



ALERTS

HHS-HRSA Terminates 340B Drug Pricing Program Registration Waiver

November 14, 2023

Highlights

The HHS-HRSA issued a notice terminating its 340B Program registration waiver for hospitals' offsite, outpatient facilities

The agency is providing hospital entities time to comply with the registration requirements, provided certain notice requirements are met

Failure to comply with the notice and registration requirements or stop purchasing 340B Program drugs for use at these facilities could result in removal of the hospital from the program and/or refunds of discounts to drug manufacturers

A group of health systems from across the country is seeking to block the HHS-HRSA in court from reinstating the registration requirements

The Health Resources and Services Administration of the U.S. Department of Health and Human Services (HHS-HRSA) [issued a notice](#) to safety net hospitals on Oct. 27 that ends the 340B offsite, outpatient hospital facility registration waiver that went into effect during the COVID-19 pandemic.

RELATED PEOPLE



Heather F. Delgado

Partner
Chicago

P 312-338-5905
F 312-759-5646
heather.delgado@btlaw.com



Jason D. Schultz

Partner
South Bend

P 574-237-1210
F 574-237-1125
Jason.Schultz@btlaw.com



Mary Elizabeth "Lizzie" Ford

Associate
Indianapolis

P 317-231-7336
F 317-231-7433
MaryElizabeth.Ford@btlaw.com

RELATED PRACTICE AREAS

Compliance and Monitorships

RELATED INDUSTRIES

Healthcare
Hospitals and Healthcare Facilities
Hospitals and Other Healthcare Providers

During the pandemic, the HHS-HRSA waived requirements that a safety net hospital's offsite, outpatient hospital facilities 1) be listed as reimbursable on the hospital's Medicare Cost Report prior to participating in the 340B Program, and 2) be registered in 340B Office of Pharmacy Affairs Information System (OPAIS) before participating in the 340B Program.

The HHS-HRSA is now terminating the waiver.

However, the agency is granting safety net hospitals opportunities to comply with the registration requirements before compliance review actions are taken and provided the following compliance timelines:

- If the safety net hospital's offsite, outpatient facilities open and begin using 340B drugs on or after Oct. 27, 2023, they must follow the HHS-HRSA's offsite, outpatient facility registration requirements immediately
- If the safety net hospital's offsite, outpatient facilities are currently listed in the hospital's Medicare Cost Report with associated costs and charges, but are not yet registered in the OPAIS, the safety-net hospital [must register the facilities](#) during the next quarterly registration period, which is Jan. 1-16, 2024.
- If the safety net hospital's offsite, outpatient facilities opened and began using 340B drugs prior to Oct. 27, 2023, but are not listed on the hospital's most recent Medicare Cost Report, the hospital must:
 - Email the HHS-HRSA at 340Bcompliance@hrsa.gov within 90 days of the date of the notice (Oct. 27, 2023) and provide 1) the names of the facilities, 2) the date the facilities will be listed in the hospital's next Medicare Cost Report, and 3) the date the facilities will be registered on the OPAIS
 - Register the facilities on the OPAIS as soon as possible

Failure to meet these requirements will require safety net hospitals to stop purchasing 340B drugs for use at non-compliant offsite, outpatient facilities or face audit and/or compliance actions.

Because of the HHS-HRSA's required registration timelines and the consequences of failing to fulfill registration requirements, a group of health systems from across the country is seeking to block the HHS-HRSA in court from reinstating the registration requirements, alleging that the registration requirements will cause a delay of roughly eight to 23 months before new, outpatient offsite facilities owned and operated by safety net hospitals are eligible for discounts under the 340B Program.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Heather Delgado at 312-338-5905 or heather.delgado@btlaw.com, Jason Schultz at 574-237-1210 or jason.schultz@btlaw.com or Lizzie Ford at 317-231-7336 or maryelizabeth.ford@btlaw.com.

© 2023 Barnes & Thornburg LLP. All Rights Reserved. This page, and all information on it, may not be reproduced, in any form, without the express

written consent of Barnes & Thornburg LLP.

This Barnes & Thornburg LLP publication should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.