers of albuterol in the U.S. stopped production, there was an uptick in off-season RSV, flu, and COVID-19 that created a shortage when it was needed most. A 503B outsourcing facility that provides compounded pediatric medication worked with children’s hospitals to secure the active pharmaceutical ingredients for albuterol. This partnership among hospitals and compounding facilities proved crucial when ensuring a stable supply chain for pediatric patients.

More time for 503B facilities to compound and distribute shortage drugs would be a useful mechanism to meet ever present shifts in demand as we experience during this recent surge.

Title IV. TRANSPERANCY

The Stop Drug Shortages Discussion Draft includes provisions to require reporting by Group Purchasing Organizations.

Comment: UnityPoint Health encourages the Committee to expand the Discussion Draft to include supply change transparency in relation to the Strategic National Stockpile (SNS). As a member of the American Society of Health-System Pharmacists, UnityPoint Health supports their recommendations to improve SNS functionality. Those recommendations¹ include:

- Finalizing and regularly updating a list of medicines necessary to respond to potential national-scale public health emergencies, which should be included in the SNS. These drugs may differ from those on the essential medicines list.
- Increasing transparency regarding the specific products and quantities of such products included in the SNS.
- Publishing a clear, nationally consistent process for making requests from the SNS, including publication of contact information for key personnel in each agency that has responsibility for managing requests and distributions from the SNS.

¹ https://www.ashp.org/advocacy-and-issues~/link.aspx?_id=7CE8B000F03C42FEA53837A13DD500F6
• Engaging pharmacists and other supply chain experts to develop process for maintaining and refreshing products in the SNS.
• Creating a standard distribution logistics process for medications and related supplies from the SNS that incorporates feedback from pharmacists and other supply chain experts, including clear expectations for how updates to these processes will be publicized, if needed, in the event of a national emergency.
• Publishing criteria that will be used to prioritize distribution of products from the SNS, including clear expectation for how updates to these criteria will be publicized, if needed, in the event of a national emergency.
• Incentivizing the creation of private sector reserves of essential medicines not adequately provided by the SNS.

Title V. FOOD AND DRUG ADMINISTRATION (FDA)

The Stop Drug Shortages Discussion Draft includes provisions to authorize: Noncompliance letters relating to volume reporting; incentives for shelf-life extension studies; a lag period for outsourcing facilities to compound and distribute drugs in shortage; additional information gathering on generic drug Active Pharmaceutical Ingredients (API); reporting on use of new authorities and requirements with respect to drug shortages; and the creation of a New Domestic Facility Inspection Pilot Program.

Comment: As a member of the American Society of Health-System Pharmacists, UnityPoint Health supports their FDA recommendations:
• Provide ratings on the quality management processes of drug manufacturers in order to help predict drug supply chain and manufacturing vulnerabilities; and
• Expand the Drug Supply Chain Security Act (DSCSA) to require manufacturers to provide transparency in active pharmaceutical ingredient (API) sources and manufacturing locations, including locations of contract manufacturers.

We are pleased to offer feedback on this Discussion Draft and its impact on our hospitals, patients and communities. 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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