UnityPoint Health

Government & External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
www.unitypoint.org

November 25, 2019

William N. Parham, III
Director, Paperwork Reduction Staff
CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10709
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

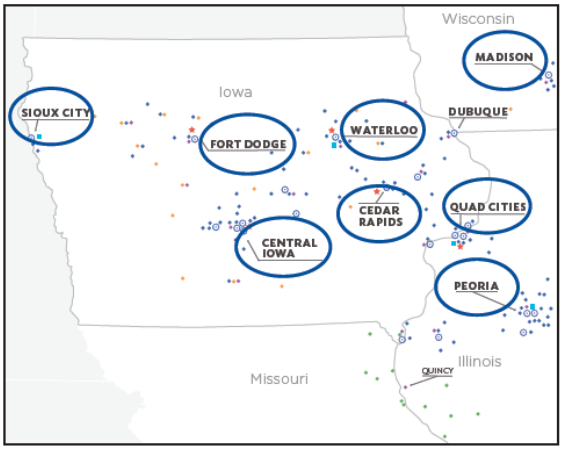
RE: CMS-10709; CMS Proposed Collection of Information, Hospital Survey for Specified Covered Outpatient Drugs, published in vol. 84 (189) Federal Register 51590-51591 on September 30, 2019

Submitted electronically via http://www.regulations.gov

Dear Director Parham:

UnityPoint Health (UPH) appreciates the opportunity to submit comments in response to the notice on a proposed information collection request (ICR) by the Centers for Medicare & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data. 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 13 UPH participating hospitals are:

- Allen Hospital – *Waterloo, IA*
- Marshalltown Hospital – *Marshalltown, IA*
- Iowa Lutheran Hospital – *Des Moines, 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*



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, **we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals**. We respectfully offer the following comments.

CMS'S PROPOSAL HARMS SAFETY-NET HOSPITALS AND LOW-INCOME PATIENTS

CMS's current payment reduction to many 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. **CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services**. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS'S PROPOSAL IS CONTRARY TO LAW

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, **the statute does not allow CMS to target a single group of hospitals for the survey**.[1]

CMS UNDERESTIMATES THE PROPOSAL'S ADMINISTRATIVE BURDEN ON HOSPITALS

Our hospitals have significant concerns regarding the amount of time it would take to respond to the survey. CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data hospitals would need to account for. Even more concerning are the extensive mathematical calculations the ICR requires hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring hospitals to (1) average the prices together for all the NDCs mapped to the HCPCS codes, which can be dozens of NDCs for a single HCPCS code, and (2) convert NDC purchase units to HCPCS dosage units. In addition to significantly adding to the burden, asking hospitals to complete calculations factoring tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report despite their best efforts.

CMS also asks hospitals to identify each provider-based department where a relevant drug was

[1] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code.[2] CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, contrary to requirements of the Paperwork Reduction Act (PRA) of 1995.[3]

In addition, CMS's data collection instructions are not clear, which will result in our hospitals engaging in making educated guesses to determine what CMS is requesting and how we would generate the data. Ultimately, this makes it impossible for our hospitals to evaluate the burden accurately and CMS will receive inaccurate and incomplete data. **If CMS elects not to withdraw this ICR, we would urge CMS to reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden**.

Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. We believe CMS has grossly underestimated the time burden, and therefore cost burden, to hospitals. Even assuming the accuracy of this estimate, this represents a significant sum of money that safety-net hospitals otherwise could use to care for our low-income and rural patients.

We appreciate the opportunity to provide input on the proposed ICR and its impact on our participating hospitals and patients. We urge CMS to withdraw this ICR for the foregoing reasons and would be happy to work with CMS to develop a less burdensome and better tailored solution. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

Nick Gnadt, PharmD, RPh
Director, Ambulatory Pharmacy
UnityPoint Health

Sabra Rosener, JD
VP, Government & External Affairs
UnityPoint Health

[2] CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals.

[3] 44 U.S.C. § 3506(c)(1)(B)(iii).