

November 15, 2018

CAPT Krista Pedley, Director
Office of Pharmacy Affairs (OPA)
Healthcare Systems Bureau (HSB)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

RE: RIN 0906–AB19 – 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; published at Federal Register, Vol. 83, No. 213, November 2, 2018.

Submitted electronically via www.regulations.gov

Dear Capt. Pedley,

UnityPoint Health (“UPH”) appreciates this opportunity to provide feedback on the proposed implementation date. As one of the largest nonprofit, nondenominational health systems in the country, the UPH network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals and Rural Health Clinics provide vital access to health care services. Through 12 hospitals at 33 locations, the 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois and Wisconsin. We respectfully offer the following comments.

PROPOSAL TO CHANGE THE EFFECTIVE DATE OF THE FINAL RULE FROM JULY 1, 2019, TO JANUARY 1, 2019

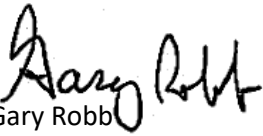
HHS is proposing an effective date of January 1, 2019, for the 340B Program Final Rule which sets forth the calculation of the 340B ceiling price and application of manufacturer civil monetary penalties (CMPs). This final rule was initially published on January 5, 2017 in Vol. 82, No. 3 Federal Register 1210-1230.

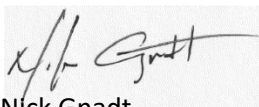
- **Comment:** This rule aligns with UPH’s position on the 340B Drug Pricing Program – we oppose any efforts to redirect resources from or place moratoriums on safety-net providers, but support initiatives to strengthen manufacturer and covered-entity transparency. This rule supports increased transparency in the program for manufacturers and therefore we support the proposed implementation date. Further, we would encourage HHS to publish the list of ceiling prices as soon as possible.

As stated in our comment letter¹ to the CY 2019 Hospital Outpatient Prospective Payment System proposed rule, we are also supportive of covered-entity transparency that accurately depicts the program. We reiterate our support of the American Hospital Association's principles for communicating the values of the 340B Program and the disclosure of Hospital's 340B estimated savings² and encourage HHS to work with stakeholders in developing future regulations. We would be happy to collaborate with HHS on these efforts.

We are pleased to provide comments on this important safety net program. To discuss our comments or for additional information, please contact Sabra Rosener, Vice President, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,


Gary Robb
Chief Pharmacy Officer


Nick Gnadt
Director, Ambulatory Pharmacy


Sabra Rosener
VP, Government & External Affairs

¹ See "2019OPPS_UPH_9-24-18.pdf" submitted via [regulations.gov](https://www.regulations.gov) on September 24, 2018; comment tracking number: 1k2-95m0-pasa.

² AHA, "340B Hospital Commitment to Good Stewardship Principles" accessed at https://www.aha.org/system/files/2018-09/Final-Stewardship-Principles_Sept-2018_0_1.pdf