PREMIER TRANSFORMING HEALTHCARE TOGETHER®

June 6, 2024

The Honorable Ron Wyden
Chair
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Senate Finance Committee
239 Dirksen Senate Office Building
Washington, DC 20510

Submitted electronically via drugshortages@finance.senate.gov

Re: Senate Finance Committee Prescription Drug Shortage Discussion Draft

Dear Chair Wyden and Ranking Member Crapo:

Premier Inc. appreciates the opportunity to submit comments to the Senate Finance Committee Prescription Drug Shortage Discussion Draft. The proposal, released as a discussion draft, would establish a new voluntary program in Medicare for hospitals and physicians to incentivize transparent, reliable, and resilient purchasing practices across supply-chain participants, healthcare providers, and drug manufacturers to secure a sustainable, high-quality supply of essential medicines for patients.

Premier has been a leader in mitigating drug shortages for over twenty years and remains committed to eliminating them. Premier applauds the bipartisan work of the Senate Finance Committee to seek a path forward on addressing the issue of drug shortages in the Medicare program. We particularly thank you for recognizing the vital role that group purchasing organizations (GPOs) play in vetting quality manufacturers and how they can play a central role in combatting shortages. Premier also appreciates the incorporation of elements we highlighted for consideration in previous comments to the Committee, including testing reimbursement models that create stability for drugs prone to shortages and leveraging private-public partnerships to nationally scale private sector innovations that have successfully helped to address drug shortages for hospitals across the country, and most importantly, patients.

Premier's response to the draft legislation focuses on opportunities to further refine the proposal to best serve the needs of patients. Specifically, Premier urges the Senate Finance Committee to consider amendments to the draft legislation that:

- Aligns all timelines for Program Participants, Payment-Eligible Providers, and Applicable Generic Manufacturers to a three-year timeline;
- Clarifies that minimum commitment volumes should be done at the National Drug Code (NDC) level;
- Ensures there are a minimum of three Program Participants across various business sectors to ensure viable competition in the marketplace;
- Creates a payment methodology for Program Participants that is a scalable flat fee based on the services provided;
- Requires Program Participants to maintain an advisory committee comprised of individuals with clinical and/or supply chain expertise from Payment-Eligible Providers to help ensure that contracting decisions are being made in the best interest of patient care and supply chain resiliency;
- Clarifies that a secondary manufacturer is not required to be added to contract if more than one manufacturer is unable to meet the stringent vetting requirements of the program;
- Studies the downstream impact of removing 340B discount eligibility on the ability of a covered entity to provide care to underserved populations;
- Prohibits Payment-Eligible Providers from seeking or accepting additional rebates, discounts, or other price concessions from Program Participants;
- Refines the buffer inventory requirements to be more cohesive;

- Permits Program Participants to centralize and collate reporting on behalf of Payment-Eligible Providers;
- Considers outcomes measures that tie back to patient outcomes; and
- Requires Applicable Generic Manufacturers to submit transparent quality and manufacturing data to Program Participants to facilitate product review and selection.

I. BACKGROUND ON PREMIER INC. AND OUR LEADERSHIP IN ADDRESSING DRUG SHORTAGES

Premier is a leading healthcare improvement company that works with more than 4,350 U.S. hospitals and 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with providers to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of Premier's alliance is our Integrated Pharmacy Program, which leverages essential clinical data to deliver reduced costs, improved quality, safety and resiliency, and increased knowledge-sharing among healthcare professionals.

Premier has been a leader in addressing drug shortages for more than twenty years and is committed to eliminating drug shortages from both a policy perspective via legislative and regulatory action as well as pursuing actionable, market-based solutions. Since 2019, Premier's voluntary ProvideGx Program identifies safe, high-quality supply sources for drugs that are or may be at risk of being added to the national drug shortage list. Guided by health systems with more than 1,600 hospitals across the nation, ProvideGx creates long-term committed buying contracts that provide participating manufacturers with the surety needed to increase production. Premier's programs, including ProvideGx, currently provide hospitals access to more than 150 drugs that are or have been recently designated as shortage drugs.

In the past five years, Premier's drug shortage programs have:

- Successfully resolved 15 drug shortages, resulting in their official delisting from the FDA shortage list.
- Ensured uninterrupted supply of many shortage drugs despite demand spikes of more than 150 percent during the pandemic.
- Continued to bring resiliency to the market by incenting the domestic manufacture of vital drugs through investments in VGYAAN and Exela Pharma Sciences, which combined are working to bring new, domestic sources of 20 different shortage drugs and counting.

A key component to Premier's success in mitigating drug shortages is the stringent contracting and vetting process manufacturers who wish to work with Premier must undergo. This includes sharing information regarding the location of their finished dose manufacturing and active pharmaceutical ingredient (API) sources. In addition, all manufacturers participating in Premier programs are vetted to enable more geographically diverse production capability, adequate buffer inventory, and surge capabilities to meet sudden spikes in demand. Finally, manufacturers are asked to share their redundancy and contingency plans to ensure ongoing supply of product and mitigate risk. Premier maintains this level of information for almost 6,000 unique National Drug Codes (NDCs) and leverages the information to assign a supply chain resiliency risk score to each product. That score is then utilized by Premier and its hospital-led advisory committees to make contracting decisions that are in the best interest of patient care and supply chain resiliency.

Premier's ongoing commitment to addressing drug shortages also includes diligent advocacy efforts over the years including serving as the lead proponent of the Mitigating Emergency Drug Shortages (MEDS) Act, which was incorporated and signed into law as part of the CARES Act in March 2020.

Premier will continue to innovate and collaborate across diverse stakeholders to address ongoing drug shortages.

II. SUGGESTED REFINEMENTS TO THE DRAFT LEGISLATIVE PROPOSAL

Premier offers the following recommendations to help refine the draft legislative proposal based upon our five years of experience operating the ProvideGx Program which leverages long-term contracts with drug manufacturers to help stabilize the market for drugs prone to shortage.

- **Alignment of Timelines**. The draft legislation would require Program Participants to enter into two-to-three-year long-term contracts with Applicable Generic Manufactures but would require Program Participants to reapply annually and provide an opportunity for Payment-Eligible Providers to switch Program Participants annually.

  In Premier's experience, the key to leveraging long-term contracts to help combat drug shortages is ensuring long-term alignment of timelines across all entities engaged in the contracting and purchasing process. In this case, that means ensuring alignment of timelines across Program Participants, Applicable Generic Manufacturers, and Payment-Eligible Providers. As such, ***Premier strongly urges the Committee to align all the timelines to a three-year timeline***. Specifically:

  - Program Participants should enter into a three-year long-term contract with Applicable Generic Manufacturers;
  - Program Participants should be approved by the Secretary to participate for a three-year term; and
  - Payment-Eligible Providers should select a primary Program Participant for a three-year term.

  Alignment across all entities is essential to ensure Applicable Generic Manufacturers receive the volume surety they need to continue to invest in quality, reliability, and a sustainable supply chain. For example, it would be detrimental if an Applicable Generic Manufacturer entered into a three-year long-term contract with a Program Participant who a year later was no longer participating in the program. Similarly, if Payment-Eligible Providers can switch Program Participants annually, that would create substantial volatility in the committed purchasing volume year over year for Applicable Generic Manufacturers negating the intent of the program.

  Furthermore, Premier offers two additional areas for the Committee to consider as it refines the legislative text:

  - First, in some circumstances, the Committee should consider up to five-year terms. In Premier's experience, there are situations where a manufacturer prefers a five-year long-term committed contract to justify participating in the program. This is especially true when a manufacturer is entering the market for a new drug and making an upfront capital investment for research and development in addition to FDA GDUFA fees.
  - Second, the Committee should consider the alignment of timelines for situations where a Program Participant adds a new drug or a new Applicable Generic Manufacturer to contract mid-cycle. For example, it is possible that an additional Applicable Generic Manufacturer may come to market after the initial contract was awarded and the Program Participant wishes to add the additional manufacturer to contract to create further resilience and stability in the market. Furthermore, situations may arise where a drug is eligible for generic competition mid-cycle and therefore added to contract by the Program Participant mid-cycle. In these situations, the Program Participant should be able to work with the Secretary to determine an appropriate contract timeline that appropriately incentivizes the Applicable Generic Manufacturer and creates minimal disruption to the program overall, including execution of existing commitments by Payment-Eligible Providers.

- **Commitment at the NDC Level**. The draft legislation would require Payment-Eligible Providers to commit to a minimum committed volume of an applicable generic annually and permit adjustments to the minimum committed volume year over year.

  In Premier's experience, commitments at the National Drug Code (NDC) level vs at the drug product level are essential to ensure Applicable Generic Manufacturers receive the volume surety they need to continue to invest in quality, reliability, and a sustainable supply chain. This is primarily due to three main reasons:

  - First, not all Payment-Eligible Providers offer the same healthcare services in their facilities. For example, while one provider may offer pediatric services and therefore need a specific NDC number of a product, another provider may not offer pediatric services and therefore would need different NDC numbers of a product. Being able to commit by NDC numbers allows providers to pinpoint which specific drugs they need to care for the populations they serve.
  - Second, Applicable Generic Manufacturers plan their manufacturing around specific NDC numbers. Having surety of volume at the NDC level allows them to better plan manufacturing cycles to ensure an adequate supply is available to meet demand.
  - Third, tying commitment to individual NDC numbers also provides needed flexibility as new drugs come to market or as provider needs change. This allows for commitments to remain dynamic versus stagnant and for additional drugs and NDC numbers to enter the program mid-cycle.

  Therefore, ***Premier strongly urges the Committee to clarify that minimum committed volumes are tied to specific NDC numbers.***

- **Diversity in Program Participants**. The draft legislation articulates entities such as group purchasing organizations (GPOs), wholesalers, non-profits, and healthcare providers are eligible to be Program Participants. However, the draft legislation does not articulate a minimum number of Program Participants.

  Premier strongly urges the Committee to clarify that there must be a minimum of three Program Participants from various business sectors to ensure viable competition in the marketplace. By dictating a minimum number of Program Participants, the legislation would avoid an arrangement where a single Program Participant is incentivized to do the bare minimum given they would be guaranteed the market share.

  Furthermore, ***Premier strongly urges the Committee to clarify that a Program Participant must offer a diverse catalog of drug products across the healthcare ecosystem***. The rationale for this clarification is to ensure that appropriate competition exists across various product categories and that Program Participants are building catalogs to appeal to most healthcare providers. By providing this level of clarity, the legislation would avoid monopolistic arrangements where a Program Participant may choose to only contract for oncology agents, for example, and thereby drive all market share for oncology agents to a single entity.

- **Payment to Program Participants**. The draft legislation is relatively silent on how Program Participants will be paid for their services but does note that Applicable Generic Manufacturers may offer a Program Participant a bona fide service fee.

  Premier strongly urges the Committee to develop a payment methodology for Program Participants that is a flat fee based on the services provided and to move away from bona fide service fees that may be tied to the cost of the drug. In addition, the flat fee should be tier-based upon the volume and size of the program that the Program Participant is administering, with opportunities for additional add-on payments for meeting certain outcomes-based

measures tied to improving supply chain resiliency and decreasing drug shortages for Payment-Eligible Providers.

Given that the various entities that are eligible to be Program Participants all collect fees in different manners (e.g. GPOs collect an administrative fee based on the contracted sales price whereas wholesalers collect a distribution fee based on the list price), Premier feels it is important for the legislation to create a level playing field for how fees will be administered given that all Program Participants will be providing the same services and be held to the same standard. In addition, fee structures should not incentivize Applicable Generic Manufacturers or Payment-Eligible Providers to choose one Program Participant over another.

Finally, Premier seeks clarification regarding Direct Program Participants who are Payment-Eligible Providers who choose to participate in the program as a Program Participant. Will a Direct Program Participant be able to collect fees from both 1) the Secretary for payments related to core standards and advanced standards as a Payment-Eligible Provider; and 2) the Applicable Generic Manufacturer as a Program Participant? Premier is concerned that if a Direct Program Participant can collect both fees, they will be double dipping. Therefore, Premier strongly urges the Committee to clarify what fees a Direct Program Participant may or may not collect.

- **Program Participant Advisory Committees**. While the draft legislation articulates the expectations of Program Participants, it does not require that Program Participants maintain advisory committees. ***Premier strongly urges the Committee to clarify that a Program Participant must maintain an advisory committee comprised of individuals with clinical and/or supply chain expertise from Payment-Eligible Providers to help ensure that contracting decisions are being made in the best interest of patient care and supply chain resiliency***.

  In Premier's experience, an advisory committee of healthcare professionals is essential to help prioritize drugs for inclusion in committed programs, vet manufacturers for quality and reliability, and receive the necessary buy-in and commitment that the providers will purchase the drug once on contract.

- **Secondary Suppliers**. The draft legislation dictates that where there is more than one manufacturer of a generic drug, that a Program Participant must contract for a secondary supplier, ideally with a different active pharmaceutical ingredient (API) source, and that Payment-Eligible Providers must commit at least 10 percent of their minimum committed volume to the secondary supplier.

  Premier has significant concerns with mandating that a secondary supplier be placed on contract as just because there is more than one manufacturer of a drug in the market does not mean that more than one manufacturer meets the stringent quality, reliability, and resiliency requirements to be considered an Applicable Generic Manufacturer for inclusion in the program by a Program Participant. Premier would not want a situation where a secondary supplier is guaranteed 10 percent market share if they are unable to meet the vetting requirements. In our experience, there are situations where only a single manufacturer has been able to meet the stringent vetting requirements of the ProvideGx program even though there were multiple FDA-approved manufacturers for the same drug.

  Instead, ***Premier strongly urges the Committee to clarify that it should be up to the discretion of the Program Participant, in conjunction with their advisory committee, whether to contract with one or more manufacturers of a specific drug in the same strength, dosage form, presentation, etc. if more than one manufacturer is able to meet the requirements necessary to be considered an Applicable Generic Manufacturer under the program***. In addition, ***Premier strongly urges the Committee to clarify that the Secretary should ensure at the program level that there is sufficient diversity in the number of contracted suppliers for specific drugs and***

that the Secretary should leverage its audit authority if it feels that manufacturers who meet the criteria of an Applicable Generic Manufacturer are not awarded contracts.

Premier also cautions the Committee to reconsider its approach for a minimal committed volume to be split between a primary and secondary manufacturer. From a healthcare provider perspective, having more than one NDC of a specific drug in the same strength, dosage form, presentation, etc. can lead to provider confusion, medication errors, and expense to manage two separate inventories of the same drug. In lieu of requiring Payment-Eligible Providers to maintain two separate NDCs of product, ***Premier strongly urges the Committee to clarify that where a Program Participant contracts with two or more Applicable Generic Manufacturers of a drug, that the Program Participant is responsible for splitting the total minimum committed volume from all Payment-Eligible Providers amongst the Applicable Generic Manufacturers such that each Applicable Generic Manufacturer receives a fair share of market share and each Payment-Eligible Provider minimizes the need to carry multiple NDCs of the same drug.***

- **Additional Discounts to Payment-Eligible Providers.** Under the draft legislation, a Payment-Eligible Provider may not seek or accept additional rebates, discounts, or other price concessions from Applicable Generic Manufacturers, including 340B discounts.

  Premier agrees with the Committee that drugs included in the program should not be subject to additional rebates, discounts, or other price concessions. However, as it relates to 340B, ***Premier urges the Committee to further study the impact of removing 340B discount eligibility from covered entities and the downstream impact to their ability to provide care to underserved populations***. Premier also urges the Committee to study whether WAC or sub-WAC discounts should continue to be permitted. Premier does note that on average a 340B discount for generic drugs is typically approximately 13 percent. Therefore, at minimum, any differential payments provided to covered entities for 340B eligible drugs should offset the lost discount.

  Premier also strongly urges the Committee to go a step further and prohibit Payment-Eligible Providers from seeking or accepting additional rebates, discounts, or other price concessions from Program Participants, inclusive of any share backs or cost plus/minus discounts. This is intended to further maintain pricing stability and ensure that the contracted price is the actual price.

- **Buffer Inventory Standards**. The draft legislation would provide an additional payment for Payment-Eligible Providers for meeting certain buffer inventory standards. Specifically, larger providers would be required to purchase a six-month supply of inventory and smaller providers would be required to maintain a three-month supply of inventory. The buffer inventory must be maintained on US soil.

  From Premier's experience, we agree with the Committee that buffer inventory is a critical component to ensuring supply chain resiliency. However, Premier is concerned that the proposed policy incentivizes individual stockpiling at the hospital level. This will create disparate stockpiles throughout the country as hospitals will compete with one another for inventory, further creating silos and fragmentation in our nation's emergency preparedness infrastructure, and resulting in potential waste of critical, limited, and valuable resources. One major lesson learned during the COVID-19 pandemic is the need for cohesive, holistic and national strategies for preparedness, not strategies that create further fragmentation.

  Instead, ***Premier strongly urges the Committee to clarify that a Program Participant should arrange for a buffer inventory to be maintained directly with the Applicable Generic Manufacturer as part of the contracting process***. The inventory should be maintained and rotated to account for the annual minimum commitment volume for all Payment-Eligible Providers and should be maintained centrally of behalf of all Payment-Eligible Providers by either the Program Participant, Applicable Generic Manufacturer or other contracted third-party. In addition, the Program Participant

should leverage technology to help ensure that during a shortage available product is dynamically distributed from the buffer inventory to the hospitals with the greatest immediate need. ***The cost for maintaining a buffer inventory should be incorporated into the contracted price of the product and therefore additional payments to Payment-Eligible Providers for maintaining a buffer inventory should no longer be necessary.***

Premier also has significant concerns with a 180-day buffer inventory as it can result in widespread national shortages of these essential medications due to how the policy would skew the supply versus demand curve for these medications. In Premier's experience and in speaking with a multitude of manufacturers of generic medications, a 90-day buffer inventory is an appropriate minimum target and appropriately protects the supply chain while efficiently accounting for capacity, carrying costs, and the need to reduce waste for most drugs. Therefore, ***Premier urges the Committee to clarify that all buffer inventories should be a 90-day buffer inventory, allowing for Program Participants and Applicable Generic Manufacturers to negotiate higher buffer inventories when deemed prudent or necessary.***

- **On-Time Deliveries**. The draft legislation requires the Secretary to develop uniform standards related to on-time deliveries for purchase orders under the program. Premier appreciates this notion as critical to the success of the program is the ability of the drugs to be distributed from the Applicable Generic Manufacturers to the Payment-Eligible Providers in a timely manner. A complicating factor that must be considered is that the distribution of drugs is primarily contingent upon wholesale distributors who often limit the ability of a hospital to purchase quantities of drugs above their historical purchasing threshold. In addition, there are often restrictions on minimum order quantities below which distribution is not prioritized, regardless of how critical the drug may be to patient care. This policy typically disadvantages small, independent hospitals in favor of providing available supply to larger health systems. In developing uniform standards, it is critical for the Secretary to ensure that normal distribution channels are available to deliver these drugs and that Payment-Eligible Providers receive priority to receive the drugs they have committed to under the program regardless of their volume or size.

- **Reporting Requirements**. The draft legislation requires Payment-Eligible Providers to report information related to their purchasing and inventory of applicable generics to the Program Participant and Secretary.

  In Premier's experience, a key to success for programs of this nature is the need to reduce administrative burden on healthcare providers and to develop the least burdensome approach. As such, ***Premier strongly urges the Committee to clarify that Program Participants can centralize and collate reporting on behalf of Payment-Eligible Providers to leverage in submitting required reports to the Secretary***. There is precedent for a policy of this nature as in the FY 2023 IPPS and CY 2023 OPPS final rules, CMS finalized a policy for differential reimbursement payments for domestically manufactured NIOSH-approved N95 surgical masks. Under CMS' policy, GPOs can reconcile purchasing on behalf of healthcare providers and provide reports that the healthcare provider can then leverage in submitting their cost reports. This policy has proven successful as it decreases provider burden.

  Additionally, perpetual inventory management of pharmaceuticals is not consistently deployed across the US healthcare system. Premier encourages the Committee to consider incentivizing Payment-Eligible Providers to maintain comprehensive inventory management and perpetual inventory systems for drugs covered under this program to further reduce the burden of manual inventory management practices commonly employed and to allow for visibility into real-time days inventory on hand metrics that will allow for greater understanding and tracking of supply challenges. As such, Premier urges the Committee to consider bipartisan legislative proposals such as H.R. 3577 – The Medical and Health

Stockpile Accountability Act – that would create near real-time visibility into critical medical supplies and drugs on US soil.

- **Outcome Measures**. The draft legislation would provide additional payments to Payment-Eligible Providers for performing well on certain outcome measures relative to their peers.

  Premier has significant concerns with the proposal to reward Payment-Eligible Providers for inventory on hand during a shortage as that would inadvertently incentivize hoarding during a shortage and therefore strongly urges the Committee to strike this provision. Instead, Premier urges the Committee to consider outcomes measures that tie back to patient outcomes such as decreases in the number of cancelled or delayed procedures, decreases in the number of medication errors or near misses due to a shortage, etc.

- **Contractual Obligations**. Premier urges the Committee to clarify the process for termination of binding agreements under the legislation. For example, can the Secretary terminate agreements, or will the parties retain the right to terminate for the usual contractual termination reasons? Namely, Premier is seeking clarification if any participant in the program would ever be forced to continue their participation if conditions were unfavorable?

- **Manufacturer Transparency.** To ensure that Program Participants and their advisory committees have sufficient data on quality, manufacturing, and resiliency for all Applicable Generic Manufacturers competing for contracts in the program, Premier urges the Committee to set minimum requirements for transparency and data sharing to facilitate product review and selection. In Premier's experience, there are situations where manufacturers are hesitant to provide the ProvideGx program with the full suite of requested information. Having a minimum set of data standards that a manufacturer must share with a Program Participant would be extremely helpful to ensure Program Participants and their advisory committees are able to make decisions in the best interest of patient care and supply chain resiliency with the same level of information available from all competing manufacturers.

III. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments on the draft legislation to inform policymaking for drug shortages. Premier looks forward to continuing to work with Congress to help prevent and resolve these shortages today and for the future. Please consider Premier a resource as you continue this important work.

If you have any questions regarding our comments or need more information, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

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Senior Vice President of Government Affairs
Premier Inc.