



April 18, 2017

Via Federal eRulemaking Portal: <http://www.regulations.gov>

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

**Re: RIN 0906-AA89
Comments on HRSA Interim Final Rule Further Delaying Effective Date of
340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary
Penalties Regulation**

Dear Capt. Pedley:

Presence Health is one of the largest health systems in Illinois with 11 hospitals, over 20 nursing and senior living facilities, more than 90 ambulatory care sites, dozens of doctors' offices, home care, hospice and one of the largest behavioral health service networks in the state. Among these sites of care, there are currently six Presence Health hospitals that are Covered Entities under the 340B Drug Pricing Program (the "340B Program"). With Presence Health's considerable participation in the 340B program, we greatly appreciate the opportunity to submit comments on the Health Resources and Services Administration's (HRSA) Interim Final Rule regarding the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) Regulation.¹

For Presence Health, the 340B Program has played an important role in the provision of pharmaceuticals to our vulnerable populations and in particular, has enabled Presence Health hospitals to stretch scarce resources and provide services for underserved and uninsured patients who cannot afford to pay for care. We rely on our 340B savings to meet the needs of the low-income uninsured, underinsured, and Medicaid patients that we serve.

¹ 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 14,332 (Mar. 20, 2017) (hereinafter "Interim Final Rule"). The Interim Final Rule proposes to delay the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017) (hereinafter "340B Ceiling Price and Manufacturer CMP Final Rule").

The 340B Ceiling Price and Manufacturer CMP Final Rule is now more than six-and-a-half years past the statutory deadline set by Congress. The enforcement of this rule has already been delayed twice. We believe that there is not a valid reason for delaying again, so we are asking for the drug manufacturers to abide by the rules. While HRSA audits of Covered Entities have drastically increased over the past few years, there has not been oversight of manufacturers to ensure they are complying with program rules. We feel that compliance responsibilities should apply to all participating players. Therefore, HRSA should implement it immediately and certainly should not delay it until October 1, 2017.

In the Interim Final Rule, HRSA delayed the effective date of the agency's 340B Ceiling Price and Manufacturer CMP Final Rule to May 22, 2017 and invited comments on whether the effective date should be further delayed to October 1, 2017. For the reasons explained below, we ask HRSA not to delay the regulation further and to instead begin enforcing the regulation immediately.

340B overcharges have long been a problem. In 2003 and 2005, the Department of Health and Human Services (HHS) Office of Inspector General issued reports showing that covered entities are frequently overcharged for 340B drugs.² In 2003 alone, six manufacturers overcharged covered entities by \$6.1 million.³ The 2005 report, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, found that "HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price."⁴

To address these oversight deficiencies, Congress included provisions in the Affordable Care Act in 2010 to improve manufacturer 340B compliance. Among those provisions, HRSA was directed to develop and publish standards for the calculation of 340B ceiling prices and to develop civil monetary penalties for manufacturers that knowingly and intentionally overcharge covered entities. Congress gave HHS 180 days to issue CMP regulations, making the deadline September 19, 2010.⁵ HHS has now missed that deadline by more than six-and-a-half years, and covered entities are still waiting for HHS to have the enforcement tools it needs to adequately ensure manufacturers are complying with their 340B pricing obligations.

Adequate enforcement of manufacturers' pricing obligations is key to the success of the 340B program, which is intended to allow covered entities to save money on drug purchases so that they can "reach[] more ... patients" and furnish "more comprehensive services."⁶ National data show that 340B disproportionate share (DSH) hospitals provide significantly more care to Medicaid and low-income Medicare patients than non-340B hospitals, and although 340B DSH

² Department of Health and Human Services Office of Inspector General (OIG), *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities* (Mar. 2003); OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program* (Oct. 2005).

³ OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program* 17 (Oct. 2005).

⁴ *Id.* at ii.

⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 825 (2010).

⁶ H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

hospitals account for only 36 percent of all Medicare acute care hospitals, they provide nearly 60 percent of all uncompensated care.⁷ 340B DSH hospitals are also significantly more likely than non-340B hospitals to offer vital health care services that are often unreimbursed, which include trauma centers, HIV-AIDS services, and immunizations.⁸

Through the 340B Program, Presence Health hospitals have increased the number of low-income patients we serve; these patients have received life-saving drugs; and the availability of these discounted drugs through the 340B program have also reduced readmissions by enabling that patients can follow physician-ordered clinical regimens. As a result, our hospitals have used the savings to invest in programs to meet essential community needs, expand health care services to the community and offset losses from uncompensated care.

We support the aim of HRSA in actively seeking to modernize and strengthen certain aspects of the 340B Program. However, we believe that it is critical that HRSA not further delay the CMP regulation and instead begin enforcing the regulation immediately. Thank you for your consideration of our comments.

If you have any questions about the comments in this letter or need more information, please contact Will Snyder, System Vice President, External Affairs, at 312.308.3222 or william.snyder@presencehealth.org.

Sincerely,

Michael Englehart
President and CEO
Presence Health

⁷ Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016) (available at http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf).

⁸ *Id.*