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340B Program Changes Coming in 2019: Penalties and Payment Cuts

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Summary

On October 31, 2018, the Health Resources and Services Administration (HRSA) at the US Department of Health and Human Services (HHS) issued a notice of proposed rulemaking to move up the effective date of a final rule that would impose penalties on drug manufacturers under the 340B Program if the manufacturers knowingly and intentionally charged a covered entity more than the ceiling price for a covered outpatient drug (CY 2019 OPPS Final Rule).

In addition, the Centers for Medicare and Medicaid Services (CMS) issued the CY2019 Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS) final rule on November 2, 2018, pursuant to which CMS will reduce the payment rate for 340B drugs administered to patients of an off-campus provider based department of a hospital so as to match its payment rate of these drugs when administered on-campus at the hospital.

In Depth

Section 340B of the Public Health Service Act, known as the "340B Program," was enacted in 1992 to lower drug costs for certain safety net providers, including public

and not-for-profit hospitals and health clinics funded with federal grants (Covered Entities), by requiring drug manufacturers to provide discounts to Covered Entities on certain outpatient drugs as a condition of the manufacturers' participation in the Medicaid program. Although HHS does not have statutory authority to issue regulations governing many key aspects of the 340B Program, the Patient Protection and Affordable Care Act (ACA) gave HHS the authority to promulgate regulations intended to increase the accuracy and transparency of prices that manufacturers can charge for drugs under the 340B Program (known as "ceiling prices").

In January 2017, HHS issued a final rule (Ceiling Price Final Rule) that would require manufacturers to calculate the ceiling price for each covered outpatient drug—generally equal to the drug's average manufacturer price minus the drug's unit rebate amount—on a quarterly basis. The Ceiling Price Final Rule would also require HHS to publish the ceiling prices. Any manufacturer that knowingly and intentionally charged a Covered Entity more than the ceiling price would be subject to a civil monetary penalty (CMP) of up to $5,000 for each instance of overcharging, where each order for a national drug code (NDC) would constitute a single instance, regardless of the number of units of each NDC ordered. The CMPs would be in addition to the manufacturer's pre-existing obligation to issue a refund to Covered Entity in the event of an overcharge.

The Ceiling Price Final Rule was originally slated to become effective on March 6, 2017. However, HHS delayed the effective date on five occasions:

- January 24, 2017: HHS delayed the effective date of the Ceiling Price Final Rule for 60 days pursuant to a regulatory "freeze."
- March 20, 2017: HHS further delayed the effective date of the Ceiling Price Final Rule to May 22, 2017, "[t]o provide affected parties sufficient time to make needed changes to facilitate compliance, and because questions were raised."
- May 19, 2017: HHS delayed the effective date to October 1, 2017, after reviewing comments to the proposed delay.
- September 29, 2017: HHS delayed the effective date to July 1, 2018, after considering further comments.
- June 5, 2018 – HHS delayed the effective date to July 1, 2019.

When announcing the last delay in June 2018, HHS asserted that it was necessary to provide manufacturers time to implement the requirements of the Ceiling Price Final Rule, and to consider alternative and supplemental regulatory provisions and allow time for such additional rulemaking. You can read a prior *On the Subject* about the Ceiling Price Final Rule here.

Most recently, HHS reversed course by issuing a notice of proposed rulemaking (Notice) on October 31, 2018, to move up the effective date of the penalty policy from July 1 to January 1, 2019, stating that it no longer believes a delay in the effective date is necessary. The Notice was published several weeks after the American Hospital Association (AHA) and several other hospital system and hospital

association stakeholders filed a lawsuit alleging that HHS violated the Administrative Procedures Act (APA) by arbitrarily and capriciously delaying implementation of the Ceiling Price Final Rule without providing a coherent explanation for either the delay or HHS's claim that 340B providers would not be adversely affected by the delays. The plaintiffs also asserted asserting that HHS is statutorily obligated to adopt certain measures set forth in the Ceiling Price Final Rule. You can read more about the Complaint here.

The Notice allows for a relatively brief comment period of 21 days, which HHS justified because the provisions in question were subject to extensive public comment and have been delayed several times. HHS also stated that it believes that it has considered the full range of comments on the substantive issues.

Shortly after issuing the Notice, CMS published the CY 2019 OPPS Final Rule on November 2. Consistent with its CY 2018 payment policy, in CY 2019, CMS will pay ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program. However, unlike the CY 2018 payment policy, the CY 2019 OPPS Final Rule will also apply the reduced rate when the drug is furnished by off-campus hospital outpatient departments subject to the Section 603 site-neutral payment cuts that were implemented in 2017. CMS will continue its policy of excepting rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment. Critical Access Hospitals also are exempt because they are not paid under OPPS. As previously described in a prior *On the Subject* about the CY 2018 OPPS rule, which can be accessed here, the ASP minus 22 percent rate represents a payment cut of almost 30 percent over the prior rate of ASP plus six percent in effect in CY 2017.

The Final Rule can be accessed here, and the accompanying CMS fact sheet can be accessed here.

Analysis

We are continuing to see significant activity in the drug cost space. Both Congress and the Trump administration have drawn attention to a the cost of drugs in the United States, including concerns regarding the growth of the 340B Program and use by Covered Entities of funds generated from participation. These regulatory actions involve several strategies intended to reduce the ultimate cost of drugs for the Medicare program and its beneficiaries.

Although HRSA noted in its proposal to accelerate implementation of the Ceiling Price Final Rule that it "envisions using these penalties in rare situations," it is unclear how aggressively the HHS Office of Inspector General (OIG) will pursue CMP actions. The prospect of OIG actions, and the OIG's discretion to interpret "knowing and intentionally," suggest that manufacturers should consider revisiting or implementing policies and procedures to ensure Covered Entities are not overcharged for covered outpatient drugs.

The continuance and expansion of the CY 2018 cut in Medicare payments for 340B Program drugs provides further insight into the current political environment for the 340B Program and suggests a potential trajectory for future payment policies and

legislative proposals. CMS noted in the CY 2019 OPPS Final Rule that reimbursing for 340B drugs at locations subject to the Section 603 payment cuts at a higher reimbursement rate than that received at locations not subject to the payment cut created incentive for hospitals to move drug administration services for 340B-acquired drugs to off-campus locations where the 340B drug reimbursement was higher. Providers and industry stakeholders can expect future CMS initiatives and rulemakings to continue to strive for site-neutral payments that may prompt providers to restructure historic relationships between provider locations and to reconsider the respective services they render.

Also of note, the Notice and CY 2019 OPPS Final Rule come at the heels of the advanced notice of proposed rulemaking regarding the proposed international pricing index model for Medicare Part B drugs, which we analyzed here.