PROPOSED CMS HOSPITAL SURVEY COULD SUPPORT CMS'S EFFORTS TO REDUCE 340B DRUG REIMBURSEMENT

On September 30, 2019, the Centers for Medicare & Medicaid Services ("CMS") published notice of a proposed survey ("Survey") of drug acquisition costs for all hospitals participating in the 340B drug discount program ("340B Program"). The Survey would require reporting of acquisition cost data on 340B discounted drugs, referred to as specified covered outpatient drugs ("SCODs"). CMS stated its intent to use the collected information to determine payment rates for SCODs acquired under the 340B Program, likely solidifying a payment rate at some level less than the historical Average Sales Price ("ASP") +6%. This proposed Survey is notable since it could constitute an admission that CMS did not have the survey data required to establish its current reduced Outpatient Prospective Payment System ("OPPS") payment of ASP -22.5% for SCODs.

Hospitals should note that the government has the obligation to provide a justification to Congress for the size of the sample used for the Survey, which does not appear to have been provided in the notice. As such, it is possible that, at a minimum, not all hospitals will be required to respond. If hospitals are eventually required to respond to the Survey, they will need to consider a number of factors including what, if any, drugs should be excluded (*e.g.*, gases), how to calculate costs, how to identify participating departments and what requirements in their purchase agreements must be met to permit disclosure of the pricing data pursuant to a government request.

Once collected, the SCOD data could be used to implement a permanent payment reduction for 340B-eligible hospitals including not just disproportionate share hospitals ("DSH"), but also those hospitals excluded from 340B OPPS payment cuts including rural sole community hospitals ("SCHs").

Affected hospitals should consider both responding to CMS's request for comment and preserving appeal/recoupment rights for the current 340B OPPS payment reductions since CMS's Survey efforts support the argument, at a minimum, that CMS did not have the data necessary to implement the ASP -22.5% reduced payment applicable to certain 340B hospitals.

In comments to CMS, 340B hospitals should consider addressing the potential burdens associated with responding to the Survey (CMS estimates 48 FTE-based hours of work), the fact that CMS plans to require all 1,400 340B hospitals to respond rather than just a sample, questions regarding CMS's basis for the survey request, the policy implications of accessing savings reserved for only non-profit or government entities and implementation questions including how to calculate actual pricing.

For more detail regarding CMS's ongoing efforts to reduce reimbursement for drugs acquired at a 340B discount, see our recent articles here and here.

BACKGROUND

In December of 2018, the U.S. District Court for the District of Columbia ruled that the Department of Health & Human Services ("HHS") exceeded its statutory authority to adjust payment rates for separately payable outpatient drugs purchased under the 340B Program from ASP +6% to ASP -22.5%. In part, the Court determined that CMS had not collected the necessary data on acquisition costs before implementing the reduction. CMS appealed the Court's ruling, but it will move forward with collecting acquisition cost data in case a court affirms the ruling on appeal.

The Survey would provide CMS with SCOD data to set payment rates based on the cost of 340B-acquired drugs when they are furnished by 340B DSH hospitals (payment adjustment percentage greater than 11.75%), children's hospitals, critical access hospitals, cancer hospitals, rural referral centers and SCHs (payment adjustment percentage of at least 8%) (collectively, "Hospitals"). As proposed, CMS would require all hospitals enrolled in the 340B program during the last quarter of 2018 and/or the first quarter of 2019 to complete the Survey (approximately 1,400 Hospitals).

As proposed, the Survey instructions state that the hospitals must provide the following:

- Hospital name, Medicare CCN and Contact Information;

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- The name of each provider-based department enrolled as a 340B child site and paid under the OPPS; and
- The HCPCS code for each SCOD identified with a status indicator of "K" (separately payable drug) or "G" (pass-through drug) for each such drug, including:
  - Name and short descriptor;
  - Dose; and
  - Average 340B price.

The Survey data collection period would begin February 17, 2020 and end March 16, 2020, and Hospitals would submit completed Surveys to their respective FI/MAC by the end of the data collection period.

PRACTICAL TAKEAWAYS

Potentially affected Hospitals should consider preserving appeal rights associated with the payment reductions to ASP -22.5% to protect any potential retroactive recoupments/remedies.

Stakeholders and interested persons are invited to submit comments regarding this notice and the data collection. Comments must be received by **November 29, 2019**.

As part of the comment process, Hospitals are encouraged to consider the work needed to respond to the Survey if asked to respond, especially given that the window of time for the survey data collection is less than a month.

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

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