AMERICA'S ESSENTIAL HOSPITALS

May 18, 2015

The Honorable Fred Upton
Chair
Committee on Energy and Commerce
US House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
US House of Representatives
Washington, DC 20515

Dear Chairman Upton and Representative Pallone:

On behalf of America's Essential Hospitals, which represents more than 250 hospitals with a mission to serve all patients, including the most vulnerable, I write to express our thoughts on a proposed amendment to the 21st Century Cures legislation that relates to the 340B Drug Pricing Program. Nearly every member of America's Essential Hospitals is eligible for and the vast majority of our members participate in the 340B program. Our members depend on the 340B program to assist them in fulfilling their deep commitment to providing care for low-income, uninsured, and vulnerable patients.

We appreciate the opportunity to comment on your proposed legislation. However, we are deeply disappointed with the extremely short timeframe given to analyze the impact of this language on our member hospitals and their millions of patients. America's Essential Hospitals has been talking to committee staff for more than four years about the challenges and complexities posed by the 340B program and have consistently, we believe, maintained an open dialogue about potential changes to the program. The Health Resources and Services Administration (HRSA), which has overseen the program since its inception, has been considering regulations and guidance to make changes to 340B for the same duration, or longer. While we understand that the legislative process often requires quick movement, we regret that we have been given less than 72 hours - most of which occurred over a weekend - to review and comment on the most significant statutory

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changes and largest increase in regulatory burden for hospitals since the creation of the 340B program. This timing was inadequate and unfair to the organizations and patients that rely on this critical program. More importantly, it almost certainly leads to poor public policy that may have negative unintended consequences. Without the ability to adequately review the legislation and discuss its impacts with our hospitals, we cannot effectively advise the committee regarding the efficacy and impact of this legislation.

It is for that reason that we strongly urge the committee to reject inclusion of this language in its mark-up of the 21st Century Cures legislation, a bill that is only tangentially related to 340B. While we have far too little information to provide comprehensive feedback on this legislation, there are three provisions which we believe would absolutely need to be changed to make the legislation workable for essential hospitals. Failure to make these necessary changes would force America's Essential Hospitals to actively oppose the 340B language and oppose passage of the 21st Century Cures legislation in its entirety.
Below, we list the provisions that require immediate changes. Following those, we also seek to provide input on other provisions included in the draft.

Provisions Requiring Immediate Changes

Each of the following provisions would significantly restrict the 340B program and hospitals' participation in it. These changes would not improve the program but rather would be a detriment to the stated purpose of the program and the patients cared for by our member hospitals. Alternative policy choices are available that can strengthen the program and address underlying concerns.

1. The Committee should remove Section (d): Definition of a Patient.

We share your concerns regarding the lack of clarity around the definition of a patient and have attempted in good faith to work with HRSA since their proposed rule in 1997 (and before) to develop implementable, nuanced policy that serves the purposes of the program. In particular, we have been told for the last two years to expect rulemaking that would involve a proposed rule and a real opportunity for notice and comment. Now, after years of awaiting an opportunity for comprehensive guidance and the opportunity for public input that it offers, the committee would undermine that work, forego the insight from the covered entities the program was created to assist, and deprive our members of the opportunity to provide informed feedback before restricting their rights under the program.

The rules defining the patients to whom covered entities may provide 340B discounted drugs are at the very core of the program. Our member hospitals serve missions that other providers are not required or committed to serve.

The proposed definition in Section (d) of the draft legislation would in fact narrow the scope of individuals to whom eligible hospitals can provide discounted drugs, taking critical support away from these systems and interrupting beneficial relationships with populations throughout their communities. Changes to the definition of patient have the potential to significantly disrupt patient access to essential services (particularly for the low income and uninsured patients whom other providers do not serve) and to undermine the efforts to coordinate care across providers that is the goal of so many other federal health care programs. The draft provision could easily, and unintentionally, provide perverse incentives to reduce consultation with specialists outside of the covered entity system, end relationships with other community services intended to support the health of the same patients, etc. That is why the rulemaking process is so critical and why HRSA planned to pursue full notice and comment even if it did not have authority to issue formal regulations.

In lieu of inclusion of Section (d) in the legislation, we recommend an amended draft retain Section (q), which would provide explicit authority and direction to HRSA to issue the regulations it intended by a date certain. The statutory definition in Section (d) would only undermine that process.

2. The Committee should amend Section (j): Additional Penalties for Violations.

We recognize that program integrity is crucial and that HRSA needs to have the tools to address inappropriate actions by covered entities. That is why we supported the provisions in the Affordable Care Act that created new authority for sanctions, including exclusion of covered entities from the program, for knowing and intentional, systematic and egregious violations of the program.

Of most significance, the proposed Section (j) would (1) revise the Secretary's existing authority to determine the appropriate period for exclusion for violations related to drug diversion and duplicate discounts, instead mandating that the Secretary impose a minimum period of exclusion of five years, and (2) create new exclusion authority for a minimum of five years for a covered entity that fails to take corrective action "in a timely manner."

A five year exclusion period is excessive compared to exclusion authorities under other federal programs. The Office of the Inspector General has a number of mandatory and permissive exclusion authorities under the Social Security Act, some of which include minimums. The only mandatory exclusions for five years, however, are for conviction of criminal offenses, including patient abuse or neglect, and felony convictions relating to fraud or controlled substances. Most exclusions are permissive and have either no mandatory minimum or a one year minimum.

The offenses warranting mandatory five year exclusions under other federal health care programs more serious than the ones at issue in the draft 340B provision. In addition, the entities are given significantly more due process than would be afforded in the 340B program before such a serious punishment as program exclusion was carried out. It is notable that HRSA's audit process is new and evolving and currently does not include the opportunity for covered entities to file for corrections or appeal a finding, as is often the case in other federal programs. Indeed, covered entities have only one chance to dispute any findings and provide supporting documentation before the finding is considered binding final agency action. A mandatory five year exclusion is a disproportionate penalty and does not afford the Secretary the level of discretion afforded in penalties under other federal programs. The committee should remove its proposed changes and instead direct the Secretary to issue regulations that define appropriate exclusion periods. This would be consistent with exclusions imposed under other federal health care programs.

In addition, the committee should amend the legislation to ensure that there be no exclusion from the program for failure to take corrective action in a timely manner unless the failure is found to be willful. As noted, the audit process and the development and implementation of compliance plans is still new to HRSA and covered entities. According to HRSA's rules, the findings in compliance plans can even include administrative errors such as a mistaken or out of date email address or phone number in the covered entity database. It cannot be the committee's intent that failure to update an email address within some unspecified period of time would automatically trigger such a serious deprivation as exclusion from the program.

3. The Committee should Remove the Section Entitled "Interaction with Correctional Facilities" and Amend the Related Requirement to Issue Regulations in Section (q)(2)

It is not clear what the committee is attempting to achieve with new Section 340B(a)(5) subparagraphs (G) and (H). If this provision is intended to address a specific issue with certain covered entities under the program, Congress should work with HRSA to address the behavior in a tailored manner, providing clear regulatory authority as necessary. As written, however, these new subparagraphs are broad and vague and could cause devastating interruptions to the work covered entities are tasked with doing (by mission or by law) with patients from correctional facilities. Given such a short period for review, we cannot contact all of our members to ensure that the work, for example, performed by a county hospital for a county jail would not now exclude that hospital from the 340B program. We do not have time or opportunity to understand the intended scope and potential impact of what it means to "share or otherwise transfer revenue from the purchase or dispensing" of a drug.

In lieu of the current draft language, the committee should allow HRSA to gather feedback on this issue, and – if desired – require the Secretary to issue proposed regulation in this area by a date certain.

Feedback on Other Provisions in the Draft

We also have a number of concerns with other provisions in the draft and would embrace the opportunity to identify and work with the committee to improve the proposed policies. For example, in Section (f) Treatment of Contract Pharmacy Services, the committee would require a covered entity to "establish [] an arrangement with each [] contract pharmacy and the State Medicaid agency involved to prevent duplicate discounts." While this makes sense in a state where the Medicaid agency receives claims directly from and makes payments directly to its providers, this does not address the role that managed care plans now play in Medicaid programs throughout the country. This provision must account for the responsibility of plans in preventing duplicate discounts. Covered entities cannot be held responsible under federal law for the complicated relationship and transmission of data among hospitals, managed care plans, and the state. The committee would also require contract pharmacies to implement a process for tracking individuals' incomes—the feasibility of which we cannot begin to assess without technical feedback from hospitals.

Believing that the impetus for this proposal is to improve program integrity, we would also be remiss not to request that the committee more fully consider implementation of manufacturer compliance as well. While there may be more rules for covered entities under the program, it is nonetheless important for Congress and HRSA to have the tools to identify and address problematic behavior by all program participants that could undermine its purpose. Congress should ensure that HRSA uses its resources to fulfill its responsibility to audit manufacturers as well as covered entities. The legislation should provide guidance to HRSA in prioritizing audits of manufacturers (parallel to the covered entity audit provision in Section k). This is particularly important where manufacturers are engaging in practices with the most potential to impact patient access to drugs (for example, changing distribution practices so that covered entities can only purchase drugs through specialty pharmacies or refusing to provide discounts when drugs with orphan designation are used for non-designation purposes).

America's Essential Hospitals is prepared to work with the committee to address these and a number of similar concerns with the legislation that can be resolved with adequate time, and to offer insight to further improve the beneficial provisions in this bill. We believe the committee's effort could be a starting point for considering how to protect and improve the 340B drug

discount program. But it should be just that—a starting point, and not hastily vetted changes to a program without necessary dialogue.

Conclusion

For more than 20 years, the 340B Drug Pricing Program has provided a lifeline of support to safety net providers - including essential hospitals - to stretch scarce resources and enhance care for their most vulnerable patients. Like the committee, America's Essential Hospitals recognizes the need for greater clarity in administration and enhanced oversight of the 340B program. We appreciate the committee's desire to improve and strengthen this vital program, and while we object to receiving inadequate time for review and comment, we believe that with adequate dialogue, this legislation could represent a first step toward comprehensive legislation that could be agreed upon by all stakeholders. We urge you to reject inclusion of this legislation in the committee mark-up of the 21st Century Cures legislation and we recommit to working with you to working with you to draft legislation that preserves and strengthens the 340B Drug Pricing Program.

Sincerely,

/s/

Bruce Siegel, MD, MPH
President and CEO

cc: Jim Macrae, Acting Administrator, Health Resources and Services Administration
Cdr. Krista Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration
Rep. Joseph Pitts, Chair, Subcommittee on Health, Committee on Energy and Commerce, US House of Representatives
Rep. Gene Green, Ranking Member, Subcommittee on Health, Committee on Energy and Commerce, US House of Representatives
Sen. Lamar Alexander, Chair, Committee on Health, Education, Labor, and Pensions, United States Senate
Sen. Patti Murray, Ranking Member, Committee on Health, Education, Labor, and Pensions, United States Senate