November 20, 2018

Captain Krista Pedley, Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Attention: RIN 0906–AB19

RE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, Notice of Proposed Rulemaking, 83 Fed. Reg. 55135

Dear Captain Pedley:

The Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, appreciates the opportunity to comment on the referenced proposed rule issued by the Health Resources and Services Administration (HRSA) regarding the 340B drug pricing program. The proposal would change the effective date of the final rule on the 340B program ceiling price and manufacturer civil monetary penalties from July 1, 2019 to January 1, 2019. CHA strongly supports moving up the effective date for the final rule.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers that participate in the Medicaid program to provide covered outpatient drugs at a discounted rate to safety net and other health care facilities serving low-income, vulnerable communities or remote rural areas. The significant pharmacy discounts available under the program allow hospitals to continue to provide and expand services that otherwise would not be available to these populations.

Manufacturer overcharges have been a significant and continuing problem, undermining Congressional intent in creating the 340B program, "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Following multiple reports by the HHS Office of the Inspector General in 2003, 2005 and 2006 which found evidence of manufacturer overcharging, Congress amended the 340B program in 2010 to provide for the imposition of civil money penalties upon

[1] H.R. Rep. No. 102-384(II), at 12 (1992).

manufacturers that knowingly and intentionally charge covered entities a price higher than that permitted under the law. HHS published a final rule to implement this provision on January 5, 2017 but the effective date has been delayed several times, most recently by a rule published on June 5, 2018 setting implementation for July 1, 2019. CHA had submitted a comment letter setting forth its opposition to further delay.

Adequate enforcement of 340B pricing is essential for the success of the program and the health of the communities served by 340B hospital. Only hospitals that provide a significant level of care to low-income patients or serve rural communities are eligible to be in the 340B program. In 2015 340B hospitals of all types provided $23.8 billion in uncompensated care[2] and $51.7 billion in total benefits to their communities.[3] 340B DSH hospitals account for only 38 percent of all Medicare acute care hospitals but they provide nearly 60 percent of all uncompensated care, and are much more likely than non-340B hospitals to offer vital health care services that are often unreimbursed, including trauma centers, HIV/AIDS services, outpatient alcohol/drug abuse services and immunizations.[4]

Once again, we reiterative our support for the proposal to move the effective date of the final rule forward to January 1, 2019. Thank you for the opportunity to comment. If you have any questions about these comments or need more information, please do not hesitate to contact Kathy Curran, Senior Director, Public Policy at 202-296-3993.

Sincerely,

Michael Rodgers
Senior Vice President
Public Policy and Advocacy

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[2] AHA 2015 Annual Survey Data
[3] AHA 340B Community Benefit Analysis, March 2018, accessed at https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf
[4] L&M Policy Research, Analysis of 340B Disproportionate Share Hospital Services to Low-income Patients (March 12, 2018)