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Advancing Health in America

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

Dear Chair McMorris Rogers:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) thanks you for the opportunity to comment on Energy and Commerce Committee Chair Rodgers' drug shortages discussion draft.

The AHA shares the committee's concern about ensuring an adequate drug supply. Our member hospitals and health systems rely on drug therapies to care for their patients. In many cases, access to these critical drugs is in peril, jeopardizing patient health. Hospitals and health systems are most concerned about preserving consistent supply of and access to source generics and other generics, which drug manufacturers may believe lack sufficient business incentive to maintain. While the AHA believes shoring up the drug supply chain is of great importance, accomplishing this goal should not come at the cost of patient care. Reducing access to the 340B Drug Pricing Program would directly impact hospitals' ability to offer a wide range of health care services to some of the nation's most vulnerable populations. We urge the committee to pursue other alternatives to support drug manufacturers committed to maintaining access to critical and often low-margin medications that would not hamper existing efforts to provide quality care to patients.

These alternatives include opportunities for the discussion draft to further address the root causes of drug shortages, in particular lapses in quality that require production-halting remediation. Currently, the bill's approach focuses on increasing drug companies' reimbursement to strengthen the drug supply chain, but it does not require manufacturers to use these additional resources to prevent and mitigate future drug shortages. We are concerned that some of the payment provisions in the current bill

may create perverse incentives for companies to keep some products in shortage. Additionally, there is opportunity for the committee to provide the Food and Drug Administration (FDA) with much-needed data regarding the pharmaceutical supply chain, as well as authority to utilize the data appropriately to improve the resiliency of the supply chain for critical generic drug production and ensure adequate supplies in the event of a shortage.

In comments below, we urge the committee to consider including provisions contained in several other pieces of legislation that AHA supports, which we believe would support drug manufacturers and protect the supply chain for essential medications without limiting patient access to care by reducing the 340B Program.

Title I. Medicaid

Section 101. Exempting Certain Drugs from Certain Increases in Rebates Under the Medicaid Program; Rebate Cap for Certain Drugs

Generic drugs are currently subject to a basic rebate of 13% off the average manufacturers price (AMP) — or the average price drug manufacturers sell the drug to wholesalers — under the Medicaid drug rebate program (MDRP) established by Congress in 1990. The MDRP also includes a provision that imposes a penalty on drug manufacturers that choose to raise the price of their drug (generic or brand) faster than general inflation. This penalty, commonly referred to as the "inflationary penalty," can result in a much larger rebate percentage and is important because it acts as a disincentive for drug manufacturers to precipitously raise the price of their drugs. Even with this penalty provision in place, a report by the Department of Health and Human Services' (HHS) Assistant Secretary for Planning and Evaluation (ASPE) shows that drug manufacturers increased prices for approximately 1,200 drugs by an average of 31.6% in just one year between July 2021 and July 2022.

This bill would eliminate and/or cap the inflationary penalty for certain generic injectable drugs used to treat patients with serious conditions or drugs in or at risk of shortage. This approach would remove altogether the important disincentive for drug companies to increase drug prices indiscriminately. Those massive drug price increases will undoubtedly be borne by patients, the government and hospitals. This cost far outweighs the marginal possibility that drug manufacturers' reduced rebate obligations would result in more adequate supply of these drugs. That possibility is further diminished by the fact that the current bill does not require that rebate savings be used by drug manufacturers to improve the drug supply for drugs in or at risk for shortage. While the bill currently eliminates the inflationary penalty for a relatively small group of drugs, this action could pave the way for legislation in the future that could expand the number of drugs that are exempt from the inflationary penalty, at which point this important penalty could be rendered moot. For these reasons and given the limited existing tools available to the government to guard against the persistent challenge of skyrocketing drug prices, elimination or capping of the inflationary penalty for any drug,

even for those in shortage or at risk of shortage, is unlikely to accomplish the committee's goal. **Therefore, the AHA opposes this provision of the bill.**

Title II. 340B Drug Discount Program

Section 201. Exempting Generic, Sterile Injectable Drugs from the 340B Drug Discount Program

The 340B Program is a critical resource to the over 2,500 hospitals and many more federal grantees that participate in the program by allowing them to purchase certain outpatient drugs at a discounted price and use those price savings to stretch scarce resources and provide more comprehensive care to more patients as intended by Congress. The Health Resources and Services Administration (HRSA), which oversees the 340B Program, estimates that the price discounts under the program range on average between 25% and 50%. These savings that result from these discounts are an important source of funding that hospitals and other participating entities need to furnish critical programs and services to their patients and communities. These programs and services include behavioral health treatment programs, medication management therapy programs, mobile treatment clinics for rural populations, and the provision of free or discounted drugs.

The committee's proposal to exempt certain generic injectable drugs from the vital 340B Program — and thus removing drug manufacturers' obligations to offer a discounted price for these drugs — is an untenable solution to address drug shortages. Drug companies' 340B obligations are a small percentage of their overall revenues and profits; 340B discounts for hospitals were estimated to be about $38 billion in 2021, while drug companies' 2021 global revenues were estimated to be $1.57 trillion. In fact, drug companies' 2021 net profits from the U.S. market alone far exceeded the collective amount of 340B discounts they provided. Therefore, the suggestion that drug companies are unable to address supply chain issues due to their 340B obligations is misguided and unsupported by the data. Instead, this provision would, in effect, relocate the burden of solving the problem of drug shortages onto hospitals and other 340B-participating entities, as well as onto the very patients who need access to these drugs. This could mean that programs and services that are supported by 340B savings and directly benefit patients could no longer be financially sustainable for hospitals and other participating entities to provide. Patients and the 340B entities providing their care had no role in creating drug shortages, and they should not shoulder the burden of solving it alone.

In addition, while eliminating the 340B discount for these drugs would certainly harm patients and providers, the bill also does not require drug manufacturers to use the additional revenue they would receive to address the issue of drug shortages. This proposal would set a dangerous precedent for future legislation that could expand the list of drugs that are exempt from 340B discounts. This undermines the intent of the program, which has had a demonstrated track record of success since Congress

established it in a bipartisan effort over 30 years ago. **Therefore, the AHA opposes this provision of the bill.**

Section 202. Study on Penny Pricing and Other Price Setting Policies

While the AHA believes the root causes of drug shortages are an important problem to study and address, we take issue with any study that would seek to divert blame from the primary entity responsible for creating drug shortages — drug manufacturers. The committee's proposal to study drugs that are "penny priced" under the 340B Program and the extent to which those drugs are in shortage fails to address the true root cause of the problem. Drugs under the 340B Program can only be "penny priced" if a drug manufacturer chooses to raise the price of their drug so much higher than general inflation that the rebate amount increases to the point that the price of the drug is a penny or less. Drug pricing decisions are made solely by drug companies and not by hospitals or other 340B participating entities. Therefore, the suggestion that "penny pricing" under the 340B program may contribute to the overall issue of drug shortages is unfounded. Hospitals and other 340B participating entities should not bear the consequences of potential impacts of "penny priced" drugs on drug shortages when they have no role in determining which drugs are penny priced or how those drugs become penny priced. Instead, the committee should focus its efforts to study why drugs fall into shortage, including the role that drug manufacturers play in establishing fragmented supply chains that may cut costs but increase the likelihood of drug shortages, and drug manufacturers' profit-seeking behavior that purposefully place drugs in shortage to mitigate against any effects on their own revenues and profit margins. **Therefore, the AHA opposes this provision of the bill.**

Section 203. Guidance on Preventing Diversion During Shortages

The AHA supports the Committee's proposal to direct HRSA to issue guidance that would allow 340B hospitals and other 340B participating entities to share drugs that are in shortage without running afoul of existing prohibitions in the program of diverting drugs to ineligible patients or providers. This is an important way that hospitals and other providers can work together to ensure that patients are able to access much-needed drugs that are in limited supply and mitigate the impact of drug shortages on patient care.

<u>Title III. Medicare</u>

Sections 302, 303, 304 and 305. Studies and a Demonstration Project

The bill includes several provisions calling for studies and a demonstration project that could provide useful information about how increasing reimbursement, changing payment policies or revising coding policies for generic sterile injectable drugs could impact the prevention or mitigation of drug shortages. These include Section 302 Study on Market-Based Pricing for Shortage Drugs Under Medicare Part B, Section 303 CMMI

Model on Alternative Payment for Generic Sterile Injectable Drugs, Section 304 Study on Medicare Coding for Drugs in Shortage or in Danger of Shortage and Section 306 MedPAC Study on Flat Fee Payment.

The AHA agrees that payment rates for low-margin generic sterile injectable drugs can influence their market availability and are a factor in shortages. However, we do not believe that these kinds of studies will do enough to address the root cause of shortages. This is because the increased payments discussed in these studies are not tied to improving drug reliability and quality. Data show that the top causes of shortages are driven by quality issues, which result from the lack of manufacturer incentives to invest in quality improvements.[1] **We encourage the committee to add accountability to these studies and to the demonstration project to determine if increases in reimbursement for drugs, when they are aligned with incentives to improve manufacturing quality, would influence the likelihood that generic sterile injectable drugs, particularly those with low margins, go into shortage.**

Section 305. Hospital Reporting of Group Purchasing Organization (GPO) Remuneration under Medicare

This provision would require that hospitals report remuneration from GPOs on their Medicare Cost Report, including remuneration tied to an ownership stake in a GPO, as a Medicare Condition of Participation (COP).

Hospitals are already required to report fee distributions from GPOs on their Medicare cost reports and are compliant in doing so. While this proposed requirement differs slightly in defining what must be reported, it is substantively duplicative and therefore unnecessary. Further, COPs are required by existing law to be issues that have a direct impact on the quality and safety of care delivered. The sole penalty invoked if a hospital fails to comply with a COP and does not rectify that failure within a specified period is expulsion from the Medicare and Medicaid programs. For most hospitals this means they would no longer be available to care for their communities and would cease to be financially viable. In other words, the hospital would close, robbing the community of needed aid in times of illness and injury.

This proposed COP is not at all related to the quality or safety of care, and therefore, the AHA believes should not be considered. Further, we cannot envision an instance in which it would be justifiable to eject a hospital from the Medicare and Medicaid programs, jeopardizing access to care for the entire community, simply because a line item was omitted from a cost report. **We urge the committee to reject this proposed requirement and instead look to see if the data already being reported is sufficient to the committee's needs.** If there is a need for additional data, we

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[1] U.S. Food and Drug Administration, "Report on Drug Shortages for Calendar Year 2020," https://www.fda.gov/media/150409/download.

encourage the committee to work with hospitals to find a mechanism other than a COP for making it a requirement.

Section 307. Clarification of Medicare ASP Payment Methodology

This section would narrow the statutory definition of bona fide service fees to exclude administrative fees paid to GPOs. Administrative fees paid to GPOs by manufacturers fund important services that would otherwise be performed by the manufacturer, including product entry, awareness of clinician preferences, uniform contracting and supply chain analytics. GPO services that involve evaluating clinical efficacy and supply chain analytics are especially important in rural and underserved areas, as well as in individual physician practices and community hospitals, which may not have the resources, scale and expertise to conduct these services themselves.
We are concerned that by narrowing the statutory definition of bona fide service fees drug manufacturers would be discouraged from working with GPOs because they would have to include the GPO administrative fees in their product prices, which would decrease their ASP. Because manufacturers would likely be less efficient in performing the services currently furnished by GPOs, we believe that this could undermine existing efficiencies in the health care supply chain and lead to increased health care costs and a less resilient supply chain.
Furthermore, decreasing manufacturer ASPs for their products would inappropriately penalize hospital-based providers and physicians by reducing payments for Medicare Part B drugs, which are paid at the rate of ASP plus 6%.
For these reasons, the AHA urges the committee to remove Section 307 from the discussion draft.

<u>Title V. Food and Drug Administration</u>

Section 501. Noncompliance Letters Relating to Volume Reporting

In 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amended the Food, Drug and Cosmetics Act (FDCA) to require that each person who registers with the FDA regarding a drug must report annually the amount of each listed drug that was manufactured, prepared, propagated, compounded or processed by such person for commercial distribution. Section 501 would amend this provision to require the FDA to issue a noncompliance letter to any person failing to comply with these volume reporting requirements, require the manufacturer to respond to the noncompliance letter within 45 days of it being issued, and make public on the FDA website such letter and any written responses within 60 days after issuing a noncompliance letter.

The AHA supports this section's intent to provide for a consequence for a manufacturer's failure to comply with this important statutory reporting requirement. We note that this provision generally aligns with the noncompliance penalty under Section 506C of the FDCA which requires manufacturers of certain

prescription drugs to notify the FDA of a permanent discontinuance or temporary interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of a covered drug in the U.S.

However, considering that the nation is dealing with a historically unprecedented number of drug shortages and the imperative that the FDA be able to rely on accurate reporting of drug volumes for clearer insight into drug supply chain, we urge the committee to revise several components of this provision. First, we believe that requiring the secretary to wait 270 days after enactment of this provision to issue any noncompliance letters is far too long, particularly since this volume reporting has been required since Feb. 15, 2022, after being previously delayed more than a year past the original Sept. 23, 2020, effective date established by the CARES Act. Second, we urge the committee to require timeframes for drug volume reporting parallel to those currently under Section 506C of the FDCA for reporting of drug discontinuances or temporary manufacturing interruptions. As such, the AHA recommends that a manufacturer's written response to an FDA letter on noncompliance for failure to report volume should be submitted to the secretary no later than 30 calendar days (rather than 45 calendar days) after the issuance of the noncompliance letter and the secretary should make such letter and any response available to the public on the FDA website not later than 45 calendar days (rather than 60 days) after the issuance of the noncompliance letter.

Section 502. Incentive for Shelf-life Extension Studies

This provision would allow the secretary to award an additional month of exclusivity to new and already marketed sterile injectable drugs if the drug's manufacturer conducts and completes shelf-life extension studies in response to a request from the secretary.

The AHA does not support this provision due to its costs and the possible unintended consequences it may create. We are concerned that a one-month exclusivity period would be costly to taxpayers and health care providers. Regulatory exclusivity periods protect new drugs from competition and allow the manufacturers to sustain the high prices charged for many brand-name prescription drugs. In this provision, even manufacturers of already marketed drugs would be protected from competition and be permitted to charge these high prices for an additional month. Instead, we believe that it would make more economic sense for the FDA to directly reimburse drug companies for conducting such studies. Furthermore, we are concerned that this provision would introduce a perverse incentive for manufacturers to initially establish a shorter shelf life for their drugs to subsequently have access to this exclusivity extension from the FDA.

Section 503. Providing for a Lag Period for Outsourcing Facilities to Compound and Distribute Drugs in Shortage

This provision would allow 503B outsourcing facilities to compound a shortage drug for up to 30 days beyond its removal from the FDA's drug shortage list and to distribute and

dispense a compounded shortage drug for up to 180 days after its removal from the drug shortage list.

The AHA supports this provision as it will provide an opportunity for outsourcing facilities to unwind their compounding activities for drugs that have been in shortage and avoid wasting active pharmaceutical ingredients (API) and finished compounded products once the shortage has been officially resolved. It will also help hospitals and health systems ensure an adequate supply of a compounded product as they gradually reestablish their stock of the FDA-approved drug, which may still be regionally difficult to obtain even after a shortage has been officially resolved. **However, we believe that allowing 180 days post-shortage for compounders to continue to distribute and dispense a compounded drug is excessive** as it is likely that the supply of the FDA-approved drugs previously in shortage will have fully recovered and using a fully approved drug is preferable to using a compounded product.

Section 504. Additional Information on Generic Drug API

This provision would require that each holder of an approved application for a new generic drug annually report on whether it relies on any one source for more than 60% of its supply of any API, and if so, identify the API manufacturer and the amount of API used. **The AHA generally supports this provision as it would improve upstream transparency of the pharmaceutical supply chain related to API and allow the FDA to better target its oversight and inspections of API manufacturers to help identify and prevent weaknesses in the pharmaceutical supply chain that could lead to shortages of a generic drug.**

However, we do not believe that this provision goes far enough to best protect the resiliency of the pharmaceutical supply chain. That is, Section 504 has certain similarities with, but is less expansive than, the provisions contained in the Drug Shortage Prevention Act (S. 2362), legislation supported by the AHA. The act would require drug manufacturers to provide more frequent and detailed reporting, specifically adding important details about their suppliers of API and other materials used in the production of their medications. Providing this additional essential information to the FDA will help the agency to better predict, mitigate and address interruptions in the supply of critical drugs. The act would also require manufacturers to notify the FDA of increased demand of covered drugs. The AHA believes this will be an integral tool for shoring up the supply chain. Increased demand in the supply chain can create prolonged acquisition difficulties for providers. Avoiding these disruptions before they occur and pursuing opportunities to mitigate their effects when they do happen will allow providers to better serve their patients.

Moreover, the AHA also supports the 'Mapping America's Pharmaceutical Supply (MAPS) Act' (S. 2364), which will more substantially address the current lack of transparency upstream in the pharmaceutical and medical/surgical supply chain, which has hampered the federal government's ability to prevent or mitigate shortages of

necessary drugs and other supplies. The MAPS Act would require the FDA, the Department of Defense and the Department of Homeland Security to support efforts, including through public-private partnerships, to map the entire U.S. pharmaceutical supply chain (including APIs) from inception to distribution and use data analytics to identify supply chain vulnerabilities and other national security threats. It would apply to the FDA's existing list of essential drugs as well as other drugs which, if they were in shortage, would pose a national security threat or otherwise pose a significant threat to the U.S. health care system or at-risk populations.

We urge the committee to incorporate key provisions of the Drug Shortage Prevention Act and the MAPS Act into the Stop Drug Shortages Act to help build a more resilient pharmaceutical and medical supply chain.

Section 506. New Domestic Facility Inspection Pilot Program

This provision would establish a new pilot program under which FDA would conduct preapproval inspections for a new domestic pharmaceutical manufacturing facility for the purposes of expediting the licensure and distribution of domestically manufactured generic drugs.

The AHA supports this proposal, which we believe could expedite and strengthen the domestic production of generic drugs. As we learned during the COVID-19 pandemic, the heavy reliance on overseas pharmaceutical sourcing, while lowering costs in the short term, risks creating supply problems.[2]

However, we caution that only enhancing the domestic production of generic drugs does not do enough to ensure that hospitals and health systems and their patients will have access to an adequate supply of high-quality essential medications. Indeed, as we have seen in multiple national disasters in the U.S., most recently in the damage to a large Pfizer plant in North Carolina that produces multiple generic sterile injectable drugs critical for hospitals, as well as in drug shortages resulting from quality system failures in domestic manufacturers, over-reliance on domestic production of drugs would also be a mistake. While we support efforts to incentivize additional domestic drug manufacturing, it is even more important to support the diversification of high-quality and redundant drug manufacturing on a wider scale. What is needed is a diversified supply chain, which involves sourcing domestically and globally.

As such, we urge the committee to consider the provisions of legislation supported **by the AHA, the Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act (S. 2510).** The RAPID Reserve Act would establish a program to improve supply chain resiliency for critical generic drug products, ensuring adequate

[2] An estimated 80% of API comes from abroad, typically China and India. Further, with India sourcing about 70% of APIs from China, a disruption in either country presents problems for the U.S. It is risky to depend so heavily on one region.

supply is available even in the event of a shortage. The legislation would award contracts to eligible domestic drug manufacturers and manufacturers in nations within the Organization for Economic Cooperation and Development that have a good quality record with the FDA to maintain a six-month buffer of these critical drugs and their API to ensure continuous production flow.

We thank you for the opportunity to submit comments on the drug shortages discussion draft and look forward to continuing to work with you on this important legislation. Please contact me if you have questions or feel free to have a member of your team contact Aimee Kuhlman, AHA's vice president of advocacy and grassroots, at akuhlman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President