



April 19, 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: Comments on HRSA Interim Final Rule Further Delaying Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (RIN 0906-AA89)**

Dear Capt. Pedley:

CHRISTUS Health appreciates 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.<sup>1</sup> 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. CHRISTUS urges HRSA to implement it immediately and not delay the final regulation until October 1, 2017.

CHRISTUS Health is an integrated, not-for-profit international health system that includes more than 40 hospitals and facilities in seven U.S. states. CHRISTUS Health serves as a safety-net provider in every community in which we operate, and provides a significant amount of uncompensated care each year. Savings from the 340B Drug Discount Program are vital to our ability to continue to provide charity care as we carry out our mission of extending the healing ministry of Jesus Christ. CHRISTUS has seventeen 340B hospitals across the system, and we rely on our 340B savings to meet the needs of the low-income uninsured, underinsured, and Medicaid patients that we serve.

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<sup>1</sup> 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").

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.<sup>2</sup> In 2003 alone, six manufacturers overcharged covered entities by \$6.1 million.<sup>3</sup> 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."<sup>4</sup>

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.<sup>5</sup> 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."<sup>6</sup> 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 hospitals account for only 36 percent of all Medicare acute care hospitals, they provide nearly 60 percent of all uncompensated care.<sup>7</sup> 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.<sup>8</sup> CHRISTUS Health uses its 340B savings in a variety of ways to

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<sup>2</sup> 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).

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

<sup>4</sup> *Id.* at ii.

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

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

<sup>7</sup> 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](http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf)).

<sup>8</sup> *Id.*

serve its indigent patients and surrounding communities. For example, CHRISTUS Spohn funds a need-based retail pharmacy which provides prescription drugs to indigent patients for free or nominal copays. Savings from the 340B Program allows the Children's Hospital of San Antonio to provide high-quality treatment to every child who presents at our hospital. Thanks to 340B pricing, CHRISTUS Louisiana can ensure low income and uninsured patients' access to free or inexpensive pharmaceuticals. We also provide programs like no cost diabetes education at various Wound Care and Hyperbaric Medicine Centers. Additionally, CHRISTUS St. Vincent provides over \$1 million annually to smaller community non-profits that provide additional safety net health care services to the region, including substance abuse, behavioral health, and crisis care with 340B savings.

Again, CHRISTUS Health respectfully requests that HRSA does not further delay the regulation and make the decision to instead begin enforcing the regulation immediately. This valuable program enables our hospitals to expand health care services to the community, increases the number of patients we can serve, and reduces pharmaceutical costs for our neediest community residents. Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in cursive script that reads "Gabriela M. Saenz".

Gabriela Saenz, JD  
VP Advocacy & Public Policy  
CHRISTUS Health