The Health Resources and Services Administration (HRSA) announced recently that 340B hospitals may use 340B drugs at certain offsite locations before such locations are reported on hospitals’ most recently filed Medicare cost report and registered in the online 340B database. Hospitals should review and, as necessary, revise written policies and procedures to reflect new eligibility and registration provisions and take steps to ensure compliance with the 340B program “patient definition,” duplicate discount prevention and other applicable 340B Program requirements.

**IN DEPTH**

On June 6, 2020, the Health Resources and Services Administration (HRSA) announced that 340B hospitals may use 340B drugs at certain offsite locations before such locations are reported on the hospital’s most recently filed Medicare cost report and registered in the online 340B database of the Office of Pharmacy Affairs (OPAIS) as a 340B “child site” of the hospital. Permissible use and prescribing of 340B drugs at such offsite locations will continue to be subject to the
340B program definition of “eligible patient” of the hospital, and hospitals remain required to register offsite locations in OPAIS once the location is reported on a filed Medicare cost report.

**Background**

Under 340B program guidance issued in 1994, “only outpatient facilities which are an integral component of [a hospital] will be included on the [hospital’s] Medicare cost report, and only those facilities will be eligible” for 340B program discount pricing. Although this guidance did not expressly require a hospital to have reported the costs of an offsite hospital location on a filed cost report before the location could become eligible to dispense and prescribe 340B drugs, HRSA has historically imposed such a requirement. This requirement has been controversial because up to 22 months could elapse before a new outpatient facility location is included on a hospital’s next-filed Medicare cost report, be registered on OPAIS and become eligible for 340B participation.

**New Guidance**

As part of its ongoing COVID-19 resources updates, HRSA has released new guidance, reflected in a new FAQ on the 340B program website, explaining that for hospitals that are unable to register their outpatient facilities because they are not yet on the hospital’s most recently filed Medicare cost report, the patients of the new site may still be 340B eligible to the extent they are patients of the covered entity. The FAQ then refers readers to HRSA’s 1996 guidance regarding the patient definition. For hospital covered entities, the 340 “patient” definition includes two components: (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.

HRSA’s FAQ also states that in order to register for the 340B program and be listed on OPAIS, HRSA must first verify that the offsite, outpatient facility is listed as reimbursable on the hospital’s most recently filed Medicare cost report and has associated outpatient costs and charges as outlined in its 1994 outpatient hospital facilities guidance. HRSA has not removed from its website an FAQ that responds to the question, “May an outpatient facility that is reimbursed by CMS as a provider based facility, but not included on the most recently filed cost report, access 340B Drugs under the final guidance published in 1994?” HRSA responded: “No. Under the final guidelines a facility must be both reimbursable and included in the hospital’s most recently filed Medicare cost report.”

Similarly, FAQs published by the 340B prime vendor, Apexus, also continue to contain an FAQ indicating, “A facility must be both reimbursable and included in the hospital’s most recently filed Medicare cost report with associated outpatient costs and charges to access the 340B Program and register in 340B OPAIS.” However, Apexus has modified its FAQs on hospital registration of 340B offsite facilities to add a new FAQ aligning with HRSA’s new FAQ. Notably, the Apexus FAQ is not
specific to COVID-19 or the public health emergency and applies the policy broadly to any new offsite, outpatient location.

Analysis

HRSA’s new FAQ suggests a shift in HRSA’s position regarding the interim period between: (1) when a location becomes eligible to be included on a hospital’s cost report (e.g., when a location qualifies as a provider-based department); and (2) when the location is actually reported on a hospital cost report and registered in OPAIS. Previously, HRSA has not permitted such locations to use 340B drugs during this interim period, while HRSA’s new FAQ suggests that such locations will be able to use 340B drugs during this interim period as long as their patients are 340B eligible as patients of the hospital. We anticipate that HRSA and Apexus will modify or revise their conflicting FAQs in the future.

The new FAQ provides only a partial picture of HRSA’s apparent shift in position, and it does not explain how HRSA reconciled the 340B authorities and its past guidance to come to its shift in position. While the language of the FAQ suggests HRSA is interpreting the “patient” definition to extend 340B eligibility from a covered entity hospital to an outpatient location that has not yet been reported on a cost report or registered on OPAIS, HRSA’s key interpretive shift appears to be regarding the definition of a hospital for purposes of qualifying as a 340B covered entity eligibility. In any case, it will be critical for offsite outpatient locations to: (1) qualify to be reported on a hospital’s cost report; and (2) ensure the “patient” definition is met, before using 340B drugs.

Takeaways

- Hospital covered entities should review and revise written policies and procedures to reflect these revised eligibility and registration provisions, as well as maintain clear written documentation to support compliance with the patient definition at any locations that are not reflected in OPAIS, but where 340B drugs are being used.

- Hospitals should ensure that offsite outpatient locations qualify to be reported on the hospital’s next filed cost report and the patients at such locations meet the two-prong “patient” test before using or prescribing 340B drugs.

- Hospitals should ensure compliance with Medicaid duplicate discount prevention requirements at locations not registered in OPAIS and, if necessary, contact applicable state Medicaid programs for further guidance.

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