

Community Health Advocates Appalled J&J's New 340B Claims Data Policy Includes CHCs

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Johnson & Johnson's new requirement for 340B-covered entities to submit extensive claims data every time a product from the company is dispensed at discounted pricing launches Sept. 15 and will apply to community health centers as well as hospitals.

Community health advocates say CHCs now face severe consequences despite not being the driving source of issues with duplicate discounts in the 340B program.

Advocates for Community Health (ACH) has yet to hear that other companies are considering applying their claims data policies to CHCs, but ACH CEO Amanda Pears Kelly worries that unless the government or lawmakers step in, more drug makers are likely to launch new policies or extend their existing ones to include CHCs.

"I think where one goes, many tend to follow, and it's not the kind of trailblazing we want to see," Kelly told *Inside Health Policy*.

Adhering to J&J new claims data policy is likely to have a damaging effect on the allocation of funding, the workforce and other limited resources CHCs depend on to operate in low-income, rural or otherwise underserved communities, Kelly said. The worst-case scenario after a CHC potentially discontinues a program, pulls back services or makes staff reductions due to an inability to keep up with the new policy, would be for the health center to close entirely.

"For years, pharmaceutical manufacturers have been chipping away at the 340B program through burdensome restrictions and requirements. Some companies had recognized that community health centers are not the problem with the program, so they excluded them from these damaging changes. Until now, this had included Johnson & Johnson, a longtime supporter of community health," Kelly said in a statement following the J&J's notice of the new policy to covered entities earlier this month.

Kelly added that between the revised 340B rebate pilot program announced by the Health Resources and Services Administration (HRSA) in July, changes in the pharmaceutical market and increasing efforts by

drug companies to rein in issues with the 340B program on their own, the nation's primary care safety net is reaching a "dangerous tipping point" and without 340B savings to offset other cuts across the healthcare system, many health centers will shut down and leave vulnerable patient populations without care across our country.

As of 2023, CHCs account for 5.4% of all drug purchases in the 340B program and ACH says that alone shows CHCs cannot be the driving force behind the volume of discounts being duplicated in the program. The group also says there are pre-existing accountability and transparency measures in place for health centers that make it nearly impossible for duplicates to occur.

There are also systems in place at the state level to prevent duplicate discounts that ACH would like to see improved while stakeholders wait on Congress to pass legislation that addresses the issue. Hospitals, CHCs and other covered entities have expressed support for Congress to establish a claims data clearinghouse that's run by a neutral third-party vendor.

The new J&J claims data submission requirement takes the place of the company's former policy that was first launched in 2023. It applies to all covered entity types regardless of drug dispensing or administration location, inventory management system or payer coverage.

In a Sept. 4 notice, J&J says the new policy was designed to create "no more than a minimal administrative burden on covered entities," stating that the limited, commercially standard claims data requested under this policy must already be maintained in covered entities' auditable records to demonstrate compliance with 340B program requirements -- data that is often already being collected, maintained, and reported through covered entities' existing third-party payer and vendor relationships.

The main objective of the policy is to crack down on duplicate discounts in Medicaid, duplicate discounts related to the "maximum fair price" of drugs selected to go through Medicare drug price negotiations, and discount diversion.

J&J joins the growing group of drug companies that have launched similar claims data submission policies in the last year. Until now, however, companies have not demanded CHCs to meet their policy requirements and have focused on 340B hospitals.

Multiple disproportionate share hospitals have sued Lilly this summer over its claims data policy after the company terminated their access to 340B discounts, hindering their ability to get affordable medications to the patients they serve. Hospitals had warned HRSA to address the issue before companies began to

terminate 340B discounts, and they now worry other companies are likely to follow suit unless the agency or Congress intervenes. -- *Gabrielle Wanneh* (gwanneh@iwpnews.com)