American Hospital Association

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May 18, 2015

The Honorable Fred Upton
Chairman
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
U.S. House of Representatives
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

***Re: Discussion Draft: 340B Outpatient Drug Discount Program***

Dear Chairman Upton and Ranking Member Pallone:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including more than 1,700 hospitals that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to share our concerns regarding the *Discussion Draft* before the committee, which will significantly impact the 340B program.

**The AHA strongly supports the 340B program's current intent and purpose. It has a proven track record of enabling eligible entities, including certain hospitals, to stretch scarce federal resources to expand and improve access to comprehensive health care services for low-income and uninsured patients.** Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to serve the most disadvantaged in our society and build healthy communities.

**While the AHA appreciates the committee's attempts to address the administration of the 340B program, we are concerned that the committee is choosing to legislate important changes to the 340B program at a time when release of long-awaited regulatory guidance from the Department of Health and Human Services is imminent. We understand the need to clarify rulemaking authority with the Secretary, but the proposed changes to the 340B program outlined in the *Discussion Draft* are significant and would benefit from a broader opportunity for review**. The Health Resources and Services Administration (HRSA) has proposed comprehensive interpretive guidance that will examine several areas pertinent to the 340B program, such as the definition of patient eligibility, contract pharmacy arrangements, mechanisms to prevent ineligible patients from receiving the benefit and duplicate discounts for

Medicaid patients. Moving legislation before the interpretive guidance is released seems premature.

Our specific concerns with the *Discussion Draft* follow.

**Clarifying Purpose:** The *Discussion Draft* changes Congress' original intent for the program, which was "to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." It departs from Congress' original intent by stating that the purpose of the program is for safety-net providers to utilize scare resources to increase access to and the receipt of health care services for the uninsured, underinsured and medically vulnerable. None of these terms, such as "safety net" or "underinsured," are defined, nor is the phrase "increasing such patients' access to and the receipt of health care services" defined. Lack of clarity surrounding these narrow definitions could have meaningful implications to current services 340B hospitals provide to their communities. For example, would 340B hospitals be precluded from using savings from the program to support hospital community-based programs to improve pharmaceutical access for the communities they serve? We believe the committee should retain the original purpose of the law.

**Patient Definition:** The *Discussion Draft* potentially narrows the current patient definition. The draft is unclear as to whether patients receiving home infusion therapy through the hospital or patients who are referred to a specialist, such as an oncologist, would be included in the patient definition and benefit from the 340B program. We suggest deletion of this section.

**Limitation on Amount Charged to Uninsured Low-income Patients:** The *Discussion Draft* requires the Secretary to develop a methodology that would limit what a covered entity and its associated contract pharmacy could charge a low-income patient. The *Discussion Draft* does not define what is meant by low-income nor describe how a covered entity such as a 340B hospital can obtain information on a patient's personal income. Hospitals do not collect income information from the patients they serve unless that patient is applying for the hospital's charity care policy. Hospitals will be burdened with the collection of income information from patients as well as the related privacy concerns associated with sharing personal information in order to meet this requirement. Failure to adhere to a requirement that may be impossible to operationalize could put 340B hospitals at risk for exclusion from the program for a five-year period. This is not a workable approach.

**Contract Pharmacy:** The *Discussion Draft* details new requirements for contract pharmacy arrangements. 340B hospitals are required to develop a mechanism with each of their contract pharmacies for tracking the income of patients and the amount the patient paid for a covered drug. Again, the *Discussion Draft* requires hospitals to develop a reporting mechanism for patients' income without regard to the privacy and feasibility challenges faced by hospitals. This will be especially problematic for critical access hospitals (CAHs).

**Independent Audits for Entities with High-volume Purchases:** The *Discussion Draft* requires that covered entities with a high volume of 340B purchases conduct annual independent audits of their compliance with the program requirements and submit audit results to the Secretary as part of their annual program recertification. This provision targets Disproportionate Share Hospitals

(DSH) participating in the 340B program since they are the highest volume purchasers of all the covered entities in the program. These hospitals are required to conduct independent audits and then to turn over the audit results to the Secretary without an opportunity to correct any discovered deficiencies. This annual audit could be an added requirement for the selected DSH hospitals on top of the other audits authorized by this *Discussion Draft*. While some additional auditing requirements in the draft are appropriate, this provision would be unfairly burdensome.

**New Penalty Authority:** The *Discussion Draft* expands HRSA's current authority to impose monetary penalties for violations by covered entities. This provision spells out that violations would be considered to have occurred when there was systematic, routine and intentional non-compliance with the program requirements. The *Discussion Draft* replaces the current language of "systematic and egregious" with "systematic and routine," but the draft provides no clarity on what is meant by routine. Further, hospitals are at risk for penalties if they do not implement the charge limit for low-income patients or fail to comply with the new and cumbersome report requirements. Overall, this provision seems very punitive for hospitals.

**HHS Audits:** In addition to HRSA's current audit authority, the *Discussion Draft* requires that the Secretary conduct audits of selected covered entities. The primary targets for these audits are DSH hospitals with high-volume purchases. This same group of DSH hospitals is already tasked with an annual independent audit, which the hospital must submit to the Secretary. The DSH hospital is burdened with two layers of audits with no appeals process identified for hospitals to challenge the results of the HHS audits.

**Hospital Reporting Requirements:** The *Discussion Draft* requires that all 340B hospitals except CAHs submit a detailed annual report to the Secretary. The *Discussion Draft* enumerates the details required in the annual report but provides no definition of terms such as uncompensated care, underserved or medically vulnerable. The *Discussion Draft* requires the reporting of aggregate acquisition costs for 340B drugs that are to be disaggregated by payer type. Hospitals would need to create new tracking systems to connect 340B drugs to payer type, thereby creating an additional burden for hospitals. Failure to meet these detailed reporting requirements puts hospitals at risk for monetary penalties as well as exclusion from the 340B program for five years.

**Covered Entity User Fee:** The *Discussion Draft* requires a user fee to be imposed on covered entities to fund program integrity requirements of the program. There is no comparable user fee for the pharmaceutical manufacturers. The AHA opposes user fees on hospitals as a solution to programmatic funding.

**Replace DSH Adjustment Percentage in 340B Hospital Eligibility Criteria:** The *Discussion Draft* requires the Secretary report to Congress on the information obtained from covered entities through the new reporting and auditing requirements. The Secretary is thereby required to develop options for dramatically changing the current hospital eligibility criteria that use DSH, and develop other hospital eligibility criteria. Medicare DSH remains an appropriate measure to determine a hospital's low-income and uninsured burden and, therefore, should continue to be used as the primary eligibility criteria for hospitals participating in the 340B program. This provision should be eliminated.

We look forward to continuing to work with the committee as it further refines and updates the discussion draft. We also would encourage the committee to strengthen the 340B program by looking at a balance between requirements imposed on hospitals and those imposed on pharmaceutical manufacturers. The current *Discussion Draft* imposes a burden on hospitals and virtually none on the drug manufacturers. If you have any questions, please contact Aimee Kuhlman, senior associate director for federal relations, at akuhlman@aha.org or 202-626-2291.

Sincerely,

/s/

Rick Pollack
Executive Vice President