



600 13TH ST., NW, SUITE 500
WASHINGTON, DC 20005
p | 202-753-5500
f | 202-347-5147

16011 COLLEGE BLVD., SUITE 250
LENEXA, KS 66219
p | 913-262-1436
f | 913-262-1575

WWW.CHILDRENSHOSPITALS.ORG

February 9, 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
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Wyden and Ranking Member Crapo:

On behalf of the nation's children's hospitals and the patients and families we serve, thank you for the opportunity to respond to your white paper, *Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs*. Our comments focus on the White Paper's questions related to drug shortage prevention and mitigation plans for hospitals and other supply chain stakeholders. We strongly urge you to incorporate pediatric drug alternatives and safety considerations into any framework for prevention and mitigation plans to forestall – and address – drug shortages to ensure that children have access to effective health care.

Our response to the White Paper focuses on pediatric-specific considerations that should be addressed as you develop policies related to prevention and mitigation plans to help ensure that children have access to needed drugs and related therapies. We also caution that mitigation plans will not address all the underlying challenges in the pediatric supply chain, because products dedicated to a small, specific patient population do not provide the same return on investment as adult products, leading manufacturers to place less of a priority on those products in supply chain planning.

The more than 200 children's hospitals that comprise the Children's Hospital Association (CHA) are dedicated to the health and well-being of our nation's children. We advance child health through innovations in the quality, cost and care delivery—regardless of payer—and serve as a vital safety net for uninsured, underinsured and publicly insured children.

A drug shortage is particularly challenging in children's health care because pediatric care requires specialized therapies and the appropriate equipment for safe administration. There are also fewer manufacturers of pediatric-appropriate drugs and related supplies, which means the pediatric supply chain is easily disrupted. As a result, children's hospitals are disproportionately impacted by drug shortages compared to non-pediatric hospitals. Pediatric essential drugs, such as antineoplastics, TPN components and plasma products used to treat critical conditions, including cancer and immune deficiencies, are more likely to be impacted by shortages. For these reasons, children's hospitals have long faced shortages of critical drugs that their vulnerable patients rely on for treatment and recovery.

Children's hospitals, and the child patients we serve are disproportionately impacted by drug shortages compared to non-pediatric hospitals and spend more hours managing shortages than non-children's hospitals—51 hours compared to 36 hours per drug shortage. Children's hospitals report that on average, the cost to manage one drug shortage from onset to correction is approximately \$50,000, in addition to the actual cost of the drug itself.

Champions for Children's Health

It is also important to note that Medicaid, on average, provides health insurance coverage for half of children's hospitals patients and for some children's hospitals patient mix, closer to three-quarters. Despite the low numbers of children covered by Medicare, its policies can affect all children even though the policies are not developed with children in mind. Medicaid and private payers often adopt Medicare rules and procedures that are intended for the adult population without evaluating their impact on pediatrics. As you explore Medicare-focused solutions to address drug shortages, we encourage you to work closely with the CMS Center for Medicaid and CHIP Services, pediatric providers and other child-focused stakeholders.

Our response to the White Paper's questions related to shortage prevention and mitigation plans are below.

What elements should be considered in hospital shortage prevention and mitigation plans?

It is critical that any framework for the development of prevention and mitigation plans for drug shortages incorporate a pediatric focus. There are specific safety concerns in pediatrics that are different from those in adult health care, such as issues related to drug formulation and dosing. For example, when an appropriate medication substitute specifically geared for pediatric patients is not readily available, pediatric care protocols can be delayed or cancelled all together. These abrupt changes in care can lead to increased rates of drug errors and possible disease relapse, with potentially detrimental impacts on a child's long-term health and well-being.

Therefore, a mitigation plan framework for hospitals should allow for the incorporation of specific product information about a pediatric drug's potential alternatives and safety concerns (e.g., does a product come in multiple concentrations which could risk a dosing error). It should also address whether drug alternatives are available for special pediatric populations, such as neonates who may need oral solutions instead of solids, or children with complex medical conditions who rely on specialty drugs.

Would it be appropriate to extend similar requirements or incentives to develop such plans to other supply chain stakeholders?

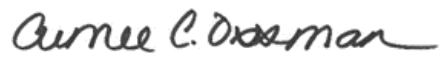
Manufacturers, distributors, Group Purchasing Organizations, and payers should be required to develop mitigation plans that ensure that pediatric drugs – and viable, safe alternatives – are available to children in a timely manner. Specifically, Congress should establish requirements that pediatric drug supply chain stakeholders have early communication plans to address shortages, including those affecting pediatric drugs, with a focus on alternative access and related payment strategies. Information exchanges can ensure that stakeholders are not caught off guard with market disruptions and help expedite children's access to needed medications.

We urge Congress to require manufacturers and distributors to develop and share risk management plans with providers and other stakeholders, particularly for essential pediatric drugs, and identify alternate suppliers and manufacturing sites to be used in times of anticipated supply disruption. It is critical that mitigation plans include the location of production of all pediatric drug components, as well as an immediate and clear timeline on pediatric product availability. The absence of this timely information hinders proactive steps that pediatric providers can take to prevent and mitigate shortages.

Thank you again for the opportunity to provide feedback. Developing a more efficient and resilient pediatric drug supply chain is essential to ensuring that our child patients receive the highest quality products in a timely manner. We look forward to collaborating with you and providing additional input as you begin to draft legislation to

address drug shortages. Please contact Natalie Torentinos at Natalie.Torentinos@childrenshospitals.org or (202) 753-5372 should you need more information.

Sincerely,

A handwritten signature in black ink that reads "Aimee C. Ossman". The signature is written in a cursive, flowing style.

Aimee C. Ossman
Vice President, Policy
Children's Hospital Association