December 17, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency; Proposed Rule 83 *Fed. Reg.* 52,789 (Oct. 18, 2018)

Dear Administrator Verma,

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) about the referenced *Regulation to Require Drug Pricing Transparency* Proposed Rule (Proposed Rule).

We appreciate CMS's ongoing interest in finding ways to improve the affordability of prescription drugs and agree that urgent action is necessary. ***We support CMS's effort to bring a measure of transparency to pharmaceutical pricing by requiring direct-to-consumer (DTC) television advertisements of prescriptions drugs and biological products to include the Wholesale Acquisition Cost ("list price") of that drug or biological product.***

The rising cost of pharmaceuticals is an issue that hospitals are working to manage on a daily basis as evidenced by the study the FAH published with the American Hospital Association (AHA) in late 2016.[1] According to the study, average annual inpatient drug spending increased

[1] Trends in Hospital Inpatient Drug Costs: Issues and Challenges, October 2016, https://www.aha.org/system/files/2018-01/aha-fah-rx-report.pdf

by 23.4 percent between FY 2013 and FY 2015 and 38.7 percent on a per admission basis over the same time period.

The study identified rising drug prices as the primary driver of increased spending. The study tracked changes in price, utilization and total spending for a select group of drugs. The study found that changes in price drove increases in spending – not changes in volume. These price increases were inconsistent and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs.

Given the opaqueness of drug pricing as evidenced by our study's findings, we agree with CMS that this limited measure of transparency will provide consumers with important information that will help inform their understanding of the costs associated with prescription drugs – costs that are often not apparent to consumers, especially when those drugs are administered through a provider.

As we noted in our comments to the Department of Health and Human Services' (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, improving transparency in prescription drug pricing is an important component to making prescription drugs more affordable for consumers and we encourage CMS to consider additional steps such as more frequently updating and increasing the amount of information on the Medicare and Medicaid Dashboards to better inform patients of the true costs of treatment options available to them.

We encourage CMS and HHS to work to support measures, across the Department, that meet the challenge of rising prescription drug costs. For example, the Food and Drug Administration (FDA) uses the Risk Evaluation and Mitigation Strategy (REMS) program to ensure that the benefits of a drug outweigh its risks. Unfortunately, drug manufacturers often engage in abusive, anti-competitive behaviors that use REMS to block generic drug companies from obtaining samples of brand drugs, effectively preventing them from pursuing the research needed to bring less expensive generic drugs to market. The FAH appreciates steps that have already been taken to use administrative action to help curb these abuses. However, we believe more can be done and welcome further actions to address anti-competitive abuses of REMS. HHS should assess whether existing REMS programs inappropriately restrict access to samples necessary for testing by generic drug makers. Lifting any inappropriate and anti-competitive restrictions in sample access will better enable generic drug makers to develop products that can inject competition into the marketplace and bring drug prices down for consumers and taxpayers.

We would note that, as CMS observes, "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public." 83 Fed. Reg. 52,789, 52,791. So, it is important that in issuing regulations CMS rely on clear authority in support of its actions.

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Thank you for your sustained approach to identifying and proposing solutions to the acute problems in the pharmaceutical market. We look forward to working with you on this and other issues in the future.

Sincerely,