

Insights

Indiana Unlikely to Deliver 340B a Reprieve from 340B Restrictions

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As the conflict between 340B over the scope of the 340B drug discount program enters its fourth year, Covered Entities are increasingly turning to state law for relief from restrictions on contract pharmacies because Congress and federal agencies have been unable to make meaningful progress. The state's role may be clarified this year when the Eighth Circuit Court of Appeals issues a decision on the legality of state laws requiring drug manufacturers to recognize contract pharmacies. Indiana, however, has not taken overt steps to relieve Covered Entities of the manufacturer restrictions placed on the program's scope, and recent legislative activity in the General Assembly suggests that little will change over the near future.

Indiana has taken a minimal role in its oversight of the 340B program. Most notably, Indiana law (**IC 27-1-24.5-19.5**) generally prohibits Medicaid managed care entities ("MCE") and pharmacy benefit managers from discriminating against 340B Covered Entities by imposing restrictions on such entities that are not similarly imposed on non-340B pharmacies. This law, which has been in place for several years, has not been interpreted to prohibit the manufacturer restrictions on contract pharmacies that are crippling covered entities. Indiana law also does not expressly prohibit the drug manufacturer restriction on 340B contract pharmacies as has been done in other states. The United States Congress introduced a similar bill in April 2023 (**Protect 340B Act of 2023**), but it has failed to gain any traction since its introduction.

The Indiana Office of Medicaid Policy and Planning ("OMPP") has expressly prohibited Medicaid fee-for-service payment for outpatient drugs distributed by contract pharmacies; however, the OMPP has not implemented policies and procedures for Medicaid MCEs to follow with respect to 340B claims. OMPP's approach to managed care billing has prompted Covered Entities to avoid taking advantage of 340B discounts for Medicaid MCE beneficiaries. On December 14, 2023, OMPP published a Bulletin (**BT2023175**) regarding the billing of 340B claims in the Medicaid managed care context. This Bulletin directed Covered Entities to file a form if they want to submit claims for 340B drugs to Medicaid MCEs. However, the Bulletin also requires Covered Entities to identify 340B claims with modifiers, and for many, the burden of identifying 340B claims in this manner is not worth the benefit.

The Indiana General Assembly is not expected to deliver any significant legislation during the 2024 General Assembly to benefit Covered Entities. In fact, the General Assembly appeared ready to further restrict the scope of the 340B program. Most recently, the General Assembly considered a law that would have required Covered Entities to submit reports on the cost of prescription drugs under the 340B program and the manner in which 340B savings were utilized by the Covered Entities. However, that bill was recently pulled from the calendar and is not likely to advance in any other form. As parties eagerly await the results of the Eighth Circuit Court of Appeals decision, Indiana may again take up the issue in 2025. Whether Indiana expands or further restricts the program based on this decision has yet to be seen.

340B Covered Entities are not without options to address 340B restrictions. If your organization is interested exploring its options with respect to the 340B program, or if you have needs related to your organization's participation in this program, please contact **Brandon W. Shirley** for more information.

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