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May 3, 2023

The Honorable Cathy McMorris Rodgers
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Brett Guthrie
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Anna Eshoo
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Representatives McMorris Rodgers, Pallone, Guthrie, and Eshoo:

On behalf of the Association of American Medical Colleges (AAMC), I thank you for the opportunity to comment on legislation considered by the House Energy and Commerce Health Subcommittee during your April 26th legislative hearing. We greatly appreciate the committee's bipartisan leadership in this area, and we are committed to working with you to achieve this goal while balancing considerations of access and education.

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC greatly appreciates the opportunity to weigh in on the legislative package under consideration by the committee. We offer the following comments on the proposed legislation:

- H.R. 2665, the Supporting Safety Net Hospitals Act

The AAMC strongly supports this legislation, which would address scheduled cuts to the Medicaid disproportionate share hospital (DSH) program. The DSH program is critical to supporting AAMC-member teaching hospitals in their mission to care for low-income and under-

resourced patients. Although our members comprise just 5% of hospitals in the U.S., they account for 27% of all Medicaid inpatient days and 30% of all hospital charity care costs. Medicaid DSH dollars help to offset teaching hospitals' uncompensated care costs, ensuring that they can continue to provide high-quality care to all patients, regardless of their ability to pay.[1]

These scheduled cuts to the Medicaid DSH program were originally included in the Affordable Care Act under the presupposition that an expansion of insurance coverage would reduce hospitals' need for supplemental Medicaid DSH payments. This assumption has not materialized, but instead, AAMC-member institutions have seen their Medicaid shortfall grow by 46.3% between fiscal years 2018 and 2020.[2] Safety-net hospitals continue to rely on the Medicaid DSH program to provide life-saving health care services to the patients and communities they serve.

In 2023, safety-net hospitals face profound financial challenges, including historic workforce shortages, an unprecedented growth in costs, and a potential surge in uninsured patients as states navigate the Medicaid redetermination process. **Now more than ever, the nation's health care safety net cannot withstand additional cuts.** The AAMC urges Congress to act swiftly to address pending cuts to the Medicaid DSH program, which are due to go into effect on Oct. 1, 2023. Absent congressional action, these cuts will significantly impact safety-net hospitals' ability to care for Medicaid enrollees, thereby restricting access to care during a critical inflection point for the program.

- HR.___ To amend title XVIII of the Social Security Act to provide for site neutral payments under the Medicare program for certain services furnished in ambulatory settings.
- H.R. ___To amend Medicare to provide parity in Medicare payments for hospital outpatient department services furnished off-campus.
- H.R.___ To amend Medicare to require payment for all hospital owned physician offices located off campus be paid in accordance with the applicable payment system for the items and services furnished.

The AAMC strongly opposes so-called "site neutral" payment policy as it disregards the real differences between hospital outpatient departments (HOPDs) and physician offices or ambulatory surgical centers (ASC), including the higher costs of providing care in an outpatient hospital setting, the complex case mix of patients seen in hospitals, and the essential role of hospitals in medical education. The HOPD cuts included in the discussion draft legislation would undoubtedly impact access to care for patients and communities and endanger teaching hospitals' ability to provide and coordinate health care services that are otherwise unavailable to under-resourced patients.

These legislative proposals disregard the fact that the cost of care delivered in HOPDs is fundamentally different from other sites of care. Hospitals must have standby capacity for

[1] Source: AAMC analysis of AHA Annual Survey Database, FY 2020.
[2] Source: Centers for Medicare and Medicaid Services, Hospital Cost Reporting Information System (HCRIS) Database, FY2018-FY2020 released September 30 of each associated year. AAMC Membership data, March 2023.

disasters and public health emergencies, remain open 24/7 to deliver emergency care, and are required to provide care to all patients coming to the emergency room. HOPDs also must comply with greater licensing, accreditation, and regulatory requirements than physician offices. Hospital-based clinics provide services for low-income and underserved patient populations that may not be available anywhere else in the community. Expanding site-neutral cuts could jeopardize access to care for Medicare beneficiaries, especially the most medically complex.

We are concerned that these proposals would predicate payment rates on the setting in which the largest volume of services is provided. We believe that volume is not automatically the best indicator of where a service should be provided or the level of reimbursement it should receive. Clinical considerations and disease burden would make some procedures riskier in certain settings. We are concerned that these proposals do not account for clinical complexity or patient safety.

Although it may be safe for *most* patients to receive a particular type of service in a freestanding physician office, it is not safe for all patients. For safety reasons, patients who are socially and medically complex often must receive services in HOPDs, which are better equipped to handle the complications and emergencies that may arise when treating these patients. Because of this, physicians will often refer their most complex patients to HOPDs for treatment. For example, if a patient faints during a nerve injection procedure in a physician's office, or has an allergic reaction to a medication, the next time they undergo the procedure, their physician would most likely recommend that the patient receive care at an HOPD. Given the complexity of the patients treated, as well as additional administrative and regulatory standards HOPDs are held to, it is more expensive for HOPDs to treat patients. Implementing so-called "site-neutral" policies could result in HOPD closures, thereby reducing access to care for Medicare beneficiaries who require these services.

Previous site-neutral proposals were not evenly distributed throughout our health care system and would have disproportionately impacted major teaching hospitals. Analyses of earlier proposals found that although major teaching hospitals represent just 5 percent of all U.S. hospitals, they would bear nearly half of all cuts. This is problematic because major teaching hospitals provide complex, coordinated care to Medicare's vulnerable patients, and as such, so-called "site-neutral" payment policies could significantly reduce access to care for this population.

HOPDs also play an important role in clinical training for medical students, residents, and other trainees. As a result of these proposed cuts, HOPDs may be forced to reevaluate or cut service lines, which would result in less exposure to primary care and ambulatory services for these trainees, as well as less access to care for the patients and communities they serve.

While we appreciate that this legislation acknowledges the impact of HOPD cuts on safety-net hospitals, we are nevertheless concerned that the proposals would have negative consequences for these hospitals, thereby jeopardizing access to care for under-resourced patients and communities. We believe that this legislation would undermine the committee's intent to support

safety-net hospitals during a difficult transition period, jeopardizing the field's already tenuous financial situation.

- H.R___ To amend title XI of the Social Security Act to increase transparency of certain health-related ownership information.

While the AAMC supports transparency, given the complexity of academic medical centers, we have fundamental concerns related to the regulatory burden associated with reporting the information proposed in the legislation. This legislation would go into effect on January 1, 2024, meaning that AAMC-member institutions would not have sufficient time to gather, compile, and report this information. Given the inherently complex structure and relationships of academic medical centers, additional time, guidance and clarity are necessary to ensure compliance. Moreover, a $5 million penalty for noncompliance is excessively punitive. We are concerned that this, coupled with a lack of regulatory guidance and a hasty implementation of the legislation, could result in unjustified financial penalties for our members.

- H.R.___ To phase out certain services designated as inpatient-only services under the Medicare program.

The AAMC opposes this legislation and urges Congress to seriously consider its potential impact on patient safety. The inpatient-only (IPO) list was established to protect Medicare beneficiaries. CMS requires that procedures on the IPO list be exclusively performed on an inpatient basis because of their invasive nature, the need for extensive post-operative recovery time, or the underlying physical condition of the patient. As a result, these procedures are inherently high-risk.

This legislation would direct the Secretary of the Department of Health and Human Services to review and analyze myriad factors, including clinical and patient safety outcomes, patient out-of-pocket costs, and total Medicare spending, related to any procedure that was included on the IPO list in the ten calendar years preceding the passage of the legislation. Given that the IPO list consists of over 1,700 procedures, this review would require extensive time and resources. We are also concerned that this legislation would preclude the HHS Secretary from designating a service to the IPO list, barring "conclusive clinical evidence that [a] service may not be safely performed in an outpatient setting."

The AAMC acknowledges that advancements in medical technology, coupled with decisions on the appropriate site of service based on clinician evaluation and patient complexity, allow for certain treatments and procedures to be safely and successfully performed in the outpatient setting. Further, CMS annually evaluates the appropriateness of removing from the IPO list certain procedures that have shown to be successfully performed in the outpatient setting, with the focus on patient safety. Incorporating Medicare spending into this evaluation may lead to some procedures being inappropriately removed from the IPO list solely based on cost. The AAMC does not support proposals could potentially prioritize cost over patient safety.

We believe that IPO list determinations should be predicated upon clinical expertise, peer-reviewed evidence, and relative risk assessment, all while prioritizing the health and safety of the

Medicare beneficiary population. As such, the AAMC recommends that CMS continue its standard process for amending the IPO list, with additional enhancements based on evidence from peer-reviewed literature (e.g., age, physical comorbidities, and social risk factors).

- H.R.___ To amend title III of the Public Health Service Act to ensure transparency and oversight of the 340B drug discount program.

The AAMC opposes this legislation, which would impose burdensome administrative and reporting requirements on 340B hospitals. We are concerned that this legislation would require hospitals to report a significant amount of data that does not accurately capture the true value of the program to patients and communities.

The AAMC is committed to promoting transparency and accountability in the 340B program. We have endorsed the American Hospital Association's "340B Good Stewardship Principles," which allow hospitals to calculate the savings they achieve from the 340B program in a standardized manner and to publicly disclose these data. The AAMC also assists our members in complying with existing oversight mechanisms. To participate in the program, 340B covered entities must maintain auditable records of all 340B and non-340B drugs and register outpatient facilities with the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs Information System (OPAIS). HRSA audits 200 covered entities per year (as compared to just five pharmaceutical manufacturers), and the AAMC supports our members' compliance with existing audit procedures.

We are concerned that this legislation would misrepresent the value of the 340B program accrued to hospitals by requiring them to report the "net revenue" generated by the administration of 340B-discounted drugs—defined as the difference between the price paid for a drug and the reimbursement the hospital received. This net revenue calculation would fundamentally overestimate the value of the 340B discount for hospitals that participate in the program. The true value of the 340B discount is the difference between the 340B acquisition price and the price a hospital would have paid for a drug if it did not participate in 340B (the group purchasing organization price).

By requiring hospitals to report charity care costs, this legislation erroneously assumes that financing said costs is the primary purpose of the 340B program. The 340B program is designed to allow covered entities to "stretch scarce...resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] As such, 340B covered entities are afforded latitude to determine how they will use their savings to best serve patients and communities.

Finally, this legislation would necessitate entirely new software systems by requiring hospitals to report comprehensive financial data, including charity care costs, for each child site location. This requirement implies that 340B savings accrued to a specific child site should be used to finance programs and services at that site. Congress intended for hospitals to use their 340B

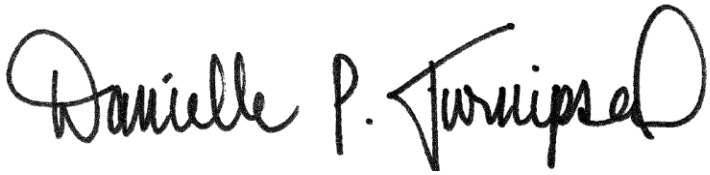
[3] https://www.hrsa.gov/opa

savings in a manner that would best serve patients and communities, regardless of the location where patients receive care. This requirement would not only increase regulatory burden by requiring 340B hospitals to invest in administrative processes, but it also reflects a fundamental mischaracterization of the congressional intent of the program.

As 340B hospitals grapple with unprecedented financial challenges, we urge Congress to reconsider this legislation, which would impose an additional administrative burden on hospitals, thereby diverting time and resources from patient care.

Again, the AAMC thanks the committee for its bipartisan work to improve patients and communities' access to care. We at the AAMC are committed to working with the entire House Energy and Commerce Health Subcommittee, and the full Congress to achieve this goal. If you have any further questions, me at dturnipseed@aamc.org or Len Marquez, Senior Director, AAMC Government Relations and Legislative Advocacy, at lmarquez@aamc.org.

Sincerely,



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