UnityPoint Health

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March 6, 2020

Paul Ray , Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: CMS Desk Officer
725 17th Street NW
Washington, DC 20503

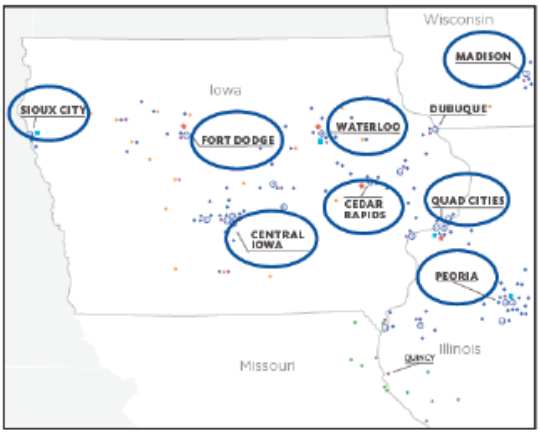
Re: Comments on CMS Proposed Collection of Information, Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709; OMB-0938-New)

Submitted electronically via OIRA_submission@omb.eop.gov

Dear Administrator Ray:

UnityPoint Health (UPH) appreciates the opportunity to submit comments in response to the notice published in the Federal Register on February 7, 2020, proposing an information collection request (ICR) by the Centers for Medicare & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data.[1] Congress enacted the 340B program to provide resources to hospitals serving high volumes of low-income and rural patients to enable those hospitals to provide more comprehensive services and treat more patients.[2] As a large nonprofit, integrated healthcare system in the Midwest, the UPH network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals and Rural Health Clinics provide vital access to healthcare services. 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. The 11 UPH participating hospitals are:

- Allen Hospital – *Waterloo, IA*
- Iowa Methodist Medical Center – *Des Moines, IA*
- Jones Regional Medical Center – *Anamosa, IA*
- Meriter Hospital – *Madison, WI*
- Methodist Hospital – *Peoria, IL*
- St. Luke's Hospital – Cedar Rapids, IA
- St Luke's Regional Medical Center – *Sioux City, IA*
- Trinity Medical Center – *Bettendorf, IA*
- Trinity Medical Center – *Muscatine, IA*
- Trinity Medical Center – *Rock Island, IL*
- Trinity Regional Medical Center – *Fort Dodge, IA*



[1] 85 Fed. Reg. 7306 (Feb. 7, 2020).
[2] Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106, Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b; see also H Rpt. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session.

Our hospitals are eligible to participate in the 340B program by virtue of high volume of Medicaid and low-income Medicare patients as well as rural locations. The 340B program enables our participating hospitals to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services by allowing our providers to address the individualized needs of the people we serve in meaningful ways. We rely on our 340B savings to meet the needs of the low-income patients and rural patients we serve.

For the reasons explained below, **UPH urges the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals**. We respectfully offer the following comments:

ACQUISITION COST PAYMENT HARMS SAFETY-NET HOSPITALS AND THEIR PATIENTS

We strongly oppose CMS's proposal to set Medicare payment for 340B drugs at acquisition cost because **it would undermine our ability to provide needed care to the low-income patients we serve.** It is well documented that 340B hospitals provide high levels of care to individuals living with low incomes. Although 340B disproportionate share (DSH) hospitals represent 38 percent of hospitals, they provide 60 percent of all uncompensated care.[3] Reducing Medicare payment to 340B hospitals' acquisition costs would eliminate 340B hospitals' ability to use the savings they accrue, by purchasing a drug at a discounted 340B price for a Medicare beneficiary, to provide more care to underserved patients, thereby frustrating the 340B program's purpose.

THE SURVEY PLACES A MASSIVE BURDEN ON 340B HOSPITALS

Even if the survey were to produce adequate data for calculating 340B hospitals' drug acquisition costs, OMB should reject CMS's ICR because it would place a massive burden on hospitals. CMS is asking hospitals to calculate average 340B prices based on Medicare HCPCS dosage units, requiring hospitals to convert a significant number of the 1,100 NDC purchase units covered to more than 400 HCPCS dosage units.[4] **This step will require hospitals to engage in extensive mathematical calculations, requiring analysis of tens of thousands of units of data, and brings in the risk of human error that could undermine the reliability of the data**. CMS can do these conversions on its own and should therefore minimize the burden of the collection by doing so. Moreover, from its original proposal, CMS has shortened the survey response period, from one month to 18 days. **Shrinking the survey response period contributes to the burden of the collection, particularly for our organization which is preparing for HRSA audits at two of our facilities during the proposed response time.**

CMS'S PROPOSAL IS CONTRARY TO LAW

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from hospitals that do not participate in the 340B program, violates the Medicare statute. Although the Medicare statute

[3] L&M Policy Research, A Comparison of Characteristics of Patients Treated by 340B and Non-340B Providers, (April 8, 2019), https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf

[4] *CMS Addendum B, October 2018,* https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/Hospitaloutpatientpps/Downloads/2018-Oct-Addendum-B.zip, There are 414 total HCPCS codes for which CMS is requesting data. For these 414 HCPCS codes, there are approximately 1,100 total NDCs mapped to them in CMS's HCPCS-NDC crosswalk.

allows for a survey of hospitals on drug acquisition costs, **the statute does not allow CMS to target a subset of hospitals for the survey**.[5]

THE SURVEY WILL COLLECT UNUSABLE DATA

The 340B statute prohibits our hospital from obtaining covered outpatient drugs through a group purchasing organization or group purchasing arrangement, requiring our hospital to purchase certain outpatient drugs at wholesale acquisition cost (WAC) prices that are significantly higher than 340B prices.[6] **CMS does not include WAC purchases in the calculation of average acquisition cost, which prevents the data collection from accurately calculating the cost of drugs billed to Medicare**.

We are pleased to provide comments on this proposed ICR and urge its withdrawal. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

Nick Gnadt, PharmD, RPh
Director, Ambulatory Pharmacy

Sabra Rosener, JD
VP, Government & External Affairs

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).
[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).