May 19, 2016

James Macrae, HRSA Acting Administrator
Office of Pharmacy Affairs
Health Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

RE: RIN 0906–AA89; 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Federal Register (Vol. 81, No. 75), April 19, 2016

Submitted electronically via www.regulations.gov

Dear Mr. Macrae:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments on the 340B Drug Pricing Ceiling Price and Manufacturer Civil Monetary Penalties. As stated in UPH comments submitted on the Proposed 340B Drug Pricing Program Omnibus Guidance published by the Health Resources and Services Administration (HRSA) on August 28, 2015, UPH generally supports HRSA’s efforts to add clarity and a more rigorous approach towards the 340B Program’s oversight and interpretation. Our comments and recommendations to HRSA reflected a strong interest in the 340B program policies that support continued access to 340B drug pricing to enable 340B-participating covered entities to stretch scarce federal resources, preserve the integrity of the program, and ultimately support patient care and health by enabling patients to afford needed medications.

UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees, our relationships with more than 290 physician clinics, 32 hospitals in metropolitan and rural communities, and home care services throughout our 9 regions, UPH provides care throughout Iowa, Illinois and Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 4.5 million patient visits. About 15% to 18% of our patients are Medicaid beneficiaries. In addition, UPH is actively engaged in numerous initiatives which support population health and value-based care.

UPH includes Disproportionate Share hospitals (“DSH”), like Iowa Lutheran Hospital (Des Moines, Iowa) and Meriter Hospital (Madison, Wisconsin), sole community hospitals (“SCH”), like Trinity Regional Medical Center (Fort Dodge, Iowa), and critical access hospitals (“CAH”), like Jones Regional Medical Center (Anamosa, Iowa). Of this mix of hospitals, some have been enrolled in the 340B program for years; others are recent enrollees with relatively new participation dates.

UnityPoint Health appreciates the time and effort spent by HHS in reopening the comment period for the purpose of inviting public comments on: Ceiling Price for a Covered Outpatient Drug Exception, New Drug Price Estimation and Definition of “Knowing and Intentional”. In general, we continue to encourage HRSA to streamline the 340B
program in order for the program to implement the good intentions of this policy. UPH respectfully offers the following comments.

**CEILING PRICE FOR A COVERED OUTPATIENT DRUG EXCEPTION**

HHS proposed that when the calculation of the 340B ceiling price resulted in an amount less than $0.01, the ceiling price would be $0.01 per unit of measure (hereinafter, penny pricing). In the notice of proposed rulemaking (NPRM), HHS recognized that it was not reasonable for a manufacturer to set the ceiling price at $0.00 per unit of measure. HHS received a number of comments supporting and opposing the penny pricing proposal and suggesting alternatives to penny pricing.

**Comment:** UPH supports calculating the ceiling price based on penny pricing. Given other proposed increases in administrative burden for 340B covered entities, a burden which may result in additional costs to the operation of the program on the part of covered entities, penny pricing preserves a benefit for the covered entities to continue to participate in the program and likewise the low-income patients that the covered entities serve. The 340B program is an important resource for low-income patients that allows qualifying individuals to purchase necessary medications at an affordable price. In order for the 340B program to be effective, it must be financially feasible for the covered entities to participate in the program. We ask HHS to also take into consideration the downstream impact that raising the ceiling price in excess of penny pricing on other existing 340B covered entity contracts and patient outcomes, including contracts for population health programming, value-based care and innovative service delivery. As an alternative to revising the ceiling price calculation, we would instead suggest that HRSA consider establishing a floor price for the manufacturers. This recognizes that manufacturers have invested money in the development of the drugs, yet provides the predictability of a clear penny pricing ceiling for the covered entities.

**NEW DRUG PRICE ESTIMATION**

In the NPRM, HHS proposed that manufacturers estimate the ceiling price for a new covered outpatient drug as of the date the drug is first available for sale, and provide HRSA an estimated ceiling price for each of the first three quarters the drug is available for sale. HHS also proposed that, beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in proposed 42 CFR 10.10(a). Under the proposed rule, the actual ceiling price for the first three quarters must also be calculated and manufacturers would be required to provide a refund or credit to any covered entity which purchased the covered outpatient drug at a price greater than the calculated ceiling price. HHS proposed that any refunds or credits owed to a covered entity must be provided by the end of the fourth quarter.

**Comment:** UPH highly supports that manufacturers estimate the ceiling price in the first three quarters and provide 340B covered entities a rebate or credit by the end of the fourth quarter. We also support the use of the wholesale acquisition cost (WAC) as the specific methodology for calculating new drug prices. The use of WAC to establish the ceiling price of new drugs provides a clear methodology for the manufacturers and the covered entities to understand and calculate both the ultimate ceiling price and any rebates or credits due to the covered entities.

**DEFINITION OF “KNOWING AND INTENTIONAL”**

The Secretary is charged with issuing civil monetary penalties for manufacturers who have “knowingly and intentionally” charged a covered entity a price that exceeds the 340B ceiling price. Although the knowing and
intentional standard was included in the NPRM issued on June 17, 2015, “knowing and intentional” was not specifically defined.

Comment: While UPH supports the levying of civil monetary penalties as a method to enforce 340B constructs, we do believe that this provision could be strengthened. First, we do not believe that $5000 is sufficient to prevent manufacturers from engaging in knowing and intentional behavior to set prices above the 340B ceiling price. Upon evidence of an intentional act, the magnitude of the civil monetary penalties should reflect this knowing disregard. For example, when the manufacturers systematically banded together in an interpretation of the orphan drug rule contrary to HRSA guidance, we do not believe that a $5000 monetary penalty would have changed this behavior. We would recommend that HRSA consider a more impactful penalty amount to discourage setting prices above the ceiling price. Second, UPH agrees that manufacturers do not need to intend specifically to violate the 340B statute; but rather to have knowingly and intentionally overcharged the 340B covered entity. We do not believe that “knowing and intentional” requires further affirmative definition beyond the common law definition. UPH is concerned that any further definition of this standard will just make it more difficult to allege and prove any violation and may not take into consideration future circumstances that may warrant inclusion within this standard. Should HHS desire to further clarify this standard, we urge HHS to use the exclusionary approach (i.e. what actions do not raise to the level of the requisite intent). We would also encourage HHS to consider past price setting practices to determine the knowingly and intentional standard.

We appreciate the opportunity to provide comments to the proposed rule and its impact on our 340B covered entities and patients. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Public Policy and Government Payors at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,

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