



AMERICA'S ESSENTIAL HOSPITALS

Dec. 2, 2024

Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services Parklawn Building
Room 13N188
Rockville, MD 20857

Ref: Sanofi's Illegal Use of Rebates to Avoid Compliance with 340B Program Requirements

Dear Administrator Johnson:

On behalf of our more than 300 member hospitals, most of which rely on the 340B Drug Pricing Program, America's Essential Hospitals is deeply concerned about pharmaceutical manufacturer Sanofi's Nov. 22 notice to 340B covered entities about its planned implementation of unauthorized rebates.¹ We urge the Health Resources and Services Administration (HRSA) to take immediate action to stop this and other calculated moves by drug companies to put roadblocks between hospitals and the statutorily required 340B discounts that support lifesaving care.

America's Essential Hospitals is the leading association and champion for hospitals dedicated to equitable, high-quality care for all, including those who face social and financial barriers to care. Since 1981, America's Essential Hospitals has advanced policies and programs that promote health, health care access, and equity. We support our members with advocacy, policy development, research, education, and leadership development.

Our members provide a disproportionate share of the nation's uncompensated care (UC), and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating with an average loss of -8.6 percent, compared with -1.4 percent at other U.S. hospitals.²

Essential Hospitals and Their Patients Rely on the 340B Program

The 340B program is a key component of the patchwork federal support essential hospitals rely on to meet their safety net mission. Congress established the 340B program to enable essential

¹ Sanofi policy update related to 340B integrity initiative. Published by STAT.

https://www.statnews.com/wp-content/uploads/2024/11/Sanofi_Credit_Model_Policy_Letter_11.22.2024_.pdf. Accessed Nov. 27, 2024.

² Taylor, J, Ramiah, K, et al., *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. October 2023. <https://essentialdata.info>. Accessed Dec. 2, 2024.

hospitals and other covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³ With their 340B savings, essential hospitals can target resources to services and programs that meet their community’s unique challenges at nearly no cost to taxpayers.

Sanofi is the Latest Manufacturer Reneging on Responsibilities under the 340B Program

Under the 340B program, manufacturers, such as Sanofi, agree to offer discounts to safety net providers according to statutorily prescribed methods in exchange for the benefit of having their drugs covered by Medicaid and Medicare. Manufacturers must meet all statutorily required responsibilities; they cannot pick and choose which rules to follow.

Sanofi’s proposed rebate model is the latest attempt by manufacturers to subvert HRSA’s authority and the rules of the 340B program. In August, Johnson and Johnson (J&J) proposed a similar rebate model, and we appreciate that HRSA took strong action to remind J&J of its statutory responsibilities. Also, a bipartisan coalition of 189 members of Congress signed a letter supporting HRSA’s actions and condemning J&J’s efforts to “upend more than 30 years of federal law.”⁴

Sanofi’s proposed rebate model flouts the law even more than J&J’s proposal because Sanofi did not request approval, as statute requires. Moreover, Sanofi’s proposal attempts to modify existing federal requirements for defining 340B patients and undermines the administrative dispute resolution process manufacturers must follow if they have concerns about whether purchases by covered entities are eligible for 340B discounts.

Using Rebates to Deny 340B Pricing Harms Patients and Essential Hospitals

Sanofi’s proposed rebate model is yet another attempt to line drug company pockets at the expense of patient care. Compared with J&J’s proposal, Sanofi is proposing to limit access to 340B benefits for more drugs and more types of covered entities. In addition to harming the patients of essential hospitals, Sanofi’s proposal also applies to patients at Critical Access Hospitals, Disproportionate Share Hospitals, Rural Referral Centers, Sole Community Hospitals, and Consolidated Health Centers.

Under the proposal, 340B-eligible hospitals would be required to purchase drugs at higher list prices and then wait for the manufacturer to distribute a rebate to receive the statutorily required 340B price. Such a delay imposes a meaningful economic hardship on essential hospitals, many of which have limited cash on hand.

We are concerned Sanofi’s proposed rebate approach also creates the opportunity to deny post-sale 340B rebates based on the manufacturer’s, and not HRSA’s, determination regarding compliance. Reducing 340B discounts for which essential hospitals are eligible will only add to the already heavy financial pressures they face as safety net providers and challenge their ability to meet their mission of care for low-income and other disadvantaged patients and communities.

³ H.R. REP. 102-384(II), p. 12.

⁴ Office of Rep. Abigail Spanberger (D-Va.). Spanberger Leads 189-Member Bipartisan Effort Urging Administration to Protect Healthcare Providers from Johnson & Johnson’s Attempt to Hike Prescription Drug Prices. 2024. <https://spanberger.house.gov/posts/spanberger-leads-188-member-bipartisan-effort-urging-administration-to-protect-healthcare-providers-from-johnson-johnsons-attempt-to-hike-prescription-drug-prices>. Accessed Nov. 27, 2024.

The net result of Sanofi's proposed policy is that essential hospitals would have to devote additional administrative resources to develop purchasing arrangements for covered outpatient drugs at non-340B prices, make appropriate rebate requests, and track and reconcile rebate payments with the 340B price for each purchased drug. These additional administrative costs do nothing to improve patient care and are designed to place an undue burden on providers that can't afford it. **It appears Sanofi designed this policy with the hope some hospitals won't be able to overcome the red tape it has put in the way of discounts it owes to hospitals. This is nothing more than a ploy by Sanofi to charge more than it should and pad its bottom line.**

HRSA Should Take Immediate Action to Protect Patients and Essential Hospitals

We appreciate HRSA's previous actions to protect the 340B program from illegal rebate schemes. HRSA should continue using all available tools in the statute to protect patients from manufacturer attempts to withhold upfront 340B discounts from safety net providers.

We appreciate your expeditious consideration of these comments on this issue, which is of utmost importance to our members. If you have questions, please contact Director of Policy Robert Nelb, at 202-585-0127 or rnelb@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO