

Ms. Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, D.C. 20201

RE: CMS-10709, Hospital Survey for Specified Covered Outpatient Drugs (*Federal Register*, Vol. 84, No. 189, September 30, 2019)

Dear Ms. Verma:

On behalf of our 107 member 340B provider hospitals, the Illinois Health and Hospital Association (IHA) welcomes this opportunity to formally comment on the proposed hospital survey for specified covered outpatient drugs. The hospital survey will require covered entities to report acquisition costs for outpatient drugs purchased under the 340B program. CMS may use these data in setting Medicare payment rates for 340B-acquired drugs moving forward.

Within the proposed survey notice, CMS expressed its opinion that the Secretary of Health and Human Services has not exceeded his authority in adjusting 340B reimbursement rates to average sales price (ASP) minus 22.5% since calendar year (CY) 2018. IHA has consistently disagreed with CMS' stance,^{1,2,3} demonstrating that lowering Medicare payments for 340B drugs undermines Congress' intent in establishing this program and undercuts the ability of hospitals with large low-income and uninsured populations to work toward equity in the provision of and access to healthcare services.

Congress created the 340B program to protect certain clinics and hospitals from drug price increases and give them access to price reductions. These clinics and hospitals, or 340B covered entities, have disproportionate share rates above 11.75%, meaning such hospitals serve a significantly disproportionate number of low-income patients. Hospitals may dispense these discounted drugs to any patient, regardless of payer, and retain the difference between the reduced price paid for the drug and the full amount at which it was reimbursed. According to the Health Resources & Services Administration, this arrangement allows covered entities to "stretch scarce federal

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¹ IHA's 2018 OPPS Comment Letter, [September 11, 2017, can be accessed at: https://www.team-ih.org/files/non-gated/advocacy/medicare/cms-comment-letter-oppo-rule.aspx?ext=.](https://www.team-ih.org/files/non-gated/advocacy/medicare/cms-comment-letter-oppo-rule.aspx?ext=)

² IHA's 2019 OPPS Comment Letter, [September 24, 2018, can be accessed at: https://www.team-ih.org/files/non-gated/advocacy/medicare/cms1695p-oppo-commentltr.aspx?ext=.](https://www.team-ih.org/files/non-gated/advocacy/medicare/cms1695p-oppo-commentltr.aspx?ext=)

³ IHA's 2020 OPPS Comment Letter, [September 27, 2019, can be accessed at: https://www.team-ih.org/files/non-gated/advocacy/ffy2020-oppo-comment-letter-nicole.aspx](https://www.team-ih.org/files/non-gated/advocacy/ffy2020-oppo-comment-letter-nicole.aspx)

resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

In Illinois, 340B covered entities have an average disproportionate share percentage above 40%. These hospitals use 340B savings to provide direct access to healthcare services and medicines to patients who cannot afford care, as well as support a variety of programs that increase access to healthcare services in their communities. For example, one of our hospitals recently established a mobile clinic program that brings healthcare services directly to low-income and underserved communities, such as providing school physicals for those in low-income neighborhoods, regardless of a family’s ability to pay. Others may be able to provide free colonoscopies and mammograms, free transportation, mobile dental vans, etc. These are the types of access-promoting programs that will be negatively impacted should 340B covered entities continue to experience Medicare reimbursement cuts.

Maintaining access to these critical healthcare services for some of our most vulnerable patients and communities is challenging, and that is why we are particularly alarmed by this proposed data collection. In the recently published outpatient prospective payment system final rule, CMS wrote that the currently enacted ASP minus 22.5% formula was, in its opinion, conservative and representative of the minimum discount that hospitals receive for 340B-acquired drugs. CMS articulated that it expects collected survey data to confirm that ASP minus 22.5% is “a conservative measure that overcompensates 340B hospitals.” This statement suggests CMS intends to use collected data not only to support its current cut, but pursue more aggressive reimbursement cuts in the future. Again, we strongly urge CMS to reconsider this path as it undermines the intent of the 340B program and may jeopardize efforts to increase access to healthcare services for low-income and uninsured individuals in the future.

If CMS chooses to move forward with this proposed hospital survey, we ask that CMS reconsider the survey methodology and burden estimate.

Regarding the survey methodology, we agree with CMS that sampling does not make sense given the intended use of these data, and we appreciate that CMS will instead attempt to collect the universe of acquisition data from 340B covered entities. However, we are concerned that CMS appears to be proposing a one-time data collection on acquisition costs that will be used to set 340B prices moving forward. CMS proposes requiring all hospitals that participated in the 340B program in the last quarter of CY 2018 and/or the first quarter of CY 2019 to supply their average acquisition cost for each specified covered outpatient drug purchased during those two quarters.

As CMS knows, drug prices are extremely volatile and can change sometimes weekly, making it unlikely that two quarters of data will provide an accurate base for setting 340B reimbursement

rates over time. In fact, the Kaiser Family Foundation⁴ analyzed actual and projected annual changes in per capita prescription drug spending from 1970 through 2027. Not only does Kaiser find that drug spending fails to track with total health spending, but that annual changes range from a decrease of 0.7% to an increase of 14.7%. Simply stated, a static point in time does not accurately reflect a market that changes and innovates so rapidly. Therefore, if CMS moves forward with this proposal, we strongly urge CMS to establish criteria for a more regular data collection schedule in an effort to better reflect prescription drug costs in their reimbursement of 340B-acquired drugs. For drugs with relatively stable pricing, CMS could stipulate utilization of an inflation index to account for reimbursement adjustments over time. For drugs that experience price changes beyond a specified benchmark, CMS could request updated acquisition data from 340B covered entities. We request that CMS think through and articulate such criteria prior to finalizing this hospital survey.

Additionally, CMS estimates the average hospital will spend 48 hours responding to this survey. We spoke with a variety of 340B covered entities in Illinois, ranging from smaller rural hospitals to larger hospitals that are part of large systems. Not one hospital believes that this time estimate is accurate. Rather, they all expressed that a 48-hour timeframe grossly underestimates the time needed to research and provide the needed information. Given this feedback, it appears this survey does not keep with CMS' important pursuit to reduce provider burden.

Finally, we appreciate CMS' desire to make prescription drugs more affordable for patients, particularly for low-income or uninsured patients. However, we reiterate that cutting Medicare hospital reimbursement for 340B-acquired drugs is not the appropriate way to address ever-rising prescription drug costs. It simply does not make sense to financially penalize providers that are trying to improve equity in terms of healthcare access and utilization. We agree CMS should address the ongoing problem of high drug prices. However, the solution lies in legislation that reins in manufacturer costs, not in regulations that cut Medicare payments to providers that are already operating on negative Medicare margins.

Ultimately, the 340B program helps maintain the health of our nation's hospital safety net system. This proposed data collection, and the ongoing cuts in Medicare reimbursement for 340B-acquired drugs, threatens this system and the vulnerable Americans who rely on it.

Ms. Verma, thank you again for the opportunity to comment.

Sincerely,
A.J. Wilhelmi
President & CEO

⁴ Kamal, Cox, McDermott. What are the recent and forecasted trends in prescription drug spending? Peterson-KFF Health System Tracker. February 20, 2019. Available from: <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start>.