

STATE OF INDIANA

EXECUTIVE DEPARTMENT INDIANAPOLIS

EXECUTIVE ORDER 25-27

**FOR: INCREASING OPPORTUNITY FOR HOOSIERS AND BUSINESSES
BY ENSURING 340B COVERED ENTITIES MEET CRITERIA FOR
ELIGIBILITY**

TO ALL WHOM THESE PRESENTS MAY COME, GREETINGS.

WHEREAS, the 340B Drug Pricing Program was designed to stretch scarce federal resources and help vulnerable patients improve access to their medicines through manufacturer discounts to specific safety-net, non-profit hospitals and federally funded clinics;

WHEREAS, during the COVID-19 Public Health Emergency (“PHE”), the United States Department of Health and Human Services (“HHS”) allowed various flexibilities across many of HHS programs, including the 340B program;

WHEREAS, the United States Health Resources and Services Administration (“HRSA”) program integrity efforts conducted since the start of the COVID-19 PHE have shown that 340B eligibility criteria flexibilities have impacted HRSA’s ability to effectively oversee ongoing compliance in the 340B program;

WHEREAS, HRSA audits of hospital covered entities conducted, in fiscal year 2023, found that more than one-third (1/3) of those hospital covered entities were using 340B drugs in unregistered sites;

WHEREAS, in October 2023, HRSA determined that ending the 340B flexibilities was appropriate given that there were no longer exigent circumstances of a nationwide PHE that require allowing hospitals to expeditiously adjust their operations and locations for providing care off-site while maintaining immediate access to the 340B program resources; and

WHEREAS, the Indiana Department of Health (“IDOH”) regulates hospitals operating in the State of Indiana;

NOW, THEREFORE, I, MICHAEL K. BRAUN, by virtue of the authority vested in me as the Governor of the State of Indiana, do hereby order that:

1. The Secretary of Health and Family Services (“HFS”), in collaboration with the Indiana Department of Health (“IDOH”) shall conduct an investigation and prepare a report determining IDOH’s authority to issue administrative rules or otherwise enforce standards to ensure:
 - a. Hospitals participating in the 340B program, including off-site outpatient facilities, are meeting all eligibility requirements;
 - b. Unregistered sites are not listed on the Medicaid Exclusion File;
 - c. Duplicate discounts are not provided by the manufacturer to both a Medicaid rebate and a 340B discount on the same drug; and
 - d. 340B covered entities, and off-site, outpatient facilities utilizing the discounts are listed on the hospital’s most recently filed Medicaid Cost Report.
2. The review and report shall also evaluate IDOH’s authority to issue administrative rules or otherwise enforce standards to ensure hospitals that are 340B covered entities and the parent organization of an off-site, outpatient facility provide the following information to HRSA:

- a. The name of the off-site, outpatient facility;
 - b. The date the site will be listed on the hospital's Medicare Cost report with associated outpatient costs and charges; and
 - c. The date the covered entity will register the site with OPAIS.
3. If the Secretary of HFS determines IDOH does not have statutory authority to issue administrative rules or otherwise enforce standards, the Secretary shall suggest statutory changes to grant IDOH the necessary authority.
 4. The review shall be completed by October 31, 2025, with a written report provided to the Governor and the Legislative Council by November 30, 2025.



IN TESTIMONY WHEREOF, I,
Michael K. Braun, have hereunto set
my hand and caused to be affixed the
Great Seal of the State of Indiana on
this 21st day of January, 2025.

Michael K. Braun
Michael K. Braun Governor of Indiana

ATTEST: *DIEGO MORALES*
Diego Morales
Secretary of State