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340B Drug Diversion: Sanofi Suit Seeks Evidence In Pharmacy Contracts With Hospitals

by Cathy Kelly

Drug maker pursuing novel approach to establishing that contract pharmacies are improperly taking 'title' to 340B-discounted drugs, leading to diversion, which is prohibited by law.

Sanofi US is asking a US federal court to order the Health Resources and Services Administration to hand over contracts between hospitals participating in the 340B drug discount program and their outside pharmacies because it believes the contracts will show the arrangements do not comply with the law.

The company's *complaint* was filed in US District Court for the District of Columbia. By seeking transparency, it takes a novel approach to manufacturers' ongoing efforts to rein in the explosive growth in the 340B program, which has been driven by the widespread participation of contract pharmacies. (Also see "*340B Program Spending Continues To Swell In 2022, Topping $53bn*" - Pink Sheet, 28 Sep, 2023.)

At issue is whether hospitals or other covered entities retain "title" to the 340B-discounted drugs that are dispensed by contract pharmacies, a standard meant to

Key Takeaways

- Sanofi is seeking records held by HRSA to show that dispensing of 340B-discounted drugs through contract pharmacies is the cause of widespread diversion of the products to individuals who are not patients of the prescribing entity.
- HRSA has resisted the company's Freedom of Information request for contracts between hospitals and pharmacies, citing

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deter improper diversion of the drugs to individuals who are not patients of the covered entity.

Sanofi is concerned that covered entities are not retaining title, that diversion is widespread, and that HRSA is not policing that aspect of the program. Pharmacies use a "replenishment" inventory and dispensing model in which discounted and undiscounted drugs are intermingled, the complaint says.

confidentiality.

- It is unclear whether the suit will prevail because the court often sides with agencies in such disputes, according to an expert. But if nothing else the complaint succeeds in portraying HRSA as 'hiding behind' FOIA to 'gloss over' its lack of enforcement.

"Only after dispensing do these pharmacies attempt to discern whether individual customers were patients of covered entities – in other words, whether individual prescriptions were eligible for the discount," Sanofi said. As a result, "pharmacies often overstate the number of discount-eligible prescriptions."

The firm noted a recent appeals court decision in a 340B contract pharmacy dispute brought by *Novartis AG* and *United Therapeutics Corporation* against HRSA reaffirmed the necessity of retaining title, which is also expressed in guidance issued by HRSA. (Also see "*340B Contract Pharmacy Confusion: Another US Court Sides With Pharma, States Enact Roadblocks*" - Pink Sheet, 23 May, 2024.)

Unsuccessful FOIA Request

Sanofi filed a Freedom of Information Act request with HRSA in 2021 requesting the contracts, with appropriate redactions. The agency refused because it said the contracts include confidentiality clauses that render them exempt from FOIA obligations, according to the complaint.

> ***The lawsuit could be "a watershed event in drug makers' attempts to undermine the replenishment model and to build the case that HRSA is not a credible source of oversight." – Regulatory consultant Bill Sarraille***

However, Sanofi "is not seeking the financial terms in the pharmacy contracts or, for that matter,

even the identities of the contracting parties," the complaint says. "It seeks only the portions of the contracts that address compliance with applicable law – including who retains title to 340B-priced drugs."

The company brought an administrative appeal of the agency's decision to withhold the contracts but HRSA has not yet responded to the appeal, which prompted the lawsuit. "Sanofi has a statutory right to the withheld records and is now entitled to judicial action enjoining HRSA from continuing to improperly withhold records and ordering the production of records improperly withheld," the complaint argues.

"For years HRSA has been withholding contracts between 340B covered entities and outside pharmacies that implicate covered entities' compliance with the 340B statute and [Department of Health and Human Services] guidance," Sanofi said.

"On information and belief, nothing in those contracts provides for covered entities to retain title to 340B-priced drugs shipped to contract pharmacies, contrary to the statute," the company maintained.

"With this information, Sanofi would be able to expose HRSA's failure to enforce the 340B statute's prohibition on diversion, more effectively defend itself against covered entities claims alleging violations of the 340B statute, and consider bringing diversion claims against covered entities," the company said.

HRSA Not Enforcing Guidance, Sanofi Suspects

Furthermore, "on information and belief, HRSA has never sanctioned a covered entity for not maintaining title for 340B drugs shipped to contract pharmacies" and "HRSA is not currently investigating any covered entities for not maintaining title," the complaint asserts.

The recently finalized 340B administrative dispute resolution process, which became effective on 19 June, is expected to be an active forum for disputes between manufacturers and covered entities over the use of contract pharmacies. (Also see "*Pharma Can Pursue Claims Against Providers For 340B Duplicate Discounts In Medicaid Managed Care, HRSA Says*" - Pink Sheet, 24 Apr, 2024.)

The lawsuit could be "a watershed event in drug makers' attempts to undermine the replenishment model and to build the case that HRSA is not a credible source of oversight," life sciences regulatory consultant Bill Sarraille said in a recent post on Linkedin.

He pointed out if the court decides in favor of Sanofi, the contract information could be used to counter state laws blocking manufacturer attempts to restrict discounts to contract pharmacies, including a groundbreaking law in Arkansas. "The biggest threat right now to manufacturers are

the state [contract pharmacy] laws and the 8th Circuit's decision that at least the Arkansas law was not 'in conflict' with federal law," Sarraille observed.

The 8th Circuit reached that conclusion by presuming that all covered entities "retained title" of contract pharmacies' drugs and that all contract pharmacies acted as the "agents" of covered entities, he said. But "this FOIA request could cripple that premise, potentially leading other courts of appeals hearing other challenges to other state laws [to] refuse to follow the 8th."

Court 'Overwhelmed' With FOIA Cases

He acknowledged, however, that it is hard to predict the outcome of Sanofi's complaint. "The DC federal court, which hears these FOIA cases, is overwhelmed by them, and, generally, fairly sympathetic to the agencies," Sarraille pointed out. "Still, most of the judges there try to find some 'middle ground' approach that allows for the release of some materials, which is the tact that [Sanofi] is taking."

For example, he noted, "on the question of 'agency,' that issue is usually addressed in an entirely 'boilerplate' clause at the end of a contract. It's one of the most common contract provisions there is. I could see a court saying that there's nothing [confidential and proprietary] about such 'boilerplate.' If so, that alone would be a huge win."

If nothing else, Sarraille pointed out, "the complaint itself effectively depicts HRSA as hiding behind FOIA to gloss over that it is not enforcing its own guidance – a terrible look for the agency."