May 23, 2023

The Honorable Cathy McMorris Rodgers, Chair
The Honorable Frank Pallone, Ranking Member
House Energy and Commerce Committee
2125 Rayburn HOB

Washington, DC 20515

Dear Chair Rodgers and Ranking Member Pallone:

As 340B hospitals and stakeholders, we are writing to share our significant concerns with two pieces of legislation that were recently passed out of the House Energy and Commerce Committee's Health Subcommittee. The first is a provision in the amendment in the nature of a substitute to H.R. 3561 regarding Medicaid managed care organization (MCO) reimbursement to 340B providers for retail drugs. The second, the amendment in the nature of a substitute to H.R. 3290, would unduly burden safety-net hospitals at a time when they are struggling with workforce shortages, increased supply costs, and inadequate federal program payment increases.

Medicaid Managed Care Reimbursement for 340B Drugs at Actual Acquisition Cost:

This Medicaid managed care provision, which was previously included in the amendment in the nature of a substitute to H.R. 3281 that passed out of the Health Subcommittee, would have harmed 340B providers and their patients by overturning existing reimbursement laws and practices in many states. We are pleased that the committee has proposed new language in the amendment in the nature of a substitute to H.R. 3561 that permits a state to reimburse above 340B acquisition cost, so long as that amount doesn't exceed the acquisition cost for a drug otherwise not covered under 340B. Without this change, 340B providers in states allowing reimbursement above 340B acquisition costs would have faced significant challenges in treating low-income, rural and vulnerable populations.

However, new language inserted in the amendment in the nature of a substitute to H.R. 3561 would put additional burdens on 340B providers in these states. The new language mandates that these 340B providers report on the aggregate spread for drugs that receive reimbursements above the acquisition cost and that the information would be published via electronic and searchable format.

We have serious concerns with this mandate, which would further burden 340B providers at a time when hospitals are treating unprecedented levels of patient illness amid high inflation, increased labor costs, and other factors. These challenges have hit especially hard for 340B hospitals, which have extremely tight operating margins. New reporting requirements would only exacerbate these challenges.

In addition, this mandate could potentially compromise proprietary financial data, making public sensitive competitive financial information that could aid competitors. We also understand that this mandate would be duplicative of some current state statutes and regulations, adding an additional layer of bureaucracy that does not promote efficiency or competition.

Please support amending the proposal to omit this new requirement to ensure that additional burdens are not shouldered by 340B providers as they face serious financial challenges in serving their patients.

Amendment in the Nature of a Substitute to H.R. 3290, 340B Hospital Reporting Bill

This bill would impose onerous reporting requirements on most 340B hospitals, on top of the many forms of reporting they already do voluntarily or as required by law. We are also concerned that the information required to be reported in the draft legislation would not show the real impact of 340B on the patients and communities these hospitals serve.

In addition to the overall burden the legislation would put on safety-net hospitals, we also have additional concerns with the legislation as presently drafted, including:

Represents an Incomplete Picture: Requiring hospitals to report charity care data assumes that covering such costs is the primary purpose of 340B and adds unnecessary burden to hospitals, which already report this information at the hospital level on Medicare cost reports. 340B is intended to help hospitals stretch scarce resources, which means it is used in many ways to support patient care, depending on the needs of patients and the community. Charity care does not account for the costs that hospitals incur in caring for underinsured patients or patients covered by government programs that chronically underpay the cost of care.

Imposes Tremendous Burden that Would Require Development of New Software Systems: Requiring hospitals to report financial data and charity care for each hospital outpatient department would require new software systems for many hospitals and improperly suggests hospitals should use their 340B savings in the specific office location to which the savings pertain. Because outpatient locations are considered part of the main hospital, they maintain integrated financial, clinical, and electronic health records. Congress intended for hospitals to use 340B savings to establish and support a variety of programs that best serve patients and benefit entire communities, not just the location where 340B drugs are used. In addition, the costs associated with complying with this mandate will be difficult to bear for many hospitals, that are already facing myriad of financial challenges due to double-digit increases in expenses from labor, drugs, as well as supplies and equipment.

Gives HRSA Unlimited and Undefined Authority with Respect to Audits. The bill would give HRSA unlimited authority to audit hospitals as to use of 340B savings, but it gives no description as to the scope or parameters of what this “audit” would entail. Audits, by their very nature, are a review of spending against established standards, with the purpose of ensuring that the audited entity is complying with those standards. Granting HRSA this authority would allow HRSA, which has no experience auditing hospitals outside of established 340B compliance rules, to identify spending requirements for hospitals, potentially undermining hospitals’ ability to determine where spending is most needed for their community.

Establishes Civil Monetary Penalties. The legislation calls for imposition of Civil Monetary Penalties (CMPs) in amounts determined appropriate by the Secretary in the case that the Secretary determines that a covered entity is not in compliance with the reporting requirements. This provision gives the Secretary wide discretion to determine non-compliance by covered entities, which could result in punishing providers that submit information in good faith.

Hospitals support transparency in how they use 340B savings, and they voluntarily share information on the impact of 340B in their communities. Hospitals also report information on community benefit spending and the high volume of care they provide to patients with low incomes under already existing federal and state reporting requirements. The information reported under the proposed 340B discussion draft would not demonstrate the true impact of 340B in Congressional districts throughout the country. Further, while significantly expanding the scope of audits of covered entities, the bill does not ensure parity in oversight of 340B stakeholders, containing no provisions to require increased transparency or audits of drug manufacturers.

Because of our substantial concerns, especially as 340B hospitals grapple with significant challenges as they work to serve increasingly vulnerable patient populations, we urge you to oppose the amendment in the nature of a substitute to H.R. 3290.

Thank you for considering these concerns.

Sincerely,

340B Health
America's Essential Hospitals
American Hospital Association
American Society of Health-System Pharmacists
Association of American Medical Colleges
Children's Hospital Association
The Catholic Health Association of the United States

CC: Members of the House Energy and Commerce Committee