

CMS Releases 340B Drug Acquisition Cost Survey, Responses Due May 15, 2020

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After receiving approval from the Office of Management and Budget (OMB) on April 23, 2020, the Centers for Medicare and Medicaid Services (CMS) released a survey on April 24, 2020, to collect information on 340B hospitals' net acquisition costs for 340B-purchased drugs. CMS announced on its Hospital Outpatient Prospective Payment System (OPPS) [webpage](#) that the survey is available through May 15, 2020, in spite of requests by hospitals and hospital groups to delay the survey's implementation because of the Coronavirus (COVID-19) emergency.

IN DEPTH

CMS indicated that submission of the survey is required for all hospitals that participate in the 340B Program, with the exception of Critical Access Hospitals (CAHs). In addition to a "detailed survey" option that follows previously released data collection instructions, CMS has provided a "quick survey" option to report purchasing at 340B ceiling prices without detailing per-drug acquisition costs. Hospitals should evaluate the risks and benefits of each survey option when deciding which option to complete.

Background

In our previous *On the Subject*, "[CMS Advances 340B Drug Acquisition Cost Survey to OMB and Solicits Final Comments Directly to OMB](#)," we described a CMS notice signaling that CMS had submitted a proposed survey of hospital 340B drug costs for OMB approval. Now that the survey has been approved by OMB and released by CMS, CMS may use the data to set future reimbursement rates for 340B drugs furnished by hospitals to Medicare beneficiaries.

Since 2018, CMS's OPPS rules have reduced hospitals' Medicare Part B reimbursement for 340B drugs from Average Sales Price (ASP) plus 6% to ASP minus 22.5%, a reduction of almost 30%. A federal district court judge struck down the Part B payment reductions in late 2018, in part because CMS did not have sufficient data to support the reductions. While the case is under appeal, CMS has

continued to reimburse 340B drugs at ASP minus 22.5%. CMS has indicated that if the appeals court rules against it, CMS will begin basing Part B payments for 340B drugs on “amounts that approximate what hospitals actually pay to acquire the drugs.”

Survey Requirements

On April 24, 2020, CMS released its Hospital Survey for Specified Covered Outpatient Drugs Average Acquisition Cost, as well as an instruction sheet providing context and information regarding the survey. The instruction sheet specifies that all hospitals that were enrolled in the 340B program in the last quarter of 2018 and/or the first quarter of 2019, excluding CAHs, are required to respond to the survey by May 15, 2020. CMS noted in the instruction sheet that covered entities must maintain accurate records documenting compliance with all 340B program requirements as a condition of participating in the 340B Drug Pricing Program, and therefore each hospital “should have readily available access to the data that is being requested via this survey.”

Contrary to what was previously reported in *Federal Register* and preliminary CMS survey documents, the final survey instrument offers two options: Hospitals can choose to either submit the quick survey or the detailed survey.

Both the detailed survey and quick survey require respondents to provide the following information:

- Hospital name, address and contact information
- Provider CCN Number
- National Provider Identifier
- Tax ID Number

Hospitals can choose to provide CMS no further information by submitting the quick survey, but by doing so, they will allow CMS to use the 340B ceiling prices obtained from the Health Resources and Services Administration as indicative of the hospital’s drug acquisition costs. After selecting this option, the survey is complete, but requires that the hospital make an affirmative representation to CMS that it acquires all 340B drugs at the 340B ceiling price. Such a statement may not be accurate for some hospitals.

Alternatively, hospitals may choose to submit the detailed survey, which requires the submission of the net acquisition cost for each specified covered outpatient drug acquired under the 340B program, *i.e.*, the sub-ceiling price after all applicable discounts. This includes, but is not limited to, 340B drugs purchased via a replenishment model or under penny pricing. The 340B drug acquisition cost should be reported regardless of whether the drug was dispensed, or whether the drug was dispensed in multiple settings. If the acquisition cost for a specific drug reported in the detailed survey is unknown, CMS will use the 340B ceiling price as a proxy. Importantly, the detailed survey appears to only provide for reporting of the average acquisition cost of drugs when purchased through a 340B account, not the actual average acquisition cost of the drug at issue. Therefore, submission of the detailed survey information would only result in reporting of costs at or below the 340B ceiling price and does not provide a mechanism to account for the fact that many hospitals must purchase drugs for outpatient dispensing on non-340B accounts and at rates higher than the 340B ceiling price.

Detailed survey respondents must complete an Excel spreadsheet with the following information:

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- HCPCS code for each drug (pre-populated)
 - Drug name/short descriptor (pre-populated)
 - Dose (as reflected in HCPCS dose descriptor) (pre-populated)
 - Q4 2018 Payment Rate (pre-populated)
 - Q1 2019 Payment Rate (pre-populated)
 - Average 340B price of drug for Q4 2018
 - If left blank, CMS will use the 340B ceiling price as a proxy.
 - Average 340B price of drug for Q1 of 2019
 - If left blank, CMS will use the 340B ceiling price as a proxy.

The survey instruction sheet provides several appendices, including an NCD-HCPCS crosswalk, two examples of how to calculate the average acquisition cost, specifically for HCPCS codes J-885 (Injection, epoetin alfa, (for non-esrd use), 1000 units), and J0878 (Injection, daptomycin, 1mg).

Hospitals with questions regarding the survey should contact the 340B Survey Technical Helpdesk Hotline at +1 833 886 5682. Hospitals should submit all survey responses to the applicable Medicare Administrative Contractor.

The survey does not clarify potential repercussions for failure to submit the survey instrument, and it remains unclear what authority CMS may rely on to enforce the reporting requirement.

Prior to using the data for future publications, including rulemaking, CMS must submit a report to OMB providing nonresponse bias and standard error analytical results. CMS must also describe any limitations in the generalizability of the information collected. This report from CMS could identify those hospitals that did not report data, potentially in a public-facing document.

Takeaways

CMS makes clear in the survey instructions that the purpose of the survey is to collect data necessary to establish “acquisition cost” payment rates for 340B drugs dispensed to hospital Medicare patients. Accordingly, it appears likely that CMS’s May 15, 2020, submission timeframe is intended to solicit the necessary information in order to propose acquisition cost-based payment rates for 340B drugs in the 2021 OPPS proposed rule (expected to be released in early July 2020) using the survey’s findings.

While it remains uncertain whether a court would agree that the survey meets the statutory requirements necessary to use the data for such purposes, if CMS is unsuccessful in its appeal of the prior 340B rate cuts, it is highly likely that CMS will use the data for both prospective rate cuts and possibly in connection with any remedies required for the prior rate cuts. Further, if the survey data reflects rates below the prior 22.5% rate cut, CMS could proceed with even more significant cuts to 340B payments.

Because the survey does not provide any mechanism to report 340B average acquisition costs above the 340B ceiling price, use of the survey for future rate setting would appear to result in a rate no higher than the 340B ceiling price. If a material number of hospitals use the detailed survey, it could result in Medicare rates for 340B hospitals at rates below the 340B ceiling price, notwithstanding that hospital outpatient drug costs may be much higher.

Although many hospitals are currently being challenged by COVID-19 response efforts, hospitals should nevertheless carefully consider whether to submit the quick survey or detailed survey,

including evaluation of such issues as the resources required to complete the survey, potential for inaccurate statements of purchasing costs to CMS, impact to future rate setting and public disclosure of reported information.

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National Law Review, Volume X, Number 118

Source URL: <https://natlawreview.com/article/cms-releases-340b-drug-acquisition-cost-survey-responses-due-may-15-2020>