



340B In The Spotlight – CMS 340B Acquisition Cost Survey Proposal & President's Budget

February 2020

As [predicted](#), 2020 is already off to a busy start for the 340B Drug Pricing Program.

- On February 7, CMS [published](#) notice in the Federal Register that it plans to release its outpatient drugs survey (SCOD ACC Survey) to 340B hospitals on March 23, 2020, due 3 weeks later (April 10). Stakeholders have an opportunity to comment regarding the burden estimate or any other aspect of this survey, including the necessity and utility of the proposed information. The 30 day public comment period ends on March 9, 2020.
- Most recently, the Administration released the [President's Budget](#) for FY 2021 that provides \$34 million (an increase of \$24 million obtained through user fees) for HRSA to improve operations and oversight of the 340B program. The budget also proposes to reform the 340B program through the language in the General Provision in the Labor-Health and Human Services-Education Appropriations Act, by providing HRSA the explicit general regulatory authority over the program “to ensure that net income from purchases under the 340B Drug Pricing Program benefit low-income and uninsured patients of the covered entities.”

CMS Survey Notice - 340B Hospitals Average Acquisition Cost of Covered Outpatient Drugs

In late 2019, CMS proposed a data collection process for the SCOD ACC Survey whereby

340B hospitals would be required to submit data on the average acquisition cost of “specified covered outpatient drugs” (SCOD). Covered entities remain concerned that CMS is proposing to collect this data (i) to set Part B reimbursement for separately payable drugs at cost on a go forward basis in the event they lose their appeal regarding its 2018-2019 payment reductions (to ASP-22.5%), and (ii) to “fix” 2018-2019 claims (and now 2020 since CMS continued its ASP-22.5% policy during the pending litigation).

On February 7, CMS posted its notice and released an updated SCOD ACC Survey and corresponding instructions. As written, the updated SCOD ACC Survey covers all SCODs with HCPCS codes assigned to status indicator “K” or “G” that 340B hospitals acquired from October 1, 2018 through March 31, 2019. The survey requires the average/net acquisition cost of any applicable SCOD that was purchased under the 340B program by any covered entity location. The survey excludes non-340B purchases/prices.

Key observations about the survey:

- This survey will involve a significant amount of time and effort by 340B covered entities given the complexity of HCPCS codes. **Additionally, Polsinelli's team has gone through the steps outlined in the SCOD ACC Survey instructions and has identified a number of**

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issues with the methodology outlined by CMS to properly complete the Survey.

- Multiple NDCs billed under a single HCPCS code are sure to cause accuracy problems and result in unreliable cost data.
- CMS's use of the term SCOD still needs to be clarified to ensure that it is limited to the statutory definition of SCOD, which generally pertains to radiopharmaceuticals and drugs on pass-through status as of a December 31, 2002.
- CMS did not address 340B covered entities' contractual confidentiality obligations with respect to pricing arrangements with manufacturers or wholesalers to the extent their contracts do not allow for such disclosure for government requests. Instead, CMS added language in the instructions that it pledges to maintain confidentiality of individual responses "to the extent provided by law" but may "make public average acquisition prices reported for each SCOD" except for some on a case by case basis.
- We believe CMS will have to collect this data every single year to be able to establish payment rates based on cost.

President's Budget for FY 2021 - 340B Drug Pricing Program

The FY 2021 President's budget request of \$10.2 million for HRSA is equal to the FY 2020 enacted level. Additionally, the FY 2021 budget request includes \$24 million from user fees as a new revenue source. In FY 2021, HRSA would begin the development of a multi-functional web-based user fee

system that would calculate user fees based on required manufacturer sales data, collect user fees from covered entities, and verify payments. HRSA bases revenue projections on collecting up to 0.1% (or \$1 for every \$1,000) of the total 340B drug purchases paid by participating covered entities. Both appropriated resources and user fee revenue would support implementation of 340B Program statutory obligations, oversight of participating manufacturers and covered entities, operational improvements, and increased efficiencies using information technology.

The FY 2021 budget request also re-proposes to reform the 340B Program audit scope by HRSA and manufacturers through the General Provision in the Labor-Health and Human Services-Education Appropriations Act that would require covered entities to report both their savings and uses to HRSA, and provide HRSA with general regulatory authority. HRSA is currently evaluating its audit process and other program integrity efforts as they relate to HRSA's ability to enforce and require corrective action in a Program that is primarily administered by guidance. Guidance documents do not provide HRSA appropriate enforcement capability, which is why HRSA has requested regulatory authority in the President's budget each year since FY 2017.

The FY 2021 budget request provides resources for the 340B Program to educate participating covered entities and prospective sites on compliance with statutory requirements. The request supports facilitation of refunds and credits to entities that are overcharged by participating manufacturers as well as enhancements to the pricing

system whereby covered entities access 340B ceiling price information via a secure website. System implementation began in the first two quarters of calendar year 2019, with manufacturers reporting data during the first quarter and prices being available to covered entities, after review and validation, on April 1, 2019.

HRSA plans to continue random and targeted audits of covered entities and manufacturers, as well as publish audit report summaries on the HRSA website to expand the 340B Program's compliance reach while managing program risk. User fees would provide the additional funding need to hire and train staff to expand capacity to conduct additional covered entity audits in the future, conduct additional manufacturer audits, and write reports, work with entities and manufacturers through the notice and hearing process, and finalize information for public dissemination.

HRSA measures 340B Program performance by two key metrics: numbers of covered entities and manufacturers audits. As of October 1, 2019, participation levels included 12,414 covered entities and 34,629 associated sites participating in the 340B Program, for a total of 47,043 registered sites. The 47,043 covered entity sites have contract pharmacy arrangements that support 25,654 unique pharmacy locations registered in the 340B database.

We will continue to monitor the activity with regard to the 340B program. Meanwhile, we have recently published an *AHLA Weekly* feature article titled "340B Drug Program Year in Review and 2020 Predictions" available [here](#).