

## ATTENTION 340B HOSPITALS: CMS COST DATA SURVEY DUE MAY 15 RAISES IMPORTANT COMPLIANCE QUESTIONS

Late last week CMS finally released its anticipated drug acquisition cost survey (“Survey”) to collect pricing data for certain directly reimbursable drugs called “Specified Covered Outpatient Drugs” that are subject to significantly reduced Medicare payment when acquired using a 340B Program discount (“SCODs” or “340B Drugs”). All hospitals enrolled in the 340B Program during the last quarter of 2018 and/or the first quarter of 2019 except for critical access hospitals (“340B Hospitals”) must respond by **May 15, 2020**. We anticipate that CMS will use the Survey results to set future 340B Drug reimbursement rates based on the acquisition cost for 340B Hospitals.

The CMS Survey provides two options for 340B Hospitals to complete the Survey. The “Quick Survey” option allows 340B Hospitals to simply attest that 340B Drug ceiling prices generally are “...reflective of your hospital acquisition costs.” The “Detailed Survey” option entails providing the detailed net acquisition cost data for each SCOD acquired during the last quarter of 2018 and first quarter of 2019. More information about the Survey and instructions for the Survey are available **from CMS**, including examples about how to calculate average acquisition costs.

Which option 340B Hospitals select is a fact-specific analysis that will ultimately require a risk assessment applying undefined terms. Therefore, 340B Hospitals should work with relevant 340B Program, compliance, finance and legal personnel to consider the options and decide which Survey option to complete. Potential future compliance risks related to inappropriate responses counsel in favor of careful consideration of which option to select.

### BACKGROUND

As we described in **our article from 2019**, CMS proposed carrying out this Survey in response to court rulings finding that CMS inappropriately reduced 340B Drug reimbursement since it did not have drug price survey data as required by the governing statute. The CMS 340B Drug payment rule reduced reimbursement for 340B Drugs by nearly 30 percent (see articles **here** and **here**). In the event that CMS loses the pending case on appeal, it is likely that CMS will use data from this Survey and base reimbursement for 340B Drugs on amounts that approximate what 340B Hospitals pay to acquire the 340B Drugs.

### SURVEY INSTRUCTIONS AND IMPLICATIONS

As mentioned above, a 340B Hospital may choose to submit a Quick Survey or a Detailed Survey. Regardless of whether a 340B Hospital submits a Quick Survey or a Detailed Survey, the 340B Hospital must provide the:

- 340B Hospital Name;
- Name, Phone, Email Address, and Mailing Address of a 340B Hospital Contact;
- Medicare CMS Certification Number (CCN);
- National Provider Identifier (NPI); and
- Tax ID Number.

If a 340B Hospital chooses to submit the Quick Survey, CMS will use the 340B Drug ceiling prices as the 340B Hospital’s 340B Drug acquisition costs. The Quick Survey takes less time, but a 340B Hospital considering this option should verify whether the 340B Drug ceiling prices are adequately “reflective” of the 340B Hospital’s acquisition costs. As this term is undefined, careful consideration should be given to this response since federal reimbursement is indirectly based on the responses.

If a 340B Hospital chooses to submit the Detailed Survey, it must submit the net acquisition cost, the sub-ceiling price after all applicable discounts, for each individual 340B Drug obtained under the 340B Program. This includes submitting the acquisition costs of 340B Drugs purchased through a 340B Program replenishment model and under penny-pricing, regardless of whether a 340B Drug was dispensed, and regardless of whether it was dispensed in multiple settings. Plainly stated, this is a heavy lift in a short amount of time.

Notably, if an acquisition cost is unknown or left blank, CMS will use the 340B Drug's ceiling price as a proxy for the acquisition cost. Since the Detailed Survey solely requests acquisition costs for 340B Drugs purchased under the 340B Program and does not account for drugs acquired outside of the 340B Program and used for outpatient dispensing, it may mean that Detailed Survey results may not account for the actual average acquisition cost incurred by 340B Hospitals. Combined with the Quick Survey, the results may be skewed towards the 340B Drug ceiling prices.

To submit a Detailed Survey, a 340B Hospital must complete a spreadsheet with the following:

- HCPCS code for each 340B Drug (pre-populated);
- 340B Drug name/short descriptor (pre-populated);
- Dose (as reflected in HCPCS dose descriptor) (pre-populated);
- Q4 2018 payment rate (pre-populated from OPPS Addendum B);
- Q1 2019 payment rate (pre-populated from OPPS Addendum B);
- Average acquisition cost of 340B Drugs for Q4 2018; and
- Average acquisition cost of 340B Drugs for Q1 of 2019.

CMS stated that it will maintain the confidentiality of individual responses that include acquisition cost for each 340B Drug, but it may make average acquisition cost information for each 340B Drug public.

## **PRACTICAL TAKEAWAYS**

340B Hospitals should assess their response with their 340B Program, compliance, finance and legal personnel. As part of this response evaluation, these individuals should coordinate and determine whether the Quick Survey or the Detailed Survey would be more appropriate. Those 340B Hospitals considering the Quick Survey option should confirm that the 340B Drug ceiling prices are an adequate and accurate representation of their 340B Drug acquisition costs as this may have additional implications from a regulatory compliance perspective.

340B Hospitals must submit completed Surveys to their Medicare Administrative Contractor by **Friday, May 15, 2020**. Failure to select the correct option or failure to submit a Survey in the first place could each have future consequences. While the Survey instructions state that questions should be directed to the 340B Survey Technical Helpdesk Hotline, note that Hotline representatives will ask for a specific Provider Transaction Access Number to be provided which will disclose the requesting 340B Hospital's identity.

In spite of the present COVID-19 pandemic, CMS has refused to delay implementation of the Survey. While this season presents unprecedented challenges for 340B Hospitals, they should carefully evaluate their options with respect to this Survey and continue working with their advocacy teams to support their 340B Programs.

If you have any questions or would like additional information about this topic, please contact:

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