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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.

Protecting the 340B Program

The savings achieved through the 340B program enables eligible hospitals to provide important community benefits through various programs and services. Congress created the program—which is administered by the Health Resources and Services Administration (HRSA) and requires drug manufacturers to sell

outpatient drugs to eligible entities at discounted prices—"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.

The 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. These ongoing costs for program administration have become more difficult with the current Medicare 340B cuts (i.e., reducing the payment rate from average sales price [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 Department of Health and Human Services Secretary 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 the 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 Healthcare Common Procedure Coding System [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 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 a hospital 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 two-three 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 full-time equivalent 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
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