November 27, 2019

Via Federal eRulemaking Portal: http://www.regulations.gov

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-10709
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

340B Health submits these comments in response to the notice published in the Federal Register on Sept. 30, 2019, requesting comments on a proposed information collection request (ICR) by the Centers for Medicare and Medicaid Services (CMS) to survey 340B hospitals to obtain drug acquisition cost data for specified covered outpatient drugs (SCODs).[1] 340B Health represents more than 1,400 public and nonprofit hospitals that participate in the federal 340B drug pricing program. 340B hospitals provide critical services and access to care to patients with low incomes and those living in underserved rural communities. Congress created the 340B program in 1992 to allow safety-net providers to "reach more patients" and furnish "more comprehensive services."[2]

This ICR announces CMS's intention to collect drug acquisition cost data from all 340B hospitals paid under the hospital outpatient prospective payment system (OPPS) in order to "set payment rates based on cost for 340B-acquired drugs when they are furnished by certain covered entity hospitals."[3] The proposed ICR comes almost two years after CMS implemented a nearly 30 percent payment reduction for Medicare Part B drugs acquired through the 340B program, which CMS said was intended to pay 340B hospitals at a rate that more closely aligns to 340B drug acquisition costs.[4] CMS's current payment reduction harms 340B hospitals' ability to provide needed care to the low-income and rural patients that they serve. Despite hearing from hospitals about these concerns and notwithstanding a federal court's rulings that the payment reductions to 340B hospitals are unlawful,[5] CMS will continue the cuts to 340B hospitals in 2020.[6]

340B Health urges CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals. We strongly oppose payment at average acquisition cost for 340B hospitals by Medicare, a move that reverses more than 20 years of Medicare payment policy. Furthering this policy will continue to harm safety-net hospitals and the low-income patients they serve, as well as significantly undermine the 340B program, which has been supporting these hospitals and their patients for decades. CMS's proposal would be particularly problematic for the 340B hospitals that CMS exempted from the Part B payment reductions due to the unique patient populations that these hospitals serve.

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[1] Centers for Medicare & Medicaid Services, Agency Information Collection Activities: Proposed Collection; CMS-10709, 84 Fed. Reg. 51590 (Sept. 30, 2019).
[2] H.R. Rep. 102-384(II) at 12 (1992).
[3] CMS 10709, Supporting Statement Part A, Hospital Survey for Specified Covered Outpatient Drugs, Page 1.
[4] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33564 (July 20, 2017) (CMS–1678–P).
[5] American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018).
[6] See Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 84 Fed. Reg. 61142, 61145 (Nov. 12, 2019) (CMS-1717-FC).

Not only would the ICR promote a harmful policy, but it is contrary to law and exceeds CMS's authority under the Paperwork Reduction Act (PRA) of 1995.[7] Aspects of the survey instructions are unclear**,** making it impossible to meaningfully comment on CMS's burden estimate. This lack of clarity by itself prohibits CMS from moving forward with the ICR without re-proposing with clear and detailed instructions that hospitals can evaluate to meaningfully comment on the burden.

I. CMS's Plan to Pay 340B Hospitals at Average Acquisition Cost Will Hurt Safety-Net Hospitals and their Low-Income Patients

340B Health is very concerned that CMS's proposal will harm 340B hospitals and the patients they serve. 340B drugs are not intended to be paid at average acquisition cost. For over 25 years, 340B hospitals have purchased drugs at discounted prices and used the difference between the 340B discounts and what hospitals would have paid for the drugs under their hospital group purchasing accounts to invest their 340B savings in additional patient care. CMS's proposed survey is intended to dramatically break with over two decades of Medicare payment policy to ultimately pay 340B hospitals at average acquisition cost for Medicare Part B drugs, thereby removing a key benefit 340B hospitals receive from the 340B program, and undermining their ability to treat their low-income patients.[8]

It is well documented that 340B hospitals provide high levels of care to low-income individuals. Although 340B disproportionate share (DSH) hospitals represent 38 percent of hospitals, they provide 60 percent of all uncompensated care.[9] 340B DSH hospitals provide the vast majority of services received by Medicaid and low-income Medicare patients and are much more likely than non-340B hospitals to provide critical health care services that are vital to low-income patients, but are often unreimbursed, including HIV/AIDS services, trauma care, and outpatient alcohol/drug abuse services.[10] 340B DSH hospitals treat significantly more Medicare Part B beneficiaries who are low-income cancer patients, and are more likely than non-340B hospitals to treat beneficiaries who are dually eligible for Medicaid, disabled, have end stage renal disease, or are racial or ethnic minorities.[11]

CMS's current payment reduction to 340B hospitals is already harming safety-net providers and their patients. For example, Medical University of South Carolina Health (MUSC), a 340B DSH hospital located in South Carolina, reports that reduced Medicare Part B payments for 340B drugs threatens the hospital's ability to sustain telemedicine services the hospital provides to patients with sickle cell disease and patients in need of psychiatric services.[12] MUSC relies on its 340B savings to provide these telemedicine services to patients who may be otherwise unable to travel extreme distances to receive treatment.[13][14]

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[7] Paperwork Reduction Act of 1995, 44 U.S.C. § 3501-3520.

[8] *See* CMS 10709, Supporting Statement Part A, Hospital Survey for Specified Covered Outpatient Drugs, Page 2 (stating that CMS "believes that utilizing a survey will enable CMS to gather hospital acquisition cost data, which will allow CMS to refine the payment rate for drugs acquired by 340B hospitals."). CMS is proposing to apply for the first time 42 U.S.C. § 1395l(t)(14)(A)(iii)(I) to set payment at average acquisition cost for 340B drugs.

[9] 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

[10] *Id.*

[11] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services to Low-Income Patients (March 12, 2018), https://www.340bhealth.org/files/LowIncomeOncology.pdf; Dobson DaVanzo, Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non340B Hospitals and Physician Offices (November 15, 2016), https://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf

[12] L. Endriukaitis, G. Hayes, and J. Mills, Economic Evaluation of Changes in Reimbursement for Medications Purchased Through the 340B Drug Pricing Program, Hospital Pharmacy Journal, (November, 2019) https://journals.sagepub.com/doi/10.1177/0018578719888907

[13] *Id.*

[14] Since the 340B payment reduction took effect on Jan. 1, 2018, 340B hospitals have collectively lost hundreds of millions of dollars, thereby threatening critical services that hospitals may be unable to fund with lower reimbursement amounts. *See* American Hospital Association v. Azar, 348 F. Supp. 3d 62, 69 (D.D.C. 2018), Plaintiffs' Motion for a Firm Date By Which Defendants Must Propose a Remedy for Violations of the Medicare Act, (filed May 10, 2019) (stating that 340B hospitals as a group have been losing $25 million per week since Jan. 1, 2018 because HHS continues to apply the illegal rate of ASP minus 22.5%).

CMS's proposal to collect 340B drug acquisition cost data from children's and free-standing cancer hospitals and hospitals with a rural sole community hospital designation from Medicare signals an even more dramatic policy change, as these hospitals are exempted from Medicare's current Part B payment reductions to 340B hospitals under the OPPS. CMS exempted these hospitals because of the unique patient populations that they serve and how they are paid under the OPPS.[15] There is no reason for CMS to collect drug acquisition cost data from hospitals exempted from the payment reductions unless CMS intends on taking these hospitals' 340B discounts from them in the future.

Not only does CMS's proposal break with over two decades of Medicare policy and undermine the 340B program, but by harming 340B hospitals and the low-income patients they serve, the proposal also conflicts with the PRA's purpose to ensure the greatest possible public benefit from agency information collections.[16] For these reasons, CMS should withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

II. CMS's Proposal to Collect Acquisition Cost Data from 340B Hospitals, and Exclude Other Hospitals, Violates the Medicare Statute and the PRA

The PRA requires agency information collections to be necessary for the proper performance of the agency's mission.[17] CMS's proposal, however, is contrary to law, and therefore, does not advance CMS's mission. CMS does not have the authority under the Medicare statute to conduct a survey of just 340B hospitals to determine drug acquisition costs. Section 1395l(t)(14)(D)(ii) of the Social Security Act allows CMS to survey hospitals to determine "the hospital acquisition cost for each specified covered outpatient drug." There is no indication in the statute that the survey can be for a subset of hospitals, such as 340B hospitals, or a subset of drugs, such as 340B drugs only.

Further, the statute requires that surveys conducted by the Secretary "shall have a **large sample of hospitals** that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."[18] The reference to a large sample of hospitals supports the fact that the survey must reflect acquisition costs across all hospitals, not just a subset of hospitals such as 340B hospitals.[19] Thus, CMS does not have the authority to survey 340B hospitals only. CMS cannot move forward, under the PRA, with a survey that would violate the Medicare statute.[20]

III. CMS Cannot Move Forward with the Proposed Collection Because It Violates the PRA's Practical Utility, Clear Instructions, and Burden Requirements

A. CMS's proposal lacks practical utility

Information collections must have "practical utility", meaning that the information collected must be useful to the government in an actual and not merely theoretical way, taking into account the information's accuracy, validity, adequacy, and reliability.[21] CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs).[22] For a given quarter, there easily can be hundreds of thousands of units of data hospitals would need to report to CMS under this ICR. Even more

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[15] Medicare Program: Hospital Outpatient Prospective Payment System, 82 Fed. Reg. 52356, 52505-52506, (Nov. 13, 2017) (exempting from the payment reduction children's hospitals, PPS-exempt cancer hospitals, and hospitals with a rural sole community designation from Medicare given the unique patient populations these hospitals serve).
[16] 44 U.S.C. § 3501(2).
[17] *See* 44 U.S.C. § 3504 (stating the Director shall oversee the use of information resources to serve agency missions, including burden reduction and service delivery to the public).
[18] 42 U.S.C. § 1395l(t)(14)(D)(iii) (emphasis added).
[19] Though CMS may set payment rates that vary by hospital group (42 U.S.C. § 1395(t)(14)(A)(iii)(I)), they are not permitted to survey only one group of hospitals for purposes of setting payment rates.
[20] The preamble to the ICR proposes a separate violation of the Medicare statute. CMS states that hospitals should leave the field blank if the acquisition cost for a drug is unknown and that CMS will use the 340B ceiling price as a proxy for the drug's acquisition cost. This is prohibited under the Medicare statute, which specifically states that when survey data are unavailable, CMS must pay hospitals at the statutory default rate of ASP plus six percent (42 U.S.C. § 1395(l)(t)(14)(A)(iii)(II)).
[21] 5 C.F.R. § 1320.3(l)
[22] There are 414 total HCPCS codes with status indicator "K" and "G". For these 414 HCPCS codes, there are approximately 1,100 total NDCs mapped to them in the HCPCS-NDC crosswalk.

concerning are the extensive mathematical calculations the ICR would require hospitals to prepare for potentially hundreds of NDCs, as explained below. Asking hospitals to complete calculations factoring hundreds of thousands of units of data means there inevitably will be human error that will contribute to inaccuracies in the data hospitals report, despite their best efforts. As such, these data will be inaccurate and unreliable, and will not meet the practical utility requirements under the PRA.

In addition, CMS asks hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program" and paid under the OPPS.[23] CMS's proposed survey instrument includes a column for hospitals to list the provider-based department name, indicating that hospitals must list their 340B acquisition costs for each relevant drug by location where the drug was used. The location of where a drug is administered in a provider-based department has no meaningful relationship to 340B acquisition cost. The information to be reported would have no practical utility and directly conflicts with CMS's statement that the proposed collection is limited "solely to the essential elements necessary to develop payment rates."[24] CMS cannot require hospitals to report drug acquisition costs by provider-based department, because this information is not necessary to set accurate payment rates under the OPPS, and therefore, serves no practical utility under the PRA.[25]

B. CMS's proposal is too vague for hospitals to evaluate the accuracy of CMS's burden estimate

There are several aspects of CMS's survey instructions that are not clear, requiring us to make several inferences regarding the precise information the ICR requests. This conflicts with the PRA requirement that agencies use plain, coherent and unambiguous terminology to ensure the collection is understandable to respondents.[26] For example, CMS's survey instructions direct hospitals to enter the average acquisition cost for each SCOD as identified by the SCOD's Healthcare Common Procedure Coding System (HCPCS) code for each SCOD purchased at any time during the last quarter of 2018 and first quarter of 2019. Based on the reference to "HCPCS code", CMS appears to be asking hospitals to calculate average 340B prices for all NDCs paid under a given HCPCS code. However, CMS's survey instructions also ask hospitals to provide the drug name that corresponds to the HCPCS code and the NDC, raising questions as to whether CMS expects hospitals to provide the average price per NDC or per HCPCS code. Contributing to the ambiguity are the inconsistent and conflicting terms CMS uses throughout the survey documents.[27]

The collection's lack of clarity makes it difficult to meaningfully comment on CMS's burden estimate. CMS, at a minimum, would need to withdraw the current proposal and propose a new collection with clear and detailed instructions to allow hospitals to evaluate the accuracy of CMS's burden estimate as required by the PRA.[28] Notwithstanding the lack of clarity, it is apparent that CMS's proposal would place a massive burden on 340B hospitals, likely several times the 48 hours and total cost of five million dollars to 340B hospitals that CMS estimates.[29]

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[23] CMS 10709, Instructions for Filling Out Survey, Page 2, Number 2.a.
[24] CMS 10709, Instructions for Filling Out Survey, Page 5, Number 5.
[25] In addition we note that CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use the information in violation of provisions of the PRA that require agency collections to "inform the person receiving the collection of the reasons the information is being collected and the way such information is to be used." (44 U.S.C. § 3506(c)(1)(B)(iii)(I-II).
[26] 44 U.S.C. § 3506(c)(3).
[27] CMS's survey instructions direct hospitals to enter the "average acquisition cost for each SCOD" in a section labeled "[a]verage 340B price of drug." CMS uses "average 340B price" of a drug and the "average acquisition cost for each SCOD" interchangeably, but "price" and "cost" are different, as the price of a drug does not necessarily reflect what a hospital pays for a drug. It is also unclear if "the average acquisition cost for each SCOD" should include 340B prices only, and not include non-340B prices. CMS asks for "the average 340B price of a drug" in the survey instrument, suggesting CMS is interested in 340B prices only. If CMS wants hospitals to report 340B prices only, this would create an additional step under the survey, as hospitals would need to filter their wholesaler reports to only include purchases made on their 340B accounts. This step, however, is not included in CMS's survey instructions. Moreover, while CMS asks for average acquisition cost data, CMS's survey instructions are titled "Centers for Medicare and Medicaid Services *Average Sales Price* Survey," further adding to the confusion (emphasis added).
[28] 44 U.S.C. § 3506(c)(2)(A).
[29] We note that CMS provides two different estimates for the time burden. The cover sheet to the survey instrument says the time required to complete the collection is estimated to average 40 hours per response, whereas Supporting Statement A says the time burden is estimated to be 48 hours per response.

C. CMS fails to minimize the burden of the collection

The PRA is intended to ensure that information collections by the federal government maximize the utility of the information collected while minimizing the burden to the public.[30] CMS should withdraw the proposed ICR because CMS fails to minimize the burden of the collection as required by the PRA.[31] Below are tasks CMS proposes to require hospitals to undertake to respond to the survey, each of which unnecessarily contributes to the burden of the collection and serve as examples of the ways CMS has failed to minimize the burden of the collection on hospitals.

Step 1: Generating a list of NDCs mapped to HCPCS codes with status indicator "K" and "G"[32]

CMS asks hospitals to provide an "average 340B price of a drug" as identified by the drug's HCPCS code.[33] Hospitals, therefore, need to know which NDCs are mapped to a given Medicare HCPCS code. For the over 400 HCPCS codes with a status indicator "K" or "G" for which CMS requests the "average 340B price", there are over 1,100 NDCs mapped to these HCPCS codes in the CMS NDC-HCPCS crosswalk, with some HCPCS codes having dozens of NDCs. CMS does not tell hospitals where to find the NDCs mapped to the HCPCS codes. By not providing this list to hospitals, CMS did not attempt to minimize the burden.

Step 2A: Averaging prices for all NDCs mapped to each HCPCS code[34]

Once hospitals have the list of relevant NDCs, they will need to run reports in their wholesaler systems to determine what the hospital paid for each NDC. Asking hospitals to calculate an average price for the various NDCs paid under a HCPCS code will take hospitals a significant amount of time, as hospitals would need to average the prices together for all the NDCs mapped to each individual HCPCS code. CMS has not minimized the burden of the collection, as CMS could have instead asked hospitals for the amount paid for NDCs and CMS could average those amounts under the HCPCS codes rather than placing this burden on hospitals.

Step 2B: Calculating the "average 340B price" based on HCPCS billing units[35]

CMS asks hospitals to calculate an "average 340B price of a drug" based on Medicare HCPCS dosage units. This would require hospitals to convert the billing units per package for the relevant NDCs for the two quarters that CMS requests data for when those purchasing units do not match the HCPCS billing unit. It is fairly common for the billing units per package for a given NDC to be different than the HCPCS billing units used by Medicare to pay for drugs under a given HCPCS code. These conversions will significantly contribute to the burden of the collection and are another example of CMS's failure to minimize the burden of the collection.

Step 3: Determining the location where a drug was administered[36]

It would be incredibly burdensome for hospitals to identify each drug used by provider-based departments, as most hospitals do not track this information this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to determine in which hospital location a drug was administered that generated the charge for each given HCPCS code. Some hospitals have estimated this step alone would take the hospital a minimum of 40 hours. This is another example of CMS's failure to minimize the burden, since this information does not have any relevance to the purpose of the ICR, as explained above, and so should not be requested.[37]

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[30] 44 U.S.C. § 3501(1)-(2).
[31] 44 U.S.C. § 3506(c)(3) (requiring agencies to minimize the burden of agency collections to the extent practicable).
[32] *See* CMS 10709, Instructions for Filling Out Survey, Page 2, Number 3.
[33] *See* CMS 10709, Instructions for Filling Out Survey, Page 2, Numbers 6-7.
[34] *See* CMS 10709, Instructions for Filling Out Survey, Page 2, Numbers 6-7.
[35] *See* CMS 10709, Instructions for Filling Out Survey, Page 2, Number 5.
[36] *See* CMS 10709, Instructions for Filling Out Survey, Page 1, Number 2.
[37] *See supra* Section III.A.

Moreover, CMS's proposal is burdensome in every way the term is defined under the PRA.[38] To respond to the collection, 340B hospitals would need to expend significant time, money, and effort beyond what CMS recognizes in its proposal. Some hospitals have expressed concerns that they will not be able to respond to CMS's ICR without investing in new technology or upgrading their wholesaler systems. Other hospitals are concerned that CMS's proposed ICR will put hospitals in a difficult position with respect to the wholesalers that hospitals purchase drugs from. Hospitals report needing to expend time and resources consulting with legal counsel to determine whether non-disclosure provisions in their wholesaler agreements would prevent hospitals from disclosing proprietary drug pricing information.

Contrary to CMS's suggestion, the burden of the collection is not minimized due to documentation and records that hospitals maintain as a result of their participation in the 340B program, as nearly every task and mathematical calculation hospitals would need to undertake to respond to the survey are unrelated to 340B program requirements and would require the generation of a multitude of completely new sets of data.[39] Moreover, this proposed collection is significantly more burdensome than other national surveys CMS conducts to collect drug acquisition cost data. For example, CMS estimates that its survey of retail pharmacies to generate the National Average Drug Acquisition Cost Data (NADAC) benchmark takes no more than 30 minutes of non-pharmacy staff time to complete.[40] Finally, we note that CMS's proposed ICR is inconsistent with CMS's "Patients Over Paperwork" initiative that seeks to eliminate unnecessary administrative burden that takes providers away from treating patients.[41]

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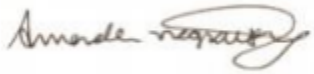
340B Health requests that CMS withdraw its proposal to collect 340B drug acquisition cost data from 340B hospitals. At a minimum, CMS should issue a new proposal with clear and detailed instructions to allow hospitals to provide meaningful comments on CMS's burden estimate. CMS should not move forward at all with a proposal to collect drug acquisition cost data from the hospitals CMS exempted from Medicare's Part B payment reductions to 340B hospitals.

Sincerely,



Maureen Testoni
President & Chief Executive Officer

Amanda Nagrotsky
Legal Counsel

[38] 44 U.S.C. § 3501(2) (including in the definition of 'burden' the resources expended for acquiring, installing and utilizing technology and systems, adjusting existing ways to comply with any previously applicable instructions and requirements, searching data sources).
[39] CMS 10709, Instructions for Filling Out Survey, Page 1.
[40] CMS-10241, Survey of Retail Community Pharmacy Invoice Prices - PART II, Supporting Statement Under the Paperwork Reduction Act.
[41] CMS Administrator Seema Verma Statement on Burden Reduction Accomplishments, (Oct. 17, 2018), https://www.cms.gov/newsroom/press-releases/cms-administrator-seema-verma-statement-burden-reduction-accomplishments