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Submitted electronically via www.regulations.gov

September 11, 2017
Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
7500 Security Boulevard
Baltimore MD 21244-1850

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program for CY 2018 (CMS-1678-P)

Dear Ms. Verma:

The Conference of Boston Teaching Hospitals, on behalf of its member hospitals, appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) proposed rule for CY2018 (CMS-1678-P).

By way of background, COBTH is an organization of thirteen Boston area teaching hospitals that that work together on issues critical to their missions of medical education and research and providing high quality care to all. Combined, COBTH hospitals have 4,816 licensed beds, saw nearly 5.9m outpatient visits last year and provided more than \$165m in charity care in FY16.

COBTH has serious concerns with the changes to the 340B drug program proposed in the pending rule. The proposed changes to the program will have a significant adverse impact on our hospitals and could hinder their ability to continue to provide essential services to the most vulnerable populations.

At the August 21, 2017 meeting of CMS's Advisory Panel on Hospital Outpatient Payment, the panel voted overwhelmingly that CMS should **not finalize** the proposed cut to 340B hospitals for CY 2018. The panel also recommended that CMS collect data to understand the impact of the proposal and assess the regulatory burden associated with the proposed modifier to identify drugs not purchased under the 340B program. **COBTH strongly opposes the CMS proposal, which will disproportionately impact hospitals that treat the most vulnerable and underserved patients and communities, and urges CMS to rescind the proposal.**

We join other hospitals from across the country in recommending that the proposed rule be rescinded for two primary reasons:

The Proposed Cuts Undermine the Intent of the 340B Program

We believe that the proposed cuts undermine the original intent of the 340B program. The program, was created to allow certain safety net hospitals and other covered entities

to purchase outpatient drugs at a discount from drug manufacturers in order to expand services that benefit vulnerable populations. Savings are generated from the 340B

Program because pharmaceutical companies are required to sell the drugs to hospitals at a reduced price - there is no cost to taxpayers. Other than a modest cost to administer the program it is self sustaining.

The 340B Program has allowed hospitals that treat large numbers of uninsured and underinsured patients to generate savings from the discounts that are then used to maintain or expand health care services and provide access to needed drugs for these vulnerable populations.

The proposed rule has targeted safety net hospitals for Medicare reductions by proposing to dramatically cut the reimbursement rate for Medicare Part B drugs purchased under the 340B Drug Pricing Program. Currently, Medicare pays for separately payable, non pass-through drugs for all hospitals at the average sales price (ASP) **plus 6 percent** (ASP +6%). CMS proposes to pay ASP **minus 22.5 percent** (ASP -22.5%) for these drugs for only 340B hospitals beginning January 2018.

Cutting Medicare payments for 340B drugs undermines the laudable purpose of the 340B Program and reduces critical drug reimbursements need by teaching hospitals and other safety net providers. Such drastic cuts to drug reimbursements will require hospitals to reduce or eliminate services elsewhere, including the programs to assist low-income patients that 340B was designed to support.

The CMS Proposal Uses Faulty Assumptions and is Unsupported by a CMS Data Analysis

We believe that CMS proposal relies on faulty assumptions and is unsupported by a CMS data analysis. We point to the comment letter submitted by the Association of American Medical Colleges and the in-depth rebuttal of the assumptions and characteristics of 340B hospital upon which CMS relies.

In particular, we are struck by CMS' contention that the 340B Program is causing unnecessary or overutilization of separately payable drugs. According to the Health Resources and Services Administration (HRSA), which administers the 340B Program, 340B sales are **less than three percent** of the total U.S. drug market. Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address drug use; rather, it will have the detrimental effect of impeding hospitals' ability to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries. It is difficult to believe changes to a program that represents less than 3% of the total U.S. drug market will result in significant changes in overall drug utilization. It is equally difficult to imagine that that reducing Medicare payments to 340B hospitals will in any way address the underlying factors driver of increased drug expenditures of volume and price.

We also believe that CMS' estimate of the financial impact of the payment decrease is unsupported by data. In the proposed rule, CMS estimates Medicare payments for the affected Part B drugs would decrease by at least \$900 million. An analysis by Watson Policy Analysis estimated that the savings are more likely to be in the range of \$1.2 to \$1.6 billion. The real financial impact on 340B hospitals will be far greater than CMS

projected in the proposed rule, lending support to the notion that the proposal is unsupported by adequate analysis.

Based on the reasons outlined above, COBTH strongly urges CMS to rescind the proposed Medicare cut to hospitals that participate in the 340B Drug Pricing Program. This proposal undermines the intent of the 340B Program, which is to provide life-saving services to underserved patients. Under this proposal, participating hospitals would be forced to reduce or eliminate critical programs that support low-income communities.

Thank you for your consideration of these concerns.

Sincerely,

A handwritten signature in black ink that reads "John Erwin". The signature is written in a cursive, flowing style.

John Erwin
Executive Director
Conference of Boston Teaching Hospitals