EMORY

HEALTHCARE

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

On behalf of Emory University Hospital Midtown (EUHM), Emory Decatur Hospital (EDH), and Emory Hillandale Hospital (EHH; collectively referred to as Emory Healthcare), we appreciate 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] We rely on our 340B savings to meet the needs of the low-income patients we serve.

For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals. Failure to do so would subject safety net hospitals to an unlawful and erroneous survey.

I. Payment at Acquisition Cost Would Harm Safety-Net Hospitals and Their Patients

We strongly oppose CMS's attempts to set Medicare payment for 340B drugs at or near 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

[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.

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.

Emory Healthcare facilities, collectively, comprise the most comprehensive healthcare system in Georgia and provide extensive inpatient and outpatient services to a diverse patient population. The facilities range from large community hospitals with over 500 beds to facilities offering the full range of outpatient services upon which hundreds of thousands of patients rely each year. Through collaboration with primary and specialty care providers, Emory Healthcare is dedicated to expanding quality hospital services to underserved communities in Georgia and relies on 340B savings to provide support in reaching those without other access to high quality care.

At EUHM, which is a 550-bed academic community hospital in the heart of midtown Atlanta, our mission is to care for patients and their families with concern not only for their illnesses, but also for their mental, emotional and spiritual well-being. EUHM, EDH, and EHH are proud to serve as safety net hospitals open to all patients in our region. We reflect that pride in the services we perform on an emergency, uncompensated, and charity care basis. EUHM sees over 185 daily patient encounters in its Emergency Department, providing life-saving emergency care that is frequently uncompensated. In 2018, EUHM provided $36 million ($27.2M per 2018 Community Benefit report) in charity care and uncompensated care and $4.4 million in community programs.

Operating three DSH hospitals in a large urban area, we are constantly working to expand access to care and provide access to research and other cutting edge initiatives to patients within and outside of our community, including underserved areas. Examples include:

- Providing complimentary health talks at the hospitals and in community facilities covering the topics of exercise, nutrition and weight control, healthy sleep, breast health, hypertension and heart disease, managing diabetes, fall prevention, understanding Medicare and when to go to the Emergency Room versus Urgent Care.
- Staff volunteering at health fairs and community events to provide blood pressure screening for hypertension.
- Assisting young families through childbirth education courses, lactation education and support services, and bereavement services in the event of infant death.
- Providing support groups for patients undergoing cancer treatment, along with support groups for family members and certified fitness programs that support returning to health.
- Emory Healthcare recently launched a telemedicine program that provides acute renal consults for hospitals in rural Georgia that do not have on-site nephrologists or in-house dialysis programs so patients can stay closer to home.
- Emory University Hospital Midtown/Winship Cancer Institute continues to triple the size of its Phase I Clinical Trials Unit, which will allow for more first-in human trials of new therapies.
- EDH/EHH issue online newsletters and health trends on various topics including women's/men's health, fitness and nutrition, aging, parenting, arthritis, cancer, and more.

[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

- An in-house medical library is available to patients and free to the community at EDH/EHH, and it is home to a large collection of medical information, including books, journals, and other resources.

Emory Healthcare simply would not be able to provide the degree of access to care that it does without the 340B Program. Emory Healthcare 340B covered entities use savings achieved under the 340B program to expand its hospitals' health care services, providing access to needed drugs for vulnerable populations.

II. 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, which would be impossible in the current form as discussed further below, 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.

While we do not have exact numbers, it is reasonable to assume that *most* 340B hospitals do not have personnel dedicated to understanding pharmacy finance and billing processes, let alone the ability to crosswalk billing and purchase data as CMS is requesting. The CMS estimate of 48 hours per hospital to complete the survey request grossly underestimates the anticipated burden for the majority of hospitals. The CMS estimate of the hourly rate of individuals completing the request ($37.89/hour) is also unrealistic as it assumes that the task is appropriate for entry-level personnel. It is not. Finally, CMS would be required to collect this data each and every year in order to establish payment rates based on cost.[5] This would place significant burden on safety net hospitals (and CMS). Further, keep in mind that drug costs change (generally increase) every quarter, so establishing payment rates based on cost in any given year will likely result in a net loss to covered entities.

In the very least, CMS can do the requested 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.

III. The Acquisition Cost Data is Likely to Be Plagued with Inconsistencies and, Therefore, Unusable

The data may be entirely unusable if it is rife with inconsistencies—as it is likely to be.

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[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 greater than 1,100 total NDCs mapped to them in CMS's HCPCS-NDC crosswalk.

[5] 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).

By statute, any CMS survey of acquisition cost data must take into account the recommendations and findings of the GAO, which was statutorily required to conduct a survey of a similar scope in 2004-2005.[6] In its 2006 report, the GAO warned CMS of the data complexities and inconsistencies: "Hospitals' information systems were diverse and produced data in many different formats, causing substantial resource and timing difficulties in the data collection process" and causing GAO to "reconfigure data submitted in multiple formats to produce data comparable across hospitals and usable for SCOD rate-setting."[7] If hospitals' information systems were diverse in 2006, one can only imagine how much more diverse they are 13 years later. The GAO report also demonstrates that, to obtain meaningful data from a statistical standpoint, CMS cannot simply take an average of prices as reported by the hospitals. The GAO took careful measures to prepare the format for data collection and engaged in sophisticated statistical analysis to account for bias in the data based on volume, hospital size, and other factors.[8]

There will almost certainly be inconsistencies and inaccuracies in the data reported across all 340B hospitals, and this is not data that can be easily cross-checked by CMS or anyone else. CMS must be prepared to conduct the type of rigorous analysis and validation that the GAO highlights in its report.[9] Furthermore, CMS should weigh this when considering how useful the ultimate data will be in setting payment rates and, looking ahead, what legal challenges might result from the use of potentially flawed data. The anticipated data inaccuracies begin and end with the flaws in CMS's survey as discussed below.

IV. Flaws in the CMS Survey Source Data Makes the Survey Impossible to Complete

Due to flaws in CMS's source data and survey methodology, it is categorically impossible to complete the survey. When attempting to utilize CMS NDC-HCPCS crosswalk data cited in its survey instructions to identify the HCPCS dosage, numerous HCPCS and NDC codes lack quantity data. Without quantity data, it is impossible to provide the true acquisition cost of a drug because pricing must be converted to match the appropriate HCPCS dosage. While the administrative burden and risk of reporting inaccurate acquisition cost data is high when the HCPCS dosage is available, the survey is completely invalid when missing HCPCS dosage information.

OMB should prohibit the use of this flawed survey now, or stakeholders risk CMS using flawed data to set significant payment policy to the detriment of critical safety net providers such as EUHM, EDH, and EHH. Safety net providers would face a long and expensive road ahead as they would be forced to file legal challenges to flawed CMS payment policy that would be based on a flawed survey that OMB is in a position to prevent now.

[6] 42 U.S.C. § 1395l(t)(14)(D)(ii).
[7] GAO-06-372: *Medicare Hospital Pharmaceuticals, Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, p. 12 (April 2006).
[8] GAO-05-581R: *Medicare Hospital Outpatient Drug Prices*, Enclosure I (June 30, 2005).
[9] *See also*, GAO-05-581R: *Medicare Hospital Outpatient Drug Prices*, Enclosure I (June 30, 2005).

Even the GAO, which previously has not included 340B drugs in its data collection given the intent of the 340B program, has recognized the difficulty of this task, recommending CMS perform the survey only once or twice per decade due to the burden associated with it.[10]

V. CMS's Proposal is Contrary to Law

a. CMS Lacks Statutory Authority to Collect Cost Data from a Subset of Participating Hospitals

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. The Medicare statute authorizes CMS to conduct periodic surveys to determine hospital acquisition costs according to the specific parameters established by Congress in § 1395l(t)(14)(D). Congress did not explicitly authorize CMS to collect data from a subset of hospitals (*i.e.*, 340B covered entities). If CMS wishes to conduct an acquisition cost survey, it must collect cost data from all participating hospitals.

b. CMS Lacks Statutory Authority to Collect Cost Data for All Covered Outpatient Drugs

Federal statute authorizes CMS to conduct periodic surveys to determine hospital acquisition cost for "*specified* covered outpatient drugs" for use in setting payment rates.[11] The definition of "specified covered outpatient drug" (or SCOD) is narrower than the term "covered outpatient drug," generally. Whereas "covered outpatient drug" is broadly defined to include most prescription drugs approved by the FDA (among other nuances), the term SCOD is defined to include only those covered outpatient drugs that are separately payable under the Outpatient Prospective Payment System (OPPS) and that: (i) is a radiopharmaceutical; or (ii) a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.[12] The definition specifically excludes all other drugs for which payment is first made on a pass-through basis after January 1, 2003, any drugs or biologicals for which a temporary HCPCS code has not been assigned, and certain orphan drugs.[13] Examples of covered outpatient drugs that are not SCODs include:

- acetaminophen, one of the most common drug ingredients used for alleviating pain;
- famotidine, one of the most common medications to treat heartburn; and
- metoprolol, one of the most common medications for reducing blood pressure.

These drugs are extremely common throughout the nation and are used in the outpatient setting.

CMS's proposed data request and supporting statements are appropriately limited to requesting acquisition cost data for SCODs alone. However, CMS has historically blurred the line between the definition of covered outpatient drug and SCOD and applied the payment methodologies of §

[10] GAO-06-372: *Medicare Hospital Pharmaceuticals, Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, pp. 13, 36 (April 2006).
[11] 42 U.S.C. § 1395l(t)(14)(D) (emphasis added).
[12] *Id.* at § 1395l(t)(14)(B).
[13] *Id.*

1395l(t)(14)(A) to both categories of hospital outpatient drugs. As stated in the preamble of the CY 2012 OPPS proposed rule:

> *It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in [42 U.S.C. § 1395l(t)(14)(A)(iii)] to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy choice rather than a statutory requirement.*[14]

This longstanding policy has yet to be challenged, although as suggested by the D.C. District Court, it is certainly open to challenge. To the extent CMS expects or attempts to require hospitals to report acquisition cost data for all covered outpatient drugs (rather than truly limiting it to SCODs), we note that CMS does not have the statutory authority to request it and hospitals are not statutorily required to provide it.

Given this limitation, we question whether collecting acquisition cost data for SCODs alone is a worthwhile exercise. If CMS's goal is to use this data to establish payment rates for 340B drugs, the data will be incomplete and insufficient to determine payment rates for all 340B covered outpatient drugs. Absent acquisition cost data for non-SCODs, CMS will likely end up with a two-tiered payment approach that applies the acquisition cost data to SCODs and an ASP methodology to non-SCODs, only adding to the administrative complexity that already exists with respect to OPPS drug reimbursement.

c. CMS's Data Request May Cause 340B Entities to Violate Confidentiality Clauses

Additionally, 340B purchasing arrangements between covered entities and wholesalers or manufacturers generally require acquisition costs to be confidential. Unless the contract contains an exception for government requests, this request may result in covered entities violating those confidentiality provisions. Even so, contracting terms governing confidentiality will vary significantly by covered entity, which has the potential to lead to inconsistent acquisition cost data rendering this exercise futile and the sample statistically invalid. CMS's pledge to maintain confidentiality of individual responses "to the extent provided by law" but with the caveat that it may "make public average acquisition prices reported for each SCOD" except for some on a case by case basis, does not alleviate this concern.[15]

Further, there is no meaningful distinction between CMS's proposed collection of acquisition cost data and HRSA's existing collection of manufacturer ceiling price data, and the latter is very clearly subject to confidentiality limitations. Namely, ceiling price data is required by statute to be published "in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure."[16] HHS has similarly recognized the importance of maintaining confidentiality of 340B pricing data: "HHS understands the importance of maintaining the confidentiality of 340B ceiling price data and will handle

[14] 77 Fed. Reg. at 68383 (Nov. 15, 2012).
[15] Supporting Statement-Part A, Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709; OMB 0938-New) Sec. B.11.
[16] 42 U.S.C. § 256b(d)(1)(B)(iii).

such data accordingly."[17] If CMS continues down the path of collecting and publishing average acquisition cost data for 340B drugs, it will be in violation of its own stated policy to maintain confidentiality of 340B pricing data. Additionally, we note that HRSA already collects this data, which the Secretary may not disclose due to certain regulatory limitations that mandate confidentiality of the information.[18] By establishing and publishing payment rates based on 340B acquisition cost, CMS would effectively disclose information on confidential pricing terms, including the average manufacturer cost.

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[17] 82 Fed. Reg. 1210, 1226 (Jan. 5, 2017).
[18] 42 U.S.C. § 1396r-8(b)(3)(D).

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Daniel Owens
Chief Executive Officer
Emory University Hospital Midtown

James Forstner
Chief Executive Officer
Emory Decatur Hospital, Emory Hillandale Hospital, and Emory Long Term Acute Care

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
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Re: Comments on CMS Proposed Collection of Information, Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709; OMB-0938-New)

Dear Mr. Ray:

Cleveland Clinic appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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.

II. The Survey Places a Massive Burden on 340B Hospitals

OMB should reject CMS's ICR because it would place a massive burden on hospitals but is not certain to produce adequate data for calculating 340B hospitals' drug acquisition costs. CMS is asking hospitals to calculate average 340B prices based on Medicare HCPCS dosage units, requiring hospitals to

[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.
[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

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.

III. CMS's Proposal is Contrary to Law

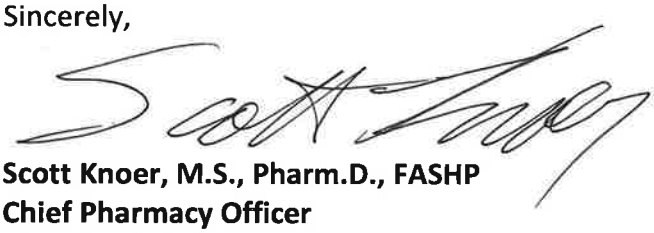
CMS's plan to collect acquisition cost data from 340B hospitals only, and not from hospitals that do not participate in the 340B program, violates the Medicare statute. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a subset of hospitals for the survey.[5]

IV. Alternative Collection Methods

While we disagree with CMS's intention to selectively survey 340B hospitals' acquisition cost, if enacted, we recommend the collection process be amended. First and foremost, a sufficient response period is necessary to accurately collect and report the requested data. We strongly recommend reverting to the original timeline of 30 days. This is critical as many hospitals will rely on drug wholesalers to provide this data and given the current supply chain issues stemming from global health concerns, we anticipate this response may be delayed. Secondly, we recommend the survey collect acquisition cost at the NDC level. This will minimize unnecessary HCPCS conversions, which will not only increase the reporting burden, but may also lead to inaccurate data due to incorrect calculations. Finally, we recommend CMS collect the average acquisition price, including 340B and non-340B, for covered outpatient drugs over the survey period. This would account for purchases that fall outside of the 340B program, but are provided to our patients.

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,



Scott Knoer, M.S., Pharm.D., FASHP
Chief Pharmacy Officer
Cleveland Clinic

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

March 09, 2020

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Paul Ray, Administrator
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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)

Dear Mr. Ray:

The University of Mississippi Medical Center ("**UMMC**"), the State of Mississippi's only academic health center, appreciates the opportunity to submit comments in response to the notice published in the Federal Register on February 07, 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 stretch scare federal resources in order 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] We rely on our 340B savings to meet the needs of the low-income patients we serve and provide healthcare services inclusive of retail medications to these vulnerable patients. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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, and UMMC provides care to high volumes of these extremely vulnerable patient populations in our state as well as surrounding states as the

[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.

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only Academic Health System offering the care these patients need inclusive of the only Children's' hospital in the State of Mississippi.

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 or otherwise deeply decrease UMMC and other 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.

II. The Survey Places an Insurmountable 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, insurmountable 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. UMMC would not be able to meet such a high burden without high costs and expenditures of resources currently unavailable to us. 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 directly contributes to the burden of the data collection. We urge the OMB to recognize that if the survey were to be imposed, and in this shortened response period, it would require extensive financial and administrative resources that UMMC and other hospitals do not readily have available to expend. This further frustrates the intent of the 340B program and reduces our abilities to care for patients.

III. CMS's Proposal is Contrary to Law

UMMC reasonably believes 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 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]

IV. 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] The GPO Prohibition is a strict element of compliance we must meet as a DSH entity requiring these WAC purchases. CMS does not include WAC purchases in the calculation of average acquisition cost, which prevents the data collection from

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

accurately calculating the cost of drugs billed to Medicare. Further, the collected data would not be a fair and accurate representation of acquisition costs as it does not consider all compliance and regulatory factors we must adhere to that impact our acquisition costs, which is different for each entity (e.g., GPO Prohibition for DSH, Orphan Drug Exclusions for SCH/RRC, etc.), and the mix of this unusable data would bring about detrimental effects.

V. Conclusion

For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals. We appreciate the opportunity to provide comments on this proposed ICR.

Sincerely,

The University of Mississippi Medical Center

Jefferson

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Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 84, No. 189), September 30, 2019.

Dear Administrator Ray,

On behalf of Jefferson Health, a 14-hospital system with campuses in Southeastern Pennsylvania and New Jersey, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. ***We have significant concerns over the intent and design of the 340B survey, and we request CMS withdraw it.***

Jefferson through its academic and clinical entities, Jefferson University and Jefferson Health, including Thomas Jefferson University Hospitals, Abington-Jefferson Health, Jefferson Health in New Jersey and Jefferson Health-Northeast, employs over 30,000 people dedicated to providing the highest-quality, compassionate clinical care for patients, educating the health professionals of tomorrow, and discovering new treatments and therapies to define the future of care. Jefferson is comprised of 10 colleges, three schools, 14 hospitals, over 50 outpatient and urgent care locations, and a multitude of physician practices throughout the region, serving more than 130,000 inpatients, 519,000 emergency visits and 3.7 million outpatients annually.

The 340B program has been critical in helping Jefferson expand access to lifesaving drugs and comprehensive health care services to low-income and uninsured individuals in our community. We continue to believe that the 340B Program has been unfairly targeted as a driver of high drugs prices, and proposals to undermine this important program are counterproductive in addressing access to affordable medication. Consistent with the intent of the program – to help stretch scarce resources as far as possible, reach more eligible patients, and provide more comprehensive services – covered entities, such as Thomas Jefferson University Hospital, Jefferson Health New Jersey and Jefferson Northeast, invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients. Since the savings come from drug manufacturer discounts, these services are provided at no cost to taxpayers. ***We are concerned that the proposed survey will***

be used by CMS to continue to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospitals. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. ***These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.***

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

Bruce A. Meyer, MD, MBA
President, Jefferson Health
Senior Executive Vice President, Thomas Jefferson University

UPMC LIFE CHANGING MEDICINE

Office of Ethics, Compliance and Audit Services
US Steel Tower, 58th Floor
600 Grant Street
Pittsburgh, PA 15219

March 9, 2020

Attention: Desk Officer for CMS ***Via Electronic Mail: OIRA_submission@omb.eop.gov***

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

Re: CMS–3427, CMS–10709, CMS–10631 and CMS–10466 Agency Information Collection Activities: Submission for OMB Review; Comment Request

Dear Mr. Ray:

On behalf of the University of Pittsburgh Medical Center (UPMC), we appreciate the opportunity to provide feedback on the Agency Collection Activities: Submission for OMB Review; Comment Request published in the Federal Register on Feb. 7, 2020.

UPMC operates a complex and far ranging health system of which 16 hospitals participate in the 340B Program as covered entities, as well as a Ryan White grantee (the Pittsburgh AIDS Center for Treatment), and outpatient clinics. UPMC, consistent with Congressional intent in establishing the program, has leveraged 340B drug savings to expand the scope of charitable services it offers to the community.

The charitable services supported by the 340B program are one important part of a comprehensive set of community benefits that UPMC offers. As a system, UPMC provides more than $1.2 billion a year in benefits to its communities, including more care to the region's most vulnerable citizens than any other health care institution in the area. UPMC provides 75 percent of inpatient services to residents of the 10 poorest neighborhoods in Allegheny County and 90 percent of care for the region's impoverished children.

UPMC offers free or discounted immunizations, vaccinations, medication, and transportation for low-income populations, programs to enable the elderly and people with disabilities to maintain their independence, and support for families and caregivers, including "care coordinators" who navigate transitions of care. Other programs and initiatives supported by the 340B Program include naloxone distribution for patients at risk for opioid overdoses, outpatient prenatal opioid addiction treatment, vaccination screening and administration to newborns and pediatric burn victims, community influenza vaccine screening, transitional care programs for homeless patients, and outpatient prescription assistance programs. In all, UPMC provides more than 3,000 established programs focused on prevention and healthy living, chronic disease management, and navigating resources.

The 340B Program is critical in supporting these charitable and community-based programs. We are concerned any 340B reductions may impact UPMC's ability to continue these critical services and ultimately impact access to care for the Medicare beneficiary and potentially impact their health.

Payment at Acquisition Cost Would Harm 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. 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 contradicting the intent of the 340B program.

The Survey Places a Massive Burden on 340B Hospitals

UPMC is concerned about the operational burden of this request. CMS is asking hospitals to calculate average 340B costs based on Medicare HCPCS dosage units. This will require hospitals to convert a significant number of the 1,100 NDC purchase units covered to more than 400 HCPCS dosage units. 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. To minimize the potential for human error, hospitals will need to invest significant capital, man hours, and 340B program savings in the development of a consolidated database and data management process to support these analyses.

As CMS will have survey data along with NDC numbers, we request CMS complete the calculations to the J code levels. This would 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 and the likelihood of data errors.

Statutory Authority

We agree with the evaluation of the American Hospital Association regarding the statutory requirements surrounding the 340B program that have been established by Congress. Under the statute, CMS may not limit the survey to a subset of hospitals. Congress in (t)(14)(C)(ii) of the statute directs CMS to collect "hospital acquisition cost for each specified covered outpatient drug for use in setting the payments rates...". We seek clarity as to CMS's authority to collect acquisition cost data from only a specific subset of all hospitals. While Congress does state in (t)(14)(A)(iii) that CMS could vary hospital OPPS payment by hospital group – based on the data gleaned from the hospital acquisition cost survey – the potential variation is premised on the requirement that the survey include all hospitals, not just a subset of hospitals. In other words, for purposes of surveying hospitals, Congress does not distinguish between hospitals paid under OPPS based on their 340B status and those that are not. Therefore, CMS's survey design and approach does not meet the statutory requirements when it specifies that only 340B hospitals are required to complete the survey. For this reason alone, CMS should not conduct the survey as currently constituted.

The Survey Will Collect Unusable Data

The 340B statute prohibits our hospitals 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. 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.

Additionally, drug prices change frequently, it is not readily apparent that two quarters of data will represent meaningful acquisition costs for 340B drugs. This may create periods of insufficient payment when drug prices rise before CMS would adjust reimbursement.

Confidentiality issues

HRSA uses the Average Manufacturer Price (AMP) reduced by the rebate percentage, or Unit Rebate Amount (URA), to calculate the 340B ceiling price. CMS is providing these pricing measures, AMP and URA, quarterly for Medicaid Drug Rebate Program reporting (https://www.hrsa.gov/opa/updates/2015/may.html). The 340B ceiling price is the maximum price that can be charged for 340B eligible drugs and is updated routinely as market prices change. CMS could use the ceiling price as an appropriate measure of 340B drug costs. Prices paid by individual covered entities are not generally considered confidential, although contractual arrangements often require covered entities to ensure confidentiality of 340B pricing (https://www.340bpvp.com/resource-center/faqs/340b-pricing-/-covered-outpatient-drugs/). Providing confidential prices to CMS would necessitate either a willful contractual breach or renegotiation of agreements to include CMS as a third party privy to confidential pricing information.

We appreciate the opportunity to submit these comments on the Agency Collection Activities: Submission for OMB Review; Comment Request.

If you have any questions, please do not hesitate to contact Kathy Noorbakhsh at (412) 864-0547 or by email at noorkj@upmc.edu.

Sincerely,

Kathy Noorbakhsh

Kathy Noorbakhsh, BSN, CPC, COC
Director, Corporate Compliance and Revenue Analysis
University of Pittsburgh Medical Center

ELECTRA MEMORIAL HOSPITAL

1207 S. Bailey St PO Box 1112 Electra, TX 76360

March 6, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Electra Memorial Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Over 30% of the patients in our clinics are on our financial assistance programs. By providing their medications, we have been able to prevent hospitalizations and reduce their overall health care costs. We would not be able to do that without the 340B program. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

Rebecca McCain

Rebecca McCain
Administrator/CEO

SPEARE
Memorial Hospital
A Critical Access Hospital

March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Speare Memorial Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

Travis M. Boucher
Chief Financial Officer
Speare Memorial Hospital

16 Hospital Road
Plymouth, NH 03264
(603) 536-1120
www.spearehospital.com

National Alliance of Safety-Net Hospitals

March 2, 2020

William N. Parham, III
Director, Office of Office of Strategic
Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: Document Identifier CMS-3427, CMS-10709, CMS-10631 and CMS-10466
OMB control number 3209-0002

Subject: Department of Health and Human Services, Centers for Medicare & Medicaid Services; Document identifier CMS-3427, CMS-10709, CMS-10631 and CMS-10466; Agency Information Collection Activities: Submission for OMB Review; Comment Request

Dear Mr. Parham:

I am writing on behalf of the National Alliance of Safety-Net Hospitals (NASH) to convey our views on the Department of Health and Human Services' proposed information collection notice published in the *Federal Register* on February 7, 2020 (Vol. 85, No. 26, pp. 7306-7308).

NASH appreciates the changes the Centers for Medicare & Medicaid Services (CMS) has made since its November 2019 information collection notice on the same subject (Document Identifier CMS-10709, published in the *Federal Register* on September 30, 2019 (Vol. 84, No. 189, pp. 51590-51591, and in particular, the steps it has taken to reduce the administrative burden on hospitals. Nevertheless, NASH and the nation's private safety-net hospitals continue to oppose the proposed collection of data involving the section 340B prescription drug discount program for three reasons:

- we oppose CMS's continued efforts to reduce 340B reimbursement to eligible hospitals;
- the proposed data collection would be very burdensome; and
- we disagree with attempting to address a matter still being litigated.

The 340B program is a vital resource in enabling private safety-net hospitals to serve their low-income communities, and we address below our individual objections to this proposed information collection.

NASH Opposes CMS's Continued Efforts to Reduce 340B Reimbursement to Eligible Hospitals

NASH recognizes that the proposed data collection is a response to a federal court decision that the Centers for Medicare & Medicaid Services (CMS) cannot reduce 340B payments to providers in the

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www.safetynetalliance.org

absence of data on the costs hospitals incur acquiring 340B-covered drugs (among several other reasons). NASH, however, opposes any attempt to reduce 340B reimbursement to eligible hospitals.

The 340B program was created by Congress to enable hospitals (and other providers) that serve low-income communities to maximize their resources when working to serve those communities. The program helps improve access to high-cost prescription drugs for low-income patients and helps put additional resources into the hands of qualified providers so those providers can do more for their low-income patients: provide more care that their patients might otherwise not be able to afford, offer more services that might otherwise be unavailable to such patients, and do more outreach into communities consisting primarily of low-income residents. This was the purpose of the 340B program when Congress created it in 1992 and Congress has not modified that purpose since that time. NASH believes that through this proposed data collection CMS is seeking to exert authority it does not have to demand of providers information to which the agency is not entitled.

The Proposed Data Collection Would be Extremely Burdensome

NASH also opposes the proposed data collection because the steps CMS has proposed for collecting data for a program that does not even formally fall under its purview would be very burdensome. While we appreciate that in this latest notice CMS proposes reducing some of the burden associated with this data collection – making reporting on national drug codes (NDCs) optional and clarifying that hospitals do not need to include information about which of the many hospital-based departments under their purview dispensed the drug – NASH continues to find this data request unacceptably burdensome.

In particular, in the proposed notice CMS calls for 340B providers to supply their average acquisition cost data for more than 400 HCPCS codes. For a given quarter, hospitals could easily need to account for thousands of units of data. The survey not only requires hospitals to compile and report the costs of the drugs they acquired in the given time period in the quantity and packaging in which they acquired it but it also mandates the standardization of data submission across all hospitals. It would require many hours of administrative staff time to reference the HCPCS crosswalk files and determine the appropriate purchase units CMS has in mind for each drug.

Even with the proposed reduction in the data that would need to be reported, NASH disagrees strongly with CMS's estimate that it would take 340B-eligible hospitals only 48 hours to collect the required data and respond to the survey. CMS's suggestion that responding to the survey would take still take 48 hours, as previously projected, is curious in light of the significant changes the agency has proposed in the data to report and suggests there is little hard evidence or analysis underlying the 48 hours estimate. As it is, NASH members believe it would take far more than 48 hours, cost far more than CMS estimates, and result in a corresponding and unfortunate reduction in the additional services these hospitals can afford to provide to their communities because they must spend so much time and so much money responding to the proposed data request.

NASH Disagrees With Attempting to Address a Matter Still Being Litigated

Twice now CMS has reduced 340B payments to eligible hospitals and twice now federal courts have rejected CMS's authority to apply that reduction. Despite this, last year CMS proposed and adopted the very same proposal a third time. The federal courts' rulings in this matter, at least so far, have been based on several considerations; CMS's lack of data on providers' acquisition costs for 340B drugs is by no means the only reason the courts have rejected CMS's 340B payment reduction proposal. NASH believes CMS should not attempt to implement piecemeal responses to the court's decisions until the litigation is concluded.

NASH also is concerned that at the very same time that CMS is attempting to introduce new data collection in response to one aspect of the court's concerns about the program it is not devoting sufficient attention to another aspect of the court's ruling. Specifically, the court directed CMS to develop a methodology for reimbursing 340B hospitals for the payments it illegally withheld from them for the past two years (and will illegally withhold for them for a third year) while CMS continues to appeal its latest defeat in court. NASH believes it is inappropriate and ill-timed for CMS to focus on collecting data that would address only one narrow aspect of the court's objections to its 340B payment-reduction attempts while at the same time it continues to systematically deny to 340B-eligible hospitals the full benefits that Congress directed that they receive nearly 30 years ago and refuses to pursue development of a plan the courts ordered to compensate providers – and the communities they serve – for the benefits it has denied them for the past two years.

* * *

The 340B program is an essential tool in the efforts of private safety-net hospitals to serve the low-income residents of the communities in which they are located. It gives them additional resources that translate into additional services, additional outreach, and additional care for people who otherwise lack the means to gain the care they need. The changes CMS has proposed – changes the courts have rejected – would detract from these efforts and hurt people. We see no value in implementing new information collection processes to support a policy change that the courts have steadfastly rejected and that would hurt people who have the least ability to help themselves – the very people the 340B program was created to help.

For the reasons outlined above, NASH urges CMS to withdraw its proposed information collection request and focus instead on reimbursing 340B-eligible hospitals, and the low-income communities they serve, for the resources they have been denied for the past two years. We appreciate your attention to this request and welcome any questions you may have about the views we have expressed.

Sincerely,

Ellen Kugler, Esq.
Executive Director

About the National Alliance of Safety-Net Hospitals

The National Alliance of Safety-Net Hospitals advocates for adequate recognition and financing of private safety-net hospitals that serve America's neediest communities. These private safety-net hospitals differ from other hospitals in a number of key ways: they serve communities whose residents are older and poorer; they serve patients who are more dependent on Medicare and Medicaid for health care; they provide more uncompensated care; and unlike public safety-net hospitals, they have no statutory entitlement to local or state funds to underwrite their costs. NASH's role is to ensure that when federal officials make policy decisions, they understand the implications of those decisions for these distinctive private safety-net hospitals. NASH pursues its mission through a combination of vigorous, informed advocacy, data-driven positions, and an energetic membership with a clear stake in the outcome of public policy debates. Until 2019 NASH was known as the National Association of Urban Hospitals, and its evolution into NASH reflects its members' recognition that private safety-net hospitals can be found serving communities not only urban but also rural and suburban across the country.

Maimonides Medical Center
4802 Tenth Avenue
Brooklyn, NY 11219
T: 718 283-3911
F: 718 283-3930
Finance
jscanlan@maimonidesmed.org

March 9, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Maimonides Medical Center, Inc., we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income and uninsured individuals in communities across the country. Maimonides inpatient patient population is 50% Medicaid and Medicaid HMO. As a safety net institution we treat more medicaid and indigent patients than any other Brooklyn hospital. Maimonides Cancer Center treats more government based Medicare and Medicaid Cancer Patients, than any other cancer center in the Borough. We can only continue to operate by accessing 340B savings on drug purchases.

Maimonides continues to ensure our patients receive their medications through our arrangement with MMC Pharmacy. MMC Pharmacy fills scripts from the Maimonides Cancer Center, and from the Maimonides Clinics and ER, so the patients will have their medications timely, and as such are not readmitted or visiting the ER with complications from not following medication orders. This actually reduces Medicaid and Medicare spending by reducing unnecessary visits and admissions.

We are concerned that CMS will use the proposed survey to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format and complete within the time specified.

In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program. If you have any questions, please do not hesitate to call me at 718-283-3911.

Sincerely,

John M. Scanlan, FHFMA
Senior Vice President, Finance

Yale
NewHaven
Health

March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Yale New Haven Health System and our 340B participating hospitals, Bridgeport, Lawrence & Memorial and Yale New Haven, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a Health System that includes three hospitals actively participating in the 340B Program, we can adequately speak to the importance of the program. Every day, Yale New Haven Health System enhances the lives of our patients by providing access to high-value, patient-centered care, in collaboration with those who share our values, regardless of their ability to pay. To this end, the 340B program has been a life-saving resource to help us achieve and sustain our vison. In short, our participation in the program has enabled us to actively fulfill its original intentions.

An important example of how resources are stretched within our health system is the magnitude of uncompensated care our hospitals provide. In the last two years alone, that number reached well over $400 million. Our participation in the 340B program has been one important way we can bear these costs while sustaining our mission committed to innovation and excellence in patient care, teaching, research and service to our communities. Our work to implement and operate a sound 340B Program is consistent with the Program's original intent to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

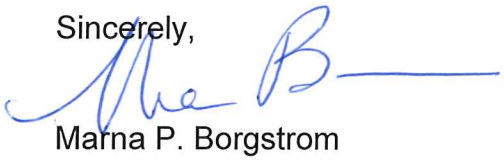
We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospitals. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are

compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As 340B hospitals, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospitals to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,



Marna P. Borgstrom
Chief Executive Officer
Yale New Haven Health System

Submitted electronically at OIRA_submission@omb.eop.gov

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

March 9, 2020

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer
Washington, DC

Re: Agency Information Collection Activities: Submission for OMB Review; Document Identifier CMS-10709

Dear Mr. Parham:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) notice 85 *Fed. Reg.* 7306 (February 7, 2020) to collect acquisition cost data for specified outpatient drugs acquired under the 340B Drug Pricing Program (340B Program). The AAMC has significant concerns with CMS undertaking this survey and ask that the Office of Management and Budget (OMB) not provide a document identifier for this survey.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

We have concerns about this data collection effort that is aimed at only a subset of hospitals, those that are committed to serving their communities and rely on the 340B Program to do so. The data collection effort appears to contravene the intent of Congress when it created the 340B Program in 1992 and, due to its success, later expanded to include more entities. As the District Court concluded in its opinion in American Hospital Association et al. v. Azar (Case number 1:18-cv-2084, December 27, 2018), CMS did not have statutory authority to implement a nearly 30 percent decrease in Medicare reimbursement for drugs acquired under the 340B Program for calendar year (CY) 2018 (later extended when CMS again imposed the decreased payment for CY 2019). In the CY 2020 Outpatient Prospective Payment System (OPPS) final rule CMS for the third time imposes draconian cuts in payments to 340B hospitals.

In this notice and the previous notice[1] announcing CMS's intent to collect this data, the Agency justifies its request for data by saying that "[w]e want to ensure that the Medicare program pays for specified covered outpatient drugs purchased under the 340B Program at amounts that approximate what hospitals actually pay to acquire the drugs." (85 FR 7307). Congress did not design the 340B Program to pay hospitals at acquisition costs. Rather, the program allows eligible hospitals to purchase covered drugs at a discounted rate below the reimbursement rate – whether the payer be Medicare or in the case of non-Medicare beneficiaries, a commercial insurer – and use the difference to generate funds that will be used to reach vulnerable patients by making more services available to them. Consistent with the intent of the program safety-net hospitals invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients at no cost to taxpayers.

CMS also seems to have prejudged the results of the data survey as it stated in the OPPS CY 2020 final rule that "[w]e thus anticipate that the survey data collected for CY 2018 and 2019 will confirm that the ASP minus 22.5 percent is a conservative measure that overcompensates 340B hospitals." (84 FR 61322). Should CMS try to set payment rates based on the data collected as a result of this notice, it will need to engage in new rulemaking. The Agency will have to make the data available as part of the proposed rule to provide stakeholders with the opportunity to analyze it and respond to any proposed change in the payment rate.

The AAMC disagrees that the data collected in this survey could be used to "craft an appropriate remedy in the event of an unfavorable decision [to CMS] on appeal." (84 FR 61322). As CMS is aware, the AAMC and other litigants have proposed an appropriate remedy that would return money to all hospitals in full. In the end, the Court will determine the remedy that is to be applied.

Additionally, we believe that CMS has grossly underestimated the expenditure of time and resources hospitals will incur in order to collect and submit the data. For example, hospitals would be expected to report the 340B acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes, easily adding up to tens of thousands of units of data a hospital would need to account for. To comply with this and other requirements, hospitals will likely be forced to redirect financial resources that would otherwise be used to care for low-income patients.

Thank you for the opportunity to present our views. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,

Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

[1] 84 FR 51591

Ochsner Health

March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Sent via email to OIRA_Submission @OMB.eop.gov

Re: CMS-10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Administrator Verma:

Ochsner Health (Ochsner) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed collection of information under a Hospital Survey for Specified Covered Outpatient Drugs (SCODs).

Ochsner, one of the nation's leading health systems, is headquartered in New Orleans and provides a comprehensive range of services through its network of 41 owned, managed or affiliated hospitals and more than 115 health centers and urgent care clinics throughout Louisiana and Mississippi. Ochsner offers a wide array of specialized and nationally ranked clinical services with its more than 4,500 affiliated physicians, including 1,500 employed physicians practicing in over 90 specialties and subspecialties, and 26,000 employees. In 2019, Ochsner physicians served over 876,000 unique or individual patients from throughout Louisiana, all 50 states, and more than 70 countries throughout the world. Ochsner is also one of the nation's largest independent academic medical centers with 300 full-time residents and fellows participating in 30 ACGME accredited programs; a global medical school partnership with The University of Queensland School of Medicine based in Brisbane, Australia, and programs of biomedical research. Further, Ochsner has established a public private partnership with Louisiana State University Health Sciences Center-Shreveport to operate the safety net hospitals, programs of graduate medical education, and faculty group practice plan in Shreveport and Monroe.

Ochsner is also the largest Medicaid provider in Louisiana and serves numerous patients that are poor, disabled, dually eligible for Medicare and Medicaid, receive Supplemental Security Income (SSI) benefits, or are uninsured. The purpose of the 340B program is to provide support

for hospitals and covered entities that serve these types of patient populations and meet specific Disproportionate Share Hospital (DSH) patient thresholds in order to be eligible for discounts on drugs. The 340B program allows Ochsner to provide patient assistance and nominal drug pricing programs offering free and discounted drugs for low income patients; financial assistance for patients that require high-cost specialty medications; specialized pharmacy services for patients with complex medical conditions and multiple chronic diseases; and, a substantial amount of community benefit programs that provide important services for patients with low incomes.

In its proposal, CMS states that this collection is in preparation for the possibility that the agency may not win the currently pending appeal of an ongoing legal challenge regarding CMS payment reductions for drugs under the 340B program from Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent. CMS contends that the collection is intended to obtain "acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B acquired drugs." The purpose of this proposed data collection completely contradicts the Congressional intent of the 340B program where savings are intended to support eligible hospitals and covered entities and not to be claimed by the federal government. The House report language accompanying the original 340B legislation states that the program was "created to give these covered entities access to price reductions the Committee intends to enable entities to stretch scarce federal resources as far as possible reaching more eligible patients and providing more comprehensive services."

The proposal will also create an extraordinarily burdensome, time consuming and costly task for 340B covered entities requiring the collection and analysis of a vast amount of data to provide the required information, which is contrary to the requirements under Public Law 104-13, the Paperwork Reduction Act of 1995, to reduce these types of collection requirements. As the Senate report accompanying the legislation states, "paperwork burdens can force the redirection of resources away from business activities that might otherwise lead to new and better products and services, and to more and better jobs. Accordingly, the federal government owes the public an ongoing commitment to scrutinize its information requirements to ensure the imposition of only those necessary for the proper performance of an agency's functions." We believe the proposed information collection will create an enormous burden and workload that will require additional staff to collect the data for the new survey and could take away resources that otherwise could be used to add value to the 340B Program.

In addition, existing relationships between healthcare organizations and business partners often do not allow for disclosure of contract terms, pricing and associated fees with outside parties. Therefore, sharing specific information could potentially create legal concerns for the covered entities or require extensive work to allow for disclosure of required elements based on current contractual agreements.

Finally, this proposal undermines and contradicts CMS' "Patients Over Paperwork" initiative designed to reduce unnecessary administrative requirements and allow providers to concentrate on their primary mission of serving patients and improving health outcomes. By requiring providers to spend extensive time devoted to additional data entry requirements, CMS will reverse the direction of this initiative, increase costs and reduce previously projected savings.

In light of these extraordinary administrative burdens and significant legislative and regulatory conflicts, we urge CMS to withdraw the proposed survey and data collection for the SCODs.

Thank you for your attention and thoughtful consideration.

Sincerely,

Mark Beckstrom
Vice President and Director of Government Relations
Ochsner Health

American Hospital Association

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March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of our nearly 2,000 340B member hospitals, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to undertake a survey of all hospitals that participate in the 340B Drug Pricing Program in order to collect actual acquisition costs for specified covered outpatient drugs (SCODs). This notice updates CMS's previous notice, including by further compressing the timeframe for which 340B hospitals must respond to the survey.

The AHA has significant concerns with the intent and design of the 340B hospital survey, and we request that CMS withdraw it. CMS has stated, in the notice as well as in the final rule for the calendar year (CY) 2020 Medicare outpatient prospective payment system (OPPS), that the agency intends to use the survey results both in future Medicare Part B 340B payment policy and also as the possible basis for a remedy related to ongoing litigation.[1] The AHA has long argued that CMS's Medicare Part B payment policy imposes such drastic reductions in the payment rate for 340B drugs that it severely undermines the benefits of the 340B program and the 340B statute.[2] The magnitude of the cuts for OPPS payment years CYs 2018-2020 has compromised 340B hospitals' ability to establish and continue the operation of programs designed to improve access to services for their patients, and the federal district court in Washington, D.C. has agreed that these cuts are impermissible under federal law. CMS's plan to collect actual acquisition cost data from *only* 340B hospitals suggests that the agency intends to continue down a policy path to abrogate the program, undermining the 340B statute.

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[1] https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-21120.pdf; https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf

[2] https://www.aha.org/legal-documents/2019-09-24-aha-associations-hospitals-reply-brief-government-appeal-340b

Congress created the 340B program to enable hospitals serving vulnerable communities, such as those with high rates of low-income and uninsured patients, "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] **For more than 25 years, the 340B program has been critical to helping hospitals expand access to a wide range of health care services, and is one of the few federal policies that addresses the sky-rocketing cost of prescription drugs used for hospital patients.**

In addition to AHA's overall objections to the design and use of survey data identified below, AHA also believes that use of survey data collected for use in rate-setting under subclause II of 42 U.S.C. Sec. 1395l(t)(14)(A)(iii) to retroactively justify 2018-20 rates established under an entirely different authority, subclause I of 42 U.S.C. Sec. 1395l(t)(14)(A)(iii), is a violation of the Medicare Act and the Administrative Procedure Act.

The following comments address specific issues about the survey approach and design, including: the statutory requirements for conducting a survey; the burden on hospitals in submitting the survey data; the challenges hospitals face in sharing drug prices; and other issues related to drug pricing and the 340B program.

Statutory Requirements. We have several concerns regarding CMS's hospital acquisition cost survey, and, based on what CMS has disclosed about the survey, we believe that it does not conform to the statutory requirements established by Congress. The Medicare statute provides CMS with two options for reimbursing covered outpatient drugs.[4] Under 42 U.S.C. Sec.1395l(t)(14)(A)(iii), CMS must base payment rates on the average acquisition costs taking into account hospital acquisition cost survey data specified by the statute, or, if hospital acquisition cost data are not available, the average price for the drug as calculated and adjusted by the Health and Human Services Secretary. With regard to the first option, reimbursement can only be based on the average acquisition costs as acquired through survey data if the survey meets the specifications spelled out in section (t)(14)(D). The statutory language here requires that the survey "…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."[5] Despite clear statutory language, CMS states in the notice that it will not be using any statistical methodology or sample selection for the survey. It appears that CMS instead intends to administer the survey to all 340B hospitals and hopes that the response rate will be high enough to yield statistically valid results. We do not believe that this approach complies with the statute, as the agency cannot assure the statistical validity of this approach because CMS has not identified a statistically valid sample and as it acknowledges it will not be able to assure that all 340B hospitals respond to the survey. In addition, CMS does not provide enough

[3] https://www.hrsa.gov/opa/index.html
[4] https://www.aha.org/legal-documents/2019-09-24-aha-associations-hospitals-reply-brief-government-appeal-340b
[5] https://www.law.cornell.edu/uscode/text/42/1395l

information to evaluate whether the results would be biased on the basis of who responds to the survey.

Another question raised by CMS's survey design is that it may not yield the true acquisition cost of each drug as required by the statute. This is because the survey instructions ask hospitals to report actual acquisition cost at the Healthcare Common Procedure Coding System (HCPCS) level, and states that reporting at the National Drug Code (NDC) level is optional. NDCs within a HCPCS level can vary widely in price, so providing acquisition cost data at the HCPCS level may not accurately reflect the true acquisition cost of each NDC within that HCPCS level. The statute in section (t)(14)(D) is clear that the survey must be designed to collect data on the average hospital acquisition cost for each SCOD. As a result, we believe that CMS's survey design does not meet the requirements set forth in the statute.

In addition, under the statute, in establishing reimbursement rates for outpatient drugs, CMS must either use average acquisition costs based on a survey that meets the requirements of the statute (subclause I of section 1395l(t)(14)(iii)) or average price based on various statutory provisions (subclause II of section 1395l(t)(14)(iii)). CMS may not use subclause I for some hospitals and subclause II for others, and thus it may not limit the survey to a subset of hospitals. Congress in (t)(14)(C)(ii) of the statute directs CMS to collect "hospital acquisition cost for each specified covered outpatient drug for use in setting the payments rates…." Nowhere in the statute does Congress give CMS the authority to collect acquisition cost data from only a specific subset of all hospitals. While Congress does state in (t)(14)(A)(iii) that CMS could vary hospital OPPS payment by hospital group – based on the data gleaned from the hospital acquisition cost survey – the potential variation is premised on the use of the authority in subclause I to establish the rate for all hospitals and thus the survey must include all hospitals, not just a subset of hospitals. In other words, for purposes of surveying hospitals, Congress does not distinguish between hospitals paid under OPPS based on their 340B status and those that are not. **Therefore, CMS's survey design and approach does not meet the statutory requirements when it specifies that only 340B hospitals are required to complete the survey. For this reason alone, CMS should not conduct the survey as currently constituted.**

Burden on 340B Hospitals. Hospitals required to complete the survey would be required to list the following information:

- HCPCS code for each specified covered outpatient drugs;
- Drug name and a short descriptor;
- Dosage unit for each drug;
- Average 340B price for the fourth quarter of calendar year 2018; and
- Average 340B price for the first quarter of calendar year 2019.

The agency estimates in the *Federal Register* notice that for the 1,338 respondents that complete the survey it would take approximately 64,224 hours to complete at a total

cost of approximately $4.9 million. The staff and technology resources that would be necessary to complete this survey suggest that the agency has underestimated the burden and cost 340B hospitals would bear in responding.

The government has previously acknowledged the burden such a survey would impose on hospitals. The Government Accountability Office (GAO), in its 2006 report to Congress about the lessons learned when conducting its hospital acquisition cost survey, stated that the survey "created a considerable burden for hospitals." The GAO reported that hospitals told the agency that, "to submit the required price data, they had to divert staff from their normal duties, thereby incurring additional costs."[6] Through this notice, CMS would exacerbate the demands on hospitals by compressing the timeframe for their responses to only three weeks, a timeframe that is untenable for most 340B hospitals. It is important to note that 340B hospitals are a diverse group ranging from small rural hospitals to large academic centers. All of these 340B hospitals already are shouldering significant costs for staff and health information and inventory management systems to ensure they are compliant with the rules and requirements of the 340B program. In addition, many 340B hospitals are operating on thin operating margins, such that these additional costs, in terms of staff time and resources, would likely need to be diverted from the primary mission of the 340B program. For our financially struggling 340B hospital members – whether in urban and rural settings – the survey burden may be insurmountable. **The AHA urges CMS to conduct a more thorough assessment of the "considerable burden for hospitals" before moving forward with the survey.**

Challenges in Sharing and Determining Drug Prices. 340B hospitals typically purchase their 340B drugs through wholesalers or directly from the drug manufacturer. These purchasing arrangements are contractual agreements. The wholesaler contracts, in particular, typically have strict non-disclosure provisions to protect against anticompetitive pricing behavior. It is our understanding that these provisions may prevent 340B hospitals from sharing any drug pricing information with any entity not party to the contract and therefore make it impossible for 340B hospitals to complete the survey. In addition, the survey requests that hospitals report drug prices at the HCPCS unit level price versus the invoiced price, which would require significant additional work on the part of the hospitals to format the data in the requested manner. Lastly, because drug prices change frequently, it is not clear that the two quarters of data CMS is requesting will represent meaningful acquisition costs for 340B drugs considering the rapid fluctuation in the drug prices.

CONCLUSION

CMS's OPPS 340B payment policy is unlawful and will severely undermine the 340B program at the detriment of vulnerable communities and place undue burden and cost on hospitals. This survey of 340B hospital acquisition cost data is part of another attempt by the agency to curtail the program. CMS should reconsider, and instead

[6] https://www.gao.gov/assets/250/249967.pdf

support, the role that the 340B program plays in allowing hospitals to better serve their patients and communities. **The agency should abandon its damaging OPPS 340B payment policy and withdraw this survey.**

We appreciate your consideration of these comments. Please contact me, if you have questions or feel free to have a member of your team contact Molly Collins Offner, director for policy, at mcollins@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President, Public Policy Analysis and Development

Allina Health
PHARMACY

2925 Chicago Avenue
Minneapolis, MN 55407

March 6, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for the Centers for Medicare & Medicaid Services

Mr. Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

On behalf of our hospitals participating in the 340B Drug Pricing Program, Allina Health appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

As a not-for-profit, integrated health care system, Allina Health is dedicated to the prevention and treatment of illness and enhancing the greater health of individuals, families and communities throughout Minnesota and western Wisconsin. Allina Health has seven hospitals currently enrolled in the 340B program, of which five qualify due to their DSH percentage. All of Allina Health's 340B hospitals are committed to being good stewards of the 340B program, as demonstrated through our multidisciplinary Allina Health 340B Compliance Committee's decision to use 340B program savings to prevent opioid overdoses in Allina Health's 12 emergency departments by providing each with Naloxone kits. In addition to supporting the production of Naloxone kits, the 340B program enables participating Allina Health hospitals that provide care to many low-income and uninsured patients by purchasing

[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.

certain outpatient drugs at discounted prices. The savings from these discounts allow our hospitals to provide an expanded range of health services to these vulnerable patients and communities.

I. Payment at Acquisition Cost Would Harm Safety-Net Hospitals and Their Patients

We strongly oppose CMS' 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.

II. 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.

III. CMS's Proposal is Contrary to Law

CMS' 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 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]

IV. The Survey Will Collect Unusable Data

340B statute prohibits our hospitals from obtaining covered outpatient drugs through a group purchasing organization or group purchasing arrangement, requiring our hospitals to purchase certain outpatient drugs at wholesale acquisition cost (WAC) prices that are significantly higher than 340B

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

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.

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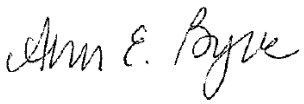
We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals. Please feel free to contact Briana Nord Parish, Manager of Federal Government Affairs, at 612-262-5768 or Briana.NordParish@allina.com, with any questions.

Sincerely,



Ann Byre
Vice President, Pharmacy Services

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

Ascension

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

March 9, 2020

Submitted electronically via: OIRA_submission@omb.eop.gov

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

To Whom It May Concern:

Ascension appreciates the opportunity to submit comments in response to the proposed new information collection request (ICR) entitled *Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (Form Number: CMS-10709 (OMB control number: 0938-New))*.[1]

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As one of the leading non-profit and Catholic health systems in the U.S., Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2019, Ascension provided $2 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 150,000 associates and 40,000 aligned providers. The national health system operates more than 2,600 sites of care – including 150 hospitals and more than 50 senior living facilities – in 20 states and the District of Columbia, while providing a variety of services including clinical and network services, venture capital investing, investment management, biomedical engineering, facilities management, risk management, and contracting through Ascension's own group purchasing organization.

Proposed New Information Collection

The Centers for Medicare & Medicaid Services (CMS) is soliciting comments on a request for a new OMB Control Number to begin obtaining acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B-acquired drugs when they are furnished by certain covered entity hospitals. In support of this request, CMS has released a sample survey and instruction sheet. Based on the survey and instructions proposed by CMS, we are extremely concerned that the proposed information collection will add significant burden on safety net hospitals participating in the 340B program, many of which are already facing financial and professional shortfalls, and we urge CMS to withdraw the proposal. In particular, CMS is asking hospitals to calculate average 340B prices based on Medicare Healthcare Common Procedure Coding System (HCPCS) dosage units, requiring hospitals to

[1] 85 Fed. Reg. 7306 (Feb. 7, 2020).

convert a significant number of the 1,100 National Drug Code (NDC) purchase units covered to more than 400 HCPCS dosage units. This will require applicable hospitals — including a large number of small, non-profit, and rural hospitals — to engage in extensive mathematical calculations, requiring analysis of tens of thousands of units of data, and creates a risk of human error that could undermine the reliability of the data collected. We agree with other commenters that CMS can do these conversions on its own and should therefore minimize the burden of the collection by doing so. Moreover, as compared to the agency's original proposed ICR[2], CMS is proposing to shorten the survey response period from one month to 18 days. Reducing the allowed survey response time will only further contribute to the burden of the collection and the likelihood of inaccuracy in the underlying data.

What 340B Means for Ascension's Patients

Across Ascension, more than 50 of our hospitals participate in the 340B program. Of these, nearly two dozen are critical access hospitals (CAHs), about two dozen more are disproportionate share hospitals (DSHs), and the remaining hospitals fall into one of a variety of other categories, including sole community hospitals, children's hospitals, and rural referral centers. Even including discounts received as a result of our participation in the 340B program, Ascension still spends more than $1 billion annually on pharmaceuticals. On average, Ascension's 340B hospitals invest more than three times as much money on charity care and other benefits to low-income communities than the discounts obtained through the 340B program, which reflects how our hospitals stretch finite resources to serve the poor and vulnerable. In 2018, Ascension's 340B hospitals realized $323 million in discounts through the 340B program. At the same time, our system overall provided roughly $2 billion in charity care and community benefit to our patients and communities.

Our 340B savings are reinvested in a multitude of programs designed to increase access to prescription medicines and other health services for low-income patients. These include, among others: providing medications at low or no cost; operating primary and specialty care clinics in urban and rural communities; providing clinical and ambulatory pharmacy services and oncology services; providing free medical care; embedding nurse services in local school districts; and operating Medical Missions at Home (free medical and dental care for low income, homeless and uninsured patients). Ascension Medical Missions deliver healthcare and social and support services in places of worship, schools, community centers, homeless shelters, and food pantries at no cost to those who might not otherwise have access to these services. Our 340B savings also fund programs to address a wide variety of healthcare conditions among our most vulnerable populations, including diabetes, cancer, and behavioral health conditions.

We strongly believe in ensuring the integrity of the 340B program and in rigorous internal oversight, to ensure that the program meets the Congressional objective: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." We support efforts to ensure that neither providers nor manufacturers take advantage of this important program, thereby diminishing its reputation and value for those hospitals and patients that rely on it. We also support efforts to prevent duplicate discounts and other clear programmatic violations, including the use of civil monetary penalties for manufacturers who fail to offer appropriate discounts.

For these reasons, Ascension has signed on to and supports the American Hospital Association's 340B Stewardship Principles. We are firmly committed to fully and effectively implementing the transparency

[2] *See* 84 FR 51590 (Sept. 30, 2019).

and oversight responsibilities that arise out of our adoption of these principles. Nevertheless, ongoing efforts to limit the breadth of the 340B program pose a significant threat to charitable programs that serve poor and vulnerable patients in our communities and across our ministries.

What CMS's Proposal Would Mean for 340B Covered Entities and Patients

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide the same robust level of services to the communities we serve. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose CMS's current proposal to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. 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. Thus, the intent and burden associated with this proposed ICR run counter to the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to stretch already-scarce resources.

Furthermore, we agree with other stakeholders who observe that 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. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

Ascension also has very significant concerns about the amount of time and resources that responding to the proposed survey would require. As noted above, CMS proposes to ask 340B covered entities for average acquisition cost data for more than 400 HCPCS codes and 1,100 NDCs. In addition to creating significant new burden on providers with already limited resources, asking covered entities to complete calculations factoring tens of thousands of units of data will undoubtedly result in human error that may contribute to inaccuracies in the data reported, despite best efforts. The entire proposal seems to run counter to the spirit of HHS' *Patients over Paperwork* effort so strongly supported by safety net and other hospitals as a way to reduce costs and target more resources on those in need.

Finally, we note that CMS estimates it will take approximately 48 hours for each 340B hospital to respond to the survey; CMS previously estimated that this would cost 340B hospitals a total of nearly five million dollars. While we continue to believe these figures are substantial underestimates, this still represents a significant sum of money that safety-net hospitals could otherwise use to provide community-based services and care for our low-income patients.

Conclusion

Given the critical importance of the 340B program to our patients and facilities, we continue to urge that CMS protect and maintain the program in accordance with its intended purpose by rescinding the reduced reimbursement rates under Medicare for drugs acquired through the 340B drug discount program and providing reimbursement at the standard rate of ASP+6%. With respect to the proposed ICR, **we believe the immense burden for safety-net hospitals that we currently anticipate the survey would impose, coupled with the issues of legality, completeness, and accuracy related to the data CMS is seeking to obtain, collectively suggest that OMB should deny CMS's proposed ICR.**

We sincerely appreciate your consideration of these comments. If you have any questions, or if there is any additional information we can provide, please do not hesitate to contact Mark Hayes, Senior Vice

President for Policy and Advocacy for Ascension, at 202-898-4683 or mark.hayes@ascension.org.

Sincerely,

Peter M. Leibold
Chief Advocacy Officer
Ascension

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March 5, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Avera McKennan Hospital and University Health Center appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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. Avera is a regional health system comprised of 300 locations in 100 communities throughout South Dakota and four surrounding states. In our own community, we have been able to use the 340B savings to support our patients through: the Avera Community Free Clinic in Sioux Falls; a pre-diabetes education program provided for one year at no cost; a free care transitions program that is provided to assist with management of complex patients while they are in their homes; increasing access to community wellness activities, and others as included in our publicly available

[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.
[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

community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its unlawful policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

II. 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.

III. 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 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]

IV. 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 appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Avera McKennan Hospital and University Health Center
Sioux Falls, S.D.

---

[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

2985 Drew St.
Clearwater, FL 33759

March 9, 2020

The Honorable Seema Verma
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Submitted via email at OIRA_submission@omb.eop.gov.

Dear Administrator Verma:

BayCare Health System appreciates the opportunity to provide comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey hospitals participating in the 340B outpatient drug pricing program regarding information around the acquisition of specified covered outpatient drugs.

BayCare is the largest not-for-profit health care system in West Central Florida, delivering high-quality health care services through 15 hospitals and more than 400 service locations across the Tampa Bay region. Our mission is to improve the health of all we serve through community-owned health care services that set the standard for high-quality, compassionate care. Inpatient and outpatient services include acute care, primary care, imaging, laboratory, behavioral health, home care, and wellness. In 2019, BayCare provided $461 million in Community Benefit, which included traditional charity care, un-reimbursed Medicaid costs, means-tested programs and community services. Together with our community partners, BayCare is committed to ensuring health equity and striving to achieve the best possible health outcomes for all.

BayCare has four qualified 340B disproportionate share hospitals. One of these hospitals, Morton Plant North Bay Hospital in New Port Richey, Florida, provides among the highest levels of charity care in the state – totaling more than 53 percent in 2019. The 340B program enables these sites to deliver high-cost outpatient pediatric and adult oncology, hemophilia and multiple sclerosis treatment, and other chronic disease management for Medicaid and uninsured patients – regardless of an individual's ability to pay.

Moreover, savings incurred from the 340B program have allowed BayCare to develop and implement significant programs to help members of our community with the medications they require. Among other programs, this includes hiring pharmacists to help patients with access to and use of prescriptions when discharged from the hospital, as well as development of a Medication Assistance Program established to provide assistance to members of the community who find themselves unable to afford their medications. In 2019, this program helped individuals in our region save an estimated $4.5 million.

BayCare takes very seriously the responsibility to ensure compliance with the 340B program's guidelines, and to serve as a good steward of savings incurred through program. ***While supportive of measures to promote transparency and integrity within the 340B program, we share concerns articulated by America's Essential Hospitals, 340B Health and others regarding the potential negative impact of the proposed survey in its current form. As outlined, the survey threatens to undermine the intent of the 340B program, while adding significant regulatory burden to those hospitals caring for those most in need of care –without corresponding benefit to patients.***

We are hopeful CMS will carefully consider these comments and ensure steps to maintain a robust 340B program moving forward. Thank you for your consideration.

Sincerely,

Michael J. Magee
VP, Chief Pharmacy Officer

March 9, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services, HHS
Office of Management and Budget
Office of Information and Regulatory Affairs
ATTN: CMS Desk Officer

RE: Form CMS-10709 (OMB Control Number: 0938-New) Request for Comment on Hospital Survey for Specified Covered Outpatient Drugs

VIA EMAIL: **OIRA_submission@omb.eop.gov**

Dear Ms. Verma:

CHRISTUS Health ("CHRISTUS") thanks CMS for the additional opportunity to provide comments on CMS's Hospital Survey for Specified Covered Outpatient Drugs ("SCODs"). Specifically, CMS seeks comments on the collection of information related to hospital 340B drug acquisition cost data in response to a United States District Court ruling that the Secretary of the Department of Health & Human Services ("HHS") exceeded its statutory authority to adjust payment rates under the Hospital Outpatient Prospective Payment System ("OPPS") for separately payable, 340B-acquired drugs. Although HHS appealed that ruling, CMS moved forward with its plan to obtain acquisition costs for the SCODs to set payment rates based on cost for 340B acquired drugs furnished to certain eligible Covered Entity hospitals. With that in mind, CHRISTUS is concerned that the survey submission window (March 23rd, 2020 to April 10th, 2020) is set to occur with only 13 days for review and consideration of comments submitted by CHRISTUS and other Covered Entities. CHRISTUS respectfully requests that CMS fully consider and thoughtfully incorporate the comments provided into the finalized Hospital Survey for SCODs.

After reviewing the updated survey, CHRISTUS is appreciative of the removal of the section requiring Covered Entities to provide a listing of all provider-based departments participating in the 340B program that are paid under the OPPS from the finalized survey, as the requirement was unnecessary for the accurate collection of acquisition cost data. Notwithstanding, CHRISTUS still believes that the collection of acquisition cost data from all hospitals that purchased SCODs in Quarter 4 of 2018 and Quarter 1 of 2019 will (1) unreasonably burden 340B Covered Entities, particularly large health systems such as CHRISTUS; (2) provide inaccurate information regarding actual 340B costs for some

919 Hidden Ridge | | Irving | TX 75038
Tel 469-282-2559 | ChristusHealth.org

medications; and (3) lead to CMS policy decisions that continue to undermine the statutory intent of the 340B Program.

1. **The Proposed Survey Will Unreasonably Burden 340B Covered Entities, Particularly Large Health Care Systems such as CHRISTUS**

CMS's survey is unnecessarily broad in scope and unduly burdens 340B Covered Entities, particularly large health systems such as CHRISTUS, that have many 340B-eligible hospitals. Based on CMS's updated survey, it is clear that CMS intends to retrieve acquisition cost data from all participating 340B Covered Entities. CMS still provides no rationale for a scope of this magnitude. Moreover, there is no explanation as to why a smaller, statistically valid sample size would be insufficient to reflect accurate drug costs for the two quarters at issue. Because actual acquisition costs for 340B medications are largely consistent across different 340B Covered Entities per statutory pricing requirements, participation by all Covered Entities is unnecessary for collecting the desired information and is overly burdensome for all parties involved, including CMS itself.

Aside from the scope of the survey, the request for information itself is unduly burdensome for 340B Covered Entities. CMS's estimate of 48 FTE-based hours per Covered Entity needed to collect the requested pricing information is not supported by evidence and likely does not accurately reflect the time some hospitals will need to produce the data. For example, hospitals with larger and more comprehensive 340B programs typically have numerous 340B purchasing accounts with various wholesalers/manufacturers, with data housed on different software systems. Therefore, collecting information from these disparate sources will be extremely time intensive and divert pharmacy and IT resources typically used to monitor 340B program compliance, patient care, and completion of other crucial tasks. Additionally, CMS's proposed survey completion time does not account for the fact that large health systems, such as CHRISTUS, would be required to coordinate and extract drug acquisition cost data from multiple hospitals and numerous IT systems, including additional manual labor by staff to ensure accuracy and consistency of the data collection.

Notwithstanding, assuming arguendo that CMS's determination of 48 FTE-based hours per Covered Entity is accurate, the survey still creates an excessive burden on Covered Entities based on the limited 19-day time period for data collection and submission. Dedicating the equivalent of 48 FTE hours (i.e., a full-time employee for 6 full business days) over such a short time frame would stretch most of these safety-net hospitals' already scarce resources thinner and divert those resources away from other key operations and responsibilities, some of which could directly affect patient care. The burden will be especially pronounced for large health systems such as CHRISTUS, which has over 20 340B Covered Entities. Dedicating nearly 1,000 FTE-based hours across the entire CHRISTUS health system to collect information that can be accurately ascertained with a significantly narrowed scope is clearly unreasonable.

To that end, CHRISTUS requests that CMS modify the scope of the survey to include fewer 340B Covered Entities and allow for a longer period of time to collect and submit the requested information.

2. **The Survey Will Not Accurately Reflect Actual 340B Costs for Some Medications**

Based on CMS's updated version of the survey, CHRISTUS remains concerned that the information collection will not take into account the volatility of the drug pricing market and not adequately reflect costs for some medications. As CMS is well aware, prices for the same drug can vary widely from quarter to quarter based on a variety of factors. A drug that loses its patent protection can drop in price precipitously from one quarter to the next. Similarly, the price of a medication can significantly increase if a different drug for the same treatment is taken off the market. Therefore, two quarters of acquisition cost data may not accurately reflect the cost for medications during future quarters.

From a 340B perspective, CHRISTUS is especially concerned that medications with 340B "penny pricing" during one of the quarters included in the survey could artificially deflate actual drug costs for that medication. The survey has made no mention of or concern for "penny pricing" in either the prior proposed survey or the current finalized version of the survey that stands with the OMB. As a reminder, 340B ceiling prices are calculated quarterly using a regulatory formula based on a variety of pricing and inflationary factors. This formula occasionally leads to a 340B ceiling price of $0.00 for some medications, which is increased to $.01 per package for the quarter. However, this low pricing typically only lasts one quarter, and the drug's 340B price significantly increases during the next quarter when the 340B ceiling price formula is recalculated. Therefore, costs for some medications with "penny pricing" during the survey period may not accurately reflect the actual higher drug cost for those medications in following quarters.

Since CMS has decided to move forward with the hospital survey, CHRISTUS requests that a longer time period be used for the data collection to more accurately reflect long-term drug pricing trends. Because this would lead to an increased amount of data to be collected, CHRISTUS would also reiterate its request above to significantly limit the scope of this survey to a smaller number of 340B Covered Entities with more time to collect such data.

3. **The Survey Will Likely Lead to CMS Policy Decisions that Undermine the Statutory Intent of the 340B Program**

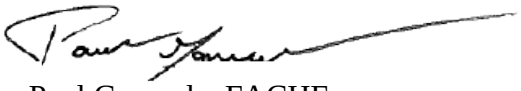
Finally, the current version of the survey will likely lead to continued CMS policy decisions that do not reflect the statutory intent of the 340B Program to stretch federal resources to at-risk patient populations. In its survey notice, CMS states that it intends to use the pricing information requested "to ensure the Medicare program pays for specified covered outpatient

drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs." However, reducing reimbursement for 340B medications deprives 340B Covered Entities of realizing drug cost savings that are designed to assist in supporting underinsured and indigent patients. The ultimate purpose of the drug purchasing discounts received by 340B Covered Entities (as opposed to non-340B entities) is to offset the financial strain of large volumes of uncompensated and undercompensated care rendered by these 340B-eligible providers. Any reduction to the savings originally contemplated by Congress threatens the capability of our safety-net providers and will likely lead to a negative impact on patient care.

As CHRISTUS has argued in previous comments submitted to CMS, concerns that 340B savings are flowing to entities that are not in need of those savings are unfounded. The Health Resources and Services Administration ("HRSA") ensures the fulfillment of this purpose by enforcing strict eligibility standards for the types of hospitals permitted to participate in the 340B Program—only those not-for-profit providers serving underserved communities or disproportionately high percentages of the indigent population are eligible to receive 340B discounts. Comprehensive studies have shown that 340B hospitals deliver significantly more care to low-income and underserved patients than non-340B hospitals, further justifying the full 340B savings amounts contemplated by Congress.[1,2] CMS should not initiate any payment reduction for 340B medications, regardless of the data it is based on.

Thank you for the opportunity to provide comments on the finalized Hospital Survey for SCODs.

Respectfully Submitted,



Paul Generale, FACHE
Executive Vice President
Chief Strategy & Network Officer
CHRISTUS Health

[1] *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patient.* L&M Policy Research, LLC. March, 2018.

[2] *340B Program Savings Improve Patient Health Outcomes*. L&M Policy Research, LLC. December 2019.

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Wagner Community Memorial Hospital - Avera, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Bryan Slaba
CEO

BEAUREGARD
HEALTH SYSTEM

March 6, 2020
Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Beauregard Health System, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

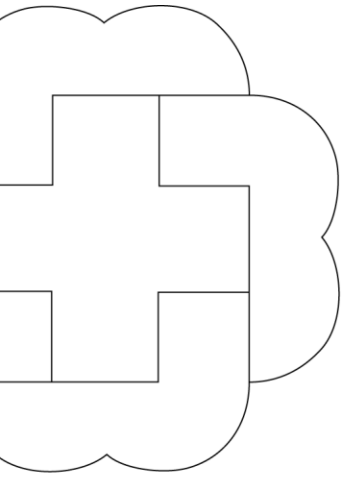
As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. We are a small 49 bed rural facility with a very small pharmacy staff. It would be almost impossible to acquire this cost data. The intent of the 340b program is to allow DSH hospitals to be able to stretch resources to care for all patients. We are not large enough to even provide free clinics or other programs. We are just one of many rural facilities trying to keep the doors open. The 340b program does not cost the government or the taxpayer a dime. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

Alex Manitzas RPh
Director of Pharmacy



BRONSON

March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Bronson Methodist Hospital, Bronson Battle Creek Hospital, and Bronson LakeView Hospital ("Bronson"), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As 340B hospitals, we have been able to use the program savings to improve patient services and help our communities, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. In our own communities, we have been able to use the 340B savings to provide counseling to each discharged patient about their medications, supply a diabetes start-up kit for every newly-diagnosed diabetic patient, and establish pharmacy programs to help low-income patients get their medications. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

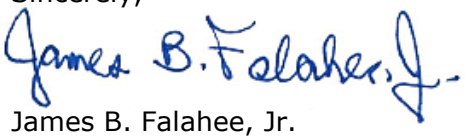
From an implementation perspective, this survey will significantly burden our hospitals. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As 340B hospitals, we purchase many of our 340B

BRONSON

drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospitals to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,



James B. Falahee, Jr.
Interim President & CEO
Bronson Healthcare
301 John Street
Kalamazoo MI 49007
(269) 341-6000

SANFORD HEALTH

March 6, 2020

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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 Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Dear Mr. Ray:

Sanford Health is a non-profit integrated health system headquartered in the Dakotas. We are one of the largest health systems in the nation with 44 hospitals, 1,400 physicians, and more than 200 Good Samaritan Society senior care locations in 26 states and nine countries. Sanford Health's 48,000 employees make it the largest employer in the Dakotas.

Sanford Health appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] Sanford Health does not deny care to anyone regardless of ability to pay. Savings from the 340B program has allowed us to provide charity care and subsidized health services for our patients who are unable to be fully responsible for the healthcare they receive. 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 the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm Safety-Net Hospitals and Their Patients

[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.

Setting Medicare payments for 340B drugs at acquisition cost 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% of hospitals, they provide 60% of all uncompensated care.[3]. By purchasing a drug at a discounted 340B price for a Medicare beneficiary, 340B hospitals are able to provide more care to underserved patients. Reducing Medicare payment to 340B hospitals' acquisition costs would eliminate 340B hospitals' ability to use the savings they accrue, thereby frustrating the 340B program's purpose.

As we have stated in previous letters, we do not believe CMS should apply payment rates differently to hospitals in the 340B program because this creates disparities between facilities in the same geographic location. CMS has historically paid the same rate for the same services provided to patients in the same location. We do not believe CMS has the authority or the obligation to adjust payments based on enrollment in a separately operated federal program.

We believe the intent of this survey is to justify the more cuts to payments for 340B hospitals. Cutting reimbursements to 340B hospitals will not address the underlying cause of high drug costs. Hospitals act as the "middle man" between the drug manufacturer and the Federal government. Reducing payment to hospitals will create a disincentive for hospitals to provide access to drugs and provides no incentive for drug manufacturers to reduce the cost of the drugs.
CMS should look at the process drug manufacturers use to develop, manufacture, market, and sell drugs in the United States, instead of making cuts to reimbursement programs for hospitals.

II. The Survey Places a Massive Administrative Burden on 340B Hospitals

Sanford Health has significant concerns regarding the amount of time it would take to respond to this survey. 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.

Due to the massive burden responding to this survey will place on 340B hospitals, we are concerned about the number of responses that will be received by CMS and the accuracy of the data that will be returned. Receiving limited responses will negatively impact potential future policy change. The survey response will cost our safety-net hospitals a significant sum of money that otherwise could have been spent service our low-income and rural patients.

III. CMS's Proposal is Contrary to Law

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[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.

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 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]

IV. The Survey Will Collect Unusable Data

The 340B statute prohibits our hospitals from obtaining covered outpatient drugs through a group purchasing organization or group purchasing arrangement, requiring our hospitals 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 reiterate our concern over the validity of the data that will be received by CMS if the proposal to collect 340B drug acquisition cost is finalized. CMS has not explained how they intend to use the information that is collected, contrary to the requirements of the Paperwork Reduction Act (PRA) of 1995.[7]

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Corey Brown
Vice President, Government Relations
Sanford Health

[5] 42 U.S.C. § 1395/(t)(14)(D)(iii).
[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).
[7] 42 U.S.C. § 3506(c)(1)(B)(iii).

UnityPoint Health

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

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

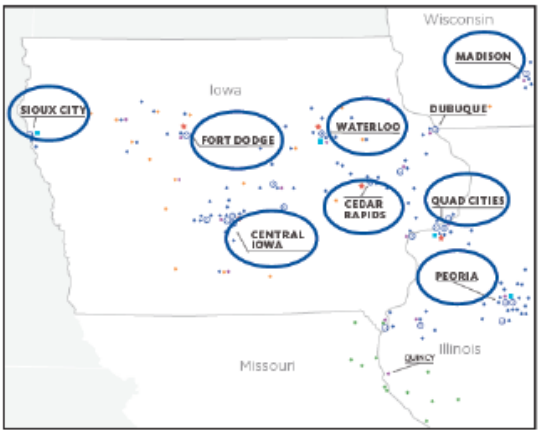
Re: Comments on CMS Proposed Collection of Information, Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709; OMB-0938-New)

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).

UMassMemorial

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www.umassmemorial.org

Eric W. Dickson, MD, MHCM, FACEP
President & CEO, UMass Memorial Health Care
Professor of Emergency Medicine,
UMass Medical School

March 5, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

UMass Memorial Health Care appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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

[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.

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.

II. 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.

III. 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 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]

IV. The Survey Will Collect Unusable Data

340B pricing is updated on a quarterly basis and for some items, the price changes from quarter to quarter could be significant. Below grid lists three examples to demonstrate the 340B price increase from one quarter to the next on the same NDC. If CMS were to just take a snapshot of 340B pricing in one quarter and reimburse using that pricing for rest of the year, 340B hospitals would potentially receive an under

HCPCS	Price Increase from Q4 CY'19 to Q1 CY'20
J9395	29%
J9280	56%
J0878	36%

[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.
[5] 42 U.S.C. § 1395/(t)(14)(D)(iii).

Also, in some cases, UMass purchases and utilizes multiple NDCs within a given quarter that share the same HCPCS, and these NDCs could have huge price differences per HCPCS unit. It's unclear how CMS would expect hospitals to calculate the average 340B prices per HCPCS units for such items. Below are three examples that demonstrate such huge price variation during Q1 CY'19.

HCPCS	Number of different NDCs Purchased	Percent Difference in price between highest and lowest priced NDC	Dollar Difference in price between the highest and lowest priced NDC
J1950	3	137%	$130.43
J9202	2	49%	$50.09
J9217	4	191%	$197.38

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 appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Eric W. Dickson, MD
CEO, UMass Memorial Health Care

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Mountain Health Network, which includes Cabell Huntington Hospital and St. Mary's Medical Center appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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.

II. 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

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[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.
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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.

III. 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 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]

IV. 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Abby Reale

Abby Reale
Director of Advocacy
Mountain Health Network

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

March 17, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

The Medical Center, Inc. Piedmont Columbus Regional Midtown appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

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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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Debbie Nowlin, Director of Pharmacy
Piedmont Columbus Regional Midtown

---

[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

Baystate Noble Hospital

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

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

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Dear Mr. Ray:

Baystate Health appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

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Baystate Health's Disproportionate Share Hospital designation reflects Baystate Health's commitment to our underinsured community. Our payer mix is weighted significantly toward Medicaid Mass Health and

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[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.
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Medicare. The savings from the 340B program allows us to continue to provide access to care for all patients, regardless of income level. Listed below are just a few examples of how Baystate Health utilizes 340B savings:

- Sustain a Pharmacy Discharge Prescription Service that focuses on medication reconciliation, post-discharge medication adherence, one-on-one medication education, the reduction of hospital readmission rates, and supporting patients' transitions of care.
- Provide clinical services in the Baystate Medical Center Community Health Centers that lead to a greater quality of care, including a Diabetes Clinic at Mason Square and an HIV/Pharmacotherapy Clinic at South Campus and Brightwood Health Center.
- Supply Narcan to first responders to help battle the local opioid epidemic in Western Massachusetts.
- Open a Neurocritical Care Unit that provides comprehensive monitoring and treatment for patients who are at the highest risk of neurologic issues.
- Embed trained Pharmacy Liaisons, which assist in providing over $15 million in direct patient financial assistance, at D'Amour Center for Cancer Care, the Children Specialty Center at Wason Avenue, and other key clinic locations.

II. 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.

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****

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Gary J. Kerr, Pharm D., MBA
Chief Pharmacy Officer
Baystate Health

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

Baystate Franklin Medical Center

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
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Baystate Health's Disproportionate Share Hospital designation reflects Baystate Health's commitment to our underinsured community. Our payer mix is weighted significantly toward Medicaid Mass Health and Medicare. The savings from the 340B program allows us to continue to provide access to care for all

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[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.
[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

patients, regardless of income level. Listed below are just a few examples of how Baystate Health utilizes 340B savings:

- Sustain a Pharmacy Discharge Prescription Service that focuses on medication reconciliation, post-discharge medication adherence, one-on-one medication education, the reduction of hospital readmission rates, and supporting patients' transitions of care.
- Provide clinical services in the Baystate Medical Center Community Health Centers that lead to a greater quality of care, including a Diabetes Clinic at Mason Square and an HIV/Pharmacotherapy Clinic at South Campus and Brightwood Health Center.
- Supply Narcan to first responders to help battle the local opioid epidemic in Western Massachusetts.
- Open a Neurocritical Care Unit that provides comprehensive monitoring and treatment for patients who are at the highest risk of neurologic issues.
- Embed trained Pharmacy Liaisons, which assist in providing over $15 million in direct patient financial assistance, at D'Amour Center for Cancer Care, the Children Specialty Center at Wason Avenue, and other key clinic locations.

II. 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.

III. 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 allows for

[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.

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

IV. 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Gary J. Kerr, Pharm D., MBA
Chief Pharmacy Officer
Baystate Health

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

Baystate Medical Center

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Baystate Health appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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.

Baystate Health's Disproportionate Share Hospital designation reflects Baystate Health's commitment to our underinsured community. Our payer mix is weighted significantly toward Medicaid Mass Health and

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[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.
[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

Medicare. The savings from the 340B program allows us to continue to provide access to care for all patients, regardless of income level. Listed below are just a few examples of how Baystate Health utilizes 340B savings:

- Sustain a Pharmacy Discharge Prescription Service that focuses on medication reconciliation, post-discharge medication adherence, one-on-one medication education, the reduction of hospital readmission rates, and supporting patients' transitions of care.
- Provide clinical services in the Baystate Medical Center Community Health Centers that lead to a greater quality of care, including a Diabetes Clinic at Mason Square and an HIV/Pharmacotherapy Clinic at South Campus and Brightwood Health Center.
- Supply Narcan to first responders to help battle the local opioid epidemic in Western Massachusetts.
- Open a Neurocritical Care Unit that provides comprehensive monitoring and treatment for patients who are at the highest risk of neurologic issues.
- Embed trained Pharmacy Liaisons, which assist in providing over $15 million in direct patient financial assistance, at D'Amour Center for Cancer Care, the Children Specialty Center at Wason Avenue, and other key clinic locations.

II. 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.

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[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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Gary J. Kerr, Pharm D., MBA
Chief Pharmacy Officer
Baystate Health

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

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

340B Health submits these comments in response to the notice published in the Federal Register on Feb. 7, 2020, proposing an 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 lower the cost of drugs purchased by 340B hospitals. The differential between the discounted purchase costs and reimbursement creates resources that allow safety-net providers to "reach more patients" and furnish "more comprehensive services."[2]

340B Health urges OMB to reject CMS's survey proposal to collect drug acquisition cost data from 340B hospitals for the following reasons. First, CMS's plan to set Medicare payment for SCODs at acquisition cost for 340B hospitals would not benefit the public, but instead would harm safety-net hospitals and their patients. Second, in violation of the Paperwork Reduction Act (PRA) of 1995, CMS's survey proposal will not produce useful data to accurately calculate average drug acquisition costs for 340B hospitals because, among other flaws, it does not adequately account for cost variations of drugs under the same Medicare billing code and does not include hospitals' purchase volumes.[3] The proposed survey also would fail to generate a statistically significant estimate of hospitals' average acquisition costs in violation of the Medicare statute. Third, CMS's survey proposal places a massive burden on 340B hospitals and does not include sufficiently clear instructions, thereby violating the PRA's burden and clear instructions requirements. Finally, CMS's plan to collect drug acquisition cost data from only 340B hospitals violates the Medicare statute. These points are explained in more detail in the following comments.

I. Background on Proposed Survey and Previous Comments

CMS states in the proposed ICR that the acquisition cost data that 340B hospitals submit in response to the survey will be used to determine Medicare Part B payment amounts to hospitals under the outpatient prospective payment system (OPPS) for drugs acquired under the 340B program.[4] In other words, CMS

[1] Centers for Medicare & Medicaid Services, Agency Information Collection Activities: Submission for OMB Review; Comment Request; CMS-10709; OMB-0938-New, 85 Fed. Reg. 7306 (Feb. 7, 2020).
[2] H.R. Rep. 102-384(II) at 12 (1992).
[3] Paperwork Reduction Act of 1995, 44 U.S.C. § 3501-3520.
[4] 85 Fed. Reg. 7306, 7307.

intends to use the data collected to set Medicare Part B payment for 340B drugs "at amounts that approximate what 340B hospitals actually pay to acquire" those drugs.[5] This would eliminate the resources that the 340B program was designed to provide. CMS has already implemented a nearly 30% payment reduction to certain 340B hospitals for Medicare Part B drugs acquired through the 340B program.[6] That payment reduction, which has been in effect since the start of 2018, harms 340B hospitals' ability to provide needed care to the patients they serve. It has also twice been ruled unlawful by a federal court judge.[7] Despite repeated pleas from hospitals, citing their concerns about the payment reduction's harm to patients, and notwithstanding the court's determination that the payment reduction is unlawful, CMS continued the cuts to 340B hospitals in 2020.[8]

340B Health submitted comments to CMS in response to its first notice announcing an intention to submit an ICR to OMB for its review regarding the survey of 340B hospitals.[9] Our comments explained that **340B Health strongly opposes payment at average acquisition cost for 340B hospitals by Medicare and that furthering payment reductions to 340B hospitals will continue to harm hospitals and patients while significantly undermining the 340B program. We noted that CMS's proposal to pay 340B hospitals at average acquisition cost would be particularly problematic for the 340B hospitals that CMS has exempted from the current Part B payment reductions, as these hospitals are not situated to absorb such a payment reduction due to the unique patient populations that these hospitals serve.** Our comments also expressed concerns that CMS's survey proposal is contrary to law and is rife with violations under the PRA due to the proposal's lack of clear instructions, the immense burden the collection would undoubtedly place on 340B hospitals, and the likelihood that the data collected would be inaccurate and unreliable given the extensive calculations CMS asked hospitals to complete for a massive amount of data.

We outlined for CMS multiple aspects of the survey proposal that are unclear and explained that the lack of clarity made it impossible to submit meaningful comment on CMS's burden estimate. Notwithstanding the lack of clarity, we told CMS that the agency's proposed collection would place a massive burden on 340B hospitals, likely several times the 48 hours for each response and the total cost of five million dollars to 340B hospitals that CMS estimates. We described the tasks CMS proposed to require hospitals to undertake to respond to the survey, each of which would unnecessarily contribute to the burden of the collection on hospitals. For these reasons, in addition to the ICR promoting a policy harmful to safety-net hospitals and their patients, we asked CMS to withdraw the ICR or, at a minimum, issue a new ICR with clear and detailed instructions to allow hospitals to provide meaningful comments on CMS's burden estimate. Unfortunately, CMS declined to do so and instead submitted this ICR to OMB for approval in order to start collecting survey data from 340B hospitals this month—only two weeks after the deadline for submission of comments—with a shorter time frame for survey responses.[10]

The OMB is charged with reviewing agency collections of information "to maximize the utility of and public benefit from information collected by or for the Federal Government."[11] The OMB is also responsible for "establish[ing] and oversee[ing] standards and guidelines by which agencies are to estimate the burden to comply with a proposed collection of information."[12] In addition to the enclosed comments, we set forth below our comments on CMS's ICR based on our review of CMS's revised survey instructions and supporting statements.

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[5] *Id.*
[6] 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).
[7] American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018); American Hospital Association v. Azar, 385 F. Supp. 3d 1 (D.D.C. 2019).
[8] *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).
[9] 340B Health's comments in response to CMS's initial proposal are enclosed for OMB's review.
[10] Although CMS did not withdraw the ICR or issue a new one for public comment, the survey instructions document accompanying the ICR submitted to OMB includes some additional explanation compared to the survey instructions document that accompanied CMS's original proposal (84 Fed. Reg. 51590 (Sept. 30, 2019)). Despite additional instruction from CMS, there are aspects of CMS's current proposal that remain unclear. *See supra* Section IV.B.
[11] 44 U.S.C. § 3504(c)(4).
[12] 44 U.S.C. § 3504(c)(5).

II. Payment at Acquisition Cost Would Not Benefit the Public but Instead Would Harm Safety-Net Hospitals and Their Patients

CMS's proposal to reimburse 340B drugs at acquisition cost and eliminate the resources the 340B program was intended to create will harm 340B hospitals and the patients they serve. Drugs purchased under the 340B program are not intended to be reimbursed 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 the higher amounts hospitals would have paid for the drugs under their hospital group purchasing accounts to invest 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 using their 340B savings.

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.[13] 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.[14] 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 and Medicare, are disabled, or are racial or ethnic minorities.[15]

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 Charleston, 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.[16] 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.[17][18]

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.[19] There is no reason for CMS to collect drug acquisition cost

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[13] 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
[14] *Id.*
[15] 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
[16] 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
[17] *Id.*
[18] Since the payment reduction for 340B drugs 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 reduced payment rate for 340B drugs).
[19] 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 and how they are paid under the OPPS. Children's and PPS-exempt cancer hospitals are "held harmless" under the OPPS and must receive outpatient payments from Medicare in the current year that are no less than the estimated amount they would have received prior to implementation of the OPPS).

data from hospitals exempted from the payment reductions unless CMS intends on taking these hospitals' 340B savings in the future through similar payment reductions.

Not only does CMS's proposal break with over two decades of Medicare policy and undermine the 340B program, but in harming 340B hospitals and the patients they serve by perpetuating the current payment reductions, the proposal also conflicts with the PRA's purpose to ensure the greatest possible public benefit from agency information collections.[20] For these reasons, OMB should reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

III. The Proposed Survey Will Not Produce Useful Data or Generate a Statistically Significant Estimate of Hospital Drug Acquisition Costs in Violation of the PRA and the Medicare Statute

A. The survey will not produce useful data in violation of the PRA's practical utility requirement

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 hospitals to calculate average 340B prices for more than 400 codes under Medicare's Healthcare Common Procedure Coding System (HCPCS) and 1,100 national drug codes (NDCs).[22] For a given calendar quarter for which CMS requests data, there easily can be hundreds of thousands of units of data hospitals would need to report to CMS under this ICR. Moreover, 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. This step will require hospitals to engage in extensive mathematical calculations, requiring analysis of tens of thousands of units of data, and increases the risk of human error that could undermine the reliability of the data. Contributing to the likelihood that the collection will not produce reliable data is the very short timeframe of just 15 business days that CMS provides hospitals to respond to the survey. The survey response period is grossly insufficient for hospitals to generate, calculate, and validate the data.[23]

CMS proposes to use prices reported by hospitals or 340B ceiling prices to determine average acquisition cost. Pricing data reported by HCPCS codes, however, do not identify average acquisition cost, as hospitals can use multiple NDCs under a given HCPCS code and each NDC could be priced higher or lower than other NDCs used under the same HCPCS code. For example, a hospital could use a high-priced NDC for part of a quarter and then a lower-priced NDC for the rest of the quarter. Therefore, knowing the price of each of the two NDCs does not identify the average acquisition cost of the drugs used under that HCPCS code for that quarter because it does not account for different quantities of hospital drug purchases at these different prices. CMS does not ask hospitals to report the NDC purchasing units that correspond to hospitals' calculations of "average 340B price." Thus, CMS's survey is fatally flawed, as it will not provide CMS with the data needed to calculate 340B hospitals' average acquisition costs. Even if hospitals choose to provide CMS with the price per individual NDC rather than the price per HCPCS code, as CMS appears to allow, CMS will not be able to calculate hospitals' average acquisition costs, as CMS asks hospitals to report only the price, but not the volume. Rendering the data even more meaningless, if hospitals choose to report the price per HCPCS code instead of per NDC, CMS will be in the dark not only with respect to hospitals' purchasing volume, but also the specific drugs purchased.

That the survey does not ask hospitals to report on purchasing volume is particularly problematic given that the variation in prices for two NDCs paid under the same HCPCS code can be very large, which could significantly distort the calculated average price for that code. For example, hospitals use multiple NDCs for HCPCS code J2469, which has seven NDCs listed in CMS's NDC-HCPCS crosswalk. The difference between the highest priced NDC and the lowest priced NDC for that HCPCS code can be as high as 1729%. CMS's plan to use

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[20] 44 U.S.C. § 3501(2).
[21] 5 C.F.R. § 1320.3(l)
[22] *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.
[23] Further calling into question the accuracy and reliability of the data is CMS's statement that the agency will not use sampling or stratification methods despite anticipating that CMS will not receive responses from all hospitals and that drug acquisition cost data may be unknown. *See* CMS 10709, OMB 0938-New, Supporting Statement B, Page 1.

340B ceiling prices to help determine average acquisition cost is also problematic because those prices do not account for hospitals' purchasing volume, and therefore, cannot identify average acquisition cost.

Another flaw in CMS's proposed survey is the limited scope of pricing data to be collected. CMS instructs hospitals to provide the "average 340B price" of a drug in the survey instruments, indicating that CMS is interested in 340B prices only.[24] Omitting other high-cost drug purchases required by the 340B program further prevents the data collection from capturing the average acquisition cost of drugs billed to Medicare by 340B hospitals. In order to participate in the 340B program, the 340B statute prohibits DSH, children's, and cancer hospitals from obtaining covered outpatient drugs through a group purchasing organization (GPO) or group purchasing arrangement.[25] 340B hospitals that are subject to the GPO prohibition are required to purchase certain outpatient drugs at wholesale acquisition cost (WAC) prices that are typically significantly higher than 340B prices. Excluding WAC purchases from the calculation of average acquisition cost prevents the data collection from accurately calculating the cost of drugs purchased under 340B program rules.

CMS's survey proposal also fails to explain how the agency will track price changes over time, further calling into question the collection's accuracy, reliability and overall practical utility. Hospitals report that separately payable Part B drugs can experience significant price increases from one quarter to another. For example, Mitomycin (HCPCS code J9280) experienced a 56% price increase this quarter compared to last quarter.

Moreover, CMS acknowledges that its NDC-HCPCS crosswalks do not provide "a complete and comprehensive list of all available NDCs for each HCPCS code."[26] Failing to provide hospitals with a complete list of NDCs for each HCPCS code could result in hospitals excluding relevant NDCs in their calculations of average 340B prices. Finally, as explained below, CMS's survey instructions are not clear, further increasing the risk that the collected data will not be accurate.[27] Permitting CMS to proceed with an information collection that lacks practical utility would violate the PRA.[28]

B. The survey will not generate a statistically significant estimate of hospitals' average acquisition costs in violation of the Medicare statute's requirements for setting payment for hospital outpatient drugs at average acquisition cost

In order to set Medicare reimbursement for specified covered outpatient drugs (SCODs) at average acquisition cost, the law requires that such reimbursement rates are established using a survey of hospital acquisition costs.[29] The survey of hospital acquisition costs must have a "**large sample of hospitals** that is sufficient to generate a **statistically significant estimate** of the average hospital acquisition cost for each SCOD."[30] A study that is "statistically significant" has results that are unlikely to be the result of random error.[31] Statistical significance is determined, in part, by the number of observations in a dataset.[32] Smaller samples are more likely to be different from the population than larger ones, and therefore, have more sampling error.[33] Also contributing to sampling error is population variability, as the more variable the population, the greater the uncertainty in an estimate. The more diverse the population, the larger the sample must be in order to reflect the population accurately.[34]

We have serious concerns that CMS's survey of 340B hospitals would fail to generate a statistically significant estimate of the average hospital acquisition cost for each SCOD in violation of the Medicare statute. First, the substantial price variations that exist for NDCs paid under a single HCPCS code will lead to similarly large variations in prices gathered at the hospital level. These variations in cost may exist both within and across hospitals. In addition, CMS does not plan to collect from 340B hospitals the volume associated with the

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[24] CMS 10709, OMB 0938-New, Instructions for Filling Out Survey, Numbers 7-8.
[25] 42 U.S.C. § 256b(a)(4)(L)(iii).
[26] CMS 10709, OMB 0938-New, Instructions for Filling Out Survey, Number 5.
[27] *See supra* Section IV.B.
[28] 44 U.S.C. § 3508.
[29] 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).
[30] 42 U.S.C. § 1395l(t)(14)(D)(iii) (emphasis added).
[31] Matrixx Initiatives, Inc., v. Siracusano, 563 U.S. 27 (2011).
[32] The National Academies Press, Reference Manual on Scientific Evidence, Third Edition, *available at*: https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf
[33] Moussouris v. Microsoft Corp., 311 F. Supp. 3d 1223 (W.D. Wash., Mar. 7, 2016).
[34] Duran v. U.S. Bank National Assn., 59 Cal. 4th 1, (2014).

hospitals' calculations of "average 340B price." As a result, CMS will not be able to weight the results by volume, and therefore, is not accounting for variability within and across 340B hospitals. This increases the likelihood that CMS's survey results will not produce a statistically valid estimate of 340B hospitals' average acquisition costs and instead will produce skewed results that can unfairly penalize certain hospitals, such as smaller institutions or those that purchase less commonly used drugs.

Considering the burden the collection places on hospitals and the short time period to respond, we also have significant doubts that CMS will obtain an adequate response rate, raising concerns that the data from those who do respond will be insufficient to generate a statistically significant estimate of hospitals' average acquisition costs. CMS's survey may not achieve an adequate number of responses from 340B hospitals overall and across hospital stratification factors such as bed size or geographic location.[35] Moreover, CMS's plan to impute 340B ceiling prices to fill in blank responses will not create a larger sample set of meaningful, representative data, as doing so would merely give a value to missing data as opposed to extrapolating relevant population characteristics from a sample to the entire 340B hospital population.[36]

During a survey of hospital acquisition costs in 2005, the Government Accountability Office (GAO) took several steps, listed below, to ensure that the survey met the Medicare statute's requirements to include a large sample of hospitals sufficient to generate a statistically significant estimate of hospitals' drug acquisition costs.[37]

- The GAO convened a panel of experts to assist with the design of the survey.
- The GAO developed a stratified random sample of hospitals consisting of 3,450 hospitals.
- The GAO used a Neyman allocation to determine the optimum sample size. To achieve a sample of 1,000 hospitals, which GAO determined would meet the Medicare statute's requirement for a "large sample of hospitals", the GAO drew a sample of 1,400 hospitals from the identified 3,450 hospitals.[38]
- To improve the precision of its estimates of average purchase price, GAO stratified the sample of hospitals with the goal of selecting strata that would represent different average purchase prices for SCODs.
- GAO used a regression model to identify stratification factors, such as teaching hospital status, that would maximize the difference in average purchase price among strata.
- Before sending the survey to the 1,400 hospitals in the sample, GAO tested the survey and consulted a number of experts, including pharmacists and hospital administrators, on methods of developing and administering the survey.
- To estimate the average purchase price, GAO used hospital weights and purchase volume in order to reflect the differences among hospitals in purchase prices and volumes.
- GAO weighted the data received from hospitals to make them representative of the population of hospitals from which the sample was drawn.[39]

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[35] A stratified random sample is a type of probability sample wherein the researcher divides the population into relatively homogeneous groups called "strata," and draws a random sample separately for each stratum. Dividing the population into strata is called "stratification." The National Academies Press, Reference Manual on Scientific Evidence, Third Edition, *available at*: https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf

[36] Utah v. Evans*,* 536 U.S. 452 (2002) (explaining that "imputation" is not "sampling.").

[37] United States Government Accountability Office, Medicare Hospital Outpatient Drug Prices, GAO-05-581R, June 2005, *available at*: https://www.gao.gov/new.items/d05581r.pdf. Note that notwithstanding GAO's efforts, the U.S. Department of Health and Human Services (HHS) expressed concerns about the accuracy of the GAO's data and acknowledged the challenges of accurately surveying hospitals for drug acquisition costs.

[38] The GAO included in the sample of 1,400 hospitals a pilot sample consisting of 48 hospitals.

[39] United States Government Accountability Office, Medicare Hospital Outpatient Drug Prices, GAO-05-581R, June 2005, *available at*: https://www.gao.gov/new.items/d05581r.pdf. The GAO also made significant efforts to secure an adequate response rate from hospitals, including substantial follow-up and allowing hospitals to submit data in any format. In contrast, CMS merely proposes to make the surveys available for download on the websites of hospitals' Medicare administrative contractors.

To conduct a survey of acquisition costs of 340B hospitals, CMS cites the same statutory authority that the GAO relied on to conduct its survey of hospital drug acquisition costs.[40] Yet, CMS does not propose to undertake any of the above steps the GAO took to ensure the data are accurate and that the survey design complies with the Medicare statute's requirements. Moreover, CMS explicitly says that the agency will not use sampling or stratification methods with respect to its survey of 340B hospitals.[41] CMS claims the "sample" will be 100% of the potential respondent universe.[42] Yet, apart from Medicare administrative contractors announcing "the availability of the survey" on their websites, CMS has utterly failed to provide concrete methods for maximizing response rates among the "potential respondent universe", making it extremely likely that the percentage of actual respondents will fall well short of CMS's "sample" of 100%.[43] Furthermore, CMS has not proposed a single step to enhance the statistical significance of the data collected through the flawed survey. For these reasons, the survey does not comply with the legal requirements for using acquisition costs to establish reimbursement rates for SCODs.[44]

IV. OMB Should Reject CMS's Survey Proposal Because It Violates the PRA's Burden and Clear Instructions Requirements

A. The collection places a massive burden on 340B hospitals that CMS has failed to minimize

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.[45] Though CMS has removed some unnecessary elements from its original proposal, such as asking hospitals to provide pricing data by provider-based department, CMS continues to include tasks that will unnecessarily contribute to the massive burden the collection places on 340B hospitals. For example, CMS asks hospitals to calculate an "average 340B price of a drug" based on Medicare HCPCS dosage units. Medicare HCPCS dosage units generally do not match NDC purchasing units. Thus, hospitals would need to convert NDC purchasing units to HCPCS dosage units in order to calculate an "average 340B price." By obtaining the relevant NDC purchasing units from hospitals, CMS can do these conversions rather than having hundreds of individual hospitals perform these calculations. Having hospitals perform 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, as CMS can do these conversions on its own.

In addition, CMS's survey proposal requests information from 340B hospitals that CMS already has access to. CMS asks hospitals to list the payment rates for each HCPCS code in the quarters for which CMS requests data and directs hospitals to obtain these payment rates from CMS's OPPS Addendum B for the relevant quarter instead of including the payment rates in the survey sent to hospitals.[46] By asking hospitals to provide CMS with payment rate information that CMS maintains and publishes quarterly, CMS has failed to minimize the burden of the collection.[47]

Further adding to the burden of the collection is the specific format CMS requires hospitals to use in providing the data. As the GAO acknowledged in conducting its survey of hospital acquisition costs, hospitals' information systems are diverse and produce acquisition cost data in different formats.[48] During its survey of hospital acquisition costs in 2005, the GAO accepted data from hospitals in any format in an effort to make the task of submitting data as easy as possible for hospitals in order to encourage their cooperation. According to the GAO, the ability of hospitals to submit the data in any format was "critical to achieving good response rates."[49] It appears that CMS is requiring hospitals to submit the data in a format that will reduce the burden on CMS as

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[40] 42 U.S.C. § 1395(l)(t)(14)(D).
[41] CMS 10709, OMB 0938-New, Supporting Statement B, Page 1.
[42] *Id.*
[43] *Id.*
[44] 42 U.S.C. § 1395(l)(t)(14)(D).
[45] 44 U.S.C. § 3501(1)-(2).
[46] CMS 10709, OMB 0938-New, Instructions for Filling Out Survey, Numbers 6-7.
[47] In addition, it is not clear how the Medicare payment rate is relevant to hospitals' drug acquisition costs, and therefore, CMS's survey proposal.
[48] United States Government Accountability Office, Report to Congressional Committees, Medicare Hospital Pharmaceuticals, Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS, (GAO-06-372), April 2006, *available at*: https://www.gao.gov/assets/250/249967.pdf
[49] *Id.* at 12, fn. 33.

the collector of the data without regard for the burden placed on hospitals by not providing for alternative submission formats or methods.

It is apparent that CMS's proposal would place an immense burden on 340B hospitals, likely several times the 48 hours per response and total cost of five million dollars to 340B hospitals that CMS estimates. We have significant concerns that CMS is disregarding its responsibility, under the PRA, to minimize the burden of the collection. Despite receiving comments from numerous hospitals and hospital associations explaining that CMS's proposal would place a massive burden on 340B hospitals, CMS shortened an already inadequate response period given to hospitals to complete the survey, from one month to just 15 business days.[50] We are concerned that this shortened timeframe will jeopardize the accuracy of the data in such a way that the data will not be usable to generate a "statistically significant" estimate of hospitals' average acquisition cost as required by the Medicare statute.

B. Aspects of CMS's survey proposal are unclear

Several aspects of CMS's survey instructions are not clear, requiring hospitals 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.[51] For example, CMS's survey instructions direct hospitals to enter the average acquisition cost for each SCOD as identified by the SCOD's HCPCS code for each SCOD purchased at any time during the last quarter of 2018 and first quarter of 2019. The ICR CMS submitted to OMB now says that hospitals can "choose to include" the NDC.[52] This new instruction appears to respond to our comment that CMS's original proposal did not clearly indicate whether CMS expects hospitals to provide the price per NDC or per HCPCS code. Under the revised instructions, hospitals can apparently choose to provide the price per each individual NDC. However, if hospitals were to provide pricing data for each NDC paid under a relevant HCPCS code, there would be no "average" 340B price to report per NDC, as the 340B price does not change within a given quarter.[53] This creates confusion because respondents will not understand what they are supposed to do to arrive at an "average" price.

In addition, CMS now proposes to ask hospitals for the "net acquisition cost" for each 340B drug, which CMS indicates is the sub-ceiling price "after all *applicable* discounts/rebates."[54] CMS does not provide any information on what constitutes "applicable" discounts/rebates. Also contributing to the ambiguity of the collection are the inconsistent and conflicting terms CMS continues to use throughout the survey documents.[55]

Finally, it is not clear if critical access hospitals (CAHs) are expected to respond to CMS's survey. CAHs are not paid under the OPPS and are therefore not subject to CMS's current payment reduction for 340B drugs. CMS's initial survey proposal stated that Medicare administrative contractors would disseminate the survey to

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[50] CMS 10709, OMB 0938-New, CMS Average Sales Price Survey, Page 1 (stating that the survey response period is March 23, 2020 through April 10, 2020); *Cf.* CMS 10709, CMS Average Sales Price Survey, Page 1 (stating that the survey response period is February 17, 2020 through March 16, 2020). In contrast, when the GAO conducted its survey of hospital drug acquisition costs in 2005, hospitals were given nearly four months to respond with the data. *See* GAO-05-581R at page 14-16 (the GAO began collecting the data on September 27, 2004 through January 15, 2005 and continued to process data received through February 22, 2005 for strata that had not yet reached GAO's target response rate).

[51] 44 U.S.C. § 3506(c)(3)(D).

[52] CMS 10709, OMB 0938-New, Instructions for Filling Out Survey, Number 5.

[53] We note that it is not entirely clear if CMS wants hospitals to report 340B prices only. CMS asks for "the average 340B price of a drug" in the survey instrument, suggesting CMS is interested in 340B prices only; however, 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, which we pointed out to CMS in the comments we submitted in response to its survey proposal. This is another aspect of CMS's survey proposal that is unclear.

[54] CMS 10709, OMB 0938-New, CMS Average Sales Price Survey, Page 1 (emphasis added).

[55] 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. 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).

all 340B hospitals *paid under the OPPS*, suggesting that CAHs would be excluded from the survey.[56] In addition, CMS expects to receive up to 1,384 survey responses, suggesting that CAHs are not expected to respond.[57] However, in its revised instructions CMS has removed the "paid under the OPPS" language regarding the surveys to be disseminated by the contractors and instructs that "[a]ny hospital that was enrolled in the 340B program as a covered entity in the last quarter of 2018 and/or the first quarter of 2019" is required to complete the survey.[58] These statements suggest that CMS expects CAHs to respond to the survey.

V. OMB Should Reject the Proposed Collection Because It Is Contrary to Law

The PRA requires agency information collections to be necessary for the proper performance of the agency's mission.[59] 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 only a subset of hospitals, such as 340B hospitals, or only a subset of drugs, such as 340B drugs.

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."[60] The reference to a large sample of hospitals indicates that the survey must reflect acquisition costs across all hospitals, not just a subset of hospitals such as 340B hospitals.[61] Thus, CMS does not have the authority to survey only 340B hospitals. Under the PRA, CMS cannot move forward with a survey that would violate the Medicare statute.

In addition, CMS says it will use 340B ceiling prices to determine average acquisition costs if hospitals do not respond to the survey or if drug acquisition cost data are unknown.[62] We reiterate that 340B ceiling prices will not identify average acquisition costs as CMS will not have information about hospital purchasing volume needed to accurately calculate an average 340B price. CMS's plan to use 340B ceiling prices also poses a separate violation of 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.[63]

Finally, CMS's plan to use the survey data to devise a remedy for the illegal underpayments made to 340B hospitals in 2018 and 2019 is also contrary to law.[64] The agency may also attempt to use the data to remedy illegal underpayments n 2020. Under the law, CMS may not use survey data to retroactively base payments on acquisition cost.

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CMS's survey will produce meaningless data and will not generate a statistically significant estimate of hospitals' average acquisition costs. In addition to the PRA and Medicare statute violations outlined above, setting Medicare payment at average acquisition cost for 340B hospitals will harm 340B hospitals and their patients and significantly undermine the 340B program, which has been supporting safety-net hospitals for decades. Contrary to CMS's suggestion, the burden of the collection is not minimized, as nearly every task and

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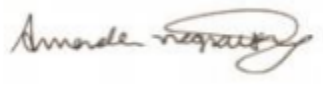
[56] CMS 10709, Supporting Statement Part B, Page 1 (emphasis added).
[57] CMS says that the sample will be 100% of the respondent universe (CMS 10709, OMB 0938-New, CMS Average Sales Price Survey, Page 1). As of October 2019, there were 2,517 hospitals enrolled in the 340B program. Excluding CAHs, the number of 340B hospitals enrolled as of October 2019 was 1,384 hospitals which equals the number of responses that CMS anticipates receiving from hospitals on the survey.
[58] CMS 10709, OMB 0938-New, CMS Average Sales Price Survey, Page 1.
[59] *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).
[60] 42 U.S.C. § 1395l(t)(14)(D)(iii) (emphasis added).
[61] Though CMS may set payment rates that vary by hospital group based on relevant hospital characteristics such as volume of outpatient services, (42 U.S.C. § 1395(t)(14)(A)(iii)(I)), CMS is not permitted to survey the acquisition costs of only one group of hospitals for purposes of setting the payment rates under the OPPS.
[62] CMS 10709, OMB 0938-New, Instructions for Filling Out Survey, Numbers 8b & 9b.
[63] 42 U.S.C. § 1395(l)(t)(14)(A)(iii)(II).
[64] 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).

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. Finally, we note that CMS's survey proposal comes at a time when hospitals must dedicate their full attention to diagnosing, isolating, and treating patients potentially infected with COVID-19. CMS should not divert hospital staff away from patients during this critical time, which is precisely what CMS's survey would do.[65] For these reasons, OMB should reject CMS's rushed and ill-conceived survey proposal.

Sincerely,



Maureen Testoni
President and Chief Executive Officer

Amanda Nagrotsky
Legal Counsel

[65] *See* United States Government Accountability Office, Report to Congressional Committees, Medicare Hospital Pharmaceuticals, Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS, (GAO-06-372), April 2006, *available at*: https://www.gao.gov/assets/250/249967.pdf (hospitals told the GAO that staff were diverted from their normal duties in order to submit the required price data).

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

[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).

hospitals, likely several times the 48 hours and total cost of five million dollars to 340B hospitals that CMS estimates.[29]

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

[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.
[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.

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]

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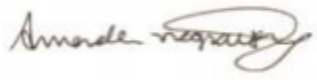
340B Health requests that CMS withdraw its proposal to collect 340B drug acquisition cost data from 340B hospitals. At a minimum, CMS should issue a new proposal with clear and detailed instructions to allow hospitals to provide meaningful comments on CMS's burden estimate. CMS should not move forward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

[37] *See supra* Section III.A.
[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

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March 6, 2020

Submitted via email to: OIRA_submission@omb.eop.gov

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer

Re: Agency Information Collection Activities: Submission for OMB Review; Comment Request (Docket No. CMS-2019-0161; Document Identifier CMS-10709 / OMB Control Number 0938-NEW)

Dear Sir/Madam,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice (Document identifier: CMS-10709) to collect hospitals' cost data for specified covered outpatient drugs (SCODs) acquired under the 340B Drug Pricing Program.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient urges CMS not to move forward with the data collection outlined in the notice for various reasons, including that **the purpose of the data collection is to implement a policy that is beyond CMS's statutory authority**. As CMS is aware, in *American Hospital Association et al v. Azar* (Case number 1:18-cv-2084, December 27, 2018) the District Court concluded CMS does not have the statutory authority to implement the current nearly 30% decrease in Medicare reimbursement for drugs acquired under the 340B Program for calendar year (CY) 2018 (then again extended when CMS imposed these payment reductions for CY 2019). Despite this decision being in opposition to CMS's position, CMS continues to advance notices for data collection[1,2] and policies that would drastically modify the payment rate for medications acquired

[1] *See* 84 Fed. Reg. 189 at 51590-51591
[2] *See* 85 Fed. Reg. 85

under the 340B Program.[3] Like the District Court, and as stated in Vizient's previous comments to CMS, we believe CMS is acting beyond its statutory authority in implementing payment reductions to 340B hospitals, and therefore, the data collection is unlikely to serve its intended purpose.

Further, CMS noted in the CY 2020 Outpatient Prospective Payment System (OPPS) Final Rule that the data collected in the survey could serve multiple purposes, either helping the agency devise a remedy to the issues related to the aforementioned litigation or setting Medicare payment amounts for 340B acquired drugs. However, the survey may also serve no purpose, as CMS also stated in the CY 2020 OPPS rule that the "hospital survey data" may not be used at all in devising a remedy.[4,5,6] To avoid imposing undue burden on 340B hospitals, Vizient recommends CMS refrain from performing the survey because it is unclear if this survey would have purpose given remedies have been proposed by both CMS and other stakeholders that do not require acquisition data.

Vizient also has concerns that this data collection effort, aimed at only a subset of hospitals which are committed to serving their communities and partly rely on the 340B Program to do so, will further undermine hospitals' ability to provide high value, accessible health care in the short and long-term. The data collection effort outlined by CMS demands hospitals report a vast amount of data in a limited amount of time (March 23-April 10). In the short-term, these hospitals will need to **divert already limited resources** to learn the data collection requirements, compile and check the information, and address any issues or reporting scenarios not addressed by CMS. Therefore, hospitals would be harmed, at minimum in the short-term, should this collection advance.

Additional consequences may be far-reaching, however, since this data collection would be used to impose a policy that would, in the longer-term, **harm hospitals serving the most vulnerable patients**. CMS would be using this data to attempt to advance a controversial (and thus far unlawful) payment policy that would severely limit 340B hospitals' long-term capacity to provide care to patients in a manner consistent with the purpose of the 340B Program. Congress did not design the 340B Program to pay hospitals at acquisition cost, which is the stated goal of CMS in this notice. Rather, Congress designed it so that eligible hospitals could purchase covered drugs at discounted rates and use the difference to reach more eligible

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[3] *See* 84 Fed. Reg. 61142

[4] 84 Fed. Reg. Reg. 61142 at 61323, "In the event 340B hospital survey data are not used to devise a remedy, we intend to consider this public input…"

[5] 84 Fed. Reg. 61142 at 61327, "we may use the survey data for 2018 and 2019 that we plan to collect from 340B hospitals to devise a remedy for prior years if the district court's ruling is upheld on appeal. A remedy that relies on such survey data could avoid the remedial complexities discussed above and in the proposed rule. If, however, 340B hospital survey data are not used to devise a remedy in the event of an adverse decision from the Court of Appeals, we intend to consider all of these suggestions in determining the appropriate remedy to propose in the CY 2021 OPPS rulemaking."

[6] 84 Fed. Reg. 61142 at 61324, "Because we hope to prevail on appeal and have our 340B policy upheld, we believe it is appropriate to finalize our proposal of ASP minus 22.5 percent rather than an alternative payment amount of either ASP+3 percent or ASP+6 percent, and to maintain the other payment policies we adopted for 340B-acquired drugs in the CY 2018 and 2019 OPPS final rules with comment period. In the event of an adverse decision on appeal, we solicited public comments on the appropriate remedy for use in the CY 2021 rulemaking."

patients and provide more comprehensive services in their communities. Safety-net hospitals invest their 340B savings in a wide variety of programs and services to meet the unique needs of their communities and help vulnerable patients, at no cost to taxpayers.

Additionally, Vizient believes that this proposal runs **counter to CMS's goal of reducing regulatory burdens** and would result in a significant expenditure of time and resources for hospitals, as noted above. CMS ignores the future implications of court decisions and provides little justification for imposing this burden on hospitals by stating, "in the event the ruling is affirmed, CMS believes that it is important to begin obtaining acquisition costs for specified outpatient drugs to set payment rates based on cost for 340B-acquired drugs…".[7] CMS does not clearly indicate why or how the specific data and processes outlined in the notice, including older acquisition data, would be essential for their future efforts. For these reasons, we ask that CMS not move forward with this data collection.

Conclusion

Vizient appreciates CMS's willingness to accept comments on this important issue, which provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on this important proposed rule. Please feel free to contact Jenna Stern, (202) 354-2673 or jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
Vice President of Public Policy and Government Relations
Vizient, Inc.

[7] 85 Fed. Reg. 26 at 7307

AMERICA'S ESSENTIAL HOSPITALS

March 9, 2020

CMS Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
Washington, DC 20503
Submitted via e-mail: OIRA_submission@omb.eop.gov

Ref: CMS-10709 (OMB control number: 0938–New): Agency Information Collection Activities: Submission for OMB Review; Comment Request

Dear CMS Desk Officer:

America's Essential Hospitals appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS') notice of proposed information collection. We are deeply concerned that the drug acquisition cost survey would impose excessive burden on hospitals participating in the 340B Drug Pricing Program and would raise many operational challenges. It would single out these hospitals—hospitals that already operate on narrower margins than others—with additional reporting requirements on top of the existing, resource-intensive obligations they adhere to under the 340B program. Moreover, CMS' notice, which is being reviewed by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA), does not meet PRA requirements on accurate burden estimates, reliability and clarity of data produced by the information collection, and the utility of requested data.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins one-fifth that of other hospitals—1.6 percent on average compared with 7.8 percent for all hospitals nationwide.[1] Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of

[1] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey*. America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed February 28 , 2020.

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their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.[2] Essential hospitals are uniquely situated to address these social determinants of health and are committed to serving these vulnerable patients. These circumstances, however, compound essential hospitals' challenges and strain their resources, necessitating flexibility to ensure they are not unfairly disadvantaged for serving the nation's most vulnerable patients and can continue to provide vital services in their communities.

By enacting the 340B program, Congress intended to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Put simply, Congress wrote the law specifically to allow qualifying hospitals to retain the 340B savings so they could serve their vulnerable communities. Savings from the 340B program are indispensable to hospitals operating on narrow margins. As the Department of Health and Human Services (HHS) works to slow the rising cost of prescription drugs, we urge the agency to keep in mind the needs of the nation's vulnerable patients and the hospitals that serve them.

CMS' inequitable and unlawful policy to reduce Part B drug payments to hospitals with the most vulnerable patients already has severely impacted essential hospitals since it was implemented in 2018. It undermines these providers' ability to offer heavily discounted drugs to patients in the face of rapidly increasing drug prices. A continuation of payment rates below 106 percent of average sales price (ASP)—whether tied to acquisition cost or to 77.5 percent of ASP—will be devastating to hospitals with the lowest margins as they work to care for vulnerable and medically complex patients. CMS must immediately withdraw its unlawful Part B payment cut, make hospitals whole for the cuts that have taken place since 2018, and revert to the full 106 percent of ASP payment rate.

In previous comments to the agency on CMS' first notice on the proposed information collection request (ICR), America's Essential Hospitals expressed concern that CMS had not considered the administrative burden of the proposed ICR or its authority to collect this information in the proposed manner.[4] It is clear from the revised documentation provided by the agency that it still has not fully evaluated both its authority to conduct this survey and the true scope of the operational complexity associated with this request. Therefore, we urge CMS to withdraw its proposed ICR.

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[2] Ibid.

[3] H.R. Rep. No. 102-384, pt. 2 (1992).

[4] America's Essential Hospitals comment letter to William Parham III. November 27, 2019. https://essentialhospitals.org/wp-content/uploads/2019/12/AEH-340B-acquisition-cost-survey-letter-11-27-19.pdf.

1. **CMS' proposed data collection exceeds its authority under the Medicare statute.**

CMS' proposed collection of drug acquisition costs—through a survey to be completed only by 340B hospitals—violates the Medicare statute's prescribed methodology for collecting acquisition costs for specified covered outpatient drugs (SCODs). In the notice, CMS states it will collect acquisition cost through a "hospital survey for SCODs." The agency's survey will be completed exclusively by 340B hospitals; hospitals not in the 340B program will not be required to report their acquisition costs. The selective collection of drug acquisition costs based on an arbitrarily selected hospital characteristic (in this case, participation in the 340B program) conflicts with the acquisition cost collection methodology that Congress outlined for CMS in the Medicare statute.

The provision of the Social Security Act that authorizes CMS to collect drug acquisition costs, section 1833(t)(14)(D), first required that the comptroller general of the Government Accountability Office (GAO) conduct a hospital acquisition cost survey in 2004 and 2005 to determine the hospital acquisition cost for each SCOD. Then, CMS is to "conduct periodic subsequent surveys to determine the hospital acquisition cost for each [SCOD] for use in setting the payment rates under subparagraph (A)." The survey requirement is for the collection of hospital acquisition costs of each SCOD—there is no reference to only 340B drugs or 340B hospitals. More significantly, the Medicare statute has specific requirements about the scope of the survey, requiring that the surveys be conducted using a "large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each [SCOD]." Hospitals in the 340B program account for only a portion of all Outpatient Prospective Payment System (OPPS) hospitals. CMS estimates that 1,338 hospitals would fill out the survey, which is only about one-third of the more than 3,600 hospitals paid under the OPPS. CMS claims in supporting statement B that it does not need to conduct sampling because it is surveying 100 percent of the "respondent population." However, CMS is arbitrarily limiting the respondent population to one group of hospitals; surveying only this group of hospitals will not produce a reliable measure of average acquisition costs for SCODs across all hospitals.

It is worth noting that hospitals not participating in the 340B program can benefit from additional discounts that allow them to purchase drugs at prices significantly below the list price. For CMS to gather data on and pay hospitals based on acquisition cost, it must collect information for all hospitals to capture the different types of discounts that can affect acquisition cost, which it does not propose to do in this ICR.

Because the survey only focuses on one type of hospital, it does not satisfy statutory sampling requirements and, ultimately, would not accurately capture average acquisition costs of all OPPS hospitals. **Therefore, CMS should withdraw its proposed information collection, which exceeds its statutory authority because it is contrary to the Medicare statute.**

2. CMS' information collection would be burdensome for hospitals and involve time and resources far exceeding CMS' estimates.

CMS' acquisition cost survey would be administratively burdensome for hospitals and for the agency and would require resources far exceeding the estimate provided by the agency. The survey is operationally complex, is bound to increase regulatory burden, and will strain hospital systems and staff resources. **We urge CMS to consider the administrative burden its proposed information collection would impose on essential hospitals.**

As part of PRA requirements, CMS estimates that the survey would take 48 hours for the average hospital to complete. CMS further notes that it has "taken steps to mitigate the burden of the survey" and that producing the required information would not be burdensome because 340B participation requires that hospitals maintain records to "ensure that such acquired drugs are used for eligible patients."[5] However, records required for 340B compliance and audits do not require hospitals to collect 340B acquisition cost data. In fact, hospitals do not have 340B drug acquisition costs readily available in their systems. The time required to extract this information, calculate average acquisition costs, and produce the data in the format CMS requires, would be substantially more than the 48 hours CMS estimates. Hospitals have noted that these burdensome requests would necessitate the diversion of existing staff from their regular duties or the hiring of additional staff.

As America's Essential Hospitals outlined in detail in its November 27 comments, CMS failed to consider the following aspects of the burden associated with the ICR:

- Hospitals do not readily have acquisition cost data available and will have to obtain it from a third party, such as their drug wholesaler. Wholesaler data are confidential and proprietary and these entities might require permission to release the data;
- Acquisition cost data downloaded from wholesalers is listed by national drug code (NDC) and will require significant manual matching and calculation to the Healthcare Common Procedure Coding System (HCPCS) code, which is the format CMS is requiring hospitals to report the data; and
- For certain drugs not acquired through the primary wholesaler, hospitals will have to request acquisition cost data from other distributors on a drug-by-drug basis.

Notwithstanding all these factors that America's Essential Hospitals and other commenters have raised, CMS has maintained the 48 hour per entity estimate from the first version of the notice issued last September. CMS has provided a few points of clarification, but these do not mitigate the burden on hospitals and their staff. For

[5] Centers for Medicare & Medicaid Services. Supporting Statement—Part A. Hospital Survey for Specified Covered Outpatient Drugs (SCODs). CMS-10709; OMB 0938-New.

example, CMS provides a list of NDC to HCPCS crosswalks that hospitals can use to convert drug acquisition cost based on HCPCS units. However, hospitals will still have to get the data from a third party, crosswalk the codes, calculate acquisition costs at the HCPCS level, and verify the data and their calculations for accuracy prior to submission to CMS.

These examples of the burden associated with producing acquisition data underscore the lack of research and preparation by CMS in creating the acquisition cost survey. To our knowledge, CMS has not worked with any stakeholders to gauge the true costs and burden involved in providing acquisition cost data. GAO, which was tasked with surveying hospitals for their acquisition costs in 2004 and 2005, highlighted the many obstacles to producing accurate acquisition cost data. It noted that surveying hospitals on acquisition cost data "created a considerable burden for hospitals as the data supplier and considerable costs for GAO as the data collector."[6] In its response to that report, HHS concurred with GAO, expressing reservations about surveying hospitals due to the burden placed on hospitals and their staff.

Under the PRA, the agency must certify that its information collections minimize burden on the individuals or entities responding to the ICR.[7] In the case of this ICR, it is clear that the agency has underestimated the associated burden and not taken sufficient steps to reduce the burden on providers. Concerns about burden are particularly pronounced for essential hospitals. There are significant administrative costs and compliance-related resources involved with 340B program participation, including the cost of hiring the appropriate staff, such as pharmacists and pharmacy technicians, to ensure compliance with the program's very technical and evolving requirements. In addition, 340B hospitals must invest in appropriate billing software and allocate resources to comply with the program and respond to audits. These costs are borne by the hospitals that already provide higher levels of uncompensated care compared with the average hospital, have margins significantly narrower than the average hospital, and treat a larger proportion of medically complex patients, such as those dually eligible for Medicare and Medicaid. **CMS should not implement a proposal of this magnitude without fully considering the impact it will have on 340B hospitals and the complexities associated with producing acquisition cost data.**

3. CMS' proposed survey instrument lacks clarity and the agency has not ensured it will produce data of appropriate quality as required by the PRA.

In the notice, CMS seeks comments on the quality, utility, and clarity of the data that will be collected through the survey. CMS has not taken appropriate steps to ensure the data produced by the survey will be of sufficient quality and clarity for the purposes of

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[6] Government Accountability Office. Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS. April 2006. https://www.gao.gov/assets/250/249967.pdf.
[7] 44 U.S.C. § 3506.

the PRA. **CMS intends to use the information collected for Medicare payment purposes, so any data that is reported from the survey must be accurate and reliable.**

First, the data that CMS intends to collect are complex and voluminous. As we explain in the previous section, producing the data in the format CMS requires is not a quick or easy undertaking. However, CMS provides a mere 18 days—from March 23 through April 10—for hospitals to collect and report this data. Assuming that CMS' ICR is approved by OMB and published before then, hospitals will have to access the survey and train their staff on its implementation. If the hospitals can complete the survey in the short timeframe provided, CMS also must validate the data and ensure that reported data are consistent and accurate. Doing so will be a timely undertaking, and the agency has not indicated if it will have such a validation process in place.

Second, there is a significant likelihood for variation in the data reported by hospitals due to unclear instructions. For example, it is unclear how hospitals are to report data when there is variation in average drug acquisition costs across NDCs associated with a particular HCPCS code. Each HCPCS billing unit corresponds to a specified unit of measure and amount for a given drug, which usually differs from the package size and dosage corresponding to an NDC for the same drug. There often are multiple NDCs that match a given HCPCS code, but the drug can be available from different manufacturers and with different units of measurement or package sizes. Average costs per unit of a drug can vary based on the NDC code, so if multiple NDCs correlate to a given HCPCS code, it is unclear if hospitals are to list each average acquisition cost for each separate NDC or only list the drug once with acquisition cost at the HCPCS code level. CMS is requesting the average acquisition cost for an HCPCS code but provides hospitals the option of listing out each NDC associated with the HCPCS code. Because of this option, there will be variability in how hospitals report this information, as well as in the average costs reported by hospitals.

Finally, there is inconsistency across the notice, the proposed survey, and the supporting documentation about the group of hospitals responding to the survey. CMS states in the notice and supporting statement Part A that the number of respondents will be 1,338 hospitals. In supporting statement B, however, CMS states that the number of respondents will be 1,384 hospitals. Further, CMS revised supporting statement B to remove language limiting the survey to OPPS hospitals that participate in the 340B program. It appears from this change that CMS is intending for all 340B hospitals—and not just 340B hospitals paid under the OPPS—to complete the survey. If this is the case, the survey would include hospitals such as critical access hospitals, which are not paid under the OPPS. Yet, CMS' estimates of the number of respondents are inaccurate in that they do not account for non-OPPS 340B hospitals. The discrepancies in the estimated number of respondents, as well as the lack of clarity on which hospitals are meant to complete the survey, could result in either too many or too few hospitals responding to the survey. This would seriously undermine the clarity and utility of the data CMS collects. For these reasons, the ICR, as proposed by CMS, will not produce

clear, high-quality data that will be reliable for use in determining Part B drug reimbursement rates.

4. **CMS' proposed ICR is not necessary for the proper performance of the agency's functions, as the agency has an established statutory default payment rate of 106 percent of ASP at which it can reimburse hospitals.**

The collection of acquisition cost data for a subset of OPPS hospitals is not only unlawful but also unnecessary to the performance of CMS' functions. The PRA states that ICRs must have practical utility and be necessary for the proper performance of the agency's functions. CMS has an established, statutorily-set payment rate that it has used since 2013—payment at 106 percent of ASP. The U.S. District Court for the District of Columbia has unequivocally held that CMS' payment cuts, which use an alternative payment rate of 77.5 percent of ASP, violate the Medicare statute. **Therefore, CMS should reverse its unlawful payment cuts to 340B hospitals and revert to the statutory default payment rate of 106 percent of ASP.**

The 340B program is critical to ensuring low-income and other disadvantaged people can access the types of services best provided by essential hospitals. Reductions in Medicare payment rates to 340B hospitals significantly erode the value of the program. These policies are most damaging to essential hospitals, given their high levels of uncompensated care, narrow margins, and large proportion of patients with Medicare and Medicaid coverage. Due to these cuts, hospitals have had to reconsider programs made possible by 340B savings. As a result of policies that significantly gut the program's benefit on top of these added expenses, some hospitals might have to pull back on the services they offer to patients or make staffing cuts.

CMS suggests it could use 340B hospital acquisition cost data to determine Medicare reimbursement rates for Part B drugs. Any cuts, whether through a reduction in the ASP payment rate or by tying payment to acquisition cost, are devastating to 340B hospitals and their patients. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the patchwork support on which they rely, including the 340B program, can threaten their ability to maintain critical services. Therefore, we strongly advise CMS against reducing payments by tying them to acquisition costs.

Payment reductions to 340B hospitals have negative consequences for essential hospitals and their patients; therefore, **we urge the agency to revert to paying 340B hospitals at 106 percent of ASP.** Preserving the intent of the 340B program will better serve low-income Medicare beneficiaries and the Medicare program at large.

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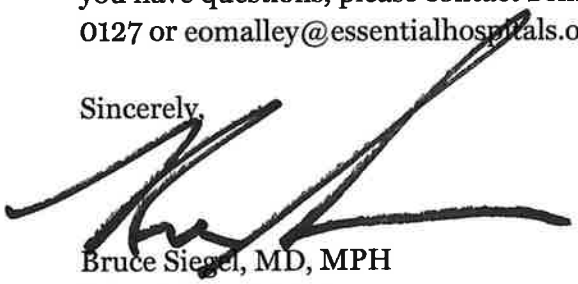
America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,



Bruce Siegel, MD, MPH
President and CEO

March 4, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Cook County Health (CCH) appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

CCH is one of the largest public hospital systems in the nation, serving the residents of the second most populous county in the United States. For over 180 years, CCH has provided care to all Cook County residents regardless of their ability to pay, insurance status, or immigration status. Clinical services are delivered through CCH's integrated delivery system, which includes our hospitals, regional outpatient centers, and community-based health centers located throughout Cook County, as well as the CORE Center, the busiest comprehensive HIV provider in the Midwest.

[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.

CCH is the largest provider of care to uninsured and underinsured individuals in Illinois, providing $500M in uncompensated care each year, more than half the total among all hospitals in Cook County. In FY2018, 35% of CCH patients were covered by Medicaid, and another 43% were uninsured. As a result of our experience serving low-income patients, CCH is uniquely positioned to understand why this proposed survey would be harmful to our health system and our patients.

I. Payment at Acquisition Cost Would Harm 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]

In Cook County, these numbers are even more extreme. The two hospitals operated by CCH provide over $500 million in uncompensated care each year, more than the other 66 hospitals in Cook County combined. Part of the way CCH is able to provide this care is through the savings realized through the 340B program. The savings realized from this program allow us to not only provide much needed pharmaceuticals, but also frees up our limited resources to provide additional healthcare services for our uninsured and low-income patients. Savings from 340B allow CCH to operate regional outpatient clinics to promote preventative care and to invest in improving the social determinants of health for residents, measures which improve population health and reduce overall Medicare and Medicaid spending.

Reducing Medicare payments 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. Any efforts to reduce or scale back the 340B program would significantly impact our ability to continue to serve the most vulnerable patients in Cook County, to the detriment of our patients and the general public.

II. The Survey Places a Massive Burden on 340B Hospitals

CCH operates one of the busiest healthcare system pharmacies in the country and is responsible for filling thousands of prescriptions each day. The calculations required from CCH are a substantial burden on our ability to operate our pharmacy department efficiently.

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 Healthcare Common

[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

Procedure Coding System (HCPCS) dosage units, requiring hospitals to convert a significant number of the 1,100 National Drug Code (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.

III. 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 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]

IV. The Survey Will Collect Unusable Data

The 340B statute prohibits CCH's hospital from obtaining covered outpatient drugs through a group purchasing organization (GPO) or group purchasing arrangement (GPA), 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.

For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals. Thank you for the opportunity to comment.

Sincerely,

Debra D. Carey

Debra D. Carey
Interim CEO
Cook County Health

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

SSMHealth

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phone: 314-994-7800
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March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

SSM Health, headquartered in St. Louis, Missouri, appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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.

For background SSM Health is the sixth largest Catholic health system in the United States. Our organization's nearly 40,000 employees and 11,000 providers are committed to providing exceptional health care services and revealing God's healing presence to everyone they serve. With care delivery sites in Illinois, Missouri, Oklahoma and Wisconsin, SSM Health is one of the largest employers in every community it serves.

SSM Health currently has 23 hospitals, 11 of which are 340B covered entities and would be subject to this ICR. Of the patients treated at our 340B hospitals nearly 27 percent are uninsured, underinsured, or have Medicaid.

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. Savings from SSM Health's 340B program help us offset the costs of uncompensated care, which totaled $179 million in 2018 alone at our 340B hospitals.

For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Paying at Acquisition Cost Would Harm 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. Through the savings generated by the 340B program we can provide various programs to our low income and vulnerable patients. Two examples include:

Pharmacy Concierge Service
SSM Health employs 16 pharmacy concierge representatives across many of our provider offices with the primary responsibility of helping patients access the medication that has been prescribed by their provider. Many times, through this work patients can obtain lifesaving medication at reasonable or little cost. In 2018, this program helped 3,664 patients in need receive $9.1 million in prescription drugs.

Long Acting Injectable Clinic
With savings generated from the 340B program SSM Health has opened a clinic in the St. Louis region and plans to open another clinic this year to help behavioral health patients access critical life changing medicines and treatments.

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

II. The Survey Places a Significant Burden on 340B Hospitals

SSM Health currently has 11 340B hospitals and no easy or tested way to collect the information that CMS is seeking. This would take substantial resources and time to complete.

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. This would need to be done for each hospital or 11 separate times for SSM Health.

Engaging in extensive mathematical calculations and requiring analysis of tens of thousands of units of data not only is very difficult but also leads to the possibility of inaccurate data being collected.

Adding to the burden, CMS has shortened the survey response period, from one month to 18 days.

III. **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 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

IV. **The Survey Will Collect Unusable Data**

Many of our 340B hospitals are by statue prohibited from obtaining drugs through a group purchasing arrangement, this is known as the GPO prohibition. This requires us to purchase drugs many times at wholesale acquisition cost (WAC) that are significantly higher than 340B prices. CMS does not include WAC purchases in the calculations of average acquisition cost which prevents the data from accurately reflecting the cost of drugs billed to Medicare.

For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

SSM Health

UNC HOSPITALS

101 MANNING DRIVE
CHAPEL HILL, NC 27514 www.unchealthcare.org

March 6, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

UNC Hospitals appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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.

II. The Survey Places a Massive Burden on 340B Hospitals

[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.
[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

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.

III. 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 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]

IV. 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

UNC Hospitals

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

GREATER NEW YORK HOSPITAL ASSOCIATION
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March
Nine
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Office of Management and Budget (OMB)
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer
Document Identifier: CMS—10709
OMB Control Number: OMB 0938-New

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020

On behalf of the 145 acute care member hospitals in the Greater New York Hospital Association (GNYHA), I am writing to comment on the Centers for Medicare & Medicaid Services (CMS) notice that it intends to collect the acquisition cost for specified covered outpatient drugs from hospitals that participate in the 340B Drug Pricing Program.

GNYHA previously commented on the CMS survey, expressing great concern about how CMS intends to use the collected information—i.e., to reduce Medicare payment for 340B drugs. This concern remains paramount, and we again urge the agency to rescind the proposed survey.

Protecting the 340B Program

The 340B program's savings enable eligible safety net hospitals to provide important community benefits to some of the nation's most vulnerable patients through various programs and services. If CMS uses the survey information to cut payments to hospitals for 340B-acquired drugs, it would substantially reduce or eliminate 340B savings, which is counter to the program's intent "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," and would ultimately jeopardize access to care. Such a policy also fails to recognize the additional costs incurred by 340B participants to ensure program compliance.

Other Concerns

In addition to our primary concern that CMS would use the information collected in the proposed survey to further erode the 340B program, we are concerned about the survey itself, including CMS's lack of authority to survey 340B hospitals in the manner proposed, increased administrative burden on hospitals, and confidentiality issues.

Lack of Statutory Authority

In setting reimbursement rates for outpatient drugs, the Secretary of the Department of Health and Human Services can only use the average acquisition costs acquired through survey data if the survey has "…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."[1] CMS's proposal to limit the universe of survey respondents to a select group of hospitals—i.e., 340B hospitals—with an unknown response rate would not meet the statutory requirements to ensure a statistically valid sample. Furthermore, the Secretary is not authorized to limit the survey to a subset of hospitals because CMS is required to collect the "hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates…"[2] For these reasons, the Secretary is not authorized to conduct the survey as proposed.

Administrative Burden and Duplicative Information Requests

The survey would impose undue administrative burden on hospitals. Based on discussions with our member hospitals, the required resources to comply with the proposed survey are significantly greater than CMS's estimate and could vary considerably by hospital depending on system configurations and staff resources. The Government Accountability Office shared our concerns in its report to Congress on its 2004 hospital survey of drug acquisition costs, stating that "[the survey] created a considerable burden for hospitals as data suppliers… [requiring hospitals] to divert staff from their normal duties, thereby incurring additional costs."[3]

CMS also proposes to require hospitals to report information already available to CMS. Specifically, the survey requires that hospitals enter Medicare payment rates for each Healthcare Common Procedure Coding System code. This information is already available to the agency and will only increase the risk of errors and inconsistent reporting, which could result in faulty conclusions by CMS.

Challenges in Sharing Drug Acquisition Costs

Most hospitals purchase their 340B drugs through wholesaler arrangements and would need to access proprietary drug prices from their wholesalers to complete the survey. Each hospital would need to disclose the variable discount (depending on volume and payment terms) on its 340B-purchased drugs to provide net prices. These wholesaler purchasing arrangements are contractual agreements with strict non-disclosure clauses, and hospitals could violate the terms of their agreements by disclosing these discounts. Depending on the individual contract, it may be difficult or impossible for a hospital to share net prices with an entity that is not party to the contract, especially within the compressed response timeframe proposed by CMS.

Thank you for the opportunity to comment. Please contact Rebecca Ryan (rryan@gnyha.org) with any questions.

Sincerely,

[1] 42 U.S.C. Section 1395l(t)(14)(D)(iii).
[2] 42 U.S.C. Section 1395l(t)(14)(C)(ii).
[3] GAO report number GAO-06-372, "Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS," (April 28, 2006). https://www.gao.gov/assets/250/249968.html.

Elisabeth Wynn
Executive Vice President
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March 9, 2020

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Submitted electronically to OIRA_submission@omb.eop.gov
Attention: CMS Desk Officer

Re: Hospital Survey for Specified Covered Outpatient Drugs (Form Number: CMS-10709 / OMB Control Number: 0938-New)

Dear Mr. Ray,

The Children's Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed hospital survey for specified covered outpatient drugs. CHA represents over 220 children's hospitals across the country, and our mission is to advance child health through innovation in the quality, cost, and delivery of care with our children's hospitals.

We had previously submitted comments[1] to CMS regarding the proposed hospital survey, and while we appreciate CMS adopting some of the recommendations we suggested, we wish to reiterate our position that children's hospitals should be exempt from the proposed hospital survey. We believe the inclusion of children's hospitals is neither necessary nor useful to the purpose of the proposed hospital survey and urge the Office of Management and Budget (OMB) to exclude children's hospitals from the proposed hospital survey.

Children's hospitals should be excluded from the proposed hospital survey

According to the information collection request, the proposed hospital survey is in response to the ruling in *American Hospital Ass'n v. Azar*. In *Azar*, the Court ruled that the Secretary of the Department of Health & Human Services exceeded his statutory authority when he reduced the payment rates under the Medicare Outpatient Prospective Payment System (OPPS) for 340B-acquired drugs from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. While CMS disagrees with the ruling and has appealed, it is collecting acquisition costs for 340B-acquired drugs in the event the ruling is affirmed.

[1] https://www.childrenshospitals.org/-/media/Files/CHA/Main/Issues_and_Advocacy/Key_Issues/Pharmaceutical_Access/Letters_and_Testimony/2019/hospital_survey_340b_drugs_comments_120219.pdf

We do not believe that children's hospitals should be included in the proposed hospital survey. First, children's hospitals are excepted from the OPPS reimbursement adjustment. The CY 2018 OPPS final rule, which was the subject of the litigation, and all subsequent OPPS final rules have all excepted children's hospitals from the payment adjustments. Furthermore, children's hospitals provide care to only a small number of Medicare beneficiaries as only children with end-stage renal disease would potentially have their care covered by Medicare. Since the stated purpose of the proposed hospital survey is to help determine the Medicare payment adjustment, children's hospitals – which are excepted from the payment adjustment and do not provide care to a significant number of Medicare beneficiaries – should be excluded from the proposed survey.

Second, the information collected from children's hospitals would not improve the information collection request, but would significantly increase our administrative burden. Children's hospitals represent a tiny portion of 340B hospitals – currently there are just over 50 children's hospitals, out of nearly 2,400 hospitals, that are participating in the 340B Program[2]. In order to complete the proposed hospital survey, children's hospitals must cross-reference Medicare resources, which may not be as familiar to our members as children's hospitals provide care to only a limited number of Medicare beneficiaries. The marginal utility of additional data from a small number of children's hospitals is far outweighed by the administrative burden the proposed hospital survey imposes. The proposed hospital survey must be appropriately tailored to achieve its purpose and we believe that including children's hospitals would unnecessarily increase the burden on children's hospitals without furthering the agency's stated purpose.

If children's hospitals must complete the survey, the proposed hospital survey should be revised to reduce administrative burden

As stated above, we believe children's hospitals should be excluded from the proposed hospital survey. However, if children's hospitals must complete the survey, the proposed hospital survey must be modified to reduce administrative burden. While we appreciate CMS heeding our suggestion and eliminating the proposal to collect information according to provider-based departments, additional revisions must be made to eliminate unnecessary burden. Since the purpose of the proposed hospital survey is to collect the prices of 340B-acquired drugs, we suggest the following changes to ensure that the proposed survey minimizes the burden on hospitals:

- The column titled "HCPCS code for each SCOD" should be deleted. The request for HCPCS codes should be eliminated because the average price of 340B-acquired drugs is not related to the HCPCS code. While our hospitals can collect the average 340B drug price from their vendors, the information from vendors may not always include the HCPCS codes. This request will require children's hospitals to devote significant time and resource to cross-reference the necessary information without contributing to CMS' stated purpose.

[2] U.S. Government Accountability Office, Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program, https://www.gao.gov/assets/700/692886.pdf.

- The columns titled "Q4 2018 Payment Rate (Obtain from OPPS Addendum B for Q4 2018)" and "Q1 2019 Payment Rate (Obtain from OPPS Addendum B for Q1 2019)" should be deleted. As described earlier, children's hospitals provide care to only a small number of Medicare patients and our members do not have the same level of familiarity with the OPPS payment rates as other hospitals. To complete the information requested in these columns will require significant time and resource to cross-reference the necessary Medicare material that children's hospitals do not commonly use. Since this information is already available to CMS, the utility and necessity of this information are minimal, if not duplicative.

- The required additional calculations should be eliminated or simplified. According to the draft instructions, the proposed hospital survey would require hospitals to conduct additional calculations to derive the 340B acquisition price of a drug if the package size purchased by the hospital does not match the unit size in the HCPCS code descriptor. (For example, if a hospital purchased a drug in a package of ten 350 mg vials, but the HCPCS code descriptor referred to the drug in 1 mg doses, the hospital would be required to convert the acquisition cost from the price of the package to 1 mg). This required calculation is complex, cumbersome, and may cause confusion, inadvertent errors, and inconsistent reporting. The proposed hospital survey should be revised to eliminate or simplify the calculations to reduce administrative burden and ensure accuracy.

* * * * *

We appreciate the opportunity to provide comments. We look forward to our continuing work with OMB to advance the needs of children. If you have questions or need additional information, please contact Steven Chen at steven.chen@childrenshospitals.org.

Sincerely,

M. Jim Kaufman, PhD
Vice President, Public Policy

Virginia Mason Memorial

March 4, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Virginia Mason Memorial appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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.

II. The Survey Places a Massive Burden on 340B Hospitals

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[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.
[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

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.

III. 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 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]

IV. 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Carole Peet
President, CEO
Virginia Mason Memorial

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

SELF REGIONAL HEALTHCARE

March 6, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Self Regional Healthcare, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Self Regional averages an annual savings of $6.4 million as a direct result of the 340B drug discount program. These savings have a direct impact on our ability to provide vital healthcare services to our 250,000 person, seven-county service area, and particularly has an impact on our ability to serve our most vulnerable citizens through charity care and community outreach grants. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

James A. Pfeiffer
President and CEO

Memorial Healthcare

03/09/2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Memorial Healthcare we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. In our own community, we have been able to use the 340B savings to: expand and enhance our services offered at our facility that we would have been unable to do without the 340B savings, provide financial assistance to patients unable to pay their medical bills, amongst several other initiatives 340B has given us the ability to do. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Jorri Tremain
Director, Revenue Cycle
Memorial Healthcare

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Avera St. Anthony's Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Todd Consbruck
President & CEO

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf Osceola Community Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Ben Davis
Hospital Administrator

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Avera St. Benedict Health Center, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Rita Blasius
President & CEO

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Avera Pipestone County Medical Center, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Bradley Burris
Hospital Administrator

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Platte Health Center Avera, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Mark Burket
Administrator

March 13, 2020

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Mercy Health Saint Mary's hospital appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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. Furthermore, the provider hospital is subject to the full risk of documentation and billing that satisfies CMS requirements, any failures result in CMS recovery of all billed amounts and for each of those cases where reimbursement is only at acquisition cost result in a full loss for each case that is not covered by the larger book of business with CMS. This is totally unacceptable and would cause many hospitals to seriously consider closing our infusion centers to avoid the unacceptable business risks.

II. The Survey Places a Massive Burden on 340B Hospitals

[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.
[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

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.

III. 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 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]

IV. 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Terry Kirkpatrick, MS, RPh
Director of Pharmacy Services
Mercy Health Saint Mary's
200 Jefferson Avenue SE
Grand Rapids, MI 49503

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf Avera Merrill Pioneer Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Craig Hohn
Hospital Administrator

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Avera Landmann Jungman Memorial Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Melissa Gale
Hospital Administrator

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf Sioux Center Health, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Cory Nelson
Hospital Administrator

Mackinac Straits
HEALTH SYSTEM
Partnering with MUNSON HEALTHCARE

March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Mackinac Straits Health System, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. In our own community, we have been able to use the 340B savings to implement prescription delivery services in our rural setting, absent public transportation. Additionally, we have been able to staff our pharmacy 7 days per week, including holidays. Previously, this was not been available in our community dating back approximately twenty years. Our patients would have to travel thirty to fifty miles if we were not available. Lastly, this program supports our oncology program, which is a critical service for the Eastern Upper Peninsula of Michigan. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

Karen Cheeseman
Chief Executive Officer

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

St. Luke's Regional Medical Center, Ltd. appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] Our hospital is eligible to participate in the 340B program by virtue of the high volume of Medicaid and low income Medicare patients we serve. In keeping with our not-for-profit mission, our hospital maintains an open-door policy, which means we care for all patients, regardless of their ability to pay. The discounts we receive from drug manufacturers by participating in the 340B program are vitally important for ensuring that valuable healthcare services and prescriptions are provided to the uninsured, underinsured, and other vulnerable populations we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

- **Payment at Acquisition Cost Would Harm Safety-Net Hospitals and Their Patients**

We strongly oppose CMS's proposal to set Medicare payment for 340B drugs at acquisition cost because 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.[2] 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. 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.

[1] 85 Fed. Reg. 7306 (Feb. 7, 2020).
[2] 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

- **The Survey Places a Massive Burden on 340B Hospitals**

Our hospital has significant concerns regarding the amount of time it would take to respond to the survey. 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.[3] 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. This would put a strain on hospitals' limited resources and would be unattainable to complete in the allotted 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 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.[4]

- **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.[5] 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Respectfully,

St. Luke's Regional Medical Center, Ltd

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[3] *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.

[4] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[5] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

March 29, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

Southcoast Health appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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.

II. 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

[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.
[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

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.

III. 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 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]

IV. 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 appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Southcoast Health
101 Page St
New Bedford, MA 02740

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

carle.org | 611 W. Park Street, Urbana, IL 61801 | (217) 383-3311

Carle

March 6, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services, HHS
Office of Management and Budget
Office of Information and Regulatory Affairs
ATTN: CMS Desk Officer

RE: Form CMS-10709 (OMB Control Number: 0938-New) Request for Comment on Hospital Survey for Specified Covered Outpatient Drugs

VIA EMAIL: OIRA_submission@omb.eop.gov

Dear Ms. Verma:

The Carle Foundation Hospital, Carle Hoopeston Regional Health Center, and Carle Richland Memorial Hospital (collectively, "Carle") thanks CMS for the additional opportunity to provide comments on CMS's Hospital Survey for Specified Covered Outpatient Drugs ("SCODs"). Specifically, CMS seeks comments on the collection of information related to hospital 340B drug acquisition cost data in response to a United States District Court ruling that the Secretary of the Department of Health & Human Services ("HHS") exceeded its statutory authority to adjust payment rates under the Hospital Outpatient Prospective Payment System ("OPPS") for separately payable, 340B-acquired drugs. Although HHS appealed that ruling, CMS moved forward with its plan to obtain acquisition costs for the SCODs to set payment rates based on cost for 340B acquired drugs furnished to certain eligible Covered Entity hospitals. With that in mind, Carle is concerned that the survey submission window (March 23rd, 2020 to April 10th, 2020) is set to occur with only 13 days for review and consideration of comments submitted by Carle and other Covered Entities. Carle respectfully requests that CMS fully consider and thoughtfully incorporate the comments provided into the finalized Hospital Survey for SCODs. After reviewing the updated survey, Carle is appreciative of the removal of the section requiring Covered Entities to provide a listing of all provider-based departments participating in the 340B program that are paid under the OPPS from the finalized survey, as the requirement was unnecessary for the accurate collection of acquisition cost data. Notwithstanding, Carle still believes that the collection of acquisition cost data from all hospitals that purchased SCODs in Quarter 4 of 2018 and Quarter 1 of 2019 will (1) unreasonably burden 340B Covered Entities, particularly large health systems such as Carle, (2) provide inaccurate information regarding actual 340B costs for some medications; and (3) lead to CMS policy decisions that continue to undermine the statutory intent of the 340B Program.

1. **The Proposed Survey Will Unreasonably Burden 340B Covered Entities, Particularly Large Health Care Systems Such as Carle**

CMS's survey is unnecessarily broad in scope and unduly burdens 340B Covered Entities, particularly health systems such as Carle, that have several 340B-eligible hospitals.

Based on CMS's updated survey, it is clear that CMS intends to retrieve acquisition cost data from all participating 340B Covered Entities. CMS still provides no rationale for a scope of this magnitude. Moreover, there is no explanation as to why a smaller, statistically valid sample size would be insufficient to reflect accurate drug costs for the two quarters at issue. Because actual acquisition costs for 340B medications are largely consistent across different 340B Covered Entities per statutory pricing requirements, participation by all Covered Entities is unnecessary for collecting the desired information and is overly burdensome for all parties involved, including CMS itself. In addition, requesting acquisition cost data for SCODs with the intent to adjust pricing for these drugs is grossly inappropriate as the sole intent of the 340B Program is to allow safety net hospitals to utilize those drug cost savings to better serve indigent and vulnerable patient populations. Adjusting 340B drug prices would effectively render the 340B Program null and void, with the neediest of our patient population paying the price.

Furthermore, CMS still does not provide a rationale as to why 340B Covered Entities are the appropriate party to provide the cost information it seeks. 340B Covered Entities and other healthcare providers have the primary responsibility of providing care to patient populations and have minimal role in determining drug prices. Rather, it is pharmaceutical companies, pharmacy benefit managers, and payers that are the primary drivers and determiners of how drugs are priced. In this regard, requesting a downstream party to provide price information is nonsensical, inefficient, and further burdens healthcare providers—both in terms of time and in costs—who should be devoting their resources to patient care. Carle vehemently believes that the request for 340B drug cost survey and its purpose is gravely against the intent of the 340B Program itself (as detailed below). Because CMS has decided to move forward with the survey, Carle still strongly urges CMS to request this information from a primary source of drug pricing – i.e. pharmaceutical companies.

Aside from the scope of the survey, the request for information itself is unduly burdensome for 340B Covered Entities. CMS's estimate of 48 FTE-based hours per Covered Entity needed to collect the requested pricing information is not supported by evidence and likely does not accurately reflect the time some hospitals will need to produce the data. For example, hospitals with larger and more comprehensive 340B programs typically have numerous 340B purchasing accounts with various wholesalers/manufacturers, with data housed on different software systems. Furthermore, in instances where health providers must engage third parties to assist with the data collection due to lack of internal resources, this will result in significant additional costs for providers for a task that is better suited for other parties, such as pharmaceutical companies. Therefore, collecting information from these disparate sources will be extremely

time intensive, costly, and will divert pharmacy and IT resources typically used to monitor 340B program compliance, patient care, and completion of other crucial tasks. Additionally, CMS's proposed survey completion time does not account for the additional time needed to coordinate and extract drug acquisition cost data from multiple hospitals and numerous IT systems, including additional manual labor by staff to ensure accuracy and consistency of the data collection.

Notwithstanding, assuming arguendo that CMS's determination of 48 FTE-based hours per Covered Entity is accurate, the survey still creates an excessive burden on Covered Entities based on the limited 19-day time period for data collection and submission. Dedicating the equivalent of 48 FTE hours (i.e., a full-time employee for 6 full business days) over such a short time frame would stretch most of these safety-net hospitals' already scarce resources thinner and divert those resources away from other key operations and responsibilities, some of which could directly affect patient care. The burden would be especially pronounced for health systems such as Carle, which has multiple 340B Covered Entities for which it would be required to collect data. Dedicating hundreds of FTE-based hours across the entire Carle health system to collect information that is more appropriately collected by pharmaceutical companies or which can be accurately ascertained with a significantly narrowed scope is clearly unreasonable.

To that end, Carle still suggests that CMS request the desired information from the party(ies) that actually set drug prices, i.e. pharmaceutical companies, PBMs, etc. Alternatively, Carle requests that CMS (1) modify the scope of the survey to include fewer 340B Covered Entities and (2) allow for a longer period of time to collect and submit the requested information.

2. The Survey Will Not Accurately Reflect Actual 340B Costs for Some Medications

Based on CMS's updated version of the survey, Carle remains concerned that the information collection will not take into account the volatility of the drug pricing market and not adequately reflect costs for some medications. As CMS is well aware, prices for the same drug can vary widely from quarter to quarter based on a variety of factors. A drug that loses its patent protection can drop in price precipitously from one quarter to the next. Similarly, the price of a medication can significantly increase if a different drug for the same treatment is taken off the market. Therefore, two quarters of acquisition cost data may not accurately reflect the cost for medications during future quarters.

From a 340B perspective, Carle is especially concerned that medications with 340B "penny pricing" during one of the quarters included in the survey could artificially deflate actual drug costs for that medication. The survey has made no mention of or concern for "penny pricing" in either the prior proposed survey or the current finalized version of the survey that stands with the OMB. As a reminder, 340B ceiling prices are calculated quarterly using a regulatory formula based on a variety of pricing and inflationary factors. This formula occasionally leads to a 340B ceiling price of $0.00 for some medications, which is increased to $.01 per package for the quarter. However, this low pricing typically only lasts one quarter, and the drug's 340B price significantly increases during the next quarter when the 340B ceiling price formula is

recalculated. Therefore, costs for some medications with "penny pricing" during the survey period may not accurately reflect the actual higher drug cost for those medications in following quarters.

Since CMS has decided to move forward with the hospital survey, Carle requests that instead of requesting two quarters worth of data from healthcare providers, CMS request that data from a more appropriate source—pharmaceutical companies—and for the data to cover a much longer time period in order to more accurately identify pricing trends (e.g. eight quarters). Even if CMS still determines it will request the data from healthcare providers, Carle still requests that a longer time period be used for the data collection to more accurately reflect long-term drug pricing trends. Because this would lead to an increased amount of data to be collected, Carle would also reiterate its request above to significantly limit the scope of this survey to a smaller number of 340B Covered Entities with more time to collect such data.

3. **The Survey Will Likely Lead to CMS Policy Decisions that Undermine the Statutory Intent of the 340B Program**

Finally, the current version of the survey will likely lead to continued CMS policy decisions that do not reflect the statutory intent of the 340B Program to stretch federal resources to at-risk patient populations. In its survey notice, CMS states that it intends to use the pricing information requested "to ensure the Medicare program pays for specified covered outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs." However, reducing reimbursement for 340B medications deprives 340B Covered Entities of realizing drug cost savings that are designed to assist in supporting underinsured and indigent patients. The ultimate purpose of the drug purchasing discounts received by 340B Covered Entities (as opposed to non-340B entities) is to offset the financial strain of large volumes of uncompensated and undercompensated care rendered by these 340B-eligible providers. Any reduction to the savings originally contemplated by Congress threatens the capability of our safety-net providers and will likely lead to a negative impact on patient care.

As Carle has argued in previous comments submitted to CMS, concerns that 340B savings are flowing to entities that are not in need of those savings are unfounded. The Health Resources and Services Administration ("HRSA") ensures the fulfillment of this purpose by enforcing strict eligibility standards for the types of hospitals permitted to participate in the 340B Program—only those not-for-profit providers serving underserved communities or disproportionately high percentages of the indigent population are eligible to receive 340B discounts. Comprehensive studies have shown that 340B hospitals deliver significantly more care to low-income and underserved patients than non-340B hospitals, further justifying the full 340B savings amounts contemplated by Congress.[1,2] CMS should not initiate any payment reduction for 340B medications, regardless of the data it is based on.

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[1] *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patient.* L&M Policy Research, LLC. March, 2018.

[2] *340B Program Savings Improve Patient Health Outcomes.* L&M Policy Research, LLC. December 2019.

Thank you for the opportunity to provide comments on the finalized Hospital Survey for SCODs.

Respectfully Submitted,

Dawn Walden
SVP, Chief Revenue Cycle Officer

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Avera Tyler Hospital, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Allen Anderson
Administrator

March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of St. Michael's Hospital Avera, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Carol Deurmier
CEO

HEALTH
UNIVERSITY OF UTAH

Hospitals and Clinics
50 North Medical Drive
Salt Lake City, UT 84132

March 4, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: CMS Desk Officer

Paul Ray
Administrator
Office of Management and Budget (OMB),
Office of Information and Regulatory Affairs
725 17th Street NW
Washington, DC 20503
Fax: (202) 395-5806
Email: OIRA_submission@omb.eop.gov

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

Dear Mr. Ray:

University of Utah Health (U of U Health) – Hospitals and Clinics appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed information collection request (ICR) published in the Federal Register (85 Fed. Reg. 7307) on February 7, 2020. We share our comments with the hope that the Office of Management and Budget (OMB) will understand how CMS' ICR will affect 340B hospitals. We urge OMB to reject CMS' proposal.

About University of Utah Health

University of Utah Hospital is a key safety-net hospital in the Mountain West region. We care for patients in Utah and five surrounding states. U of U Health qualifies for the 340B program as a Disproportionate Share Hospital (DSH) as we serve a large low-income and uninsured population. We rely on our 340B savings to provide critical services to patients in our expansive service area who would otherwise lack access to care and improve patient outcomes. The 340B program is critical to our mission to improve health and quality of life—so much so that without our 340B savings, we would need to cut many vital programs and services.

About CMS' Proposal

CMS is proposing to collect covered outpatient drug acquisition cost data from 340B hospitals in order to set reimbursement rates specific to 340B hospitals. CMS' discriminatory reimbursement policy to 340B hospitals undermines the intent of the 340B program by eliminating our savings. In addition, the data request imposes a significant data collection and manipulation burden—a burden that CMS grossly underestimates. Finally, despite their best and honest attempts, hospitals will inevitably provide inconsistent and inaccurate data.

CMS' proposal negatively affects safety-net hospitals and their patients

CMS' Medicare Part B reimbursement cuts to 340B hospitals have already significantly affected our ability to serve our community. In CY2018, we experienced ~$11 million in lost revenue from Medicare. With CMS' expansion of the payment cuts to additional department types (non-excepted, off-campus, provider-based departments) in CY2019, we experienced an additional $1.5M in lost revenue. In 2020, we continue to experience these reimbursement cuts, despite multiple court rulings that CMS did not have the statutory authority to make the payment cuts. These material reductions have constrained our resources and ability to care for our under-served populations.

CMS' proposal is extremely burdensome and the data collected will be inconsistent and unusable

In response to CMS' original ICR published in the Federal Register (84 Fed. Reg. 51590) on September 30, 2019, we commented that CMS underestimates the time and burden 340B hospitals will face in collecting the drug acquisition cost data. Now, CMS' accelerated timeline and shortened timeframe to respond further exacerbates this burden while continuing to ignore the complexity.

CMS outlines the expected steps in its Average Sales Price Survey Instruction Sheet (https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10709, accessed on February 20, 2020). CMS expects each hospital to copy information from various sources available to CMS (Addendum B, multiple NDC-HCPCS crosswalks, etc.) into the survey and then convert average 340B price *per purchase unit* to average 340B price *per HCPCS unit*. CMS should not expect every hospital to perform the same data manipulation (steps 2-7 of the instruction sheet) that CMS itself can perform using its own data. This will inevitably result in error and unusable data.

CMS provides an example that illustrates the complexity of these calculations (copied below). Multiply the effort for just this one common example by 400 HCPCS codes corresponding to more than 1,100 national drug codes (NDCs), and the burden exponentially increases as well as the risk for calculation error and variation in response between hospitals.

CMS's example calculation:

"HCPCS code J0885 (Injection, epoetin alfa, (for non-esrd use), 1000 units) include products sold under the brand names Epogen and Procrit. The drug products are sold in a variety of amounts, including vials and syringes that contain between 2000 units and 40,000 units of epoetin packaged in amounts that vary from 4 to 25 vials. On the CMS NDC-HCPCS Crosswalk files, the "HCPCS Dosage" column indicates that CMS payment of J0885 to outpatient hospitals (and other providers billing Part B by HCPCS codes) is based on 1,000 units of epoetin. For the survey, CMS is seeking the 340B average acquisition cost of J0885 per 1,000 units. Therefore, if the acquisition cost of a package of ten 20,000 unit epoetin vials is $1800, the acquisition cost of each 20,000 unit epoetin vial in the 10 vial package is $180. For reporting, the acquisition cost per 1,000 units of epoetin (corresponding to the amount in the HCPCS dosage as well as the HCPCS code dose descriptor) would be $180 divided by 20, or $9.00."

Before even performing the above calculations, CMS expects hospitals to use several different NDC-HCPCS crosswalks to convert NDCs purchased to HCPCS units. CMS admits that its crosswalks do not contain all NDCs; therefore, hospitals would need to identify all NDCs purchased, map each to the correct HCPCS, and correctly convert between NDC purchase units to HCPCS units. This adds a manual and burdensome step. In addition, drug purchase data is fraught with nuances requiring a high level understanding in order to avoid inadvertently including non-340B prices in the calculations, which would skew the data. Variation in expertise will result in variation in response.

We sincerely appreciate the opportunity to provide comments on this proposed ICR. We understand CMS' goal is to reduce healthcare spending. We are fully supportive of that goal. However, we urge CMS to consider other options that do not negatively affect safety-net hospitals. Thank you for your consideration and please do not hesitate to reach out if you have any questions.

Sincerely,

Gordon Crabtree, CPA, MBA
Chief Executive Officer
University of Utah Health – Hospitals and Clinics

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

The University of California Health system (UC Health) appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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]

The UC Health system includes 19 health professional schools and five academic medical centers located at the Davis, Irvine, Los Angeles, San Diego, and San Francisco campuses, collectively known as UC Health. UC Health is part of California's safety net hospitals and health systems, which provide access to high-quality health care for vulnerable populations. Our academic medical centers have participated in the 340B disproportionate share hospital (DSH) program for more than two decades. We rely on our 340B savings to meet the needs of the low-income patients we serve.

For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm 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

[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.
[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

discounted 340B price for a Medicare beneficiary, to provide more care to underserved patients, thereby frustrating the 340B program's purpose.

II. 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.

III. 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 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]

IV. 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.

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We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Carrie Byington

Carrie Byington, M.D.
Executive Vice President—UC Health

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

UNIVERSITY
MEDICAL CENTER
OF EL PASO

March 9, 2020

Via Electronic Mail: OIRA_submission@omb.eop.gov
Attention: Desk Officer for CMS

Mr. Paul Ray
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
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)

Dear Mr. Ray:

University Medical Center of El Paso appreciates the opportunity to submit comments in response to the notice published in the Federal Register on Feb. 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] We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge the Office of Management and Budget (OMB) to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals.

I. Payment at Acquisition Cost Would Harm Safety-Net Hospitals and Their Patients

We 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% of hospitals, we provide 60% 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.

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[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.
[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

II. 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 as 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.

III. 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 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]

IV. 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.

On behalf of University Medical Center, I appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge OMB to reject CMS's proposal to collect drug acquisition cost data from 340B hospitals. Please feel free to contact me at (915) 521-7662 should you have any questions or concerns.

Sincerely,

Myron Lewis
Director of Pharmacy
University Medical Center of El Paso

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[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.

[5] 42 U.S.C. § 1395*l*(t)(14)(D)(iii).

[6] 42 U.S.C. § 256(b)(a)(4)(L)(iii).

UNIVERSITY of ROCHESTER

Submitted electronically via OIRA_submission@omb.eop.gov

March 9, 2020

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

Re: CMS–10709; OMB-0938-New; Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Mr. Ray:

I write on behalf of UR Medicine to offer comments in regard 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 for specified covered outpatient drugs. We have significant concerns with the intent and design of the survey, and urge the Office of Management and Budget (OMB) to reject the proposal by CMS to collect drug acquisition cost data from 340B hospitals.

Four hospitals in the UR Medicine system – Strong Memorial Hospital, Highland Hospital, Noyes Memorial Hospital, and Jones Memorial Hospital – are 340B covered entities and rely on the savings the program provides to expand access to care and meet the needs of our patients across the Finger Lakes and Southern Tier regions of New York State, consistent with Congressional intent for the program. In 2018, UR Medicine provided $367 million in community benefit, including nearly $165 million in uncompensated and charity care. In addition to providing low and no cost life-saving medications to low-income, uninsured, and underinsured patients, our 340B savings allows to us to provide comprehensive mental health care, outpatient chemical dependency services and opioid treatment programs, overdose training programs, pediatric complex care, complex neuromedicine, and offer access to oncology care at 12 sites throughout the region, in addition to many other important programs.

We are deeply concerned that the proposed survey will be used by CMS to continue to cut Medicare payments to 340B hospitals and would harm our ability to care for our patients. Although 340B disproportionate share (DSH) hospitals represent 38 percent of hospitals, they provide 60 percent of all uncompensated care. Reducing Medicare payment to acquisition cost for 340B drugs would eliminate the ability of hospitals like Strong Memorial, Highland, Noyes, and Jones Memorial to use the savings

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they accrue, by purchasing a drug at a discounted 340B price for a Medicare beneficiary, to provide more care to underserved patients, thereby undermining the purpose of the 340B program. We are also concerned that reducing hospital payments to acquisition costs would not assist in the Administration's overall goal of lowering pharmaceutical drug prices.

From an implementation perspective, this survey will significantly burden our hospitals. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In the ICR, 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. For a given quarter, there can easily be tens of thousands of units of data we would need to account for, and would involve significant staff time as well as complex health information and inventory management systems to complete. In addition to significantly adding to the administrative burden, asking hospitals to complete calculations factoring tens of thousands of units of data increases the likelihood of human error that may contribute to inaccuracies in the data reported, despite our best efforts. Moreover, CMS has shortened the survey response period from its original proposal, from one month to 18 days, which only contributes to the burden of the collection and the likelihood of error.

In addition, the 340B statute prohibits our hospitals from obtaining covered outpatient drugs through a group purchasing organization or group purchasing arrangement, requiring us to purchase certain outpatient drugs at wholesale acquisition cost (WAC) prices that are significantly higher than 340B prices. 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.

340B hospitals operate on already thin margins and incur considerable costs to ensure compliance with the existing stringent program rules and requirements. Any changes to the program – whether cuts to reimbursement rates or additional reporting requirements that would require additional staff time and hospital resources to implement – would harm our ability to provide care and services to patients in need. For the above mentioned reasons, we urge CMS should withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

Thank you for your consideration of the above comments, and please do not hesitate to contact me if I can provide any additional information.

Sincerely,

Peter Robinson
Vice President & Chief Operating Officer, URMC
Vice President, Government and Community Relations

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March 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of Wagner Community Memorial Hospital - Avera, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, and we request that CMS withdraw the survey.

As a 340B hospital, we have been able to use the program savings to improve patient services and help our community, as Congress intended. The 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Some ways the savings are used to support our patients include community wellness programs, outreach programs, and others as included in our publicly available community benefit documents. We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, we would need to access and assess proprietary drug prices from our wholesaler. As a 340B hospital, we purchase many of our 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,
Bryan Slaba
CEO

ADVOCATE. ADVANCE. LEAD.

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March 9, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 85, No. 26), February 7, 2020.

Dear Ms. Verma:

On behalf of our more than 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) notice to survey all 340B hospitals to collect actual acquisition costs for specified covered outpatient drugs. We have significant concerns over the intent and design of the 340B hospital survey, as well as the burden this will place on already overburdened hospitals, and we request that CMS withdraw the survey.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid- and large-sized academic medical centers. We have hospitals in every part of the state – from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

WHA Supports 340B

WHA has been a strong supporter of the 340B prescription drug discount program. We take issue with the nearly 30% cuts made to PPS 340B hospitals and other continued efforts of this administration to undermine the success of the 340B program. We believe the program is currently functioning as Congress intended it, by allowing hospitals to stretch scarce federal resources by offsetting a small portion of the losses hospitals experience due to shortfalls in funding in government programs like Medicare and Medicaid, as well as uncompensated care.

Wisconsin Hospitals Continue to Face Medicare Underpayments and Growing RX Drug Costs

In Wisconsin alone, Medicare underpayments grew from $2.2 billion in 2017 to $2.5 billion in 2018. Wisconsin hospitals' uncollected bad debt also grew from $215 million in 2017 to $228 million in 2018. This government underfunding is projected to only grow as Wisconsin's population ages and more beneficiaries transfer from commercial to Medicare coverage. Much of these costs get passed onto the private sector in a hidden healthcare tax that also acts to drive up the cost of private health insurance premiums

While government funding grows, prescription drugs costs also represent a growing cost for our members that is often beyond their control. According to a 2019 report by NORC at the University of Chicago, an average

hospital saw total inpatient drug spending grow by $1.8 million from 2015-2017. Meanwhile, outpatient drug spending grew by nearly 30% during the same period. Perhaps most notably, growth in expenditures per hospital admission on inpatient drugs exceeded the Medicare reimbursement update five-fold during the period.

340B Helps Hospitals Offset Losses and Aids their Ability to Support their Communities

Programs like 340B help hospitals offset some of these costs, and also expand important services to local communities they serve. The 340B program has been critical in helping Wisconsin hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. In addition to offsetting government underfunding, hospitals use 340B savings to benefit their local communities by expanding access to important health care services. Examples of this include:

- Funding low cost or free dental clinics.
- Funding remote prescription drug dispensing sites, so that folks in rural areas do not have to drive as far to obtain prescription drugs.
- Funding low cost or free health care clinics to ensure people without insurance or with inadequate insurance have access to essential care and affordable medications.

This 340B Survey will Add to Hospitals' Already Significant Government Regulatory Burden

We are concerned that the proposed survey will be used by CMS to continue its policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

We are also concerned that this survey will significantly add to the burden our hospitals. An average size hospital already dedicates 59 full-time-equivalent positions to regulatory compliance, with over one-quarter of those individuals being physicians and nurses. Time spent on red tape and regulatory compliance results in less time with patients, frustration by providers and burnout. The American Hospital Association estimates the annual cost of hospital regulatory compliance to equate to $1,200 per hospital admission. 340B hospitals operate on thin margins and already incur considerable costs to ensure compliance with program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems, and routine internal audits.

This survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified. In addition, to complete the survey, our hospitals would need to access and assess proprietary drug prices from their wholesalers. Our 340B hospitals purchase many of their 340B drugs through wholesaler purchasing arrangements. These arrangements are contractual agreements that often include strict non-disclosure conditions that restrict the sharing of any drug pricing information to any entity not party to the contract. These non-disclosure provisions would make it exceedingly difficult for our hospital to share the data necessary to complete the survey in the time specified.

Thank you for the opportunity to provide comments. We urge CMS to withdraw this survey and cease any further Medicare Part B payment policies that will undermine the intent of the 340B program.

Sincerely,

Eric Borgerding
President & CEO