



Charles N. Kahn III  
President and CEO

September 6, 2023

The Honorable Cathy McMorris Rodgers  
2188 Rayburn House Office Building  
United States Senate  
Washington, D.C. 20515

Dear Chairwoman McMorris Rodgers,

On behalf of the Federation of American Hospitals (FAH), we appreciate the Committee's focus on ensuring an adequate and reliable drug supply in the United States and we are pleased to provide the following comments on the *Stop Drug Shortages Act*, which address the burdensome reporting requirements and unbalanced incentives in Sections 305, 307, and 401 of the legislation.

The FAH is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

Hospitals and health systems rely on consistent supplies of critical medications to provide care and treat patients 24/7/365, and we support the Committee in its search for policy solutions to this difficult and increasingly relevant problem. We believe drug shortage prevention efforts should not come with the cost of excess regulatory burdens and reporting requirements on hospitals, and should not create perverse incentives or weaken and hamper existing efforts to maintain access to critical medications and provide quality care to patients.

**Section 305: Requiring hospitals to report group purchasing remuneration under Medicare**

Imposing Section 305's mandate for hospitals to report Group Purchasing Organization (GPO) remuneration as a Medicare Condition of Participation (COP) is redundant and administratively burdensome and would not directly improve the quality or safety of patient care.

Hospitals already are required to report financial interactions with GPOs through their annual Medicare cost reports, in accordance with existing laws like the Discount Safe Harbor. Elevating reporting requirements to be a COP in Medicare and Medicaid not only contradicts CMS' 2019 "Patients over Paperwork" initiative but also places an undue burden on healthcare providers, especially smaller and rural hospitals operating on thin margins. A failure to meet this COP would result in the severe penalty of expulsion from the programs, effectively shutting down hospitals and jeopardizing access to care.

Additionally, the proposed reporting requirements raise concerns about disclosing competitive and confidential information regarding private negotiations and thereby negatively impacting competition.

Rather than adding an unnecessary layer of bureaucracy, the Committee's efforts should instead focus on optimizing current well-functioning reporting systems and mechanisms to better serve both healthcare providers and patients.

**Section 307: Requiring clarification of Medicare average sales price payment methodology to provide a statutory definition for bona fide service fees**

GPOs play a pivotal role in driving efficiencies across the healthcare supply chain by negotiating contracts, facilitating product entry, and aiding in the understanding of clinician preferences. These administrative services funded by manufacturers help individual practices and community hospitals, especially those in rural and underserved areas, to focus on patient care rather than supply chain logistics. Narrowing the statutory definition of bona fide service fees to exclude administrative fees paid to GPOs would weaken and undermine GPO efficiencies.

GPOs specialize in optimizing supply chain management—something that manufacturers are not as well-equipped to handle. The proposed changes would encourage providers to move away from using GPOs, leading to a more fragmented and less efficient supply chain. Removing the incentive for manufacturers to collaborate with GPOs has the potential to increase healthcare costs, as manufacturers are generally less efficient at these specialized tasks.

Moreover, the proposed changes would disproportionately affect those providers that do not receive any administrative fee distribution from GPO contracts, leading to an uneven impact across the healthcare landscape particularly in rural and underserved regions where healthcare providers lack the scale, resources, and specialized knowledge to undertake activities such as supply chain analytics and clinical efficacy evaluations.

Requiring clarification of Medicare average sales price payment methodology to provide a statutory definition for bona fide service fees would result in a less resilient and less efficient healthcare supply chain. It would weaken the role of GPOs, thereby decreasing the resiliency of the supply chain and potentially resulting in the unintended consequence of more frequent and severe drug shortages.

**Section 401: Requiring GPOs to annually report written agreements and disclosures to HHS and OIG**

The proposed requirement for GPOs to annually report written agreements and disclosures to the Health and Human Services (HHS) Secretary and the Office of Inspector General (OIG) is both unnecessary and burdensome. The existing regulations under the GPO Safe Harbor already require a robust level of reporting. This includes the requirement for GPOs to disclose all administrative fees earned on member purchases at least annually, and these disclosures can be requested by the HHS Secretary.

The additional reporting requirements under Section 401 are redundant given existing regulations and do not ultimately address the end goal of solving our nation's drug shortage issues.



Thank you for taking these comments under consideration as you draft legislation to address our nation's drug shortages. If you have any questions or would like to discuss these comments further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. ...". The signature is stylized and cursive.