340B UPDATE: HRSA SEEKS FIFTH DELAY OF FINAL RULE ON 340B PRICING AND MANUFACTURER CMPS; BUDGET DOCUMENT SHEDS LIGHT ON 340B USER FEE AND OTHER HRSA PRIORITIES

Date: 10 April 2018

U.S. Health Care Alert

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The 340B Drug Pricing Program ("340B Program") remains in the regulatory spotlight. Most recently, on March 27, 2018, the Health Resources and Services Administration ("HRSA") indicated it is poised to delay for the fifth time its final rule addressing drug pricing calculations and civil monetary penalties ("CMPs") for manufacturers that knowingly and intentionally overcharge covered entities under the 340B Program. In addition, new budget documents highlight HRSA's 2018 priorities and provide detail on HRSA's proposed user fee on 340B Program covered entities.

In regard to the final rule, 340B Program stakeholders should not only review the impact of the delayed effective date but should also consider any other concerns within the final rules and consider raising issues with regulators through public comments. In addition, hospitals and other 340B Program stakeholders should carefully monitor these developments more broadly and consider engaging directly with policymakers in Congress and the administration as the debate over the 340B Program moves forward.

HRSA REQUESTS A FIFTH DELAY FOR FINAL RULE ON 340B PRICING AND MANUFACTURER CMPS

On Tuesday, March 27, 2018, HRSA submitted a request to the White House Office of Management and Budget ("OMB") to delay the effective date of a final rule that would address drug pricing calculations and CMPs for manufacturers that knowingly and intentionally overcharge covered entities. [1] See our prior alerts on the final rule for more background. If implemented, this would be the fifth time that the effective date has been delayed from its original effective date of March 6, 2017. In the past, HRSA has justified similar delays on the basis that more time is required to analyze stakeholder objections and to continue to engage in additional rulemaking. At this time, neither HRSA nor OMB has published a new proposed effective date or deadline for public comments if the extension is approved.

BUDGET DOCUMENT SHEDS LIGHT ON ADMINISTRATION PRIORITIES

In addition, HRSA recently released its Congressional Budget Justification ("CBJ") for Fiscal Year ("FY") 2019. [2] Many of the changes and priorities proposed in HRSA's budget request are consistent with those that were

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identified in the Trump administration's original FY 2019 budget documents (see our prior alert on this topic). According to statistics provided by HRSA, as of January 1, 2018, there were 12,823 covered entities and 29,663 associated sites participating in the 340B Program, for a total 42,486 registered sites. Twenty-seven percent of the 42,486 covered entity sites have contract pharmacy arrangements that support 20,757 unique pharmacy locations registered in the 340B Program database. [3]

New User Fees

As part of HRSA's budget request, the CBJ projects $16 million in new revenues that HRSA expects to receive from user fees — expected to be approximately 0.1 percent of the total 340B Program drug purchases of participating covered entities. [4] Once implemented, HRSA indicates that the user fees will support improvements to the 340B public database, program audits, and the 340B Program's automated compliance management tool. [5]

Changes to Patient Definition and Covered Entity Eligibility

Notably, HRSA also indicates that it will be seeking to clarify the definitions of eligible patients and covered entities, pursuant to a recommendation from the Government Accountability Office. [6] A federal court ruled in 2014 that HRSA's rulemaking authority is limited to three distinct areas: dispute resolution, ceiling prices, and CMPs. [7] Accordingly, mirroring the president's budget, the CBJ proposes that Congress grant HRSA broad regulatory authority to set enforceable standards of participation and require all covered entities to report on 340B Program savings and the use of those savings. [8]

Other FY 19 Priorities

In addition to continued audits of covered entities and manufacturers, the CBJ identifies the following priorities for HRSA in FY 2019:

- Price Verification – Compute 340B Program ceiling prices using data that manufacturers supplied to the Centers for Medicare and Medicaid Services, based on an agreement with HRSA. Conduct random spot checks of these prices with information submitted voluntarily by a small group of manufacturers.
- Price Submission – Maintain a secure system for all manufacturers to submit 340B price information, allowing regular spot checks of prices and any necessary follow-up on pricing errors.
- Refunds and Credits – Facilitate refunds and credits to entities that are overcharged by participating manufacturers.
- Pricing System – Continue to develop a system whereby covered entities can access 340B Program ceiling price information via a secure website. HRSA indicates that implementation of the pricing system is expected once the final rule on ceiling price calculations and CMPs has been finalized (likely to be delayed beyond the current effective date of July 1, 2018, as discussed above) and any necessary changes to the system have been implemented.

Given the potential for significant changes to the 340B Program this year, stakeholders should assess their compliance with existing 340B Program requirements and continue to plan for future changes that could result from new guidance or regulations in 2018 and potential legislation from Congress. Hospitals and other stakeholders may also wish to continue or begin pursuing policy advocacy. K&L Gates' Health Care practice and

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Public Policy and Law practice regularly advise clients on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the administration.

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[1] Virgil Dickson, *HHS Seeks Another Delay for 340B Changes,* MODERN HEALTHCARE (Mar. 28, 2018), http://www.modernhealthcare.com/article/20180328/NEWS/180329900. *See also* Office of Information and Regulatory Affairs, OMB, https://www.reginfo.gov/public/Forward?SearchTarget=RegReview&textfield=340b (accessed on Apr. 4, 2018) (showing RIN 0906-AB18 titled, "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Further Delay of Effective Date," with Status marked as "Pending Review" and "Received Date" marked as 03/27/2018).

[2] *Justifications of Estimates for Appropriations Committees,* HEALTH RESOURCES AND SERVICES ADMINISTRATION, p. 257, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf.

[3] *Id.* at 259.

[4] *Id.*

[5] *Id.* at 258.

[6] *Id.*

[7] *Pharmaceutical Research and Manufacturers of America v. U.S. Dep't of Health and Human Servs.*, Civ. Action No. 13-1501 (D.D.C May 23, 2014).

[8] *Justifications of Estimates for Appropriations Committees*, HRSA, p. 257, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf.

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