

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

May 15, 2020

The Honorable Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health & Human Services Baltimore, MD 21244-1850

Re: 340B Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709)

Submitted electronically via Seema.Verma@cms.hhs.gov

Dear Administrator Verma:

UnityPoint Health (UPH) submitted 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 UPH is writing to further explain our choice of the Quick Survey option for responding to the Centers for Medicare & Medicaid Services (CMS) 340B Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709).

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. Our comments are on behalf of UPH participating hospitals impacted by this survey:

- Allen Hospital Waterloo, IA
- Iowa Methodist Medical Center Des Moines, IA
- 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

We respectfully offer the following comments.

QUICK SURVEY OPTION

CMS gave hospitals two options to complete the survey: Quick Survey using 340B ceiling prices or Detailed Survey. Our hospitals chose the Quick Survey option, as it was not possible to complete the Detailed Survey within the three-week time frame provided. We simply could not confidently calculate

¹ 85 Fed. Reg. 7306 (Feb. 7, 2020).

340B volume weighted average acquisition costs for more than 400 codes under Medicare's Healthcare Common Procedure Coding System (HCPCS), which encompasses 1,100 national drug codes (NDCs) and would require converting NDC purchase units to HCPCS dosage units. We were able to complete initial calculations to estimate the number of billing units purchased and the total cost paid for each NDC. From there we calculated the volume weighted average acquisition cost and compared it to the current ceiling price from the OPAIS which may or may not be a reasonable approximation of the ceiling prices for the quarters being surveyed as we do not have access to previous ceiling prices.

However, these calculations are very complex and include thousands of lines of data. For us to be confident in the analysis we have done thus far would require us to do substantial data validation prior to submitting the results. These tasks would take a significant amount of time by hospital staff who already are consumed responding to the COVID-19 pandemic. Given the burden of work required, the narrow turnaround time allowed, and the immediate priority to address the COVID-19 public health emergency, the Detailed Survey was not a viable option for our hospitals.

Our hospitals chose the Quick Survey option, which required only that we check a box if we "prefer that CMS utilize the 340B ceiling prices obtained from the Health Resources and Services Administration (HRSA) as reflective of your hospital acquisition costs." CMS did not make clear what it means for hospitals to prefer CMS use the 340B ceiling prices. We are writing to make clear that in selecting the Quick Survey option, our hospitals were acknowledging only our preference for the less-burdensome Quick Survey as opposed to the Detailed Survey. This was not intended to be an acknowledgment that the 340B ceiling prices exactly match our 340B drug acquisition costs.

DELAY OF NON-ESSENTIAL ACTIVITIES

Finally, UPH notes that we disagree with CMS's decision to proceed with a survey of 340B hospitals as we grapple with the enormous impact of the COVID-19 pandemic. Safety net providers across the country are facing unprecedented disruptions not just to patient care but also to our very financial viability. Should a similar situation arise in the future, we urge CMS to support safety net providers by delaying non-essential activities such as this survey.

To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Government and External Affairs at <u>cathy.simmons@unitypoint.org</u> or 319-361-2336.

Sincerely,

x/fr Gritt

Nick Gnadt, PharmD, RPh Ambulatory Pharmacy Director

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cc: Wisconsin Physicians Service Government Health Administrators - Chris Severson: <u>chris.severson@wpsic.com</u> National Government Services, Inc. - PSR@anthem.com