There are initial indications that the Health Resources and Services Administration (HRSA), which administers the federal 340B drug pricing program, may allow hospitals to begin using 340B drugs at offsite locations (“Child Sites”) as soon as those locations meet Medicare provider-based requirements, even if they do not yet appear on a filed Medicare cost report. This policy change could advance 340B participation of Child Sites by as much as one year or more. As noted below, we confirmed this change with Apexus, HRSA’s 340B prime vendor, and verbally with HRSA. However, this is still a developing issue, so hospitals should consider the risks and challenges posed by proceeding in light of HRSA’s changed position.

Historically, HRSA has prohibited hospitals from utilizing 340B drugs / generating 340B contract pharmacy prescriptions at Child Sites until they appeared on a filed Medicare cost report and were registered in the 340B Program. Even in a best case scenario, this resulted in a waiting period of approximately 6 months. This apparent change in position brings welcome news, particularly during the COVID-19 pandemic. However, there are still some unanswered questions that Polsinelli’s 340B team continues to explore. Examples include: how will this change appear in the HRSA / Bizzell audit process, will HRSA auditors now need to validate provider-
based compliance to assess if pre-registration 340B utilization was appropriate, and how will this change the Child Site registration process?

On June 4, 2020, Apexus published a new FAQ which suggests that although a Child Site must report reimbursable outpatient costs and charges on its most recently filed cost report to be listed on the 340B Office of Pharmacy Affairs Information System (OPAIS), the Child Site may be able to qualify drugs for 340B before it is listed on the cost report / registered. The FAQ would also give hospitals the flexibility to begin using 340B drugs at Child Sites under circumstances where the hospital, subject to the 340B program’s prohibition on group purchasing, has moved a clinic outside the four walls, but the clinic has not yet reported costs and charges on the cost report. The new Apexus FAQ reads as follows.

Apexus FAQ 4301

Q: Are hospital covered entities able to register offsite, outpatient facilities before being listed as reimbursable on their Medicare Cost Report?

A: In order to register for the 340B Program and be listed on the 340B Office of Pharmacy Affairs Information System (340B 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 HRSA’s 1994 Outpatient Hospital Facilities Guidelines (see here).

HRSA notes that for hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. More information on HRSA’s patient definition guidance can be found here.

These situations should be clearly documented in the covered entity’s policies and procedures. In addition, a covered entity is responsible for demonstrating compliance with all 340B Program requirements and ensure that auditable records are maintained for each patient dispensed a 340B drug.

Key takeaways for impacted covered entities:

- Applicable hospitals should ensure that their policies and procedures address qualification of 340B drugs dispensed at Child Sites for services not yet included in the most recently filed Medicare cost report — based on whether those locations meet Medicare provider-based requirements, whether the 340B covered entity maintains the responsibility and records of the patient’s care, and whether the health care professional prescribing the 340B drugs to the patient has a relationship with the 340B covered entity.

- Once charges for the Child Site appear on a filed Medicare cost report, hospitals must register that location with the OPAIS.

- Hospitals should continue to maintain auditable records to demonstrate that Child Sites qualify for 340B accordingly i.e., they meet the provider-based
regulations at 42 C.F.R. § 413.65 before 340B drugs are administered / dispensed.

- Hospitals with an upcoming fiscal year end date should assess this potential policy change to determine if it impacts provider-based conversion schedules.

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