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November 27, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-10709
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Verma:

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, appreciates the opportunity to comment on CMS' notice to survey all hospitals that participate in the 340B Drug Pricing Program to collect actual acquisition costs for specified covered outpatient drugs.

HANYS fully aligns its comments with those submitted by the American Hospital Association. We have significant concerns about the intent and design of the 340B hospital survey and strongly urge CMS to withdraw it.

In the notice and the Medicare Outpatient Prospective Payment System final rule for the calendar year 2020, CMS stated that it intends to use the survey results not only in future Medicare Part B 340B payment policy but also as the possible basis for a remedy related to ongoing litigation.[1]

The healthcare industry has long argued that CMS' unlawful Medicare Part B payment policy imposes such drastic payment reductions for 340B drugs that it severely undermines the benefits of the 340B program, which AHA successfully litigated. The magnitude of the cuts for OPPS CYs 2018 through 2020 has compromised 340B hospitals' ability to establish and continue the operation of programs designed to improve access to services for their patients — which is the very purpose of the 340B program.

[1] *Federal Register*, Sept. 30, 2019, https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-21120.pdf; *Federal Register*, Nov. 12, 2019, https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf

Congress created the 340B program to permit hospitals serving vulnerable communities, such as low-income and uninsured patients, "*to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services*,"[2] while mitigating losses such hospitals experience due to chronic underpayments from public payers like Medicaid.

HANYS' member hospitals that participate in the 340B program report using resultant savings to operate a variety of programs and services that otherwise may not be financially viable, including:

- free or substantially discounted prescriptions for uninsured or low-income patients;
- medication therapy management programs to improve patient care and reduce overall healthcare costs and hospital readmissions;
- mobile units to bring care to rural and other medically under-served communities without local primary care options or pharmacies;
- free oncology services for low-income patients;
- multidisciplinary clinics offering substance abuse and mental health treatment; and
- transportation support for patients who need to use emergency room services.

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

STATUTORY REQUIREMENTS

HANYS aligns with AHA's belief that CMS' hospital acquisition cost survey approach does not conform to the statutory requirements established by Congress.

The Medicare statute provides CMS with two options for reimbursing covered outpatient drugs.[3] Under 42 U.S.C. Sec.1395l(t)(14)(A)(iii), CMS must base payment rates on the average acquisition costs, but only if the hospital acquisition cost survey data meets the specifications spelled out in paragraph (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."[4]

The statutory language is clear that the survey should be a large enough sample size of hospitals to generate a statistically significant estimate. However, CMS states that it will not use any statistical methodology or sample selection for the survey. It appears that CMS will administer the survey to all 340B hospitals and believes that the response rate will be high enough to yield statistically valid results. We do not believe that this approach complies with the statute. We have serious concerns about the statistical validity of this approach because

[2] Health Resources and Services Administration, https://www.hrsa.gov/opa/index.html
[3] AHA, Associations, Hospitals Reply Brief, https://www.aha.org/legal-documents/2019-09-24-aha-associations-hospitals-reply-brief-government-appeal-340b
[4] 42 U.S. Code § 1395l.Payment of benefits, https://www.law.cornell.edu/uscode/text/42/1395l

there are no selection criteria. Also, CMS does not provide enough information to evaluate whether the results would be biased on the basis of who responds to the survey.
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 the "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 requirement that the survey include *all* hospitals, not just a subset of hospitals.

For purpose of surveying hospitals, Congress does not distinguish between hospitals paid under OPPS based on their 340B status and those that are not. **Therefore, CMS' survey design and approach do not meet the statutory requirements when specifying 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

HANYS echoes AHA's comments on the burden of collecting this information and implores CMS to reject any approach that does not align with the administration's aim to reduce regulatory barriers.

There appear to be inconsistencies in the information and instructions found in the notice published in the *Federal Register* and the supporting documentation (Supporting Statements A and B), which may cause confusion among 340B hospitals and other stakeholders. In the notice, CMS states that it would require "certain" hospitals enrolled in the 340B program in the last quarter of 2018 and/or the first quarter of 2019 to complete the survey.

However, there is confusion around exactly which 340B hospitals and how many are expected to complete the survey. That is, the *Federal Register* survey notice and the Supporting Statement – Part A state that all 340B hospitals, which would include Critical Access Hospitals, children's hospitals, freestanding cancer hospitals and other rural hospitals, would be required to complete the survey. The survey's Supporting Statement - B, however, suggests only those 340B hospitals paid under OPPS are required to complete the survey.

The inconsistency between the published notice and the supporting documentation is confusing and may lead to less meaningful responses.

CMS estimates 46,610,448 survey responses, which would take about 33,500 hours to complete. The lack of detailed information from CMS makes it challenging for the public to assess the predicted impact of the survey and its burden. However, this appears to be a gross underestimation of the burden 340B hospitals would bear in both gathering the data elements to adequately respond to the survey and formatting the data in the manner required by CMS.

340B hospitals already operate on thin operating margins, such that these additional costs could jeopardize certain programs and services. This survey would require staff time and resources, which would need to be diverted from the primary mission of the 340B program. The survey burden may be insurmountable for our financially struggling 340B hospital members in urban and rural settings.

HANYS urges CMS to conduct a more thorough assessment of the "considerable burden for hospitals" before moving forward with the survey.

Challenges in Sharing Drug Prices

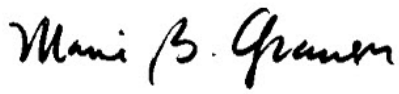
HANYS supports AHA's view on potential challenges with sharing the requested information. 340B hospitals typically purchase their 340B drugs through contractual agreements with wholesalers or directly from the drug manufacturer. The wholesaler contracts, in particular, typically have strict non-disclosure provisions which may prevent 340B hospitals from sharing any drug pricing information with any entity not party to the contract. This makes it impossible for these hospitals to complete the survey.

In addition, the survey requests that hospitals report drug prices at the Healthcare Common Procedure Coding System 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.

HANYS urges CMS to abandon its damaging OPPS 340B payment policy, which the courts have declared unlawful, and withdraw this survey.

Thank you for the opportunity to provide comments on this survey collection tool. If you have any questions regarding our comments, please contact Kevin Krawiecki, vice president, fiscal policy, at kkrawiec@hanys.org or (518) 431-7634.

Sincerely,



Marie B. Grause, RN, JD
President

MBG:lw

TEMPLE HEALTH

Katherine E. Levins, JD, MBA
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215-707-4851

November 27, 2019

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. 84, No. 189), September 30, 2019.

Dear Administrator Verma:

Thank you for 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 appreciate CMS' efforts to protect taxpayer funds while maintaining beneficiary access to the drugs they need to heal. In light of our concern over the design of the survey, however, we respectfully request that CMS withdrawal its proposed plan for 340B data collection.

Temple University Hospital is exactly the type of hospital that the Congress intended to benefit from the 340B drug discount program. Without dispute, Temple is an indispensable provider of health care in the largest city in America without a public hospital. Among Pennsylvania's full-service safety-net providers, Temple University Hospital serves the greatest volume and highest percentage of patients covered by Medicaid. In the absence of a public hospital, Temple provides a critical, albeit fragile, safety-net for one of America's most vulnerable populations.

The savings that Temple University Hospital achieves under the 340B are critical to its ability to provide continuous access to high quality care to those living in our low income community. Last year, Temple provided $19 million in charity care, $44 million under-reimbursed Medicaid and $11 million in subsidized health services. We also provided a broad array of services to improve the health, safety and quality of life for residents of the vulnerable communities we serve. Some of these programs are described more fully in Temple University Hospital's Community benefit Report which can be accessed through this link: Community Benefit Report.

We are concerned that the proposed survey will be used by CMS to continue its damaging policy of reducing 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 Temple University Hospital, which operates on a thin margin and already incurs 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. 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. Again, 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,

Katherine C. Levins

Illinois Health and Hospital Association

November 29, 2019

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

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

Dear Ms. Verma:

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

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

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

[1] IHA's 2018 OPPS Comment Letter, September 11, 2017, can be accessed at: https://www.team-iha.org/files/non-gated/advocacy/medicare/cms-comment-letter-opps-rule.aspx?ext=.
[2] IHA's 2019 OPPS Comment Letter, September 24, 2018, can be accessed at: https://www.team-iha.org/files/non-gated/advocacy/medicare/cms1695p-oppscommentltr.aspx?ext=.
[3] IHA's 2020 OPPS Comment Letter, September 27, 2019, can be accessed at: https://www.team-iha.org/files/non-gated/advocacy/ffy2020-opps-comment-letter-nicole.aspx

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

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

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

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

As CMS knows, drug prices are extremely volatile and can change sometimes weekly, making it unlikely that two quarters of data will provide an accurate base for setting 340B reimbursement rates over time. In fact, the Kaiser Family Foundation[4] analyzed actual and projected annual changes in per capita prescription drug spending from 1970 through 2027. Not only does Kaiser find that drug spending fails to track with total health spending, but that annual changes range from a decrease of 0.7% to an increase of 14.7%. Simply stated, a static point in time does not accurately reflect a market that changes and innovates so rapidly. Therefore, if CMS moves forward with this

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

proposal, we strongly urge CMS to establish criteria for a more regular data collection schedule in an effort to better reflect prescription drug costs in their reimbursement of 340B-acquired drugs. For drugs with relatively stable pricing, CMS could stipulate utilization of an inflation index to account for reimbursement adjustments over time. For drugs that experience price changes beyond a specified benchmark, CMS could request updated acquisition data from 340B covered entities. We request that CMS think through and articulate such criteria prior to finalizing this hospital survey.

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

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

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

Ms. Verma, thank you again for the opportunity to comment. If you or your staff have any questions on these comments, they should be addressed to Cassie Yarbrough at cyarbrough@team-iha.org or 630-276-5516.

Sincerely,

A.J. Wilhelmi
President & CEO

Gibson Area Hospital
& Health Services
GIBSON GETS IT

1120 N. Melvin, Gibson City, IL 60936
Administration – (217) 784-2600
FAX: (217) 784-2610
Hospital Main Number: (217) 784-4251

11/27/2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of **The Gibson Community Hospital Association,** 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 CMS to 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 improve patient access by adding clinics in underserved areas and by offering behavior health services in rural settings. 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.

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,

Matthew Ertel
CFO

Magnolia
Regional Medical Center

November 22, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of **Magnolia Regional 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 CMS to 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 fund the opening of our community's first Rural Health Clinic to meet a large unmet primary care need, as well as to provide in excess of $200,000 of prescription medications to our uninsured and underinsured populations. 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.

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,

Rex E. Jones
Chief Executive Officer

St Luke's University Health Network
801 Ostrum Street
Bethlehem PA 18015

11/27/19

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of St Luke's University Health Network, 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 CMS to 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 use the savings/revenue generated by the 340B program to offset the hospital's charity care costs, and stretch the hospital's resources further in providing care to our area's indigent/non-paying population. 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.

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,
Patrick Ferguson
Network Director of Pharmacy

GUNDERSEN
HEALTH SYSTEM®

November 29, 2019

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

RE: CMS–10709: Agency Information Collection Activities: Proposed Collection Comment Requests

Dear Mr. Parham:

Gundersen Health System appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)).

Gundersen Health System is an integrated healthcare delivery system providing services throughout nineteen counties in western Wisconsin, southeastern Minnesota and northeastern Iowa. Our system includes a primary hospital in La Crosse, four critical access hospitals and over 50 clinics throughout the region. With over 7,000 employees, we are the largest employer in the Coulee region. We are committed to supporting public policy that helps to enrich every life through improved community health, outstanding experience of care, and decreased cost burden.

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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

Impact to Safety-Net Hospitals and Low-Income Patients

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B

drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

Conflicts with Current Law

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

Administrative Impacts the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes

it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

Conclusion

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals. We urge CMS to work together with hospitals and physician groups to ensure payment programs are working to achieve the goals of better quality and lower cost. We look forward to continuing to provide feedback new and existing payment programs.

If you have any questions or need clarification, please feel free to contact us at any time.

Sincerely,

Kay P. Marsyla, FHFMA
Director, Reimbursement
Gundersen Health System

National Alliance of Safety-Net Hospitals

November 27, 2019

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-10709

Subject: Department of Health and Human Services, Centers for Medicare & Medicaid Services; Document identifier CMS-10709; Agency Information Collection Activities: Proposed Collection; 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' agency information collection notice published in the *Federal Register* on September 30, 2019 (Vol. 84, No. 189, pp. 51590-51591).

NASH and the nation's private safety-net hospitals 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 exceptionally 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 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 extremely burdensome.

In the proposed notice, CMS calls for asking 340B providers to supply their average acquisition cost data for more than 400 HCPCS codes and 1100 national drug codes (NDCs). For a given quarter, hospitals could easily need to account for tens of thousands of units of data. No less burdensome would be the extensive calculations the information collection request would require of hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under 400-plus HCPCS codes, which would require hospitals to average the prices together for all the NDCs mapped to the HCPCS codes – which can be dozens of NDCs for a single HCPCS code – and to convert NDC purchase units to HCPCS dosage units.

CMS also is asking hospitals to identify each provider-based department at which a relevant drug was administered. This would be extremely burdensome because most hospitals do not track data this way and would need to run numerous reports out of their billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. It also is not clear what information CMS seeks to collect on provider-based departments.

NASH disagrees strongly with CMS's estimate that it would take 340B-eligible hospitals 48 hours to respond to the survey and collect the proposed data. To the contrary, our 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, CMS recently 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 stubbornly 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.

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November 29th, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Holton 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 CMS to 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 provide an extremely successful intensive outpatient group therapy program for seniors in our community. Without the savings from this program, the monthly cost of this program would be prohitable for our organization. This program has been up and running for two years now, and we are hoping to expand and offer a second tract. 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.

From an implementation perspective, this survey will significantly burden our hospital. Our organization operates on thin margins incurs 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,

Carrie Saia, CEO
Holton Community Hospital
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Sutter Health
Sutter Coast Hospital

November 27, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Sutter Coast 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 CMS to 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, Sutter Coast Hospital was able to take full advantage of 340B in 2019, which has reduced pharmacy costs from $3,474 to $1,443 per visit. 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.

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

Sutter Health
Sutter Coast Hospital

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,

Mitchell J. Hanna
CEO

Sutter Coast Hospital
800 E. Washington Blvd, Crescent City, CA 95531
Main Phone: (707) 464-8511

Office of the Chief Financial Officer

UVA Health

November 26, 2019

William Parham III
Director
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Director Parham:

UVA Health appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS') notice of proposed information collection. UVA Health includes an academic medical center located in Charlottesville, Virginia with the UVA School of Medicine and its strong biomedical research enterprise, a 612-bed hospital, a level I trauma center, nationally recognized cancer, stroke, heart and pediatric centers along with several primary and specialty clinics throughout Virginia. More than 65 percent of UVA Medical Center's patients are Medicare, Medicaid and indigent patients. Relative to other hospitals in our state, UVA Medical Center provides a disproportionate share of services to Virginia's indigent and Medicaid beneficiaries, thus serving as a key safety net provider in Virginia. As such, the medical center is eligible to participate in the 340B Drug Pricing Program.

Congress created the 340B program to allow eligible providers to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. No. 102-384, pt. 2 (1992)). The program allows us to purchase prescriptions drugs at a discount from drug manufacturers. Instead of using our resources to purchase drugs at a higher cost, we can instead repurpose those expenditures to ensure economically disadvantaged patients have access to needed prescription drugs and specialized care.

Under the proposed information collection, CMS would collect from hospitals participating in the 340B program drug acquisition cost data for specified covered outpatient drugs (SCOD) through a hospital survey. Hospitals enrolled in the 340B program in the last quarter of 2018 or the first quarter of 2019 would complete the survey between Feb. 17 and March 16, 2020. We urge CMS to withdraw its proposed information collection request, given the agency has not fully evaluated both its authority to conduct this survey and the burden and scope of the operational complexity associated with the proposed survey. In addition, we would oppose the use of acquisition costs to justify further reduced Medicare outpatient payments for Part B drugs.

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

UVA Health questions whether CMS is exceeding it authority with the proposed survey. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, it does not allow CMS to only target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)). The proposed survey would only direct 340B hospitals to report acquisition costs.

In addition, the Medicare statute has specific requirements about the scope of the survey, including 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. As a result, the survey does not satisfy statutory sampling requirements and, ultimately, would not accurately capture average acquisition costs of all OPPS hospitals.

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

CMS' acquisition cost survey would also be administratively burdensome for 340B hospitals and runs counter to the administration's efforts to reduce provider burden through its Patients Over Paperwork initiative. The survey is operationally complex and will likely divert staff resources beyond the amount of time outlined in the notice.

Specifically, the survey requests average acquisition cost data for more than 400 Healthcare Common Procedure Coding System (HCPCS) codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data for which hospitals would need to account. Such cost data is not necessarily readily available and will have to be obtained from our drug wholesaler. However, our contract agreement governs the types of information we can share with other parties, and the data possessed by the wholesaler are confidential and proprietary. We would have to evaluate our contract to ensure it would not require modification to allow us to share the information with CMS.

Should we be able to obtain permission from our wholesaler to retrieve and share acquisition cost data, the data provided by the wholesaler will not be in the format CMS requests. CMS proposes to require that hospitals report average acquisition cost for two quarters (the fourth quarter of calendar year 2018 and the first quarter of calendar year 2019) for all SCODs with status indicator K or G, by HCPCS code. Once we have the information from the wholesaler, we would have to cross-reference the list provided to find drugs with status indicators K or G. The data we receive from the wholesaler will be identified by National Drug Codes (NDCs). 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. Matching NDC codes to HCPCS codes will require extensive manual effort by hospital staff. There is currently no master database that cross-references this information in a standard way between NDCs, package size, dosage size, HCPCs, and billing units. Relying on each hospital to do this on their own will result in variation and discrepancies in the calculation of average acquisition cost.

Once our staff has assigned all NDCs to given HCPCS codes, they will have to calculate the average acquisition cost, which can differ for each individual NDC associated with a given HCPCS code. This process of obtaining the information in the format CMS requires will be extremely burdensome for hospital staff, which already are burdened by existing compliance and recordkeeping requirements.

In addition, there are times we need to purchase some drugs through distributors that are not our designated wholesaler, such as limited distribution drugs, directly sourced items, and drug shortages. In these situations, we would have to acquire individual invoices for purchases through these channels and then consolidate this information with the report from its wholesaler. Pulling individual invoices for drugs not purchased through the primary wholesaler would be cumbersome for hospitals, given that many manufacturers distribute their drugs directly to customers. This can be around 20 percent of NDCs for some hospitals based on the variety of drugs needed in the acute care setting.

CMS should not reimburse 340B hospitals less than the statutory default rate of 106 percent of Average Sales Price (ASP).

CMS suggests that 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, undermine the intent of the program and 340B hospitals' ability to do more to serve their patients. Given the financial position of many 340B hospitals, policy changes that jeopardize any piece of the patchwork support on which we and other hospitals rely, including the 340B program, can threaten the ability to maintain critical services for Medicare beneficiaries. Therefore, we strongly advise CMS against reducing Part B payments by tying them to acquisition costs.

Instead, we urge the agency to revert to paying 340B hospitals at 106 percent of ASP. The U.S. District Court for the District of Columbia has unequivocally held that CMS' payment cuts, which the agency intends to continue for a third year in 2020, violate the Medicare statute. As we have urged in our previous comments, CMS should reverse these payment cuts and pay hospitals back at 106 percent of ASP plus interest.

Thank you for your consideration.

Sincerely,

Douglas E. Lischke
Health System Chief Financial Officer

Submitted electronically at www.regulations.gov

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November 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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Attention: Document Identifier CMS-10709/OMB Control Number ____

Dear Administrator Verma:

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 to collect acquisition cost data for specified outpatient drugs acquired under the 340B Drug Pricing Program (340B Program).

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% 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. 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.

In the notice CMS writes 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." (84 Fed Reg 51591). Congress did not design the 340B Program to pay hospitals at acquisition costs. Congress designed the program so that eligible hospitals could purchase covered drugs at a discounted rate below the Medicare reimbursement rate and use the difference to reach more eligible patients and provide more comprehensive services. 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 says 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." (p. 61322). Should CMS try to set payment rates based on the data collected as a result of this notice, it would have to engage in new rulemaking and make the data

available at the time a change is proposed 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." (p. 61322). As CMS is aware, the AAMC and other litigants have proposed an appropriate remedy that would return money to all hospitals in full.

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. Therefore, we ask that CMS not move forward with the data collection.

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

cc: Ivy Baer

November 29, 2019
VIA ELECTRONIC MAIL
regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8013
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Re: CMS–10709, Proposed Collection and Comment Request on 340B Acquisition Cost Data

Dear Ms. Verma:

On behalf of AdventHealth, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed collection of acquisition cost data for 340B drugs. AdventHealth includes 50 hospital facilities located across nine states, some of which rely substantially on savings from the 340B program to provide a variety of services to vulnerable populations. This includes programs that provide medication reconciliation and home-based bedside medication delivery.

Our flagship facility, AdventHealth Orlando, is the largest single-site Medicare provider in the nation. Patients who seek care at AdventHealth reflect the communities we serve, diverse in age, race, ethnicity, income and payor. Many of our facilities depend on the 340B program to serve complex patients in socioeconomically challenging settings. After two years of payment cuts to this vital program, we have seen the negative impact the 340B reimbursement rate reduction has had on communities. For example, at AdventHealth Hendersonville, one of our rural facilities in North Carolina, the impact of the 340B reductions can jeopardize the hospital's ability to provide free and reduced cost drugs to low-income patients on discharge. As the Agency continues this reduced rate, hospitals like these will be unable to meet the needs of the community they serve.

In this information collection request, CMS has outlined its intent to collect acquisition cost data from hospitals for status K covered outpatient drugs that are eligible for 340B program discounts. CMS seeks comments on estimated burden and how to enhance the quality, utility and clarity of the data. The feedback we provide below seeks to offer insight into the complexities of capturing 340B drug costs, as well as how to make the acquisition cost data more meaningful.

While we support efforts to improve the 340B program, we urge the Agency to refrain from instituting further payment cuts. In 1992, Congress created the 340B program to

allow safety-net hospitals to stretch scarce federal resources.[1] This was done because of the understanding that Medicare and Medicaid do not reimburse hospitals for the full cost of providing care. Three decades later, this continues to be the case. Many hospitals, particularly those in rural and low-income communities, rely on the 340B savings for the provision of clinical care. To help contextualize and enhance the usefulness of CMS' data request, AdventHealth offers the following comments for consideration.

Estimated Burden

CMS's information collection request would take the form of a hospital survey that all 340B eligible hospitals would have to complete between February 17 and March 16, 2020. Under the survey, hospitals would be required to provide the following:

- Hospital name, Medicare CCN and contact information;
- The name of each provider-based department enrolled as a 340B child site and paid under the OPPS; and
- The HCPCS code for each drug identified with a status indicator of "K" (separately payable drug) or "G" (pass-through drug), including the name and a short descriptor, the dose, and average 340B price.

AdventHealth appreciates the opportunity to share feedback on the estimated administrative burden that would result from this data collection request. **While we understand CMS' desire to collect cost acquisition data, we would like the Agency to be aware that the human resources needed to complete this survey are likely to strain the administrative capacity of certain hospitals**. Obtaining the exact cost for 340B drugs would be very difficult. Often, even though a drug is replenished at the 340B price and dispensed when the patient is an outpatient, the actual drug dispensed could have been purchased at Wholesale Acquisition Cost (WAC) or other non-340B account. Accordingly, many hospitals would need to review invoices to compare with patient status to provide the most accurate acquisition cost.

Since each 340B facility must complete the survey, we are concerned that smaller facilities in rural and low-income communities, such as AdventHealth Manchester, would be unduly burdened by this data collection effort. The community of Manchester, Kentucky, has an employment rate of 10.3%, and about 40% of its residents live in poverty. As a result, about 80% of the payments to AdventHealth Manchester come from Medicare or Medicaid, forcing the hospital to run on a very small operating margin. At hospitals like these, not only do the 340B reimbursement reductions negatively impact its ability to provide access to care, but limited staff resources would also be severely

[1] Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967-4971 (1992).

strained to produce this data within the parameters CMS is proposing. **Because this process is labor and time intensive, if CMS decides to proceed with this data collection, we urge the Agency to consider lengthening the time allowed to complete the survey or otherwise provide opportunities for exemption for limited resource facilities.**

Quality, Utility and Clarity of the Data

CMS states that cost acquisition data collected through the survey will be used to "help determine payment amounts for drugs acquired under the 340B program" in a way that reflects what hospitals actually pay for the drugs. However, AdventHealth cautions that acquisition cost data does not actually reflect what hospitals are spending for 340B drugs. To complete CMS's survey, hospitals would have to tie every 340B drug to an invoice, reflecting a point-in-time measurement that may no longer correctly represent what a hospital is paying for that drug. In addition to significantly adding to the burden, asking hospitals to complete calculations factoring tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report. We are concerned this may lessen the utility and accuracy of the data.

AdventHealth recommends that CMS, rather than strictly consider the acquisition cost data for the 340B inventory, considers the acquisition cost across all inventories for status K drugs and associated administrative and regulatory costs. As a result of policies such as the Health Resources and Services Administration's Group Purchasing Organization (GPO) exclusion, which prevents Disproportionate Share Hospital (DSH) qualified 340B hospitals from using a GPO for purchasing covered outpatient drugs, many hospitals must purchase initial drug orders through an often higher-priced WAC inventory. Because of the GPO policy, a 340B acquisition cost can only be determined upon replenishment of an outpatient drug, and the time period for replenishment can vary significantly among drugs and geography.

Due to this complex process, hospitals typically maintain a three-inventory system (GPO, 340B and WAC). For example, $100,000 spend on a single drug through a 340B account is likely to represent the acquisition of many more units of that drug than the same spend in a GPO or WAC account. This is because the per unit cost of drugs purchased at 340B discounts is significantly less. However, because there is a cost associated with arriving at the 340B price, the actual savings may be less than the difference between the market price and the discounted price paid. Accounting for these associated costs would also help provide a more accurate depiction of what hospitals are spending through the 340B program.

Contextualizing the acquisition cost data with associated regulatory and administrative costs can enhance the Agency's understanding of the challenges of operating this program. We are concerned that the aims of the data collection do not adequately

account for the costs incurred by 340B hospitals to comply with the 340B program. This includes adhering to the statute's GPO prohibition, as well as maintaining software, hiring staff and conducting paid audits. For many hospitals, the savings from 340B discounts are the only way they can maintain this vital program. We remind CMS that the inability of hospitals to continue providing these drugs would have an adverse effect on low-income patients who may find it difficult to access the drugs, as physician offices are not as willing to accept the financial risks of treating under or noninsured patients.

As mentioned earlier, the 340B program is of significant value to hospitals and the communities we serve. However, drug prices continue to rise rapidly, making it more difficult for hospitals to purchase and make these drugs accessible to patients. The Agency's payment reductions aggravate this situation even further. They constrain the financial ability of covered entities to support a range of high-cost services that are often provided to vulnerable patients for little or no payment.

While we welcome the opportunity to improve the 340B program, we believe there is value in the program's original intent to help safety-net hospitals reach eligible patients. Currently, the 340B program savings are not only beneficial for drug purchasing; they are also reinvested in programs designed to increase access to prescription medicines and other health services for low-income patients. For example, Adventist GlenOaks Hospital is a rural hospital within our system located in Glendale, Illinois. This 340B covered entity uses the savings from the program to provide a medication reconciliation and bedside medication delivery. Losing those savings may affect the viability of those programs and negatively impact patients, communities and the accessibility of health care.

Conclusion

AdventHealth welcomes the opportunity to discuss policies designed to improve the effectiveness of the 340B program and safeguard its original intent. We urge the Agency to work collaboratively with both Congress and health care stakeholders to identify policy solutions that best meet such goal. If you have any questions or would like further information, please do not hesitate to contact Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,

Michael E. Griffin
Vice President of Advocacy and Public Policy
AdventHealth

AdvocateAuroraHealth

November 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1711-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Hospital Survey for Specified Covered Outpatient Drugs (SCODs) [CMS–10709]

Dear Administrator Verma:

Advocate Aurora Health (Advocate Aurora) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule requesting comments on a proposed information collection request (ICR) by CMS to survey 340B hospitals to obtain 340B drug acquisition cost data.

ADVOCATE AURORA OVERVIEW

Advocate Aurora is a not-for-profit integrated health care delivery system based in Illinois and Wisconsin and the leading employer in the Midwest. The result of a recent merger between two legacy health organizations – Advocate Health Care in Illinois (Advocate) and Aurora Health Care in Wisconsin (Aurora) – Advocate Aurora employs more than 70,000 people, including more than 8,100 physicians and 22,000 nurses. Our clinicians are nationally recognized for their expertise in cardiology, neurosciences, oncology, and pediatrics, and while we are home to the largest employed medical staff in the Midwest region, we are also home to the largest home health organization in the region. In 2018, Advocate Aurora's four home health agencies – two in Wisconsin and two in Illinois – served more than 20,000 Medicare patients and 12,000 Medicare Advantage patients. Moreover, we are proud to be one of the nation's leaders in clinical innovation, health outcomes, consumer experience, and value-based care. Each year, we serve nearly 3 million patients across more than 500 sites of care, and we are engaged in hundreds of clinical trials and research studies.

The drug discounts provided through the 340B program allow our participating hospitals to reinvest the savings in specific patient care programs and to provide community benefits and charity care to the individuals, families, and communities we serve. We appreciate your consideration of the comments that follow below.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to

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

CMS's Proposal is Contrary to Law

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated

guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospitals to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden. Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. Even assuming the accuracy of this estimate, this is a significant sum of money that safety-net hospitals otherwise could use to care for our low-income patients. Moreover, as explained above, we believe CMS has grossly underestimated the time burden, and therefore cost burden, to hospitals.

CONCLUSION

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals. Please do not hesitate to contact me (202-603-4979, Joyce.Rogers@AdvocateHealth.com) or Tony Curry (703-786-2571, anthony.curry@aurora.org) should you have any questions or if we can be of any assistance.

Sincerely,

Joyce Rogers
Advocate Aurora Health
Chief Government Affairs Officer

American Hospital Association

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November 27, 2019

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. 84, No. 189), September 30, 2019.

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.

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 not only in future Medicare Part B 340B payment policy but 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.[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 – which is the very purpose of the 340B program.

Congress created the 340B program to permit hospitals serving vulnerable communities, such as 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

[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

[3] https://www.hrsa.gov/opa/index.html

in helping hospitals expand access to comprehensive health care services, including access to lifesaving prescription drugs, in vulnerable communities across the country, including low-income and uninsured individuals in these communities. Given the rapid escalation in the cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build and promote healthy communities. CMS's plan to collect actual acquisition cost data from *only* 340B hospitals confirms the agency's intent to continue down its policy path for 340B hospitals and their patients.

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 approach and whether it conforms 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, but only if the hospital acquisition cost survey data meets the specifications spelled out in paragraph (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] The statutory language is clear that the survey should be a large enough sample size of hospitals to generate a statistically significant estimate. However, CMS states that it will not be using any statistical methodology or sample selection for the survey. It appears that CMS will be administering the survey to all 340B hospitals and believes that the response rate will be high enough to yield statistically valid results. We do not believe that this approach complies with the statute. We have serious concerns about the statistical validity of this approach because there are no selection criteria. Also, CMS does not provide enough information to evaluate whether the results would be biased on the basis of who responds to the survey.

In addition, 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… ." 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 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

[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

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. There appear to be inconsistencies in the information and instructions found in the notice published in the *Federal Register* and the supporting documentation, Supporting Statements A and B, which may cause confusion among 340B hospitals and other stakeholders. In the notice, CMS states that it would require "certain" hospitals enrolled in the 340B program in the last quarter of 2018 and/or the first quarter of 2019 to complete the survey. However, there is some confusion around exactly which 340B hospitals and how many are expected to complete the survey. That is, the *Federal Register* survey notice and the Supporting Statement – Part A state that all 340B hospitals, which would include critical access hospitals, children's' hospitals, freestanding cancer hospitals and other rural hospitals, would be required to complete the survey. The survey's Supporting Statement – Part B, however, suggests only those 340B hospitals paid under OPPS are required to complete the survey. The inconsistency between the published notice and the supporting documentation is confusing and may lead to less meaningful responses.

For those hospitals required to complete the survey, each would be required to list, by each provider-based department of the hospital enrolled in the 340B program, the following information:

- Healthcare Common Procedure Coding System (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 761 respondents that complete the survey, they would submit approximately 46,610,448 survey responses, which would take about 33,500 hours to complete. On face value, this appears to be a gross underestimation of the burden 340B hospitals would bear in both gathering the data elements to adequately respond to the survey and formatting that data in the manner required by CMS. In addition, here is another example where the supporting documents are not consistent with the published notice. That is, in Supporting Statement – Part B, CMS notes that it expects 1,338 340B hospitals to respond, again making it challenging for the public to assess the predicted impact of the survey and its burden.

In any event, the burden of reporting acquisition cost data remains a concern. 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." In addition, 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] It is important to note that 340B hospitals are a diverse group ranging from small rural hospitals to large academic centers that care for significant numbers of low-income patients. All of these 340B hospitals already are shouldering significant costs for staff, software, health information and inventory management systems to ensure they are compliant with the rules and requirements of the 340B program. In addition, 340B hospitals are operating on thin operating margins, such that these additional costs, in terms of staff time and resources, which will need to be diverted from the primary mission of the 340B program. For our financially struggling 340B hospital members 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 – for example, McKesson Pharmaceuticals – or directly from the drug manufacturer. These purchasing arrangements are contractual agreements. The wholesaler contracts, in particular, typically have strict non-disclosure provisions. It is our understanding that they may prevent 340B hospitals from sharing any drug pricing information with any entity not party to the contract. These non-disclosure provisions may make it impossible for 340B hospitals to share the data necessary 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 will 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.

The AHA continues to believe that CMS's OPPS 340B payment policy is so disruptive that it will severely undermine the 340B program. The survey of 340B hospital acquisition cost data is another tool for CMS to use to accelerate its efforts to curtail the program. CMS should reconsider, and instead 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 or Roslyne Schulman, director for policy, at rschulman@aha.org.

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

Sincerely,

/s/

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Government Relations and Public Policy

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Cynthia Hundorfean
President and Chief Executive Officer

November 27, 2019

Ms. 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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of the Allegheny Health Network (AHN), 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 respectfully request that CMS withdraw the survey.**

As a health system with two participating 340B hospitals, as well as a Ryan White Clinic, 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.

AHN's 340B savings allow us to reach more patients and provide comprehensive health care to many more uninsured and underinsured patients in our service areas. Specific AHN programs and services supported by 340B program savings include:

- access to oncology care and treatment in multiple communities throughout the Western Pennsylvania region so patients can receive care close to home,
- designing a comprehensive system that provides patients with access to quality care and a better patient experience through necessary support services such as social work, navigation, financial counseling and charity care for cancer patients,
- providing technologically advanced and expensive oncological care as a supplement or alternative to traditional chemotherapy,
- prescription medications for free and/or reduced prices,
- providing new and cutting edge drugs that would otherwise be a burden on any organization and most standalone physician practices,
- expansion of "care coordination clinics," such as West Penn Hospital's Care Partner Clinic, which identify high risk patients throughout Western Pennsylvania that do not have resources to obtain healthcare or medications,
- free annual influenza and pneumonia vaccines for high risk populations which prevents hospitalizations and deaths;
- prevention of the spread of HIV transmission through programs to increase medication compliance,
- the Perinatal Hope Program – a one-stop care program aimed at ensuring successful outcomes for expectant mothers addicted to drugs or alcohol and their newborn babies, and
- the Positive Health Clinic – a Ryan White Care Act/HRSA funded medical clinic for persons with HIV, providing comprehensive state-of-the art primary and specialized care to HIV-positive persons, regardless of their medical insurance coverage or ability to pay.

The 340B program is a lifeline for vulnerable patients and diverse communities, as it extends the reach of scarce health care dollars to best serve our patients. We are concerned that the proposed survey will be used by CMS to continue its harmful policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the good work accomplished through the program and impacting our ability to care for all patients that need our care.

From an implementation perspective, this survey will significantly burden our participating 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 health system 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 help us maintain the original program savings that were intended when the 340B program was adopted so we can continue to take care of *all* the patients that need our services.

Sincerely,

Cynthia Hundorfean
Chief Executive Officer and President

cc: Jacqueline M. Bauer, General Counsel and Chief Administrative Officer, Allegheny Health Network
Jeffrey T. Crudele, Chief Financial Officer, Allegheny Health Network
Daniel A. Onorato, Executive Vice President, Corporate Affairs, Highmark Health

Ascension

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

November 29, 2019

Submitted electronically via: www.regulations.gov

Re: Agency Information Collection Activities: Proposed Collection; Comment Request: Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Dear Mr. Parham:

Ascension appreciates the opportunity to submit comments in response to the Comment Request on a Proposed New Collection entitled *Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)* recently issued by the Centers for Medicare & Medicaid Services (CMS).[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

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.

[1] 84 Fed. Reg. 51590 (Sept. 30, 2019).

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 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 information collection request (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. CMS proposes to ask 340B covered entities for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). As noted by others, there can easily be tens of thousands of units of data in any given quarter for which hospitals would need to account. Even more concerning are the extensive mathematical calculations the ICR would require applicable covered entities to prepare for potentially hundreds of NDCs. CMS is further asking covered entities to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring us to 1) average the prices together for all the NDCs mapped to the HCPCS codes, which can be dozens of NDCs for a single HCPCS code, and 2) convert NDC purchase units to HCPCS dosage units. In addition to 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.

CMS also proposes to ask that covered entities identify each provider-based department where a relevant drug was administered. This, too, would be extremely burdensome, as most hospitals do not track data this way and would need to run numerous unique reports out of the hospital's billing systems and electronic medical record systems to be responsive. Furthermore, CMS fails to explain the purpose of collecting this data on provider-based departments or how CMS intends to use this information, which suggests a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). CMS's proposed survey instructions would also ask respondents to list each provider-based department of the hospital that is "enrolled in the 340B program." However, the Health Resources and Services Administration (HRSA) currently requires that all outpatient clinics and services located outside of the four walls of a hospital that intend to use or purchase 340B drugs for its patients must register with the 340B program. This, therefore, raises questions about what new information CMS is seeking to collect such that it warrants the increased burden this added reporting would create. 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, costing 340B hospitals a total of nearly five million dollars. We echo concerns raised by others that CMS's proposed instructions are not sufficiently clear, making it extremely difficult for us to fully evaluate the resources necessary to comply. While we do 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 lack of clarity on the actual data CMS is seeking to obtain, collectively suggest that CMS should withdraw the 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

November 29, 2019

[Submitted electronically at www.regulations.gov]
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number l, Room C4–26–05,
7500 Security Boulevard, Baltimore, Maryland 21244–1850

Re: CMS–10709— Proposed Collection of 340B Costs.

ASHP appreciates the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS) regarding its proposed collection of hospital acquisition costs for drugs purchased through the 340B drug pricing program (the "notice"). ASHP is a national professional organization representing nearly 50,000 members including pharmacists, pharmacy residents, student pharmacists, and pharmacy technicians, who provide patient care services in acute care and ambulatory settings, including hospitals, health systems, and clinics. For 75 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

ASHP strongly supports the 340B drug discount program and we are deeply troubled by CMS's continued insistence, despite overwhelming evidence to the contrary, that the program contributes to high drug costs. Many of our members practice in 340B-participating hospitals and health systems and have seen firsthand how the federal 340B program allows providers to stretch scarce resources for the benefit of patients. We continue to oppose any cuts to 340B reimbursement and believe that CMS should immediately rescind all cuts to 340B reimbursement for hospitals and their outpatient departments.

Although ASHP supports reasonable transparency around drug pricing, we have the following serious concerns with the proposed data collection of hospitals actual acquisition costs (AAC) for 340B drugs:

- Flawed Methodology: The notice is vague, but our understanding is that CMS intends to survey all 340B-eligible hospitals. We question the need to collect data from all institutions when a simpler statistical sampling method could be used. Further, the notice's lack of specificity raises questions about exactly which price CMS expects hospitals to report. For instance, sub-ceiling or negotiated prices are proprietary and CMS should not expect hospitals to disclose them. CMS could avoid the entire survey process by using the 340B ceiling price as the proxy for hospital AAC. CMS already has this data. Thus, the rational choice is to use it and forego an expensive, unnecessary, and burdensome hospital survey.

- Regulatory Burden: Given that this Administration is committed to reducing regulatory burden, we question the choice to conduct a survey that imposes significant burden and produces low-quality data. Based on conversations with our members, who would likely lead hospital survey responses, CMS underestimates the burden associated with the survey. It will take, at minimum, two highly-skilled FTEs 40 – 48 hours to compile the information, with a cost of $67 per hour for each – much higher than the CMS estimates. We must emphasize that this is not an easy collection – it will require manipulation of, and extreme fluency with, the data. Some hospitals have staff members who specialize in drug pricing and reimbursement, but others do not have those resources. Based on the variation in ability and methods among respondents, it is highly likely CMS will receive inaccurate, inconsistent survey results. Thus, as noted above, we question why CMS does not simply use ceiling price as a proxy for AAC.

- Damage to Patients Who Rely on the Program: CMS' motivation for this request appears to be driven by the desire to reduce resources available to 340B hospitals. This will jeopardize care for thousands of patients who benefit from the 340B program and runs counter to Congress' stated purpose for authorizing the 340B program.

We urge CMS to reconsider the proposed data collection based on the associated burden and the likelihood that it will not yield correct, usable data. Additionally, we reiterate our request that CMS immediately reinstate full 340B reimbursement. Thank you for your consideration of our comments. If you have any questions, I can be reached at 301-664-8696 or jschulte@ashp.org.

Sincerely,

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

Beaumont

November 27, 2019

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

Dear Mr. Parham:

Beaumont Health appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Beaumont Health operates six (6) hospitals that participate in the 340B program, five (5) of which are eligible by virtue of the high volume of Medicaid and low-income patients they serve. The sixth hospital is eligible for 340B participation because of its status as a rural referral center. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

Our organization has significant concerns regarding the amount of time it would take to respond to the survey. CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data hospitals would need to account for, and Beaumont Health has six (6) hospitals that are 340B covered entities. Even more concerning are the extensive mathematical calculations the ICR requires hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring hospitals to 1) average the prices together for all the NDCs mapped to the HCPCS codes, which can be dozens of NDCs for a single HCPCS code, and 2) convert NDC purchase units to HCPCS dosage units. In addition to requiring significant administrative resources, asking hospitals to complete calculations involving tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report, despite their best efforts.

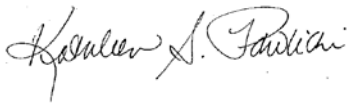
CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for Beaumont Health, as tracking data in this way requires significant effort, including the need to run numerous reports out of the hospital's billing and electronic medical record systems in order to match the location where the HCPCS code charge was generated to where the drug was administered. There may be functionality in our electronic health record that can increase efficiency, but it will require a costly and time consuming upgrade to implement. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995 (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions need additional clarification. Our hospitals had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospitals to accurately evaluate the amount of additional resources required to comply with this request, and these resources could be better used to provide care to low-income patients. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

Sincerely,



Kathy Pawlicki
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THE CARLE FOUNDATION
611 W. Park Street | Urbana, Illinois 61801

Carle

November 26, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services, HHS
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Attention: CMS-10709
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-10709 Request for Comment on Proposed Hospital Survey for Specified Covered Outpatient Drugs

Dear Ms. Verma:

The Carle Foundation Hospital, Carle Hoopeston Regional Health Center, and Carle Richland Memorial Hospital (collectively, "Carle") thanks CMS for the opportunity to provide comments on CMS's proposed Hospital Survey for Specified Covered Outpatient Drugs ("SCODs"). Specifically, the agency 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 his statutory authority to adjust payment rates under the Hospital Outpatient Prospective Payment System ("OPPS") for separately payable, 340B-acquired drugs. Although HHS has appealed that ruling, CMS stated that it is important to begin obtaining acquisition costs for the SCODs in an effort to set payment rates based on cost for the 340B acquired drugs when they are furnished to certain eligible Covered Entity hospitals.
Carle believes that the collection of acquisition cost data, as proposed, from all hospitals that purchased SCODs in the fourth quarter of 2018 and the first quarter of 2019 would 1) unreasonably burden 340B Covered Entities, particularly health systems such as Carle and 2) not accurately reflect actual 340B costs for some medications. Additionally, the proposed survey would likely lead to CMS policy decisions that continue to undermine the statutory intent of the 340B Program.

1. **The Proposed Survey Would Unreasonably Burden 340B Covered Entities, Particularly Health Care Systems such as Carle**

CMS's proposed survey is unnecessarily broad in scope and unduly burdens 340B Covered Entities, particularly health systems such as Carle that have multiple 340B-eligible hospitals. Although the scope of the survey is somewhat unclear, it appears that CMS may attempt to collect 340B pricing data from all 340B Covered Entities. CMS 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. Because actual acquisition costs for 340B medications are largely consistent across different 340B Covered Entities per statutory pricing requirements, inclusion of all Covered Entities is unnecessary for collecting the requested information and is overly burdensome for all parties involved, including CMS itself.

Furthermore, CMS 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 who should be devoting their time to patient care. Although 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), if CMS decides to move forward with the survey, Carle would urge CMS to request this information from a primary source of drug pricing – i.e. pharmaceutical companies.

Aside from the scope of the audit, the request for information itself would be unduly burdensome for many 340B Covered Entities, if required to participate. Firstly, CMS's estimate of forty-eight (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 a large number of different 340B accounts set up through various wholesalers/manufacturers with data housed on different software systems—collecting information from all of these disparate sources would be extremely time intensive and divert pharmacy or IT resources typically used to monitor 340B program compliance, patient care, or complete other crucial tasks. Additionally, CMS's proposed survey completion time does not appear to account for the fact that health systems, such as Carle, 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, even if CMS's determination of 48 FTE-based hours per Covered Entity is accurate, the survey creates an excessive burden on Covered Entities based on the limited one-month time period for data collection and submission. Dedicating the equivalent of 48 FTE hours (i.e, a full-time employee for six 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 can be accurately ascertained with a significantly narrowed scope is clearly unreasonable.

To that end, if CMS opts to move forward with this survey, Carle 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 Proposed Survey Would Not Accurately Reflect Actual 340B Costs for Some Medications**

Carle is also concerned that the proposed collection of information 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. Drug shortages, which have become increasingly more common for a variety of factors, also cause drug prices to rise significantly, further causing a misrepresentation of drug costs. 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. 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 $0.01 per package for the quarter. However, this low pricing typically only lasts one quarter, and the drug's 340B price significantly increases during the subsequent 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.

Furthermore, as stated and explained above, 340B Covered Entities are not the most appropriate party to request drug pricing information from. Because healthcare providers are merely the recipients of drug prices and play minimal roles in the setting of such prices, CMS would more greatly benefit from requesting information directly from those that determine drug prices, such as pharmaceutical companies. Doing so would allow CMS to receive information directly from the source, rather than a downstream party, such as healthcare providers. It would also prevent CMS from unnecessarily impeding the provision of healthcare to patients by allowing FTEs at 340B Covered Entities to direct time toward patient care rather than data collection.

To that end, if CMS opts to move forward with the survey, Carle requests that (1) a larger time period be used for the data collection to more accurately reflect long-term drug pricing trends and (2) the information be requested from parties that actually determine drug prices, such as pharmaceutical companies. Alternatively, 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. Allowing for a greater time period to collect and submit the data would also slightly diminish the interruption of time that would otherwise be devoted to tasks that further patient care.

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

Finally, the Proposed Survey would likely lead to continued CMS policy decisions that do not reflect the statutory intent of the 340B Program to stretch scarce 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 core 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 very likely lead to a negative impact on patient care and the ability of the nation's safety-net providers to effectively reach the most vulnerable of the patient population.

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. That is, 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. Specifically, studies have shown that Disproportionate Share Hospitals alone (only one of the several different types of qualifying 340B Covered Entities) make up over 35 percent of all acute care hospitals, yet provide approximately 60 percent of the entire nation's uncompensated care.

The delivery of uncompensated care necessarily drives down a provider's ability to stay financially viable, expand patient services (particularly specialty services), provide charity care, and effectively reach the most vulnerable of the nation's patient population. The 340B Program was created and continues to exist to provide a mechanism of financial support for providers whose mission is to serve those of us who may otherwise be completely void of healthcare. To diminish the 340B Program in the ways that CMS continually seeks to implement, such as through the purpose of the proposed 340B drug cost survey and other reimbursement cut activities, is to effectively abandon under- and uninsured patients and promote a message that only those with the financial means to afford healthcare are deserving of it. The continual attempts to undermine the 340B Program is a travesty that threatens a chilling ripple effect, ultimately causing the most vulnerable among us to pay the price.

As such, CMS should not initiate any payment reduction for 340B medications, regardless of the data it is based on, as the 340B Program serves as a vital mechanism for safety-net providers, such as Carle, to be equipped to reach vulnerable patients who may not otherwise be able to receive the quality of care that 340B Covered Entities are able to provide. Carle urges CMS to recognize the value and asset that the 340B Program provides to communities across the nation and the grave effects that will necessarily occur should CMS proceed with its intent to reduce 340B drug prices.

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

Respectfully Submitted,

Dawn Walden
Senior Vice President
Chief Revenue Cycle Officer

Kurt Leifheit
Vice President
Corporate Counsel

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November 27, 2019

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10709 / OMB 0938-New
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Hospital Survey for Specified Covered Outpatient Drugs

Dear Mr. Parham,

On behalf of our over 225 members, 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. According to the information collection request, the proposed hospital survey seeks to collect acquisition costs for specified covered outpatient drugs acquired under the 340B Drug Pricing Program (340B Program). CMS intends to use the survey to help determine the Medicare payment amounts for hospitals that received a payment adjustment under the Hospital Outpatient Prospective Payment System (OPPS). We believe children's hospitals should be excluded from the proposed hospital survey because children's hospitals are generally not reimbursed under Medicare as there are very few children covered by Medicare. However, if children's hospitals must complete the survey, we urge CMS to revise the survey to reduce the regulatory burden on hospitals. We provide more detailed comments below.

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 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.

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. Since the purpose of the proposed hospital survey is to collect acquisition costs to determine the appropriate Medicare payment for hospitals subject to the payment adjustments, children's hospitals should be excluded from the survey as we are excepted from the payment adjustments.

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[1]. 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. Price information gleaned from this small number of children's hospitals that participate in the 340B Program would not provide much information to CMS, but would significantly increase the burden to children's hospitals. We urge the administration to consider the significant burden the proposed hospital survey would impose and exempt children's hospitals from the requirement.

Finally, confidentiality provisions in many purchase agreements with vendors prohibit children's hospitals from disclosing price information. Many supply arrangements contain contractual restrictions that prohibit children's hospitals from disclosing negotiated price information to outside parties. The proposed hospital survey would force children's hospitals to choose between complying with CMS request or violating purchase agreements, potentially subjecting our members to breach of contract penalties.

CMS should revise the proposed hospital survey 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, CMS should modify the proposed hospital survey to reduce administrative burden. Since the purpose of the proposed hospital survey is to collect acquisition costs of 340B-acquired drugs, we suggest the following changes to ease the administrative burden on hospitals while helping CMS achieve its stated purpose:

- CMS should remove the column titled "Provider Based Department Name." The average price of 340B-acquired drugs is not dependent on where the drug is administered, so this information is not relevant to the agency's stated purpose. The amount of effort, however, necessary to identity the 340B-acquired drugs administered in each provider-based department will be significant and costly for children's hospitals.

- CMS should remove the column titled "HCPCS code for each SCOD." Similar to provider-based department name, 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 typically do not 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.

[1] 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.

- CMS should clarify that the column "Dose (as reflected in descriptor)" refers to a drug's package size and rename it accordingly. The term "dose" is commonly used to refer to the amount administered to a particular patient; we do not believe this patient-level information – which would be enormously cumbersome to gather and unnecessary for CMS' stated purpose – is what was intended and we ask CMS to clarify and limit the information collection request to only data relevant to its purpose.

- CMS should remove 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)." 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 and does not pertain to the average 340B price, which is the stated purpose of the information collection request, we urge CMS to remove these columns to alleviate the administrative burden imposed on children's hospitals.

* * * * *

Finally, we want to reiterate that the 340B Program is vital to children's hospitals – as the price of new pharmaceutical therapy continues to grow, the 340B Program gives children's hospitals access to expensive drugs at a more affordable price, thus allowing the hospitals to stretch scarce resources to provide needed care to more patients. As safety-net providers with more than half of our patients being covered by Medicaid, children's hospitals provide care to many low-income, uninsured, and under-insured patients. This would not be possible without the support of the 340B Program. While we applaud and support CMS' intent to preserve the sustainability of the Medicare program, we urge CMS to carefully consider any action that may jeopardize the 340B Program, and the many providers who rely on the program to care for their patients.

We appreciate the opportunity to provide comments. We look forward to our continuing work with CMS 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

Tampa General Hospital

November 26, 2019

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

Dear Mr. Parham:

On behalf of the patients and staff of Tampa General Hospital we appreciate the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is eligible to participate in the 340B program by virtue of our high DSH percentage and rely on our 340B savings to meet the needs of patients.

With over 1,000 beds, Tampa General Hospital, is one of the most comprehensive medical facilities in Florida serving over twelve counties with a population in excess of 4 million. We are the area's only Level 1 Trauma Center and the region's leading Safety Net hospital, committed to providing quality health care to all patients regardless of ability to pay. Our hospital is home to one of the leading organ transplant centers in the country, having performed more than 10,000 adult solid organ transplants. We are a nationally certified comprehensive stroke center and offer other outstanding services through our diversified specialties including internal medicine, cardiovascular, orthopedics, high risk and normal obstetrics, urology, ENT, endocrinology, neurosurgery, gastroenterology, the Thyroid Cancer & Parathyroid Institute and the Children's Medical Center including the Jennifer Leigh Muma Neonatal Intensive Care Unit. In addition, we are the primary teaching hospital for the USF Health Morsani College of Medicine offering training for over 60 ACGME accredited programs. Tampa General is committed to providing area residents with excellent and compassionate health care ranging from the simplest to the most complex medical services, and TGH consistently sustains a Medicare Disproportionate Share (DSH) adjustment above 23%.

For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

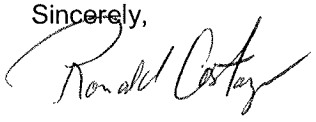
Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

If you have any questions, please contact me at (813) 844-4801.

Sincerely,



Ronald Costanzo
Director of Reimbursement

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November 27, 2019

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. 84, No. 189), September 30, 2019.

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.

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 not only in future Medicare Part B 340B payment policy but 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.[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 – which is the very purpose of the 340B program.

Congress created the 340B program to permit hospitals serving vulnerable communities, such as 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

[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

[3] https://www.hrsa.gov/opa/index.html

in helping hospitals expand access to comprehensive health care services, including access to lifesaving prescription drugs, in vulnerable communities across the country, including low-income and uninsured individuals in these communities. Given the rapid escalation in the cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build and promote healthy communities. CMS's plan to collect actual acquisition cost data from *only* 340B hospitals confirms the agency's intent to continue down its policy path for 340B hospitals and their patients.

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 approach and whether it conforms 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, but only if the hospital acquisition cost survey data meets the specifications spelled out in paragraph (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] The statutory language is clear that the survey should be a large enough sample size of hospitals to generate a statistically significant estimate. However, CMS states that it will not be using any statistical methodology or sample selection for the survey. It appears that CMS will be administering the survey to all 340B hospitals and believes that the response rate will be high enough to yield statistically valid results. We do not believe that this approach complies with the statute. We have serious concerns about the statistical validity of this approach because there are no selection criteria. Also, CMS does not provide enough information to evaluate whether the results would be biased on the basis of who responds to the survey.

In addition, 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… ." 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 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

[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

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. There appear to be inconsistencies in the information and instructions found in the notice published in the *Federal Register* and the supporting documentation, Supporting Statements A and B, which may cause confusion among 340B hospitals and other stakeholders. In the notice, CMS states that it would require "certain" hospitals enrolled in the 340B program in the last quarter of 2018 and/or the first quarter of 2019 to complete the survey. However, there is some confusion around exactly which 340B hospitals and how many are expected to complete the survey. That is, the *Federal Register* survey notice and the Supporting Statement – Part A state that all 340B hospitals, which would include critical access hospitals, children's' hospitals, freestanding cancer hospitals and other rural hospitals, would be required to complete the survey. The survey's Supporting Statement – Part B, however, suggests only those 340B hospitals paid under OPPS are required to complete the survey. The inconsistency between the published notice and the supporting documentation is confusing and may lead to less meaningful responses.

For those hospitals required to complete the survey, each would be required to list, by each provider-based department of the hospital enrolled in the 340B program, the following information:

- Healthcare Common Procedure Coding System (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 761 respondents that complete the survey, they would submit approximately 46,610,448 survey responses, which would take about 33,500 hours to complete. On face value, this appears to be a gross underestimation of the burden 340B hospitals would bear in both gathering the data elements to adequately respond to the survey and formatting that data in the manner required by CMS. In addition, here is another example where the supporting documents are not consistent with the published notice. That is, in Supporting Statement – Part B, CMS notes that it expects 1,338 340B hospitals to respond, again making it challenging for the public to assess the predicted impact of the survey and its burden.

In any event, the burden of reporting acquisition cost data remains a concern. 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." In addition, 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] It is important to note that 340B hospitals are a diverse group ranging from small rural hospitals to large academic centers that care for significant numbers of low-income patients. All of these 340B hospitals already are shouldering significant costs for staff, software, health information and inventory management systems to ensure they are compliant with the rules and requirements of the 340B program. In addition, 340B hospitals are operating on thin operating margins, such that these additional costs, in terms of staff time and resources, which will need to be diverted from the primary mission of the 340B program. For our financially struggling 340B hospital members 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 – for example, McKesson Pharmaceuticals – or directly from the drug manufacturer. These purchasing arrangements are contractual agreements. The wholesaler contracts, in particular, typically have strict non-disclosure provisions. It is our understanding that they may prevent 340B hospitals from sharing any drug pricing information with any entity not party to the contract. These non-disclosure provisions may make it impossible for 340B hospitals to share the data necessary 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 will 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.

The AHA continues to believe that CMS's OPPS 340B payment policy is so disruptive that it will severely undermine the 340B program. The survey of 340B hospital acquisition cost data is another tool for CMS to use to accelerate its efforts to curtail the program. CMS should reconsider, and instead 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 or Roslyne Schulman, director for policy, at rschulman@aha.org.

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

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

MARSHALL
MEDICAL CENTER
It's about you

November 26, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Marshall 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 CMS to 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 certain hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. The 340B program allows us to stretch resources to meet the needs of our most vulnerable community members.

We are concerned that the proposed survey will be used by CMS to continue its policies deemed unlawful 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 complex 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 additional 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. Our wholesale agreements often include strict non-disclosure conditions that prohibit the sharing of any drug pricing information. These non-disclosure provisions and necessary resources would make it exceedingly difficult for our hospital to share the data necessary to complete the survey at all, let alone in a timely manner.

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. Thank you for your consideration of our comments.

Sincerely,

Shannon Truesdell
COO

Morris County Hospital
600 N Washington
Council Grove, KS 66846
(620) 767-6811-Ext 121
Fax (620) 767-5611

November 27, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Morris County 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 CMS to 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 improve compliance with critical insulin utilization by numerous underfunded diabetic patients, as well as other patients without medication insurance. We have actually galvanized our entire medical community together so that we can take advantage of the savings afforded the 340B program, which has led to new services for our small rural town. Our city leaders know that its hospital's survival is critical to our community's survival. 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.

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals operate on thin to negative 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,

Kevin A. Leeper CEO

Avera
McKennan Hospital
& University Health Center

1325 South Cliff Avenue
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Sioux Falls, SD 57117-5045
(605) 322-8000

www.AveraMcKennan.org

November, 26th, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Avera McKennan Hospital & University 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 CMS to 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 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 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.

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,

David Flicek
President & CEO

Northern Light Health

Northern Light Health
Government Relations
43 Whiting Hill Road
Brewer, Maine 04412

Office 207-861-3282
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Northern Light Health
Acadia Hospital
A.R. Gould Hospital
Beacon Health
Blue Hill Hospital
C.A. Dean Hospital
Eastern Maine Medical Center
Home Care & Hospice
Inland Hospital
Maine Coast Hospital
Mercy Hospital
Northern Light Health Foundation
Sebasticook Valley Hospital

November 26, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Northern Light Health 340B participating hospitals, 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 CMS to 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 support oral oncology patients with the management of their prescriptions as well as helping with the coordination of patient care. This program operates at a loss and is not reimbursable by Medicare. The funding provided by 340B allows us to continue this essential support for our cancer patients when they need it most. Funding provided through the 340B program also supports adding a primary care pharmacist to our team in Northern Maine to provide one-on-one patient education and medication management as an extension of a patient's primary care provider. These are just a few examples of 340B savings benefit provided to the communities we serve. 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.

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,

Lisa Harvey-McPherson RN, MBA, MPPM
Vice President Government Relations

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0002
Comment on CMS-2019-0142-0001

Submitter Information

Name: Adolphe Edward

General Comment

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

Dear Mr. Parham:

El Centro Regional Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B

hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B

program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0003
Comment on CMS-2019-0142-0001

Submitter Information

Name: Adolphe Edward

General Comment

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

Dear Mr. Parham:

El Centro Regional Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B

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CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0004
Comment on CMS-2019-0142-0001

Submitter Information

Name: Michael Hull

General Comment

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

Dear Mr. Parham:

Virginia Mason Memorial appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to

register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0005
Comment on CMS-2019-0142-0001

Submitter Information

Name: DIANE LYNN

General Comment

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

Dear Mr. Parham:

Ascension Columbia St. Mary's appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to

register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0006
Comment on CMS-2019-0142-0001

Submitter Information

Name: Israel Camacho

General Comment

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

Dear Mr. Parham:

Adventist Health & Rideout appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the

payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

Sincerely,

Adventist Health & Rideout

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Received: November 22, 2019
Status: Draft
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PUBLIC SUBMISSION

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0007
Comment on CMS-2019-0142-0001

Submitter Information

Name: Rory Phillips

General Comment

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

Dear Mr. Parham:

Southern Ohio Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

burden, and therefore cost burden, to hospitals.

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Southern Ohio Medical Center

PUBLIC SUBMISSION

As of: 11/25/19 7:46 AM
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Tracking No. 1k3-9dgh-t1j4
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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0008
Comment on CMS-2019-0142-0001

Submitter Information

Name: Kyle Brauer

General Comment

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

Dear Mr. Parham:

St. Joseph's Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to

register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

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PUBLIC SUBMISSION

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0009
Comment on CMS-2019-0142-0001

Submitter Information

Name: Chris Grace

General Comment

Dear Mr. Parham:

Memorial Hospital of Carbondale appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

As of: 11/25/19 7:41 AM
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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0010
Comment on CMS-2019-0142-0001

Submitter Information

Name: Kyle Brauer

General Comment

Dear Mr. Parham:

WInter Haven Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0011
Comment on CMS-2019-0142-0001

Submitter Information

Name: Morgan Harden

General Comment

Dear Mr. Parham:

Southern Illinois Healthcare Cancer Institute appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing

safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR

as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0012
Comment on CMS-2019-0142-0001

Submitter Information

Name: GARRY HORNE

General Comment

Dear Mr. Parham:

San Mateo Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0013
Comment on CMS-2019-0142-0001

Submitter Information

Name: Mustafa AlSorougi

General Comment

Dear Mr. Parham:

UofL Health Jewish appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0014
Comment on CMS-2019-0142-0001

Submitter Information

Name: Clementine Mehrens

General Comment

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

Dear Mr. Parham:

St. Luke's Magic Valley Medical Center, Ltd. appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital could not absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. Even assuming the accuracy of this estimate,

this is a significant sum of money that safety-net hospitals otherwise could use to care for our low-income patients. Moreover, as explained above, we believe CMS has grossly underestimated the time burden, and therefore cost burden, to hospitals.

For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

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Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0015
Comment on CMS-2019-0142-0001

Submitter Information

Name: Clementine Mehrens

General Comment

St. Luke's Regional Medical Center, Ltd. appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

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

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0016
Comment on CMS-2019-0142-0001

Submitter Information

Name: Tim Wolters
Address:

Bolivar, MO, 65613

Email: tim.wolters@citizensmemorial.com
Organization: Citizens Memorial Hospital

General Comment

Rural sole community hospitals should be exempted from this proposed collection. More rural hospitals have closed in 2019 than in any year in recent memory, and roughly half of rural hospitals are operating at a loss. Rural sole community hospitals are facing numerous battles trying to keep their doors open to provide care to Medicare beneficiaries in isolated rural areas. Rural sole community hospitals were appropriately exempted from the outpatient drug cut imposed on most 340B hospitals. As they are exempted, collecting such data from them may distort the results CMS would obtain from other 340B hospitals. We urge CMS to exempt rural sole community hospitals from this collection.

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0018
Comment on CMS-2019-0142-0001

Submitter Information

Name: Tammy Nadler

General Comment

Dear Mr. Parham:

Golden Valley Memorial Healthcare appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Golden Valley Memorial Healthcare

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0019
Comment on CMS-2019-0142-0001

Submitter Information

Name: Kimberly Metcalf

General Comment

Dear Mr. Parham:

UConn Health appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

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

Sincerely,

UConn Health

PUBLIC SUBMISSION

As of: 11/26/19 8:54 AM
Received: November 25, 2019
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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0020
Comment on CMS-2019-0142-0001

Submitter Information

Name: Michelle Tuttle

General Comment

Dear Mr. Parham:

Madison Health appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

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

Sincerely,

Madison Health

PUBLIC SUBMISSION

As of: 11/26/19 8:56 AM
Received: November 25, 2019
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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0021
Comment on CMS-2019-0142-0001

Submitter Information

Name: Terrence Wernette

General Comment

Dear Mr. Parham:

Covenant Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately.

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

Sincerely,

Covenant Medical Center

PUBLIC SUBMISSION

As of: 11/26/19 8:57 AM
Received: November 25, 2019
Status: Draft
Tracking No. 1k3-9dif-7p5n
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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0022
Comment on CMS-2019-0142-0001

Submitter Information

Name: Ellie Amorry

General Comment

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

Dear Mr. Parham:

Meadville Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. Even assuming the accuracy of this estimate, this is a significant sum of money that safety-net hospitals otherwise could use to care for our low-income patients.

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Meadville Medical Center

PUBLIC SUBMISSION

As of: 11/26/19 8:59 AM
Received: November 25, 2019
Status: Draft
Tracking No. 1k3-9dif-a658
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0023
Comment on CMS-2019-0142-0001

Submitter Information

Name: Tracy Gilmore

General Comment

Dear Mr. Parham:

Labette County Medical Center D/B/A Labette Health appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Tracy Gilmore

340B Specialist
Labette County Medical Center D/B/A Labette Health

PUBLIC SUBMISSION

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Received: November 25, 2019
Status: Draft
Tracking No. 1k3-9din-a46k
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0027
Comment on CMS-2019-0142-0001

Submitter Information

Name: Chad Austin
Organization: Kansas Hospital Association

General Comment

November 25, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of the Kanas Hospital Association and our member hospitals, 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 CMS to withdraw the survey. At present, more than 80 Kansas hospitals are participating in the 340B program.

Kansas hospitals participating in the 340B program have been able to use the program savings

to improve patient services and help their 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. Kansas hospitals 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.

From an implementation perspective, this survey will significantly burden Kansas 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, Kansas hospitals would need to access and assess proprietary drug prices from their wholesaler. Many 340B hospitals purchase their 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 Kansas 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,

Chad Austin
Senior Vice President, Government Relations
Kansas Hospital Association

PUBLIC SUBMISSION

As of: 11/26/19 4:17 PM
Received: November 26, 2019
Status: Draft
Tracking No. 1k3-9dj3-grps
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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0029
Comment on CMS-2019-0142-0001

Submitter Information

Name: Michael Pasternak

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Penn Highlands DuBois appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing

safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Penn Highlands DuBois

PUBLIC SUBMISSION

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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0030
Comment on CMS-2019-0142-0001

Submitter Information

Name: Bruce Latimer

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Kingman Regional Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

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

Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Kingman Regional Medical Center

PUBLIC SUBMISSION

As of: 11/27/19 9:57 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djq-rgtj
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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0046
Comment on CMS-2019-0142-0001

Submitter Information

Name: Cynthia Williams

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Riverside Regional Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse.

CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Riverside Regional Medical Center

PUBLIC SUBMISSION

As of: 11/27/19 9:58 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djq-76vm
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0047
Comment on CMS-2019-0142-0001

Submitter Information

Name: Cynthia Williams

General Comment

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

Dear Mr. Parham:

Riverside Shore Memorial Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

In addition, 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Sincerely,

Riverside Shore Memorial Hospital

PUBLIC SUBMISSION

As of: 11/29/19 7:15 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-6zvi
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0048
Comment on CMS-2019-0142-0001

Submitter Information

Name: Roy Guharoy

General Comment

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

Dear Mr. Parham:

Riverside Shore Memorial Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

In addition, 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Sincerely,

Baptist Health System

PUBLIC SUBMISSION

As of: 11/29/19 7:18 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-ghxx
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0049
Comment on CMS-2019-0142-0001

Submitter Information

Name: Robert Murphy

General Comment

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

Dear Mr. Parham:

Ascension St. Vincent Warrick appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Ascension St. Vincent Warrick

PUBLIC SUBMISSION

As of: 11/29/19 7:19 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-ha8w
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0050
Comment on CMS-2019-0142-0001

Submitter Information

Name: Amar Sharma

General Comment

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

Dear Mr. Parham:

UCSD Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already

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

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the

ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

UCSD Medical Center

PUBLIC SUBMISSION

As of: 11/29/19 7:21 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-suue
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0051
Comment on CMS-2019-0142-0001

Submitter Information

Name: Michael Bonck

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

St. Joseph Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to help meet the needs of the low-income, non-insured and underinsured patients we serve in our community. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

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

those who can least afford care. The social determinants of care are very difficult and challenging within our community. The number of homeless patients and non-insured patients is increasing within our community. 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. It makes absolutely no sense to do this. That would be on top of our Medicaid payments in the State of Washington that are below 340B cost!! In addition, if we have dual-eligible patients (Medicare/Medicaid), we never receive additional reimbursement from Medicaid. If we are reimbursed at cost by Medicare for these patients, reimbursement will be below cost!!

Our hospital has significant concerns regarding the amount of time it will take to respond to the survey. CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data hospitals would need to account for. Even more concerning are the extensive mathematical calculations the ICR requires hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring hospitals to 1) average the prices together for all the NDCs mapped to the HCPCS codes, which can be dozens of NDCs for a single HCPCS code, and 2) convert NDC purchase units to HCPCS dosage units. In addition to significantly adding to the burden, asking hospitals to complete calculations factoring tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report despite their best efforts. This will take much longer than the 48 hour estimate that we have seen.

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Sincerely,
Michael J. Bonck, RPh
St. Joseph Medical Center

PUBLIC SUBMISSION

As of: 11/29/19 7:26 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-ilbz
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0054
Comment on CMS-2019-0142-0001

Submitter Information

Name: Chris Jellison

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Parkview Hospital, Inc. appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse.

CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Chris Jellison
Corporate Pharmacy Director
Parkview Hospital, Inc.

PUBLIC SUBMISSION

As of: 11/29/19 7:27 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-peat
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0055
Comment on CMS-2019-0142-0001

Submitter Information

Name: Kidane Geda

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Bayhealth Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing

safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Bayhealth Medical Center

PUBLIC SUBMISSION

As of: 11/29/19 7:28 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djr-ow93
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0056
Comment on CMS-2019-0142-0001

Submitter Information

Name: Michelle Mattingly

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Flaget Memorial Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B

drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Flaget Memorial Hospital

PUBLIC SUBMISSION

As of: 11/29/19 7:32 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djs-rqqn
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0059
Comment on CMS-2019-0142-0001

Submitter Information

Name: Marybeth Balbo

General Comment

William N. Parham, III
Director
Paperwork Reduction Staff

Dear Mr. Parham:

Niagara Falls Memorial Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction

to 340B hospitals, we strongly oppose this ICR, as it would make a bad policy even worse. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

Niagara Falls Memorial Medical Center

PUBLIC SUBMISSION

As of: 11/29/19 7:38 AM
Received: November 27, 2019
Status: Draft
Tracking No. 1k3-9djt-tv04
Comments Due: November 29, 2019
Submission Type: API

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0064
Comment on CMS-2019-0142-0001

Submitter Information

Name: Courtney Pool
Address:
Austin, TX, 78751-2316
Email: courtney.pool02@hhsc.state.tx.us
Organization: Texas Health and Human Services Commission

General Comment

Federal Register Number 2019-21120 CMS Docket Number CMS-2019-0142

Comment:
The acquisition cost data hospitals submit in response to this survey will be used to help determine payment amounts for drugs acquired under the 340B program. This information is also important to Medicaid programs. We also want to ensure that the Medicaid program pays for specified covered outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs. This will ensure that the Medicaid program uses taxpayer dollars prudently while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs. Please consider issuing guidance on how this information can be used in Medicaid programs.

PUBLIC SUBMISSION

As of: 11/29/19 8:03 AM
Received: November 28, 2019
Status: Draft
Tracking No. 1k3-9dkn-rimv
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0083
Comment on CMS-2019-0142-0001

Submitter Information

Name: Jeffrey Woodard
Organization: Erlanger Health System

General Comment

As an employee of a safety net, 340b hospital, I concur fully in America's Essential Hospitals' ("AEH") submitted analysis of the proposal to collect drug acquisition cost data from hospitals participating in the 340B drug pricing program. As a point of emphasis, however, the comments here to echo AEH's comments regarding CMS' estimate that information collection/survey completion would take, on average, 48 hours to complete. Please note that this CMS' appraisal woefully underestimates the necessary work here for each of the reasons expressed by AEH. Regardless and more importantly I think, CMS should appreciate that obligating hospitals to dedicate its already scarce and essential resources to identify acquisition costs, much, if not all, of which information CMS already has access to, (whether it takes 48 hours or 480 hours), will needlessly impose additional hardships on strained and overburdened safety net hospitals such as ours.

PUBLIC SUBMISSION

As of: 11/29/19 8:04 AM
Received: November 28, 2019
Status: Draft
Tracking No. 1k3-9dkp-n8vn
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0084
Comment on CMS-2019-0142-0001

Submitter Information

Name: Cindy K Bartlett

General Comment

Dear Mr. Parham:

St. Charles appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is eligible to participate in the 340B program by virtue of the rural location of our hospital. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

St. Charles

PUBLIC SUBMISSION

As of: 11/29/19 8:04 AM
Received: November 28, 2019
Status: Draft
Tracking No. 1k3-9dkp-6b12
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0085
Comment on CMS-2019-0142-0001

Submitter Information

Name: Lauren Trumbo

General Comment

Dear Mr. Parham:

St. Catherine Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Sincerely,

St. Catherine Hospital

PUBLIC SUBMISSION

As of: 11/29/19 8:05 AM
Received: November 28, 2019
Status: Draft
Tracking No. 1k3-9dkp-nfvv
Comments Due: November 29, 2019
Submission Type: Web

Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0086
Comment on CMS-2019-0142-0001

Submitter Information

Name: Leslie Pires

General Comment

Dear Mr. Parham:

Kent County Memorial Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0087
Comment on CMS-2019-0142-0001

Submitter Information

Name: Gregory Weller

General Comment

Dear Mr. Parham:

St. Luke Community Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

St. Luke Community Hospital

PUBLIC SUBMISSION

As of: 11/29/19 8:07 AM
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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0088
Comment on CMS-2019-0142-0001

Submitter Information

Name: Cynthia Martens

General Comment

Dear Mr. Parham:

Monroe County Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Monroe County Hospital

PUBLIC SUBMISSION

As of: 11/29/19 8:08 AM
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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0089
Comment on CMS-2019-0142-0001

Submitter Information

Name: Leslie Pires

General Comment

Dear Mr. Parham:

Women & Infants Hospital of Rhode Island appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0090
Comment on CMS-2019-0142-0001

Submitter Information

Name: Ausaf Tak

General Comment

Dear Mr. Parham:

Calais Regional Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Calais Regional Hospital

PUBLIC SUBMISSION

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Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0091
Comment on CMS-2019-0142-0001

Submitter Information

Name: Michael Tretina

General Comment

Dear Mr. Parham:

Bayhealth Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0092
Comment on CMS-2019-0142-0001

Submitter Information

Name: Chuck Beams

General Comment

Dear Mr. Parham:

Chuck Beams appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0093
Comment on CMS-2019-0142-0001

Submitter Information

Name: Leigh Cornell

General Comment

Dear Mr. Parham:

Pomona Valley Hospital Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0094
Comment on CMS-2019-0142-0001

Submitter Information

Name: Laura Matthews

General Comment

Dear Mr. Parham:

East Alabama Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0095
Comment on CMS-2019-0142-0001

Submitter Information

Name: Christopher Durkin

General Comment

Southern Baptist Hospital of Florida d/b/a/ Baptist Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0096
Comment on CMS-2019-0142-0001

Submitter Information

Name: Timothy Collier

General Comment

Dear Mr. Parham:

Timothy J Collier appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0097
Comment on CMS-2019-0142-0001

Submitter Information

Name: Paul Soukup

General Comment

Dear Mr. Parham:

St. Luke Community Hospital and Nursing Home Inc. appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

One question I have is. How will this impact Medicare Advantage Plans?
Will it allow them to suck more dollars out of the program, from the providers and the patients?
Will it be an enhancement to their bottom lines?

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

St. Luke Community Hospital and Nursing Home Inc.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0098
Comment on CMS-2019-0142-0001

Submitter Information

Name: Meridith Dandridge

General Comment

Dear Mr. Parham:

Seattle Children's Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a children's hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Seattle Children's Hospital

PUBLIC SUBMISSION

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Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0099
Comment on CMS-2019-0142-0001

Submitter Information

Name: Joseph Palomba

General Comment

Dear Mr. Parham:

UCONN HEALTH, JOHN DEMPSEY HOSPITAL appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0100
Comment on CMS-2019-0142-0001

Submitter Information

Name: Sandy Yeh

General Comment

Dear Mr. Parham:

University San Diego California appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Docket: CMS-2019-0142
Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0101
Comment on CMS-2019-0142-0001

Submitter Information

Name: Ambre Ayoub

General Comment

Dear Mr. Parham:

Seattle Children's Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a children's hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

Seattle Children's Hospital

PUBLIC SUBMISSION

As of: 11/29/19 8:19 AM
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Tracking No. 1k3-9dkp-3ues
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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0102
Comment on CMS-2019-0142-0001

Submitter Information

Name: Ben Gibson

General Comment

Dear Mr. Parham:

University of Chicago Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0108
Comment on CMS-2019-0142-0001

Submitter Information

Name: Wes Cowell

General Comment

Dear Mr. Parham:

FirstHealth Moore Regional Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is eligible to participate in the 340B program by virtue of the rural location of our hospital. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0111
Comment on CMS-2019-0142-0001

Submitter Information

Name: Jami Mann
Address:
Chapel Hill, NC, 27514
Email: jami.mann@unchealth.unc.edu

General Comment

Dear Mr. Parham:

University of North Carolina Hospitals appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. We urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals. We have significant concerns regarding the amount of time it would take to respond to the survey. CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data hospitals would need to account for. Even more concerning are the extensive mathematical calculations the ICR requires hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring hospitals to 1) average the prices together for all the NDCs mapped to the HCPCS codes, which can be dozens of NDCs for a single HCPCS

code, and 2) convert NDC purchase units to HCPCS dosage units. In addition to significantly adding to the burden, asking hospitals to complete calculations factoring tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report despite their best efforts.

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. Even assuming the accuracy of this estimate, this is a significant sum of money that safety-net hospitals otherwise could use to care for our low-income patients.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS's proposed ICR frustrates the 340B program's purpose as stated by Congress by reducing safety-net hospitals' ability to reach more patients and furnish more comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

We appreciate the opportunity to provide comments. For the reasons outlined above, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

University of North Carolina Hospitals

PUBLIC SUBMISSION

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0119
Comment on CMS-2019-0142-0001

Submitter Information

Name: Mark Bowen

General Comment

Dear Mr. Parham:

Nebraska Medicine appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

beneficiary.

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0120
Comment on CMS-2019-0142-0001

Submitter Information

Name: Matthew Shivers

General Comment

Dear Mr. Parham:

Great River medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is eligible to participate in the 340B program by virtue of the rural location of our hospital. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Comment On: CMS-2019-0142-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals

Document: CMS-2019-0142-DRAFT-0122
Comment on CMS-2019-0142-0001

Submitter Information

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General Comment

November 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: Document Identifier CMS-10709/OMB Control Number

Dear Administrator Verma:

The Ohio State University Wexner Medical Center (OSUWMC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) notice to collect acquisition cost data for specified outpatient drugs acquired under the 340B Drug Pricing Program (340B Program). Our comments are aligned with those of the Association of Academic Medical Centers (AAMC).

OSUWMC is a high DSH institution. For SFY 19, OSUWMC discharged 20,141 hospital patients on Medicaid, 29% of total discharges. Certain areas within OSUWMC's hospital units had a much higher volume of Medicaid patients in SFY 19, including 47.2% for our behavioral health hospital and 34.6% for our main hospital and 39.2% for our University Hospital East.

We recommend that CMS not proceed with this data collection proposal for the following reasons:

This data would not be useful to "craft an appropriate remedy in the event of an unfavorable decision [to CMS] on appeal." (p. 61322). The remedies that we proposed in our OPPS comment letter, which mirror those proposed by the AAMC and other litigants, would return money to all hospitals in full. There is no additional data needed to fulfill that task.
CMS appears to already have prejudged the results by stating that 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." (p. 61322)
This request contradicts CMS's Patients over Paperwork initiative as it adds administrative burden to collect all this data, a burden that exceeds CMS's estimate. To collect and submit this data we would have 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. Complying with this task will take staff and other resources away from existing important duties, which could include providing assistance and care for low-income patients.

In addition, given that the District Court concluded in its American Hospital Association et al. v. Azar opinion (Case number 1:18-cv-2084, December 27, 2018), that CMS did not have statutory authority to implement a nearly 30% decrease in Medicare reimbursement for drugs acquired under the 340B Program for calendar year (CY) 2018, CY 2019 and now CY 20, we see no reason why CMS should collect data for a task that the District Court ruled CMS cannot implement.

Thank you for the opportunity to present the views of OSUWMC. If you have questions regarding our comments, please feel free to contact me at Jennifer.carlson@osumc.edu

Sincerely,

Jennifer Carlson
Associate VP, External Relations & Advocacy
OSU Wexner Medical Center and Health Sciences

November 29, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Attention: CMS-10709
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-10709 Request for Comment on Proposed Hospital Survey for Specified Covered Outpatient Drugs

Dear Administrator Verma:

CHRISTUS Health (CHRISTUS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS') proposed Hospital Survey for Specified Covered Outpatient Drugs (SCODs). CHRISTUS is an integrated, not-for-profit international health system that includes nearly 350 services and facilities, including more than 50 hospitals in seven U.S. states. Consistent with its mission as a faith-based provider, CHRISTUS serves areas with some of the highest rates of uninsured. We participate in the 340B Drug Pricing Program, and have over 20 340B hospitals across the system. We rely heavily on our 340B savings to meet the needs of the low-income uninsured, underinsured, and Medicaid patients that we serve. Without the 340B program, it is unlikely that CHRISTUS would be able to continue to provide the same level of charity care to vulnerable populations.

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 has appealed that ruling, CMS stated that it is important to obtain acquisition costs for the SCODs in an effort to set payment rates based on cost for the 340B-acquired drugs when they are furnished to certain eligible Covered Entity hospitals.

CHRISTUS believes that the collection of acquisition cost data, as proposed, from all hospitals that purchased SCODs in Quarter 4 of 2018 and Quarter 1 of 2019 would 1) unreasonably burden 340B Covered Entities, particularly large health systems such as CHRISTUS; and 2) not accurately reflect actual 340B costs for some medications. Additionally, the proposed survey would likely lead to CMS policy decisions that continue to undermine the statutory intent of the 340B Program.

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

CMS' proposed survey is unnecessarily broad in scope and unduly burdens 340B Covered Entities, particularly large health systems such as CHRISTUS that have numerous 340B-eligible hospitals.

Although the scope of the survey is somewhat unclear, it appears that CMS may attempt to collect 340B pricing data from all 340B Covered Entities, however, CMS 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. Because actual acquisition costs for 340B medications are largely consistent across different 340B Covered Entities per statutory pricing requirements, inclusion of all entities is unnecessary for collecting the requested information and is overly burdensome for all parties involved, including CMS itself.

Aside from the scope of the audit, the request for information itself would be unduly burdensome for many 340B Covered Entities, if required to participate. First, CMS' 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 a large number of different 340B accounts set up through various wholesalers/manufacturers with data housed on different software systems. Collecting information from all of these disparate sources would be extremely time intensive and divert pharmacy or IT resources typically used to monitor 340B program compliance, patient care, or complete other crucial tasks. Additionally, CMS' proposed survey completion time does not appear to 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.

Even if CMS' determination of 48 FTE-based hours per Covered Entity were accurate, the survey creates an excessive burden on Covered Entities based on the limited, one-month 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 CHRISTUS, which has over 20 304B Covered Entities for which it would be required to collect data. 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.

If CMS decides to move forward with this survey, CHRISTUS requests that the Agency: (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 Proposed Survey Would Not Accurately Reflect Actual 340B Costs for Some Medications

CHRISTUS is also concerned that the proposed collection of information 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. 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.

If CMS opts to move forward with the survey, CHRISTUS requests that a larger 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 Proposed Survey Would Likely Lead to CMS Policy Decisions that Undermine the Statutory Intent of the 340B Program

Finally, the Proposed Survey would 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 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 nation's safety-net providers and will likely lead to a negative impact on patient care.

As CHRISTUS has noted in previous comments submitted to CMS, concerns that 340B savings are flowing to entities that are not in need of those savings are largely 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. CMS should not initiate any payment reduction for 340B medications, regardless of the data on which it is based.

The 340B program is vital to CHRISTUS' ability to continue to provide charity care and to carry out our mission as a safety-net provider in every community in which we operate. Thank you for your consideration of our comments on the proposed Hospital Survey for SCODs, and please feel free to contact Linda Townsend (linda.townsend@christushealth.org or 469.282.2559) if you have any questions or would like additional information.

Respectfully submitted,

Paul Generale
Executive Vice President
Chief Strategy & Network Officer

Catholic Health

November 27, 2019

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

RE: Comments on CMS Proposed Collection of Information (CMS-10709)

Dear Mr. Parham:

Catholic Health System appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Catholic Health System has two hospitals (Sisters of Charity Hospital – DSH330078 and Mount St. Mary's Hospital – DSH330188) that are eligible to participate in the 340B program by virtue of high volumes of Medicaid and low-income Medicare patients. We rely on our 340B savings to meet the needs of the vulnerable patient population that we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on

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Ph: (716) 828-3730 • Fax: (716) 828-2703 • www.chsbuffalo.org

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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. Even assuming the accuracy of this estimate, this is a significant sum of money that safety-net hospitals otherwise

Catholic Health

could use to care for our low-income patients. Moreover, as explained above, we believe CMS has grossly underestimated the time burden, and therefore cost burden, to hospitals.

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

Sincerely,

Tristan Greer
340B Program Business Manager
Catholic Health System
Buffalo, NY 14203

Einstein
HEALTHCARE NETWORK

More than Medicine

November 26, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of **Albert Einstein 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. Einstein Medical Center Philadelphia (EMCP), the flagship hospital of Einstein, is a community-based academic medical center situated in North Philadelphia, serving one of the most diverse and disadvantaged populations in the United States. EMCP is a safety-net hospital, bearing a large share of responsibility for caring for the poor as measured by service to Medicaid, Medicare SSI, and uninsured patients. Over 85% of our patients are covered by Medicare or Medicaid, and the reimbursement we receive generally does not cover the cost of care. We have significant concerns over the intent and design of the 340B hospital survey, and we request CMS to 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. Einstein uses 340B savings to operate clinical areas that traditionally lose money such as oncology, obstetrics and a large HIV clinic. We also use 340B savings to increase access to medication. All discharged inpatients without prescription drug coverage are given a free thirty-day supply of discharge prescriptions. We employ clinical pharmacists to manage patient therapy and perform medication counseling which promotes drug adherence especially in specialized diseases such as hepatitis C, oncology and multiple sclerosis. Our pharmacists have also enrolled many patients in various patient assistance programs to reduce their out of pocket costs. Without 340B savings, it would be difficult for our hospital to continue offering these much-needed services.

For the past decade, in this country and in the city of Philadelphia, there has been an alarming increase in the rate of opioid addiction, abuse, and fatal overdose. In 2014 alone there were almost 19,000 deaths related to prescription opioid pain relievers and 10,500 deaths related to heroin in the U.S. The percentage of Philadelphia hospital emergency department visits related to opioid overdoses increased from approximately 0.4% in 2007 to nearly 0.7% in 2015. In 2015, 3,383 drug-related overdose deaths

were reported in Pennsylvania, an increase of 23.4% from the total number of overdose deaths (2,742) reported in 2014. Philadelphia was responsible for 720 of those overdoses with detection of heroin in 56.15%, Fentanyl in 26.67% and Oxycodone in 16.15% of patients according to the Medical examiner's office. According to Becker's Hospital Review, Pennsylvania ranks 8th in the country in overdose deaths. Albert Einstein Medical Center utilizes its 340B savings to make the life-saving medication Naloxone readily available to patients who are at high risk for overdoses. Albert Einstein Medical Center also provides timely medication assisted treatment programs available to its patients with a comprehensive approach. Albert Einstein Medical Center has prioritized its scare resources to include a multitude of providers, an onsite clinic, and social supports that is responsive to the vital needs of the community it serves in order to address the opioid crisis.

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.

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,

Walt Wyatt
Vice President, Finance

Einstein
MEDICAL CENTER MONTGOMERY

Beth Duffy
President & Chief Operating Officer
Executive Office

More than Medicine

November 26, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Einstein Medical Center Montgomery, 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 CMS to 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 used the 340 B savings to grow and expand the services that we provide to the greater Norristown area patients and implement programs that enhance elements of our Community Health Needs Assessment. 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.

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,

Beth Duffy

Beth Duffy
President & Chief Operating Officer

Flushing Hospital Medical Center
4500 Parsons Blvd
Flushing, N.Y. 11355

11/26/2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of The Flushing Hospital 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 CMS to 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, The Flushing Hospital Medical Center is committed to utilizing 340 B savings to benefit the patients and community we serve by establishing and maintaining comprehensive patient care services, including:

- NY State DOH Designated Stroke Center
- Center for Excellence for Bariatric Surgery
- Inpatient Chemical Dependency Unit
- Hospice Unit
- Mental Health Services
- Women's Health Services
- Development and implementation of Clinical Programs
- Expansion of In-patient and Outpatient Services
- In-patient and Out-patient Antibiotic Stewardship
- Pharmacy Concierge Service
- Community Service Plan Initiatives
- Disaster relief
- Pain Management
- Support Groups
- Smoking Cessation
- Wound Care Services
- Comprehensive Ambulatory Care Services
- Ophthalmology / Dental Services

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.

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,

Rehana Jamali,
Director of Pharmacy

INTEGRIS

CHRIS HAMMES, FACHE
Executive Vice President / Chief Operating Officer

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

November 27, 2019

Dear Mr. Parham:

INTEGRIS Health, Inc. ("INTEGRIS") appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). INTEGRIS is submitting this response on behalf of 5 covered entities, specifically:

1. INTEGRIS Bass Baptist Health Center, located in Enid, Oklahoma;
2. INTEGRIS South Oklahoma City Corporation, located in Oklahoma City, Oklahoma;
3. INTEGRIS Grove Hospital, located in Grove, Oklahoma;
4. INTEGRIS Miami Hospital, located in Miami, Oklahoma; and
5. INTEGRIS Baptist Medical Center, located in Oklahoma City, Oklahoma (effective January 1, 2020).

Our hospitals are eligible to participate in the 340B program by virtue of the high volume of Medicaid and low-income Medicare patients we serve. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

<u>CMS's Proposal Would Harm Low-Income Patients.</u>

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

hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS' Proposal is Potentially Contrary to the Medicare Statute.

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)).

CMS Grossly Underestimates the Massive Administrative Burden.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a potential violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Also, it is not clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

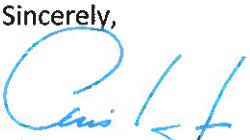
Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and INTEGRIS had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for INTEGRIS to evaluate the burden accurately. At a minimum, if CMS does not withdraw the ICR, CMS should reissue the proposal with more detailed instructions to meet the requirements of the Paperwork Reduction Act of 1995 and allow hospitals to submit meaningful comments on the burden.

Finally, we note that CMS estimates it will take 48 hours for each 340B hospital to respond to the survey, costing 340B hospitals a total of nearly five million dollars. Even assuming the accuracy of

this estimate, this is a significant sum of money that safety-net hospitals otherwise could use to care for our low-income patients. Moreover, as explained above, we believe CMS has grossly underestimated the time burden, and therefore cost burden, to hospitals. Using the CMS time estimates, INTEGRIS would spend a minimum of **240 hours**, and potentially more time, trying to fulfill the ICR. That is time that INTEGRIS could potentially be pulled away from focusing on patient care.

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

Sincerely,



Chris Hammes, FACHE
Executive VP & COO
INTEGRIS Health, Inc.

DSH370016	INTEGRIS Bass Baptist Health Center
DSH370106	INTEGRIS South Oklahoma City Corporation
SCH370113	INTEGRIS Grove Hospital
DSH370004	INTEGRIS Miami Hospital
DSH370028	INTEGRIS Baptist Medical Center (effective January 1, 2020)

November 27, 2019

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

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

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

Dear Administrator Verma:

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

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

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

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

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

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

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

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

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

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

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

[9] L&M Policy Research, A Comparison of Characteristics of Patients Treated by 340B and Non-340B Providers, (April 8, 2019), https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf

[10] *Id.*

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

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

[13] *Id.*

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

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

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

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

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

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

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

A. CMS's proposal lacks practical utility

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

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

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

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

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

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

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

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

C. CMS fails to minimize the burden of the collection

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

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

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

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

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

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

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

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

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

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

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

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

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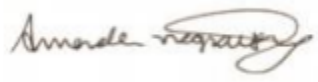
340B Health requests that CMS withdraw its proposal to collect 340B drug acquisition cost data from 340B hospitals. At a minimum, CMS should issue a new proposal with clear and detailed instructions to allow hospitals to provide meaningful comments on CMS's burden estimate. CMS should not move forward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

Sincerely,



Maureen Testoni
President & Chief Executive Officer

Amanda Nagrotsky
Legal Counsel

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

AMERICA'S ESSENTIAL HOSPITALS

November 27, 2019

William Parham III
Director
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Director Parham:

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 proposed 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 and invest substantial resources into program compliance—with additional reporting requirements on top of the existing, resource-intensive obligations they adhere to under the 340B program.

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 November 7, 2019.

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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 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 the most vulnerable patients.

We are concerned that CMS has not considered the administrative burden of the proposed information request or its authority to collect this information in the proposed manner. In our detailed comments below, we urge CMS to withdraw its proposed information collection request, given the agency has not fully evaluated both its authority to conduct this survey and the true scope of the operational complexity associated with this request.

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 notes that it is only directing 340B hospitals to report acquisition costs through the survey; hospitals not in the 340B program will not be required to report their acquisition costs because CMS believes ASP data is "an adequate measure of the drug acquisition costs" of these hospitals. The selective collection of drug acquisition

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

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 which 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.

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. Hospitals that are part of large systems leverage their size to procure volume discounts. Non-340B hospitals can use group purchasing organizations—which 340B hospitals are statutorily prohibited from using for 340B drugs—to negotiate sizable discounts on their drugs. 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 information collection request.

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. This administration has emphasized the importance of reducing provider burden and focusing on patient care, as exemplified in its Patients Over

Paperwork initiative.[4] America's Essential Hospitals commends the administration for its attempts to reduce regulatory and administrative burden through such initiatives. CMS' proposed information collection, however, would be a setback to the agency's efforts to reduce provider burden. 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 Paperwork Reduction Act 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. Further explanation of why the request is particularly burdensome is outlined below.

First, hospitals likely will have to obtain this information from a third party, such as their drug wholesaler. Hospitals enter into detailed contractual agreements with their wholesalers governing the types of information they can share with other parties. The data possessed by the wholesaler are confidential and proprietary, and hospitals would have to evaluate these contracts to ensure they do not require modification to allow them to share the information with CMS. In addition to the proprietary nature of the data, many wholesaler agreements place limits on the time period for which acquisition cost data can be downloaded. Requesting older data from the wholesaler that do not fall within the look-back period is an additional burden that requires the hospital to submit a special request to the wholesaler.

Second, even if hospitals can obtain permission from their wholesaler to retrieve and share acquisition cost data, the data provided by the wholesaler will not be in the format CMS requests. CMS proposes to require that hospitals report average acquisition cost for two quarters (the fourth quarter of calendar year 2018 and the first quarter of calendar year 2019) for all SCODs with status indicator K or G, by Healthcare Common Procedure Coding System (HCPCS) code. Once a hospital can download the information from its wholesaler, hospitals will have to cross-reference the list provided

[4] Verma S. Remarks delivered at the Health Care Payment Learning and Action Network Fall Summit. October 30, 2017. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html. Accessed November 6, 2019.
[5] Centers for Medicare & Medicaid Services. Supporting Statement—Part A. Hospital Survey for Specified Covered Outpatient Drugs (SCODs). CMS-10709; OMB 0938-New.

to find drugs with status indicators K or G. The data hospitals receive from their wholesaler will be identified by National Drug Codes (NDCs), not by 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. Matching NDC codes to HCPCS codes will require extensive manual effort by hospital staff. Once the hospital staff has assigned all NDCs to given HCPCS codes, they will have to calculate the average acquisition cost, which can differ for each individual NDC associated with a given HCPCS code. This process of obtaining the information in the format CMS requires will be extremely burdensome for hospital staff, which already are burdened by existing compliance and recordkeeping requirements.

Third, providers may purchase some drugs through distributors that are not their designated wholesaler. In these cases, the hospital would have to acquire individual invoices for purchases through these channels and then consolidate this information with the report from its wholesaler. Pulling individual invoices for drugs not purchased through the primary wholesaler would be cumbersome for hospitals.

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.

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.

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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/250/24e

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 should not reimburse 340B hospitals less than the statutory default rate of 106 percent of ASP.**

CMS should reverse its unlawful payment cuts to 340B hospitals and revert to the statutory default payment rate of 106 percent of ASP. The U.S. District Court for the District of Columbia has unequivocally held that CMS' payment cuts, which the agency intends to continue for a third year in 2020, violate the Medicare statute. As we have urged in our previous comments, CMS should reverse these payment cuts and pay hospitals back at 106 percent of ASP plus interest.

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.

CMS suggests that 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.

****

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

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November
Twenty-Nine
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Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—10709; OMB 0938-New
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Ms. Verma:

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) Information Collection Request, "Hospital Survey for Specified Covered Outpatient Drugs (SCODs)."

CMS proposes to require hospitals to report their average acquisition costs for drugs purchased through the 340B Drug Pricing Program with the stated intent of using the information collected to determine Medicare payment for 340B drugs in the future and/or as a possible remedy to the recent court decision finding that the current Medicare Part B payment policy is unlawful. According to the notice on the proposed survey, CMS's goal is "to ensure that the Medicare program pays for specified covers outpatient drugs purchased under the 340B program at amounts that approximate what hospitals actually pay to acquire the drugs."

GNYHA strongly urges CMS to rescind the proposed hospital survey of 340B drug acquisition costs because the agency intends to use the data to justify cutting payments to safety net hospitals, undermining the intent of the 340B program, and it would impose excessive burden on our members.

We offer comments on the importance of protecting the 340B program and why CMS's intent to base payment rates on cost would effectively eliminate the benefits of this important program to safety net hospitals and the communities they serve. We also discuss several issues related to CMS's request for feedback on the "necessity and utility of proposed information collection for proper performance of the agency's functions" and the "accuracy of estimated burden," as required by the Paperwork Reduction Act of 1980 (PRA).

Protecting the 340B Program

The savings achieved through the 340B program enables eligible hospitals to provide important community benefits through various programs and services. The program—which is administered by the Healthcare Resources and Services Administration (HRSA) and requires drug manufacturers to sell outpatient drugs to eligible entities at discounted prices—was created by Congress "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." These services include breast cancer screenings, community outreach, neonatal intensive care, obstetrics care, and psychiatric care. It was also intended to help safety net hospitals manage rising prescription drug costs while expanding critical health care services for the most vulnerable communities.

These 340B savings only exist if hospitals receive payment for 340B drugs at a rate that exceeds their acquisition cost. Without this margin, hospitals would not receive the intended benefit of the 340B program on behalf of their Medicare patients and their patients may not receive the benefits intended by Congress when it created the program.

With CMS's stated goal of setting Medicare reimbursement rates for 340B drugs based on acquisition costs from the proposed survey, it is once again attempting to undermine the intent of the 340B program and HRSA's authority to administer it. In addition, such a policy fails to recognize additional costs that 340B participants incur to ensure program compliance, such as purchasing software to track 340B inventory separately from drugs purchased at wholesale acquisition cost (WAC). These ongoing costs for program administration have become more difficult with the current Medicare 340B cuts (i.e., reducing the payment rate from ASP plus 6% to ASP minus 22.5%). Any further erosion of 340B savings would limit hospitals' ability to maintain access to lifesaving treatments, especially during drug shortages.

Lack of Authority to Survey Only 340B Hospitals

According to Section 1395l(14)(D)(i)(II)(iii), a survey conducted by the Secretary of HHS to determine the hospital acquisition costs for SCODs for use in setting payment rates "…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." This authority does not allow the Secretary to limit its universe of respondents to 340B hospitals. Limiting the survey to a specific group of hospitals is insufficient to generate a "statistically significant estimate of the average hospital acquisition cost." In other words, the statute refers to "the average hospital acquisition cost for each [SCOD]," not the average acquisition cost for 340B hospitals. Therefore, the Secretary would exceed his statutory authority by surveying only 340B hospitals.

Administrative Burden and Complexity

In addition to opposing CMS's attempts to undermine the 340B program and its lack of authority to do so—whether through the proposed survey or otherwise—we have major concerns about the burden that proposed survey itself would impose on 340B hospitals.

Department-Level Reporting

In discussions with our members about the proposed survey, the requirement to report data at the department level was consistently cited as requiring extensive resources and being unnecessarily burdensome since the acquisition cost for a drug is the same across all departments., Hospitals do not purchase drugs at the department level and therefore, would need to allocate purchasing data to each department to determine which clinics used each 340B drug during the specified reporting quarter. In addition, since there is no standard definition of "department" the data is likely to be reported inconsistently. The requirement to report at the department level adds complexity without any benefit and therefore, it should be eliminated.

Providing Data at the Billable Unit Level

CMS proposes that hospitals report acquisition costs at the billable unit level (i.e. by HCPCS code) rather than at the invoice level (i.e., by National Drug Code [NDC]). While HCPCS codes generically refer to a drug type, NDCs are product-specific and therefore multiple NDCs (which may be acquired at different prices) can map to a single HCPCS code. Reporting average acquisition cost data at the HCPCS code level would require cross-walking NDCs to the applicable HCPCS codes and recalculating each drug's acquisition cost at the billable unit level, a complex and time-consuming task for hospitals.

The proposed survey does not include the list of applicable NDCs so the burden would be on hospitals to identify this universe. This would require hospitals to search their electronic medical records to determine which 340B-eligible NDCs were referenced during the given quarter, map the NDCs to the charge codes in their billing systems, and then link this information to the purchasing codes used by the wholesaler to determine the average acquisition cost. Complying with the survey request would therefore involve multiple departments and a dedicated information technology professional to run the necessary queries and prepare the reports. In some cases, departments other than pharmacy might purchase drugs directly, which would require additional coordination.

The fact that many of the HCPCS code descriptions in the Medicare outpatient prospective payment system (OPPS) Addendum B do not indicate a dosage further complicates the task. That is, hospitals would need to determine the billable unit dosage so they can convert each NDC's average acquisition cost at the item or package level to the HCPCS code level.

For example, HCPCS code J9305 is a status indicator "K" drug listed in Addendum B with the descriptor "Pemexetred injection" and a payment rate of $69.472. From researching the drug, it appears that only one manufacturer, Alimta, produces the drug, but it has two NDC numbers with different dosages—500mg and 100mg—and both are single-use vials. Because Addendum B does not indicate a dosage and the drug clearly has multiple dosage options, a hospital would be unable to convert the payment rate to one of these dosages without performing additional research. An internet search would reveal the more detailed HCPCS code descriptor, showing that the J9305 payment rate is for 10mg of Pemexetred. The hospital would then need to divide each NDC's average acquisition cost by 10mg to calculate the acquisition cost at the billable unit level. This manual process would be time consuming and would have to be performed each time this situation occurred.

Another example is HCPCS code J0480, a status indicator "K" drug listed in Addendum B with the descriptor "Basiliximab" and payment rate of $3,799.932. In this case, Basiliximab has only one NDC (00078-0331-84; Simulect, 20mg injection), so presumably the payment rate listed in Addendum B is for a 20mg injection. However, this is not entirely clear, and a hospital would need to research every such instance to make sure it understands which dosage is associated with the payment rate in Addendum B.

Although we urge CMS to rescind the survey for numerous reasons, we believe that at a minimum it should list each applicable NDC in the template—i.e., those that map to the HCPCS codes with status indicators "K" and "G"—and allow hospitals to report the average acquisition cost at the NDC level.

However, we note that even if CMS allows hospitals to report at the NDC level without mapping them to HCPCS codes, some hospitals may need to request custom reports from their wholesalers to comply with this request. This could incur additional expenses, assuming the wholesalers are even able to provide the information within the limited time period. Also, some wholesalers may not be able to provide this information beyond a specified look-back period, such as one year.

Reporting Template

The proposed survey template would require hospitals to make numerous assumptions, which is not conducive to consistent data reporting. To reduce burden, reduce the risk of errors, and ensure data completeness and consistency across submissions given that hospitals would be entering information manually into Excel, CMS could provide a template with the following fields pre-populated: NDCs and HCPCS codes for status indicator "K" and "G" drugs (with NDCs cross-walked to HCPCS codes), descriptions, and dosage at the NDC level and the billable unit level. Alternatively, CMS could remove HCPCS codes and related dosages from the template, require hospitals to report acquisition costs at the NDC level, and then CMS could perform the necessary calculations on the back end to convert the data to the billable unit level. In addition, CMS should delete unnecessary fields such as the department name (see earlier comments on the complexity in reporting this information) and the Medicare payment rates, which are already known to CMS, from the template. In addition, we recommend a new field for hospitals to indicate that it does not provide a drug listed in the template. .

Although we believe hospitals would face a significant administrative burden when providing the requested acquisition cost data and therefore oppose the survey, below is an example of how CMS could, at a minimum, improve the template to reduce workload (hospitals would only complete the fields that are not pre-populated).

CCN	HCPCS code	Drug Name/ Descriptor	NDC #	N/A (Indicate with "X" if Drug is not Provided)	Dose (as reflected in descriptor)	Average 340B Drug Acquisition Cost for Q4 of CY 2018	Average 340B Drug Acquisition Cost for Q1 of CY 2019
	J1234	Example 1	1000		1 mg		
	J1235	Example 2	1001		20 mg		

Confidentiality Clauses in Wholesaler Contracts

Most hospitals purchase their 340B drugs through wholesaler arrangements and would need to access proprietary drug prices from their wholesalers to complete the survey. To comply with 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. However, 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 short response time proposed by CMS.

Estimated Burden

CMS's published notice estimates the number of respondents as 761 yet Supporting Statement Part B shows that CMS expects 1,338 340B hospitals to respond. This inconsistency makes it difficult to evaluate CMS's estimated burden. Assuming the latter number is what CMS intended (since it is more in line with the number of 340B hospitals nationwide), CMS's burden estimate is 48 hours per respondent.

Based on discussions with our member hospitals, we have determined that the required resources to comply with the proposed survey are significantly greater than CMS's estimate. The estimated burden could vary considerably by hospital, depending on each hospital's systems configurations and staff resources. However, the hospitals we spoke to about the proposed survey consistently reported that reporting acquisition costs by HCPCS code would be especially time consuming (most estimated 2-3 weeks) and that reporting at the department level would require additional time and resources. Several smaller hospitals expressed concerns that generating the requested data would require dedicated FTE hours that they may not have. This anticipated burden was echoed by the Government Accountability Office (GAO) in its report to Congress on its 2004 hospital survey of drug acquisition costs. The GAO found 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."[1]

CMS also has not indicated whether it would stop surveying hospitals after it receives the two proposed quarters of data or if it plans for this to be an ongoing or occasional request with similar limited notice. Therefore, hospitals would not be able to plan for such complex data requests in the future and make informed decisions about whether to invest in reconfiguring their systems or hiring additional staff. Hospitals also expressed concerns about CMS using two quarters of acquisition cost data to set payment rates given the fluctuations in drug prices. For certain drugs, prices could vary significantly from quarter to quarter, which means that Medicare could end up reimbursing hospitals below cost for 340B drugs if CMS chooses to use historical 340B acquisition cost data to set payment rates for future time periods.

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

[1] 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.

Sincerely,

Elisabeth Wynn
Executive Vice President
Health Economics & Finance

November 26, 2019

William Parham III
Director
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Director Parham:

Hennepin Healthcare System welcomes and appreciates the opportunity to comment on **CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request.**

Our integrated hospital and clinics system of care includes a nationally recognized Level 1 Adult Trauma Center and Level 1 Pediatric Trauma Center and acute care hospital, as well as a clinic system with a Cancer Center and primary care clinics located in Minneapolis and across Hennepin County. We provide care to low-income, uninsured and vulnerable populations with complex health care needs, including many dual eligible Medicare and Medicaid patients. Our services also include a psychiatric program, burn care, retail pharmacy, home care and hospice, a research institute, an innovation center and a philanthropic foundation. We are committed to providing the best possible care to every patient we serve. Our physicians and advance practice providers are dedicated to promoting, maintaining and restoring the health of our patients.

The 340B program was intended to help spread scarce federal resources to those hospitals that care for the uninsured and the underinsured. The money saved helps to provide services for underserved patient populations. For any other government health program to regard this particular savings as a pool that could be spread across all hospital entities is to neutralize the original program set up by the Health Resources and Services Administration.

Although the reduction in recent years in the 340B payment is budget neutral for CMS, taking those earmarked dollars away from hospitals that need to use them as intended has undermined the purpose of the prior 340B Drug Pricing Program. Thanks in part to 340B, we have built a strong infrastructure to provide the clinical care for our patients and to support obtaining the medications and services needed for their therapy. The recent cuts have already had a negative impact on hospitals that care for dual-eligible patients and other socio-economically disadvantaged patients.

We were disappointed to learn that CMS plans to continue these cuts into 2020, only intensifying these issues. The following services could be at risk if the 340B program cuts continue:

- Employment of 15+ MTM pharmacists, based in our clinics, who provide comprehensive medical reviews and medication teaching to some of our most vulnerable patients. This improves their adherence with their medication regimens, improves the chances of meeting clinical goals, decreases readmissions, visits to the Emergency Department, etc.
- Focus on reduced readmissions from the MTM and transition of care teams – there has been a significant drop in readmissions due to pharmacist involvement in the care / transitions for patients. One study showed a 50% reduction in readmissions, over two months, with the intervention of pharmacists and pharmacy residents.
- Provided millions of dollars of reduced or no cost medications to the underinsured.
- Support for the Patient Assistant Program (PAP) and Prior Authorization (PA) teams work with our patients to obtain financial support for our under and uninsured patients.
- Provided copay assistance for our large population of Ryan White eligible patients.

Additionally, the recent announcement of a cost survey in February-March 2020 has caused the following deep concerns:

- **CMS should not reimburse 340B hospitals less than the statutory default rate of 106 percent of ASP.**

CMS should reverse the payment cuts to 340B hospitals and revert to the statutory default payment rate of 106 percent of ASP. The U.S. District Court for the District of Columbia has unequivocally held that CMS' payment cuts, which the agency intends to continue for a third year in 2020, violate the Medicare statute.

These 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.

We strongly advise CMS against reducing payments by tying them to acquisition costs. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the net on which they rely, including the 340B program, can threaten their ability to maintain critical services. **We urge the agency to revert to paying 340B hospitals at 106 percent of ASP**.

- **CMS' information collection would be burdensome for hospitals.**

We have appreciated the emphasis of this administration on reducing provider's administrative burdens. CMS' acquisition cost survey would be administratively burdensome for hospitals and for the agency. The process of obtaining the information in the format CMS requires will be extremely burdensome for hospital staff, which already are burdened by existing compliance and recordkeeping requirements. Invoices from distributors who are not wholesale retailers may need to be pulled and consolidated with other data, which will be cumbersome for hospitals.

There are significant resources involved with 340B program participation, including the cost of hiring the appropriate staff, such as pharmacists and pharmacy technicians, to ensure compliance, appropriate billing software and audit response, with the program's very technical and evolving requirements. **CMS should not implement this survey without fully considering the complexities associated with producing acquisition cost data.**

Preserving the intent of the 340B program will better serve low-income Medicare beneficiaries and the Medicare program at large, and support our mission to provide exceptional care without exception.

Sincerely,

John K. Cumming, MD, MBA
Interim Chief Executive Officer
Hennepin Healthcare System

inspira HEALTH NETWORK

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November 25, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of the Inspira Health Network, and Inspira Medical Center Vineland, in particular, 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 CMS to 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 patients in Cumberland County to improve patient services, community outreach programs or help low-income patients get their medications, in a county with the most challenging health outcomes in New Jersey. 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.

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,

Peter A. Kaprielyan

Peter A. Kaprielyan
Vice President, Government and External Relations

Jefferson

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November 29, 2019

Seema Verma
Administrator
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Washington, DC 20201
Submitted electronically to http://wwww.regulations.gov

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 Verma,

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

Jamaica Hospital Medical Center
8900 Van Wyck Expwy
Jamaica, N.Y. 11418

11/26/2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of The Jamaica Hospital 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 CMS to 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, The Jamaica Hospital Medical Center is committed to utilizing 340 B savings to benefit the patients and community we serve by establishing and maintaining comprehensive patient care services, including:

- Level I Trauma Center
- Chest Pain/Stroke Center
- Hospice Unit
- Mental Health Services
- Women's Health Services
- Development and implementation of Clinical Programs
- Expansion of In-patient and Outpatient Services
- In-patient and Out-patient Antibiotic Stewardship
- Pharmacy Concierge Service
- Community Service Plan Initiatives
- Disaster relief
- Pain Management
- Support Groups
- Smoking Cessation
- Wound Care Services
- Comprehensive Ambulatory Care Services
- Ophthalmology / Dental Services

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.

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,

Louis Cosenza
Director of Pharmacy

KENSINGTON HOSPITAL

A Non-Profit Community Hospital

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

11/25/19

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 Ms. Verma:

On behalf of Kensington 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 CMS to 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 allow access to high quality care regardless of affordability. We provide significant uncompensated care, and provide access to comprehensive treatment for serious illnesses. We provide detoxification and acute care services specializing in addiction such as opioid use disorders, which includes a Methadone Clinic. We also provide access for wellness at a primary care clinic. We have been able to offer specialized care for a high risk population affected by HIV/AIDS, Diabetes; we have a podiatrist and a dental clinic as the 340B program has allowed us to accommodate specific health needs of the community. 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.

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,

Christopher Walmsley

Christopher Walmsley
Chief Financial Officer
Kensington Hospital
136 W Diamond Street
Philadelphia, PA 19122
215-426-8100 ext. 6335

DENVER HEALTH™
est. 1860
FOR LIFE'S JOURNEY

November 27, 2019

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. 84, No. 189), September 30, 2019.

Dear Administrator Verma:

On behalf of Denver Health & Hospital Authority, 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 respectfully request CMS withdraw the survey.

As a significant safety net provider in metro Denver, our mission is to transform the health of our most vulnerable patients and communities, including low income and homeless individuals who struggle with social and economic challenges on top of their medical conditions. The 340B program has been a vital lifeline for safety net providers, supporting critical health care services and helping to expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in our community. Denver Health provided $246M in uncompensated care in 2018, takes care of 1 in 3 children in Denver, 72% of our patients are low income or uninsured and has 27 school based health centers and FQHCs scattered around Denver, providing primary and specialty care. The savings we realize from the 340B program helps ensure we can continue to fulfill our mission, as intended by Congress.

For example, we have been able to use the 340B savings to:

- Create a medication assistance treatment on demand program – creating immediate access to appropriate care for substance use disorders and providing a pathway for treatment and recovery;
- Hire a clinical pharmacist and technician to expand the number of Hepatitis C patients who can treat, increasing from ~ 100 patients to more than 600 patients in 2018;
- Add comprehensive pharmacy services in our FQHCs, to help manage chronic diseases such as diabetes and hypertension; and
- Cover high cost, lifesaving medication therapies for patients without the ability to pay so they can complete their treatments and prevent readmissions.

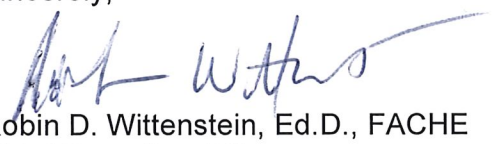
We are concerned that the proposed survey will be used by CMS to continue its unlawful policies to reduce Medicare Part B payments to 340B hospitals, thus undermining the intent of the program and harming our ability to care for our patients.

OFFICE OF THE CHIEF EXECUTIVE OFFICER
777 Bannock Street, Mail Code 0278 Denver, Colorado 80204-4507 Phone 303-602-4920 Robin.Wittenstein@dhha.org

From an implementation perspective, this survey will significantly burden our hospital. 340B hospitals like Denver Health 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,



Robin D. Wittenstein, Ed.D., FACHE
Chief Executive Officer
Denver Health and Hospital Authority

NORTON HEALTHCARE

P.O. Box 35070
Louisville, KY 40232-5070
(502) 629-8025

November 27, 2019

Via electronic submission to http://www.regulations.gov

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10709
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-10709; Comments on the Hospital Survey for Specified Covered Outpatient Drugs

Dear Administrator Verma:

Norton Healthcare, Inc., ("Norton") respectfully submits the comments set forth below on the Hospital Survey for Specified Covered Outpatient Drugs ("SCODs"). Norton appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' ("CMS") intention to survey hospitals about their acquisition costs for SCODs under the 340B Drug Pricing Program ("340B Program").[1]

In short, Norton respectfully requests:

- CMS should calculate future payments to hospitals for 340B-acquired drugs under the Hospital Outpatient Prospective Payment System ("OPPS") and any remedial payment for prior years based on the statutory rate of Average Sales Price ("ASP") plus 6 percent rather than the acquisition cost data the agency would collect under the Hospital Survey for SCODs ("Proposed Survey"). As CMS is aware, in *American Hospital Ass'n v. Azar*, the U.S. District Court for the District of Columbia ("district court") held that CMS acted in an *ultra vires* manner in compensating 340B-acquired drugs below this rate beginning in Calendar Year ("CY") 2018.[2] The district court found that not only did CMS lack the necessary data to support such rate, but also that its "magnitude and its wide applicability" inexorably lead to the conclusion that CMS altered the statutory scheme.[3]

- CMS should refrain from issuing the survey as proposed given the significant operational difficulties and burden that the Proposed Survey would place on 340B hospitals. The survey as proposed is contrary to CMS's stated goal and current efforts to reduce the regulatory burden on healthcare providers. In this regard, the survey creates a substantial new regulatory burden and

[1] CMS, Agency Information Collection Activities: Proposed Collection; Comment Request, Hospital Survey for Specified Covered Outpatient Drugs (CMS-10709), 84 Fed. Reg. 51,590 (Sept. 30, 2019).

[2] *See* Am. Hosp. Ass'n v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018), appeal pending, Nos. 19–5048 & 19–5198 (D.C. Cir.).

[3] *Id.* at 85-87.

contains ambiguities that will not only pose onerous operational difficulties on hospitals, but may also undermine the purpose of the survey and result in unintended consequences, including variation of data reported by 340B hospitals that could provide inaccurate estimates to CMS.

- If, however, CMS decides to move forward with a hospital survey of 340B acquisition cost data, Norton respectfully requests that the agency provides clarification on the issues outlined below. In particular, CMS should provide further clarification with regard to the universe of SCODs that would be subject to the survey as well as the specific acquisition costs the agency is requesting.

I. Background on Norton

Norton is a leading comprehensive health system serving adult and pediatric patients throughout Greater Louisville, Southern Indiana, the state of Kentucky, and beyond. Norton is Louisville's fourth largest employer,[4] providing care at more than 250 locations throughout Kentucky and Southern Indiana.[5] Norton includes five hospitals with 1,837 licensed beds; seven outpatient centers; 14 Norton Immediate Care Centers; more than 14,600 employees; nearly 1,000 employed medical providers; and approximately 2,000 physicians on its medical staff.[6] The hospitals provide inpatient and outpatient general care as well as specialty care including heart, neuroscience, cancer, orthopedic, and women's and pediatric services.

Norton's mission is to provide quality health care to all those it serves in a manner that responds to the needs of the community and honors its faith heritage.[7] As part of its commitment to improving the health of the community, Norton provides funding for services that benefit the public, including charity care and unpaid Medicaid costs for patients who cannot afford health care.[8] Norton also offers scholarships and educational assistance, sponsorships of community programs, community cancer initiatives, and community service activities.[9] In 2018, Norton provided more than $165 million in community benefit through charity care, educational programs, public service, and support for other organizations.[10]

Norton also has a demonstrated commitment to quality and transparency, being the first health system in the country to display quality outcome metrics on its website, enabling patients and providers to compare performance with statewide and national results, as available.[11] Demonstrating its commitment to improving community health and promoting health and wellness for its workforce, Norton was named by

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[4] *See* Louisville Business First, Louisville's Largest Employers 2018, https://www.bizjournals.com/louisville/subscriber-only/2018/07/19/louisvilles-major-employers.html (last accessed Nov. 6, 2019).

[5] *See* Norton, Community Health Needs Assessment 2019, https://nortonhealthcare.com/wp-content/uploads/2019-community-health-chna-report.pdf (last accessed Nov. 6, 2019) [hereinafter Community Health Needs Assessment].

[6] *Id.*

[7] Norton's faith history includes founding organizations and other faith communities: Episcopal Church, The United Methodist Church, United Church of Christ, Presbyterian Church and Roman Catholic Church.

[8] *See* Norton, 2018 Report to our Community, https://nortoncares.com/ (last accessed Nov. 6, 2019).

[9] *Id.*

[10] *Id.*

[11] *See* Community Health Needs Assessment.

Becker's Healthcare as one of the top places to work in 2019.[12] Norton was also recognized by Forbes as one of America's Best Employers and Healthiest Employers as the fourth healthiest place to work in 2018.[13]

II. Comments on the Proposed Survey

A. CMS Should Calculate Future Payments to Hospitals for 340B-Acquired Drugs under the OPPS and Any Remedial Payment for Prior Years Based on the Statutory Rate of ASP Plus 6 Percent Rather than the Acquisition Cost Data Collected Under the Proposed Survey.

In the OPPS final rule for CY 2020, CMS finalized a proposal to continue to pay ASP minus 22.5 percent for 340B-acquired drugs notwithstanding the district court's ruling that the payment reductions for 340B-acquired drugs under the OPPS are unlawful. [14] The district court specifically ruled that the Secretary of the U.S. Department of Health and Human Services exceeded his authority to adjust payment rates for 340B-acquired drugs from ASP plus 6 percent to ASP minus 22.5 percent beginning in 2018.[15]

Norton objects to CMS's continued pursuit of reduced reimbursement for 340B-acquired drugs under the OPPS, particularly in light of the district court's ruling. Congress mandated that CMS reimburse hospitals for covered outpatient drugs at ASP plus 6 percent, which the agency implemented from CY 2013 to CY 2017.[16] In ruling that the Secretary acted *ultra vires* in adjusting the payment rates, the district court reasoned that not only did the Secretary lack the necessary data to support such payment rate, but also that "the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates."[17] Just as there was no basis for paying less than the statutory ASP plus 6 percent for CYs 2018 and 2019, there is no basis for continuing to pay less than the statutory payment rate for 2020.

In this regard, CMS's reduced payment rate undermines the 340B Program's mission of enabling participating hospitals and other covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[18] Consistent with this mission, savings from the 340B Program have allowed Norton to provide funding for services that benefit the public, including charity care and unpaid Medicaid costs for patients who cannot afford health care. Reduced payment will only constrain the ability of providers to offer services to vulnerable populations.

Additionally, as part of its supporting statement for the Proposed Survey, CMS stated that the acquisition cost data that hospitals submit would be used to help determine payment amounts for 340B-

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[12] *See* Norton, Norton Healthcare named a top place to work in healthcare, https://nortonhealthcare.com/news/norton-healthcare-named-a-top-place-to-work-in-healthcare (last accessed Nov. 6, 2019).

[13] *Id.*

[14] Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots (to be published Nov. 12, 2019), https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24138.pdf [hereinafter OPPS Final Rule for CY 2020].

[15] *See* Azar, 348 F. Supp. 3d at 82–83.

[16] 42 U.S.C. § 1395w-3a(b)(1)(A)-(B).

[17] *See* Azar, 348 F. Supp. 3d at 85-87.

[18] *See* H.R. Rep. No. 102-384(II), at 12 (1992).

acquired drugs.[19] Further, in the OPPS final rule for CY 2020, CMS addressed the ongoing litigation concerning its reduced payment rate for 340B-acquired drugs and acknowledged that it may use the survey data not only to determine future payment amounts for 340B-acquired drugs under the OPPS, but also to devise a remedy if the ruling of the district court that such payment reductions are unlawful is upheld.[20]

Norton objects to CMS's basis for the survey request. There is no basis for paying less than the statutory ASP plus 6 percent for 340B-acquired drugs. As noted above, the district court objected not only to CMS effectuating the payment reduction with inadequate data, but also to the reduction's "magnitude and wide applicability," finding that it amounts to a "drastic departure from the statutorily mandated rates."[21] Accordingly, CMS should calculate any remedy for CYs 2018 and 2019 based on the statutory ASP plus 6 percent. Specifically, CMS should calculate payments due to affected 340B hospitals using the "JG" modifier, which identifies claims for 340B-acquired drugs that were reduced under the CY 2018 and CY 2019 OPPS rules. Norton believes that this remedy is appropriate and easier to administer than the Proposed Survey which, as explained further below, would subject 340B hospitals to significant burden.

Accordingly, Norton urges CMS to calculate future payments to hospitals for 340B-acquired drugs under the OPPS, as well as any potential remedies for prior years, based on the statutory rate of ASP plus 6 percent rather than the acquisition cost data the agency intends to collect as part of the Proposed Survey.

B. CMS Should Refrain from Issuing the Survey as Proposed Given the Regulatory Burden and Significant Operational Difficulties That the Proposed Survey Would Place on 340B Hospitals.

Norton appreciates CMS's stated goal and continued efforts to improve federal programs while eliminating unnecessary burdens on providers. In this regard, CMS should refrain from issuing the Proposed Survey. As explained below, the survey creates a substantial new regulatory burden on 340B hospitals that would undermine CMS's objective of minimizing regulatory burdens on providers. Specifically, the survey as proposed contains ambiguities that will not only pose onerous operational difficulties on hospitals, but may also undermine the purpose of the survey and result in unintended consequences, including significant variation of the type of data reported by 340B hospitals that could provide inaccurate estimates to CMS.

Under the Proposed Survey, CMS is requiring all hospitals that participated in the 340B program in the last quarter of CY 2018 and/or first quarter of 2019 to supply their average acquisition cost for each SCOD during that period. CMS notes that it is only asking for data for SCODs with status indicator "K" or "G" identified in Addendum B on the CMS Website.[22] However, it is not clear whether CMS is asking for the 340B acquisition costs for those drugs as to Medicare reimbursed patients or as to all 340B drugs purchased on that list, including those dispensed to commercial patients. Additionally, it is not clear which specific cost data CMS is requesting. In the survey, CMS requests the "average acquisition cost" for each

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[19] *See* Hospital Survey for Specified Covered Outpatient Drugs, Supporting Statement A, CTRS. FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html [hereinafter Supporting Statement A].

[20] *See* OPPS Final Rule for CY 2020 at 562.

[21] *See* Azar, 348 F. Supp. 3d at 85-87.

[22] *See* Hospital Survey for Specified Covered Outpatient Drugs, Centers for Medicare and Medicaid Services Average Sales Price Survey, CTRS. FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html [hereinafter Hospital Survey for SCODs].

SCOD.[23] However, it is not clear from the survey whether the average acquisition cost refers to the weighted price. It is similarly unclear whether CMS is requesting the 340B ceiling price or the price received by the hospital after applicable wholesaler discounts.

These ambiguities are likely to result in significant operational difficulties for 340B hospitals. It is generally difficult for hospitals to find drugs and identify their costs, particularly in the case of cost per claim. Invoices do not allow hospitals to determine prices. Hospitals need a download from their revenue departments and match with wholesaler pricing data. Accordingly, the survey would also create a considerable burden on wholesalers, who would need to report to hospitals the pricing offered by the wholesalers for each particular drug during a particular time period and some wholesalers may not be able to accommodate this data request using current systems and databases in a timely manner. In this regard, there are also privacy concerns related to wholesaler pricing. Norton understands that CMS may make public the average prices reported.[24] While CMS has noted that it does not intend to make such prices available in an individually identifiable manner,[25] the agency should further elaborate on how it intends to protect the confidentiality of individual hospital's responses.

In this regard, Norton notes that it is subject to confidentiality provisions in numerous contracts with third parties that could be implicated by the data request as proposed. Hospital contracts with wholesalers and drug manufacturers generally contain restrictions on the disclosure of pricing information. Given such restrictions, the Proposed Survey places 340B hospitals in the difficult position of having to report pricing data that they are not contractually allowed to disclose. Accordingly, the reporting requirements are in conflict with the confidentiality obligations of hospitals.

Moreover, frequently, 340B qualified drugs must be purchased at wholesale acquisition cost ("WAC") because the drug purchase is a first-time purchase in a replenishment model, or because the 340B accumulator values are insufficient for a 340B ordering quantity to be purchased from the wholesaler. In addition, any drug that is part of a shortage and may require direct purchasing from the manufacturer will often be purchased at WAC and used for 340B qualified patients. If these costs are not taken into account, the average 340B cost, and certainly the 340B ceiling price, will be lower than the actual cost of the drugs captured as part of the survey.

CMS has estimated the time associated with collecting the requested data and submitting the survey to be 6 working days (6 days x 8 hours = 48 hours).[26] Based on that estimate, CMS further estimates the cost for this survey to be $3,637.44 per hospital ($75.78 per hour x 48 hours per hospital).[27] However, given the significant operational difficulties outlined above, Norton estimates the time associated with attempting to collect the data and submitting the survey to be a minimum of 21 working days (21 days x 8 hours = 168 hours), and a minimum cost of the survey as $13,327.44 per hospital ($79.33 per hour x 168 hours, but in any case, a much more significant amount of time and cost for each hospital than CMS estimates in its proposal. The former is of particular concern because CMS would require 340B hospitals to complete the survey between February 17 and March 16, 2020,[28] thus providing little time to collect the data, which will as a practical matter further drive up the time and cost involved in complying with the request.

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[23] *Id.*

[24] *See* Hospital Survey for SCODs at 6.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *See* Hospital Survey for SCODs at 1.

All in all, CMS has acknowledged that "[d]ata received in response to this collection may be used in a manner that would have significant impact on 340B hospitals' payment."[29] Given the potential impact of the Proposed Survey and the significant operational difficulties and burden that the Proposed Survey would place on 340B hospitals, Norton urges CMS not to issue the survey as proposed. If, however, the agency decides to move forward with a hospital survey of 340B acquisition cost data, Norton respectfully requests that the agency provides clarification on the issues described above and simplifies the process.

In particular, Norton recommends that CMS:

1. Confirms if the reporting requirement applies only to OPPS reimbursed drugs. If only on OPPS reimbursed drugs, Norton would note that this information will be particularly difficult to obtain.
2. Excludes commercial outpatient claims and drugs dispensed in multiple settings (e.g. retail claims excluded for drugs dispensed in outpatient and retail settings).
3. Confirms if reporting package size cost or dispensed dose cost. Again, if the latter is contemplated, Norton notes this information would be tremendously difficult to calculate.
4. Confirms if reporting includes the weighted average cost of any drugs purchased at WAC due to insufficient 340B accumulator values or first-time purchases in a true replenishment model.
5. Confirms if reporting 340B price as reported by OPA or COGS after application of wholesaler discounts; in this regard, the proposal contemplates that the statutory 340B price will be used if the hospital does not have the necessary data, suggesting actual acquisition cost (after discounts is what is contemplated), but Norton notes that in this regard post-purchase rebates applied to aggregate purchases can be difficult to attribute to specific 340B purchases.
6. Ensures that reporting does not conflict with contractual confidentiality obligations to third parties, including wholesalers and manufacturers.

III. Conclusion

Thank you for your consideration of Norton's comments set forth above. Norton appreciates the opportunity to submit public comments relating to CMS's proposed hospital survey for SCODs. Norton looks forward to continuing to work with the agency on matters related to the 340B Program.

Sincerely,

Michael W. Gough
Executive Vice President and
Chief Operating Officer

Paul Allen
System AVP, Pharmacy

[29] *See* Hospital Survey for Specified Covered Outpatient Drugs, Supporting Statement B, CTRS. FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.

cc: The Honorable Mitch McConnell, Majority Leader, United States Senator for Kentucky
The Honorable Randall Paul, United States Senator for Kentucky
The Honorable John Yarmuth, United States House of Representatives, 3rd District of Kentucky
The Honorable Steven Brett Guthrie, United States House of Representatives, 2nd District of Kentucky

Memorial Healthcare System
MEMORIAL REGIONAL HOSPITAL • JOE DIMAGGIO CHILDREN'S HOSPITAL
MEMORIAL HOSPITAL WEST • MEMORIAL HOSPITAL MIRAMAR • MEMORIAL HOSPITAL PEMBROKE

November 29, 2019

William Parham III
Director
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Director Parham:

On behalf of Memorial Healthcare 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 are alarmed by the intent and design of the 340B hospital survey and the harm that these continued payment reductions will have on our patients. We request CMS to withdraw the survey.

Courts have already ruled against CMS

The US District Court for the District of Columbia has already held that the payment cuts to 340B hospitals are unlawful. It is clear that the intent of the 340B statute was to provide an additional financial benefit to covered entities to enable them to "stretch scarce federal resources" and provide more services to the vulnerable populations that they serve. Taking those benefits away from covered entities and using them to increase payments to non-covered entities runs exactly counter to that purpose. No treatment of 340B-eligible hospitals differently than any other hospital makes any sense.

Because the intended use of this information is to enact by other means a payment cut the courts have already deemed unlawful, **this data collection proposal should be withdrawn.**

The Secretary has limited authority to use a survey for drug payment rate determinations

The section of the statute that provides any authority to conduct this survey is found at 42 USC §1395(t)(14)(A)(iii)(I):

"…to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or **other**

relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D);" [emphasis added].

A hospital's **340B covered entity status is not a "relevant characteristic"** to differentiate one group of hospitals from any other group. It would be akin to differentiating hospitals based on the relative effectiveness of a hospital's group purchasing organization or drug wholesaler. That is, hospitals able to do a better job of negotiating drug prices would get paid less?

And since the covered entity should be retaining the 340B margin generated by the discounts, the **340B acquisition cost is not relevant** to any payment calculation difference between covered and non-covered entities. Therefore, this proposed data collection and use is **outside of the Secretary's statutory authority and should be withdrawn**.

The proposed data use embeds a critical error

The 340B price for a drug is a manufacturer's defined "best price" and there is a different relationship between Average Sales Price (ASP) and best price by NDC code (by drug, by manufacturer). An overall average reduction from ASP assumes that all 340B-eligible hospitals have a similar mix of drug utilization, which ignores differences in service mix, clinical protocols used, and wholesalers' drug access. Hospitals with large oncology practices use a significantly different mix of drugs than hospitals with large cardiology or surgical programs. Their **average 340B discounts will vary significantly**.

Even if CMS were to adopt a different discount by HCPCS code, different providers access different manufacturers. Each manufacturer may have its own 340B price. And the price per billing unit may differ based on the package size, even from a sole-source manufacturer. As a result, **even a uniform average discount by NDC would unjustly benefit some providers and harm others**.

There is no means to use this data to fairly determine payment rates even among just the group of 340B-eligible hospitals, so **this data collection proposal should be withdrawn.**

* * * * *

We appreciate this opportunity to provide our comments. If you have any questions, please contact me.

Sincerely,

Scott Davis
Administrative Director, Reimbursement
And Revenue Integrity
Memorial Healthcare System
954-265-5105
sdavis@mhs.net

Oregon Association of Hospitals and Health Systems

November 27, 2019

Submitted Electronically

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS–10709
P.O. Box 8013
Baltimore, MD 21244-1850

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 Secretary Seema Verma:

On behalf of Oregon's 49 acute care hospitals that participate in the 340B program, and the patients they serve, the Oregon Association of Hospitals and Health Systems (OAHHS) appreciates the opportunity to provide comments on the Hospital Survey for Specified Covered Outpatient Drugs comment request. We have outlined our comments below for your consideration.

OAHHS is concerned about 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 CMS to withdraw the survey.

For the 49 Oregon hospitals that participate in the 340B program, they are using the program savings to improve patient services and help their 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. 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 Oregon's hospitals ability to care for their patients.

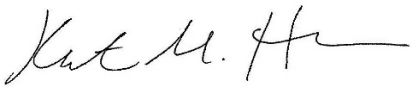
From an implementation perspective, this survey will significantly burden Oregon's hospitals. 340B hospitals operate on thin margins and already incur considerable costs to ensure they are compliant with program rules and requirements. These costs include dedicated staff time, as well as complex health 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, they would need to access and assess proprietary drug prices from their wholesalers. As you know, 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

4000 Kruse Way Place, Bldg. 2, Suite 100
Lake Oswego, Oregon 97035
503-636-2204 Fax 503-636-8310

non-disclosure provisions would make it exceedingly difficult for hospitals to share the data necessary to complete the survey in the time specified.

Thank you for the opportunity to submit 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,



Katie M. Harris
Director of Rural Health & Federal Policy

4000 Kruse Way Place, Bldg. 2, Suite 100
Lake Oswego, Oregon 97035
503-636-2204 Fax 503-636-8310

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS- 2019-0142 Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709)

Dear Administrator Verma,

On behalf of ProMedica, I appreciate the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data. Hospitals within our system are eligible to participate in the 340B program by virtue of the high volume of Medicaid and low-income Medicare patients we serve. We rely on our 340B savings to meet the needs of the rural and low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

Most importantly, we believe this proposal is contrary to current law and could be deemed unlawful. 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B

program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospitals would have to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospitals to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

Sincerely,

Christopher Trimbath
340B Program Manager
ProMedica

November 20, 2019

Director William N. Parham, III,
Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

BY ELECTRONIC DELIVERY

Re: Agency Information Collection Activities; Proposals, Submissions, and Approvals CMS-2019-0142-0001, Federal Register Number: 2019-21120

Director Parham,

Thank you for the opportunity to submit comments on the CMS Agency Information Collection Activities; Proposals, Submissions, and Approvals with regards to the 340B program and Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709). As a Master of Public Health candidate at George Washington University, I have gained tremendous insight into the disparities within our prescription drug market and the necessity of reform.

The 340B program is designed to establish a ceiling on the price that eligible providers pay for outpatient drugs, thereby helping to ensure access to care and prudent use of taxpayer dollars within Medicare. While judicial appeals continue over whether CMS exceeded its statutory authority to adjust payment rates based on the Average Sale Price (ASP) under the 340B Program from ASP +6% to ASP -22.5%, it is important to consider if the ASP itself is a fair or relevant benchmark from which to determine payment rates.

Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare used another industry-reported benchmark - the Average Wholesale Price (AWP). Analysis at the time by CMS showed as much as a 72% difference at the median for generic drugs between AWP and ASP, resulting in provisions that changed the basis of reimbursement for drugs from AWP to ASP.[1] This clearly demonstrates how industry self-reporting has been leveraged to ensure higher profit margins in the United States. Furthermore, when this change was made, it was accompanied in the same legislation by a noninterference clause ensuring that the Department of Health and Human Services cannot negotiate prices, thereby offering a replacement mechanism for the industry to maintain high prices within the U.S.

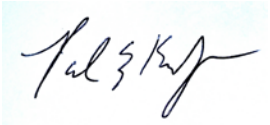
While the ASP+6% may constitute a significant decrease from previous reimbursement models and the proposed ASP-22.5% would be an even more drastic cut, it must be recognized that any proposal relative to this measure would be inherently flawed. Aside from relying on potentially problematic industry self-reporting as previously described, the ASP is predicated on already-inflated US prices. CMS defines ASP as “a manufacturer’s sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter.”[2] This definition is inherently problematic,

however, because it is determined as an average of the much higher prices paid by smaller purchasers specifically in the US, all of which have considerably less bargaining power and higher prices than an empowered HHS would have as the largest purchaser. Instead, Medicare patients, even where 340B programs were implemented ostensibly to keep such costs down, would pay at least 6% more for drugs the average privately insured U.S. patient who is already paying a higher baseline price.

Attempts to modify drug pricing, whether via executive order, legislation or regulation, are generally met with resistance from numerous stakeholders within the industry. Whereas these same pathways may be susceptible to the same industry influence that has yielded the current status quo of demonstrably high prices, changes in the definition of ASP could effectively create a method for calculating lower, more reasonable costs without creating the need for broader regulation or legislation. For instance, removing "in the United States" from the ASP definition would enable the same calculation, yet would include pricing paid by all payers, including countries that are not prohibited from price negotiations and hence have much lower costs. This would result in an ASP reflective of average global prices, rather than those higher prices paid only by smaller U.S. purchasers. Or, changing "in the United States" to "outside of the United States," would result in a lower ASP given that artificially high U.S. prices wouldn't bring up the average. Either of these changes could result in substantial savings for Medicare, avoiding conflicts with the noninterference clause and yet still using prices that offer (non-U.S.-based) profit margins manufacturers have negotiated worldwide.

If the 340B program is truly designed to enable providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," [3] then regulations should seek those ends rather than ensuring outsized profits to market participants. Whether through legislation, regulation, executive order or judicial action, significant further changes are warranted within the U.S. prescription drug markets, and fixes to these guidelines can lead the way to broader innovation.

Sincerely,



Paul Katz
MPH candidate
Milken Institute School of Public Health,
George Washington University

1. *Medicaid drug price comparisons : Average sales price to average wholesale price.* Washington, D.C: Department of Health and Human Services, Office of Inspector General; 2005.

2. *Average sales prices : Manufacturer reporting and CMS oversight.* Washington, D.C: Department of Health and Human Services, Office of Inspector General; 2010.

3. Health Resources & Services Administration. 340B drug pricing program. https://www.hrsa.gov/opa/index.html. Updated 2017. Accessed Nov 20, 2019.

STAMFORD HEALTH
Healing. Reimagined.

Affiliate: Columbia University College of Physicians and Surgeons
A Planetree Hospital
A Magnet® Recognized Hospital

November 29, 2019

William Parham III
Director
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Director Parham:

Stamford Health appreciates the opportunity to submit comments on the above-captioned proposal, which calls for information collection from 340B hospitals.

Stamford Health is a nonprofit, tertiary-care level hospital serving Fairfield County in Connecticut. We are committed to serving all people, regardless of income or insurance status. A significant number of our patients face socio-demographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy.

We are deeply concerned that despite a federal district court's ruling that it was unlawful, CMS continues its nearly two year, 27 percent cut of 340B reimbursements. Stamford Health implores CMS to reverse course and make hospitals whole for years' worth of inappropriate underfunding. CMS's cuts irreparably harm low-income patients and financially distress the nonprofit hospitals like Stamford Health committed to treating them.

CMS now proposes collecting 340B acquisition cost information for specified covered outpatient drugs through a hospital survey directed only to 340B hospitals. Other hospitals would not be required to report their drug acquisition costs. CMS purports to be requesting this data to set 340B payment rates should it lose its appeal of the above mentioned court decision.

CMS's proposed data collection exceeds its legal authority under Medicare and imposes an undue operational burden on 340B hospitals. For these reasons, we urge CMS to withdraw its proposal.

1. Proposal Exceeds Authority Under Medicare

CMS's 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 outpatients drugs (SCODs). In its notice, CMS states it will collect acquisition costs through a "hospital survey for SCODs." The Agency notes that it is only directing 340B hospitals to report acquisition costs through the survey. Hospitals not in the 340B program will not be required to report their acquisition costs because CMS believes ASP data is "an adequate measure of the drug acquisition costs" of these hospitals. The selective collection of drug acquisition costs based on an arbitrary selected hospital characteristic (in this case participation in the 340B program) conflicts with the acquisition cost collection 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 34B 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 costs for each [SCOD]." Hospitals in the 340B program account for only a portion of all Outpatient Prospective Payment Systems (OPPS) hospitals. CMS estimates that 1,338 hospitals would fill out the survey, which his only about one-third of the more than 3,600 hospitals paid under the OPPS.

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. Hospitals that are part of large systems leverage their size to procure volume discounts. Non-340B hospitals can use group purchasing

organizations – which 340B hospitals are statutorily prohibited from using for 340B drugs – to negotiate sizable discounts on their drugs. For SMS to gather data on and pay hospitals based on acquisition costs, 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 information collection request.

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 with draw its proposed information collection, which exceeds its statutory authority because it is contrary to the Medicare statutes.

2. Proposal Fails to Recognize Operational Burden on Proposed Data Collection

Stamford Health commends the Administration for its attempts to reduce regulatory and administrative burden through such initiatives as the Patients over Paperwork Initiative. CMS's proposed information request would contradict these initiatives. It is operationally complex and burdensome.

Records required for 340B compliance and audits do not require hospitals to collect 340B acquisition cost data. In fact, hospitals, including Stamford Health, do not have 340B drug acquisition costs readily available in their systems. The time required to extract this information from third parties, calculate average acquisition costs, and produce the data in the format CMS requires, would be substantially more than the 48 hours CMS estimates. Meeting these requirements would require Stamford Health to divert existing resources or hire additional staff. For this reason, we urge CMS to withdraw its proposal.

Sincerely,

Kathleen Silard, RN, BSN, MS, FACHE
President & CEO
Stamford Health

Regional One Health

November 22, 2019

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

Dear Mr. Parham:

Regional One Health appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

Sincerely,

Reginald W. Coopwood, MD
President and CEO

SAN MATEO COUNTY HEALTH
SAN MATEO MEDICAL CENTER

San Mateo Medical Center
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San Mateo, CA 94403
650-573-2222 T
smchealth.org/smmc

November 22, 2019

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

Dear Mr. Parham:

San Mateo Medical Center appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw

SAN MATEO COUNTY HEALTH
SAN MATEO MEDICAL CENTER

the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

Sincerely,

Gary L. Horne, RPh. MHSA
Director of Pharmacy

Cc: C. J. Kunnappilly, M.D., Chief Executive Officer

SCL Health

November 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attn: Document Identifier/OMG Control Number CMS-10709
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

We appreciate the opportunity to comment on CMS's proposal to collect drug acquisition cost data to inform the Medicare payment policy for 340B drugs. We have significant concerns regarding CMS's authority to collect meaningful data and the severe administrative burden this will place on safety net hospitals eligible for the 340B program. For reasons discussed below, we ask that CMS retract its data collection request and reconvene with industry stakeholders to identify an equitable reimbursement methodology for 340B drugs that is consistent with Congress's clear mandate in Section 1833 of the Social Security Act.

I. The 340B Program is Vital to Our Mission to Serve All Patients in Need

SCL Health is a faith-based, nonprofit healthcare organization dedicated to improving the health of the people and communities we serve, especially those who are poor and vulnerable. Our health network provides comprehensive, coordinated care through 9 hospitals, more than 100 physician clinics, and home health, hospice, mental health and safety-net services primarily in Colorado and Montana. We relentlessly focus on delivering safe, high-quality, effective care to every patient, every time, everywhere.

SCL Health treats all patients regardless of their ability to pay. We rely heavily on federal funding to operate. SCL Health hospitals operate with a margin that is less than half of many other hospitals, and we depend on vital savings from the 340B Program to coordinate care and improve the health of low-income and other disadvantaged patients. Savings from the 340B Program are used to partially offset some of our uncompensated care and Medicaid losses and to provide direct financial assistance to the working poor. CMS's persistent attempts to reduce payment for 340B drugs and to increase administrative burden and associated costs on 340B-eligible entities will continue to limit SCL Health's ability to furnish aid and charity care programs while for-profit entities and other non-340B hospitals continue to benefit from the ASP+6% formula mandated by Congress.

II. The Data Request Undermines the 340B Program and is Subject to Statutory Limitations

A. The Data Request and Ultimate Payment at AAC Undermines Intent of 340B Program

The intent of the 340B provisions of the Public Health Service Act of 1992 is clear – to allow covered entities to stretch scarce *federal* resources to reach more eligible patients and provide more comprehensive services.[1] Nonetheless, misconceptions about the intent of the 340B program have been propagated by interested parties and include, for example, that it is a patient discount program so that discounts received by the covered entities should be directly translated as prescription discounts to recipient eligible patients.[2] Now, through its efforts 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," CMS is adding yet another layer to that misconception. CMS's continuation of payment reductions to covered entities for certain 340B drugs is contrary to Congress's clear mandate when it created the 340B program.

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.[3] 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.[4] 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.[5] Examples of covered outpatient drugs that are not SCODs include:

- acetaminophen, one of the most common drug ingredients used for alleviating pain;

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[1] H.R. REP. NO. 102-384(II), 12; *see also* U.S. Gov't Accountability Office, GAO-11-836, DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 2 (2011). In Part A of CMS's Supporting Statement, it cites the goal of allowing Medicare beneficiaries to stretch "their scarce resources," which appears to be a response to our argument. We do not disagree generally with CMS policies that allow Medicare beneficiaries to reduce costs, but we do object when those policies conflict with clear Congressional intent and create corresponding hardship on safety net hospitals.

[2] *See e.g.,* Energy & Commerce Comm., Review of the 340B Drug Pricing Program, 9, 66-70 (2018).

[3] 42 U.S.C. § 1395l(t)(14)(D) (emphasis added).

[4] *Id.* at § 1395l(t)(14)(B).

[5] *Id.*

- 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 § 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.*[6]

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

Federal 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.

D. 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

[6] 77 Fed. Reg. at 68383 (Nov. 15, 2012).

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.

In addition, 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."[7] 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 such data accordingly."[8] 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.[9] 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.

III. CMS Underestimates the Burden and Overestimates the Utility of Collecting this Data

A. CMS Underestimates the Administrative Burden of This Request

The information collection request applies only to 340B hospitals (1,338 according to CMS), again targeting this subset of hospitals for additional costs not borne by other for-profit hospitals who do not meet 340B criteria. The data is complex and will need to be reported based on J-code, not NDC, as discussed in more detail below. Therefore, the CMS estimate of 40-48 hours per hospital to complete the survey request may be realistic for very large, sophisticated hospitals with pharmacy and finance personnel dedicated to 340B compliance and billing, but for the majority of hospitals, this will be a much more extensive and burdensome project. 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.[10] 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.

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 given the burden associated with it.[11]

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[7] 42 U.S.C. § 256b(d)(1)(B)(iii).
[8] 82 Fed. Reg. 1210, 1226 (Jan. 5, 2017).
[9] 42 U.S.C. § 1396r-8(b)(3)(D).
[10] 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).
[11] 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).

B. The Acquisition Cost Data is Likely to Be Plagued With Inconsistencies and, Therefore, Unusable

As noted above, CMS does not have the authority to request data regarding acquisition cost for *all* 340B covered outpatient drugs (only SCODs), significantly limiting its overall utility. Beyond that, the data may be entirely unusable if it is rife with inconsistencies—as it is likely to be.

Collecting and reporting the actual acquisition cost for individual drugs in a uniform manner will require hospital personnel to map drugs by NDC and HCPCS to purchase price data and to account for different units of measure for a particular drug. Likewise, hospitals will have to develop a mechanism to average the cost of multiple drugs that may be mapped to a single HCPCS code. 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. In addition, to the extent a hospital has different purchasing accounts for different provider-based departments, that will only increase the degree of difficulty for personnel tasked with gathering this data.

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.[12] 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."[13] 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.[14]

CMS appears to believe the data reporting is as simple as a single Excel spreadsheet that hospitals will complete uniformly, and this simply will not be the case. 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.[15] 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.

C. We Strongly Urge CMS to Account for Overhead and Compliance Cost in Calculation of Final Payment Rate

[12] 42 U.S.C. § 1395l(t)(14)(D)(ii).
[13] 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).
[14] GAO-05-581R: *Medicare Hospital Outpatient Drug Prices*, Enclosure I (June 30, 2005).
[15] *See also*, GAO-05-581R: *Medicare Hospital Outpatient Drug Prices*, Enclosure I (June 30, 2005).

CMS is statutorily authorized to adjust drug payments to take into account "overhead and related expenses, such as pharmacy services and handling costs" (SSA § 1833(t)(14)(E)(ii)). 340B hospitals not only sustain the standard overhead costs incurred by all entities furnishing drugs (*e.g.,* regulatory compliance, pharmacy services, and handling costs), but also must manage day-to-day 340B compliance, interaction with manufacturers, and other 340B-specific costs. We strongly encourage CMS to account for the extensive overhead costs borne by 340B hospitals, beyond those incurred by others. If not, CMS risks underpaying 340B hospitals to the point that they may actually lose significant money on each dispense when other, non-340B hospitals are making a profit or at least breaking even, and the 340B Program is no longer viable overall.

IV. SCL Health is Eager to Help CMS Craft Practical Solutions

We are proud to deliver health care services to those who would otherwise lack access to critical health care. Hospital services, inpatient and outpatient, are extremely valuable to our community. We are dedicated to providing excellent patient care by: (1) focusing on excellent patient care quality, outcomes and service through a holistic, patient-centered approach; (2) recruiting, developing and training an engaged workforce; (3) offering innovative technologies; and (4) expanding services and partnering with others to meet community needs.

CMS must encourage policies that maximize hospitals' ability to meet these community needs and provide the highest quality of care possible, ensuring they have the resources to invest in equipment and personnel as necessary and to provide charity care to those who need it most. It is imperative to our patients that the 340B program reimbursement be strengthened and that hospitals are not continually burdened with administrative tasks that do not ultimately improve care. We stand ready to work with you to ensure the Medicare program delivers its beneficiaries with quality care in an an efficient and effective manner. Please let me know if you have any questions or if we can be of any assistance.

Sincerely,

Ashley Mains Espinosa
System Director, Pharmacy Business Services

Amber J. Ter-Vrugt
Senior Director, Government Relations
Office of the President
Scripps Health

10140 Campus Point Drive, CPA-320
San Diego, CA 92121
Tel 858-678-6893

November 27, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Scripps 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 CMS to 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.

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. 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.

Thank you for your consideration,

Amber J. Ter-Vrugt
Senior Director, Government Relations

The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

November 27, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents 340B hospitals and health systems across the commonwealth, 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. However, we have significant concerns over the intent and design of the 340B hospital survey, and we respectfully request CMS to withdraw the survey.

As an association with 340B member hospitals, we have seen first-hand how hospitals are using the program savings to improve patient services and help their 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. Some examples of what hospitals are doing include: providing prescription medications at significantly reduced cost, or no cost at all; funding community wellness programs; providing healthy food initiatives; creating transportation partnerships to help people get to medical appointments; establishing satellite urgent care centers closer to where vulnerable patients live and operating an HIV clinic. We have significant concerns 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 the ability to care for patients.

From an implementation perspective, this survey will significantly burden all 340B hospitals. These facilities operate on thin margins and already incur considerable costs to ensure they 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 everything within the time specified. In addition, to complete the survey, hospitals would need to access and assess proprietary drug prices from wholesalers. These 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 340B hospitals to share the data necessary to complete the survey in the time specified.

Thank you for your consideration of our comments. We strongly 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,

Jolene H. Calla, Esquire
Vice President, Health Care Finance and Insurance

SENTARA®

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www.sentara.com

November 27, 2019

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

Dear Mr. Parham:

Sentara Norfolk General Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). 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. We rely on our 340B savings to meet the needs of the low-income patients we serve. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's Proposal Would Harm Safety-Net Hospitals and Low-Income Patients.

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

CMS's Proposal is Contrary to Law.

CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospital had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our hospital to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

Sincerely,

Tim Jennings, VP and Chief Pharmacy Officer
Sentara Healthcare

SHARP®

November 26, 2019

Ms. 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. 84, No. 189), September 30, 2019.

Dear Administrator Verma:

Sharp HealthCare (Sharp), San Diego's largest provider of care to the Medicaid population, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to survey 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 CMS to withdraw the survey.

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. San Diego County does not operate a public hospital. As a result, Sharp is a vital part of the region's safety net and our three 340B hospitals use the program savings to improve patient services and help our community, as Congress intended. For example, Sharp uses 340B savings to expand our outpatient services to behavioral health patients and chronic care disease management, including high cost injectables and infusion drugs. In both these examples, medications reduce the need for costly hospitalization and in the case of behavioral health injectables also increases medication adherence. 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.

From an implementation perspective, this survey will significantly burden Sharp. 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 undermine the intent of the 340B program.

Sincerely,

Christopher Howard

Christopher D. Howard
President and CEO

8695 Spectrum Center Boulevard ■ San Diego, California 92123-1489

HEALTH
UNIVERSITY OF UTAH

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

November 26, 2019

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

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

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

Dear Mr. Parham:

University of Utah 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 (84 Fed. Reg. 51590) on September 30, 2019. We share our comments with the hope that CMS will understand how its ICR will affect 340B hospitals.

University of Utah Hospital qualifies for the 340B program as a Disproportionate Share Hospital (DSH) serving a large low-income and uninsured population. We are a key safety-net hospital in the Mountain West region, which is comprised of Utah and five surrounding states. We rely on our 340B savings to improve patient outcomes in our large service area and provide critical services to patients who would otherwise lack access to care. 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.

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

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 non-excepted, off-campus, provider-based departments in CY2019, we experienced an additional $1.5M in lost revenue. These material reductions have constrained our resources and ability to care for our under-served populations.

CMS' proposal is extremely burdensome—a burden that CMS underestimates

As required by the Paperwork Reduction Act (PRA) of 1995, CMS is requesting feedback on the estimated time and burden to collect the requested data. We believe that CMS' time estimate of 48 hours per 340B hospital is a gross underestimate. The average acquisition costs for more than 400 HCPCS codes corresponds to more than 1,100 national drug codes (NDCs), which translates to more than tens of thousands of units of data. Contributing to the burden is the complex data manipulation required to provide the information CMS is requesting. In order to provide the average acquisition cost by HCPCS code, hospitals would need to:

1) determine a weighted average of the purchase price for all the NDCs mapped to each HCPCS code, and
2) convert NDC purchase units to HCPCS units.

CMS is also asking hospitals to identify each provider-based department where each drug was administered. This would be extremely burdensome for hospitals as we do not track drug purchase data by administration location and would need to make major assumptions or extrapolations. We estimate that it would take our hospital at least 120 hours to collect and begin to analyze the data, and despite our best efforts, the data will be inaccurate. The administrative time and cost to hospitals responding to CMS' survey will syphon resources away from value-added services for our patients.

The data will be in inconsistent at best and incorrect at worst

In addition to the time and resource burden, we believe that the data CMS receives will be inconsistent between hospitals and even incorrect due to the complexity of the process. For example, for process 1 above, we do not currently have a way of identifying the NDC administered for a particular HCPCS code. As such, the weighted average purchase price by HCPCS code will be inaccurate. For process 2 above, HCPCS units may change on a quarterly basis, and drugs purchased in a particular quarter may be administered in subsequent quarters. The inevitable period mismatching between purchases and administrations will also lead to inaccurate information. Furthermore, we believe the entire effort of data collection will actually end in futility because of the

infinite variances in data reporting that can occur with such a complex process over so many hospitals.

We sincerely appreciate the opportunity to provide comments on this proposed ICR. We understand CMS' goal is to reduce healthcare spending. You may notice the irony in CMS promulgating burdensome, unfunded mandates to 340B hospitals with the eventual objective of further reducing their Medicare payments. 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

UC Health

Subject: Comments on CMS Proposed Collection of Information (CMS-10709)

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

Dear Mr. Parham:

With patient care, research and education as our foundation as Cincinnati's academic health system, **UC Health** – and therefore, Cincinnati – is at the forefront of medicine. Through direct affiliation with the University of Cincinnati (UC) College of Medicine, we conduct groundbreaking research that leads to new treatments and cures, we train the next generation of physicians and medical professionals, and we pioneer new ways to deliver highly specialized, complex subspecialty care that would not otherwise be available to patients in our region.

UC Health's UC Medical Center is one of the nation's premier teaching hospitals. Since opening in 1823 as the country's first teaching hospital, UCMC has served the region as the only *essential* hospital by:

- Providing specialized, lifesaving services, such as level I trauma and neonatal intensive care, emergency psychiatric services, and the region's only comprehensive stroke center.
- Training the next generation of healthcare professionals to ensure the community's supply of doctors, nurses and other caregivers meets demand.
- Delivering comprehensive, coordinated care across large ambulatory networks and integrated teams to bring services to where patients live and work.
- Filling a public health role by improving population health, and by preparing for and responding to natural disasters and other community crises.
- Providing all of these services and more to everyone, regardless of their ability to pay.

We appreciate the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). UC Medical Center is eligible to participate in the 340B program by virtue of the high volume of Medicaid and low-

income Medicare patients we serve. We rely on our 340B savings to meet the needs of our low-income patients. We urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

CMS's current payment reduction to 340B hospitals for Medicare Part B drugs already undermines our ability to provide needed care to the low-income patients we serve. CMS now proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. For the same reasons we oppose Medicare's current payment reduction to 340B hospitals, we strongly oppose this ICR since it adds to the complexity for covered entities and does not meet the intent of the program as stated by Congress. Further, this requirement will reduce the essential hospitals' ability to reach more patients and furnish additional comprehensive services. Reducing Medicare payment to 340B hospitals' acquisition costs eliminates any savings 340B hospitals would accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary.

CMS's 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)).

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

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. Further, CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995 (44 U.S.C. § 3506(c)(1)(B)(iii)). It is not clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each

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

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and we had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for us to accurately evaluate the burden. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

We appreciate the opportunity to provide comments on this proposed ICR. In summary, we are concerned that the proposal harms essential hospitals and low-income patients, is contrary to law, and grossly underestimates the administrative burden the proposal would place on hospitals. We respectfully urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

Sincerely,

Michelle Dusing Wiest, PharmD, BCPS, FASHP
Vice President
Pharmacy Services
UC Health
Adjunct Associate Professor
The James L. Winkle
College of Pharmacy
University of Cincinnati

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

Dear Mr. Parham:

UMass Memorial Health Care appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). All three hospitals in our health system – UMass Memorial Medical Center, HealthAlliance-Clinton Hospital and Marlborough Hospital are eligible to participate in the 340B program because it provides healthcare services to a disproportionate share of low-income patients. We rely on our 340B savings to as one way to sustain the services to meet the healthcare needs of the underserved patients. For the reasons explained below, we urge CMS to withdraw its proposal to collect drug acquisition cost data from 340B hospitals.

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

CMS's Proposal is Contrary to Law.
CMS's plan to collect acquisition cost data from 340B hospitals only, and not from other hospitals, is contrary to law. Although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow CMS to target a single group of hospitals for the survey. (42 U.S.C. § 1395l(t)(14)(D)(iii)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals.
Our hospital system has significant concerns regarding the amount of time it would take to respond to the survey. CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data that hospitals would need to account for. Even more concerning are the extensive mathematical calculations the ICR requires hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring hospitals to 1) average the prices together for all the NDCs mapped to the

HCPCS codes, which can be dozens of NDCs for a single HCPCS code, and 2) convert NDC purchase units to HCPCS dosage units.

In addition to significantly adding to this administrative burden, asking hospitals to complete calculations factoring tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report despite their best efforts.
CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for us, as we don't track data this way and would need to run numerous reports out of our hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code.

CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

Given the immense burden the collection would place on hospitals, CMS should withdraw the ICR. Moreover, CMS's instructions are not clear, and our hospitals had to make several educated guesses to determine what CMS is requesting and how we would generate the data. This makes it impossible for our system to evaluate the burden accurately. If CMS does not withdraw the ICR as we request, CMS should reissue the proposal with more detailed instructions to meet the requirements of the PRA and allow hospitals to submit meaningful comments on the burden.

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

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

Sincerely,

Eric W. Dickson, MD, MHCM, FACEP, President and CEO, UMass Memorial Health Care

UNIONTOWN HOSPITAL
We Will Make a Healthy Difference in the Lives We Touch

November 26, 2019

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

BARBARA A. WEISS, CPA
Executive Director, Finance/CFO
500 West Berkeley Street
Uniontown, PA 15401-5596
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weiss@utwn.org

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 Ms. Verma:

On behalf of **Uniontown 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 CMS to 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, many patients have limited transportation or are unable to understand the care they need. We have a high incidence of Diabetes and associated comorbidities, leading to one of the highest rates of Diabetes-related amputations in the country. Also a high percentage of the community uses our Emergency Department as their source for primary care needs. These challenges are addressed through our Community Charity Care Program, which is designed to assist patients who have been treated or seek treatment at our facility but are unable to pay for the medical services because of financial hardship. The program allows individuals to receive medically necessary services at no charge or reduced charge when certain eligibility requirements are met. The estimated cost of Charity Care including Bad Debts and Unreimbursed Medical Assistance for Uniontown Hospital is estimated at $12,259,000 for the year ending June 30, 2020. Although the 340B drug program can't take care of this entire problem, it does help the Hospital to provide certain outpatient drugs at reduced rates to our patients including the high disproportionate share of Medical Assistance and other low-income patients. The 340B program and similar other programs allow hospitals like Uniontown, to remain financially viable and keep the doors open. 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.

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,

Barbara Weiss
Executive Director, Finance / CFO

UnityPoint Health

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

November 25, 2019

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

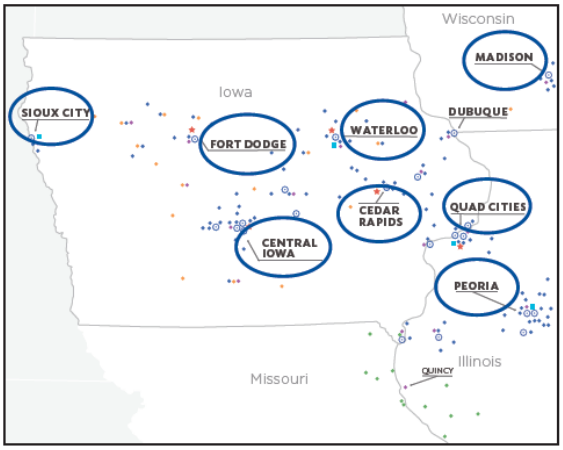
RE: CMS-10709; CMS Proposed Collection of Information, Hospital Survey for Specified Covered Outpatient Drugs, published in vol. 84 (189) Federal Register 51590-51591 on September 30, 2019

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

Dear Director Parham:

UnityPoint Health (UPH) appreciates the opportunity to submit comments in response to the notice on a proposed information collection request (ICR) by the Centers for Medicare & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data. As a large nonprofit, integrated healthcare system in the Midwest, the UPH network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals and Rural Health Clinics provide vital access to healthcare services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois and Wisconsin. The 13 UPH participating hospitals are:

- Allen Hospital – *Waterloo, IA*
- Marshalltown Hospital – *Marshalltown, IA*
- Iowa Lutheran Hospital – *Des Moines, IA*
- Iowa Methodist Medical Center – *Des Moines, IA*
- Jones Regional Medical Center – *Anamosa, IA*
- Meriter Hospital – *Madison, WI*
- Methodist Hospital – *Peoria, IL*
- St. Luke's Hospital – *Cedar Rapids, IA*
- St Luke's Regional Medical Center – *Sioux City, IA*
- Trinity Medical Center – *Bettendorf, IA*
- Trinity Medical Center – *Muscatine, IA*
- Trinity Medical Center – *Rock Island, IL*
- Trinity Regional Medical Center – *Fort Dodge, IA*



Our hospitals are eligible to participate in the 340B program by virtue of high volume of Medicaid and low-income Medicare patients as well as rural locations. The 340B program enables our participating hospitals to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services by allowing our providers to address the individualized needs of the people we serve in meaningful ways. We rely on our 340B savings to meet the needs of the low-income patients and rural patients we serve.

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

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

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

CMS'S PROPOSAL IS CONTRARY TO LAW

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

CMS UNDERESTIMATES THE PROPOSAL'S ADMINISTRATIVE BURDEN ON HOSPITALS

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

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

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

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

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

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

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

Sincerely,

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

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

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

[3] 44 U.S.C. § 3506(c)(1)(B)(iii).

November 27, 2019

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-10709

Re: Department of Health and Human Services, Centers for Medicare & Medicaid Services; Document identifier CMS-10709; Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Mr. Parham:

On behalf of the University of Pennsylvania Health System (UPHS), we appreciate the opportunity to comment on the Department of Health and Human Services' agency information collection notice published in the *Federal Register* on September 30, 2019 (Vol. 84, No. 189, pp. 51590-51591).

UPHS is comprised of three academic medical centers, two community hospitals and one community health system that service the city and suburbs of Philadelphia, Central Pennsylvania and Central New Jersey. Our hospitals (the Hospital of the University of Pennsylvania, Penn Presbyterian Medical Center, Pennsylvania Hospital, Chester County Hospital, Princeton Medical Center and Lancaster General Hospital) provide this region with a full spectrum of health care services – from neonatal to Organ Transplantation to advanced Oncology services and treatments. Combined, we provide inpatient services to over 50,000 Medicare inpatients and over 1 million Medicare outpatients on an annual basis. Three of our five hospitals qualify for the 340B Drug Discount program as Medicare Disproportionate Share hospitals, and one of our hospitals qualifies as a rural referral center.

We have significant concerns over the intent and design of the 340B hospital survey, and we request CMS to withdraw the survey. The 340B program is a vital resource in enabling private safety-net hospitals to serve their low-income communities, and we address below our concerns to this proposed information collection. 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 providers 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.

The Proposed Data Collection Would be Extremely Burdensome

UPHS is concerned that the steps CMS has proposed for collecting data for the program would create administrative burden.

In the proposed notice, CMS calls for asking 340B providers to supply their average acquisition cost data for more than 400 HCPCS codes and 1100 national drug codes (NDCs). For a given quarter, hospitals could easily need to account for tens of thousands of units of data. The proposal also includes extensive calculations the information collection request would require of hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under 400-plus HCPCS codes, which would require hospitals to average the prices together for all the NDCs mapped to the HCPCS codes – which can be dozens of NDCs for a single HCPCS code – and to convert NDC purchase units to HCPCS dosage units.

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.

UPHS 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, CMS recently 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. UPHS believes CMS should not attempt to implement piecemeal responses to the court's decisions until the litigation is concluded.

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, UPHS 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.

STRONG MEMORIAL HOSPITAL

Department of Pharmacy

UNIVERSITY of ROCHESTER MEDICAL CENTER

Curtis E. Haas, PharmD, FCCP, BCPS
Director of Pharmacy

Submitted electronically though the Federal eRulemaking Portal at http://www.regulations.gov

November 27, 2019

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

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 Mr. Parham:

I write to submit comments on behalf of UR Medicine in response to the proposed information collection request (ICR) published in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) to survey 340Beligible hospitals to obtain 340B drug acquisition cost data. We have significant concerns with the intent and design of the 340B hospital survey, and believe its implementation would undermine the intent of the 340B Drug Pricing Program and harm safety-net hospitals and the patients we serve. We request that CMS withdraw its proposal 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 – participate in the 340B program 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. We use our 340B savings to provide low and no cost life-saving medications to low-income, uninsured, and underinsured patients and to maintain and extend access to needed care and services throughout the region. Thanks to savings from the 340B program, we are able 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.

The implementation of the 28.5% cut to Medicare Part B reimbursement for some 340B-eligible drugs put in place by CMS in calendar year 2018 has already begun to affect our ability to maintain and expand access to care and services for the patients we serve. In 2018, the cut resulted in a $24 million loss to UR Medicine, and in 2019, is expected to grow to $30 million. 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. Further reducing Medicare reimbursement to hospitals for 340B eligible drugs to acquisition cost would eliminate any of the remaining savings we accrue by purchasing a drug at a discounted 340B price for a Medicare beneficiary and would undermine the intent of the program.

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340B hospitals operate on thin margins and already incur considerable costs to ensure we are compliant with the existing stringent program rules and requirements. These costs include dedicated staff time, as well as complex health information and inventory management systems. The proposed survey would require considerable resources to gather the data requested, convert the data into the requested format, and complete within the time specified – without a clear indication as to how the information will be utilized. We believe that CMS has grossly underestimated the administrative burden that compliance with this proposal would place on hospitals:

- In the ICR, CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there can easily be tens of thousands of units of data we would need to account for. The extensive mathematical calculations the ICR would require hospitals to prepare for potentially hundreds of NDCs would involve significant staff time to complete. In addition to significantly adding to the 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 hospitals report, despite our best efforts.

- CMS asks hospitals to identify each provider-based department where a relevant drug was administered. Like most hospitals, we do not track data this way, and doing so would require running numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how it intends to use this information. It is also not clear what information CMS seeks to collect on provider-based departments. Compiling this data would be a massive undertaking requiring significant staff time, and is particularly concerning, given that CMS has not provided a clear explanation as to why it requires this data.

- 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 to data necessary to complete the survey in the time specified.

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, and please do not hesitate to contact me if I can provide any additional information.

Sincerely yours,

Curtis E. Haas, Pharm.D., FCCP
Director of Pharmacy

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November 29, 2019

Submitted electronically via the Federal eRulemaking Portal: http://www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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 Verma,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to collect acquisition cost data for specified outpatient drugs acquired under the 340B Drug Discount 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

As a result of CMS's current payment reduction to 340B hospitals for Medicare Part B drugs, many Vizient members are already straining to provide needed care to the low-income patients they serve. As you know, the District Court has concluded in American Hospital Association et al v. Azar (Case number 1:18-cv-2084, December 27, 2018) that 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). Vizient 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 their ability to provide high value, accessible health care. This data collection effort appears to counter the intent of Congress when it created the 340B Program and, due to its success, later expanded it to include additional covered entities.

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 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 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, in fact, would result in a significant expenditure of time and resources for hospitals in order to collect and submit this data. Hospitals are expected to report data for more than 400 HCPCS codes and 1,100 national drug codes, equaling tens of thousands of units of data. This is a significant undertaking, one which inevitably could lead to human error and where hospitals would likely need to redirect financial resources that would otherwise be used to care for low-income patients. 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 me at (202) 354-2607 or shoshana.krilow@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.

November 25, 2019

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

Dear Mr. Parham:

Chippewa County War Memorial Hospital appreciates the opportunity to submit 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 & Medicaid Services (CMS) to survey 340B hospitals to obtain 340B drug acquisition cost data (84 Fed. Reg. 51590 (Sept. 30, 2019)). Our hospital is a rural sole community hospital that is exempted from the Medicare Part B payment reductions that have been in effect for certain 340B hospitals since 2018. CMS exempted our hospital from the payment reductions given the unique patient populations that we serve. It is not clear, however, if CMS is proposing to collect 340B drug acquisition cost data from exempted hospitals. We request that CMS make clear that the hospitals exempted from the payment reduction are not required to respond to the survey.

CMS's Proposal Would Harm Safety-Net Hospitals and Patient Care

CMS proposes to collect acquisition cost data from 340B hospitals to set Medicare payment for 340B drugs at acquisition cost. CMS should not move forward with a survey that includes hospitals exempted from the payment reduction. Given the unique patient populations that we serve, our hospital is not situated to absorb any sort of payment cut. For the reasons CMS exempted our hospital from the payment reduction, CMS should also exempt our hospital from the survey.

CMS's Proposal is Contrary to Law

In addition, 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)).

CMS Grossly Underestimates the Massive Burden the Proposal Would Place on Hospitals

Our hospital has significant concerns regarding the amount of time it would take to respond to the survey. CMS proposes to ask 340B hospitals for average acquisition cost data for more than 400 HCPCS codes and 1,100 national drug codes (NDCs). For a given quarter, there easily can be tens of thousands of units of data hospitals would need to account for. Even more concerning are the extensive mathematical calculations the ICR requires hospitals to prepare for potentially hundreds of NDCs. CMS is

asking hospitals to calculate average 340B prices for all NDCs paid under the 400-plus HCPCS codes, requiring hospitals to 1) average the prices together for all the NDCs mapped to the HCPCS codes, which can be dozens of NDCs for a single HCPCS code, and 2) convert NDC purchase units to HCPCS dosage units. In addition to significantly adding to the burden, asking hospitals to complete calculations factoring tens of thousands of units of data means there inevitably will be human error that may contribute to inaccuracies in the data hospitals report despite their best efforts.

CMS also asks hospitals to identify each provider-based department where a relevant drug was administered. This would be extremely burdensome for hospitals, as most hospitals do not track data this way and would need to run numerous reports out of the hospital's billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. CMS does not explain the purpose of collecting data on provider-based departments or how CMS intends to use this information, suggesting a violation of the Paperwork Reduction Act of 1995. (44 U.S.C. § 3506(c)(1)(B)(iii)). Nor is it clear what information CMS seeks to collect on provider-based departments. CMS's survey instructions ask hospitals to list each provider-based department of the hospital that is "enrolled in the 340B program." The Health Resources and Services Administration (HRSA) requires hospitals to register each service provided in the same provider-based department located outside the four walls of the hospital, which raises questions about what information CMS seeks to collect from 340B hospitals on provider-based department locations.

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

We appreciate the opportunity to provide comments on this proposed ICR. For the reasons outlined above, we urge CMS to exempt our hospital from the survey.

Sincerely,

David B. Jahn, FACHE
President & CEO
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Yale
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Health

November 25, 2019

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. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of Yale New Haven Health System and our 340B participating hospitals, Bridgeport Hospital, Lawrence & Memorial Hospital and Yale New Haven 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 CMS to 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, in this past fiscal year alone, we have been able to use the 340B savings to subsidize expansions of our clinical pharmacy patient oriented services in the Adult Ambulatory Care clinics, Children's Hospital, and Infectious Disease Programs. All of these new initiatives are in keeping with the original intent of the 340B program, as well our long-standing tradition of providing more care to more patients regardless of their ability to pay. 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.

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. None of these aforementioned costs required to compliantly participate in the 340B program appear to be reflected in the drug cost data CMS seeks, and therefore stand to be uncompensated.

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,

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

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