



HRSA Ending 340B Offsite Facility Registration COVID-19 Waiver

Hospitals that have been using 340B product for offsite, outpatient facilities that have not yet met requirements regarding the covered entity's Medicare Cost Report and Office of Pharmacy Affairs Information System (OPAIS) registration must take action, before January 25, 2024, to register those facilities in order to continue their participation in the 340B program.

On October 27, the Health Resources and Services Administration (HRSA), which regulates all 340B covered entities, [announced](#) that it would be ending the waiver of 340B hospital offsite facility registration requirements with a 90-day "grace period" for covered entities to come into compliance.

For background, HRSA has required that a 340B hospital's offsite, outpatient facilities be listed as reimbursable on the hospital's most recently filed Medicare Cost Report, include associated outpatient costs and charges on the most recently filed Medicare Cost Report, and register and list with the 340B OPAIS.

Because OPAIS registration is conducted quarterly, effective the following quarter, and Medicare Cost Reports are filed annually up to five months after the provider's fiscal year, offsite locations could wait many months before 340B priced drugs are available to them. In the meantime, because the facilities were part of the 340B covered entity, other forms of discounts would not be available to them. Hospitals advocated consistently that this was an unnecessary and unintended burden.

In June 2020, in the context of relaxing rules and regulations to better allow 340B covered entities to respond to the COVID-19 pandemic, HRSA issued an FAQ that offered a waiver of the registration requirements for 340B hospital offsite facilities. Specifically, HRSA waived its enforcement of the requirement that an offsite,

outpatient facility be listed as reimbursable on the hospital's most recently filed Medicare Cost Report and be registered in OPAIS to be eligible to use 340B drugs. At the time, there were signals from HRSA's prime vendor that the change would be permanent, which was a welcome shift for covered entities that no longer had to experience substantial delays in realizing 340B savings for their outpatient locations.

On May 11, the COVID-19 public health emergency officially ended. HRSA took this opportunity to evaluate whether the offsite facility registration waiver was still appropriate, given that hospitals have now generally returned to typical operations. HRSA subsequently determined that compliance verification and auditing were hampered by the waiver policy, and the exigent circumstances necessitating the implementation of the waiver are no longer affecting 340B covered entities. As of October 27, HRSA will be returning to enforcing the traditional 340B offsite, outpatient facility registration requirements.

HRSA Offering "Grace Period" Under Two Circumstances

HRSA is offering a "grace period" during which 340B covered entities that were utilizing the waiver up until October 27, under two specific circumstances can continue to use 340B drugs for patients at unregistered offsite facilities while they come into compliance with the offsite facility registration requirements. The two scenarios in which the grace period applies include:

1. 340B hospitals that are utilizing offsite, outpatient facilities that are not yet listed as reimbursable on the hospital's most recently filed Medicare Cost Report have 90 days from October 27 to submit information to allow the facilities to continue purchasing 340B drugs through the date they will be registered with OPAIS. Such hospitals must send the following information via email to 340Bcompliance@hrsa.gov before January 25, 2024:
 - a. The name of all unregistered offsite, outpatient facilities,
 - b. The date each site will be listed on the hospital's Medicare Cost Report (this must be the next filed Medicare Cost Report), and
 - c. The date the site will be registered in OPAIS (expected to be the next quarterly registration period following the site being listed on the Medicare Cost Report).

2. 340B hospitals that have offsite, outpatient facilities listed on their most recently filed Medicare Cost Report but have not yet registered the facilities in OPAIS must register the facilities in OPAIS during the next quarterly registration period, which will be from January 1-16, 2024.

After the grace period has ended, all offsite, outpatient facilities must be listed as reimbursable on the hospital's most recently filed Medicare Cost Report, have associated costs and charges on that report, and be registered in OPAIS to be eligible to purchase and/or use 340B drugs. Any 340B covered entity that does not come into compliance during the grace period, and any offsite facilities not meeting one of the two circumstances described above, will have to cease using 340B drugs at the unregistered offsite facility and could face audit and compliance action.

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