



November 21, 2018

Krista Pedley, Pharm.D, MS  
Director, Office of Pharmacy Affairs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
Re: RIN 0906-AB19  
5600 Fishers Lane  
Rockville, MD 20857

RE: RIN 0906-AB19 – 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Submitted electronically via Federal eRulemaking Portal <http://www.regulations.gov>

Dear Captain Pedley,

Trinity Health appreciates the opportunity to respond to the Department of Health and Human Services (HHS) 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) regulation. Our comments reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. Implementation and enforcement of the long-delayed 340B Ceiling Price and Manufacturer CMP final rule is critical to ensuring that 340B covered entities are receiving the correct 340B price and thereby that the program is best able to meet its intended objective.

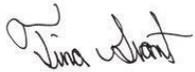
Trinity Health includes 33 hospitals that participate in the 340B Drug Pricing Program. The 340B Program provides essential savings critical to helping these eligible hospitals comprehensively serve and improve the health of the vulnerable communities in which they serve. The 340B Program is supporting improved patient care, increased medication access and adherence, and decreased hospital readmissions in these vulnerable communities.

Trinity Health is pleased to see the Health Resources and Services Administration (HRSA) propose to make January 1, 2019 the compliance effective date—after repeated and lengthy previous delays—and urges HRSA to stick by the commitment to this date and to publish the final rule in time to meet the January 1 deadline. The 340B Ceiling Price and Manufacturer CMP final rule is now more than eight years past the statutory deadline set by Congress. Trinity Health supports HHS setting a clear path forward and ceasing further delay by moving forward the effective date of the final rule from July 1, 2019 to January 1, 2019. Again, Trinity Health encourages HHS to stick by this commitment and to publish the final rule in time to meet that deadline.

The accuracy of drug discounts have long been a problem for covered entities, including Trinity Health's participating hospitals. To address this accuracy and manufacturer overcharges that often result, Congress amended the 340B statute in 2010 directing HRSA to develop rules for calculating 340B ceiling prices, publish the ceiling prices on a website available to covered entities, and develop CMPs for manufacturers that knowingly and intentionally overcharge covered entities. Congress gave HHS 180 days to issue CMP regulations, making the deadline September 19, 2010. However, HHS has missed that deadline by more than eight years. Trinity Health also encourages HHS to publish that website promptly, which is critical to enforcement of the 340B Program, as soon as possible after January 1, 2019. Adequate enforcement of manufacturers' pricing obligations is key to the success of the 340B Program, which is intended to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Trinity Health supports ceasing further delay of the final 340B Ceiling Price and Manufacturer CMP rule and moving forward its effective date to January 1, 2019 as well as ensuring that the website be published as soon as possible after January 1 as the website is essential for effective enforcement of the 340B Program. Thank you for the opportunity to respond on this important issue. If you have questions on our comments, please feel free to contact me at [grantw@trinity-health.org](mailto:grantw@trinity-health.org) or 734-343-1375.

Sincerely,

A handwritten signature in black ink that reads "Tina Weatherwax Grant". The signature is written in a cursive, flowing style.

Tina Weatherwax Grant, JD  
Vice President, Public Policy and Advocacy  
Trinity Health