August 13, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Dept. of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

I write on behalf of Sanofi to address the concerns raised by the American Hospital Association (AHA) regarding Sanofi's new 340B Program integrity initiative. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to strengthening its mission. Under our initiative, 340B covered entities will upload de-identified claims data to a secure system so that Sanofi can identify and prevent duplicate discounts in compliance with applicable law. This initiative will allow us to continue meeting our commitment to the 340B program while improving program integrity.

I. Duplicate Discounts Pose a Widespread Compliance Threat

The 340B statute prohibits duplicate discounts, meaning that manufacturers cannot be compelled to double pay a Medicaid rebate and 340B discount on the same drug.[1] Moreover, duplicate discounting in Medicare Part D and commercial insurance is counterproductive for program sustainability.

Notwithstanding this prohibition, duplicate discounts pose a widespread threat. In 2018 and 2019, HRSA identified Medicaid fee-for-service duplicate discounting in over 30% of its covered entity audits. Duplicate discounts likely are even more prevalent in Medicaid managed care because HRSA does not audit covered entities regarding their ability to prevent Medicaid managed care duplicate discounts and because HRSA has not created any mechanism to prevent them.[2] The growth of Medicaid managed care -- 35 states reported providing Medicaid

[1] 42 U.S.C. § 256b(a)(5)(A)(i) ("A covered entity shall not request payment under [Medicaid] . . . with respect to a drug that is subject to an agreement under this section [a 340B-priced drug] if the drug is subject to the payment of a [Medicaid] rebate to the State . . . .").

[2] GAO, 340B Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 at 39, 45 (June 2018), https://www.gao.gov/assets/700/692697.pdf.

prescription drug benefits through Medicaid managed care in a 2018 survey[3] -- exacerbates this problem. Moreover, 340B "contract pharmacy" arrangements, i.e., arrangements where a drug is shipped to a third party pharmacy and billed at the 340B ceiling price to a 340B covered entity, "create complications in preventing duplicate discounts" according to HHS OIG.[4] The GAO has reported "weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies,"[5] and CMS has recognized that "some states face challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies."[6] Contract pharmacies likewise contribute to duplicate discounting outside the Medicaid context as well. Accordingly, the rapid growth in contract pharmacy arrangements compounds the duplicate discounting problem. Between 2010 and 2019, the number of 340B contract pharmacies has grown 1,700 percent to about 23,000 in 2019.[7]

II. Sanofi's Compliance Initiative Will Not Burden Covered Entities and Will Comply with Applicable Law

To address these concerns, Sanofi is launching a new program integrity effort. Under this initiative, Covered Entities will register and submit data every two weeks regarding dispenses of certain Sanofi drug products through contract pharmacy arrangements, using a secure online portal (340BESP.com). The uploaded data will be de-identified (HIPAA-compliant) and will consist of data that contract pharmacies already collect and submit to third party payors when seeking insurance reimbursement. (Likewise, Sanofi collects similar claims-level data when validating payor price concessions.) Sanofi will collect 340B claims data only for contract pharmacy dispenses, and Sanofi will omit physician-administered drugs from this initiative. Data uploaded by 340B covered entities will be used by Sanofi to identify and resolve duplicate Medicaid and commercial rebates, by comparing these data against Medicaid and commercial payor data. Prior to October 1, 2020, covered entities will need to register with 340B ESP™ and submit claims level-detail on all 340B contract pharmacy utilization in order to be eligible for 340B Bill To / Ship To replenishment orders for Sanofi products dispensed

[3] Kaiser Family Foundation, Medicaid's Prescription Drug Benefit: Key Facts (May 1, 2019), https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/.

[4] Memorandum Report: Contract Pharmacy Arrangements in the

340B Program, OEI-05-13-00431 at 2 (February 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[5] 340B Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 35.

[6] CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid at 3 (January 8, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

[7] GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 at 2 (Jan. 2020), https://www.gao.gov/assets/710/703966.pdf.

through a contract pharmacy. However, all 340B covered entities will remain able to purchase Sanofi products at the 340B price for shipment to their own facilities.

Thus, although AHA mischaracterizes our initiative as intended to limit distribution of 340B-priced drugs, instead our program solely seeks the information needed to protect our company from duplicate discounts. Further, Sanofi plans to inform participating covered entities of the pharmacies that are dispensing 340B purchased drugs to Medicaid patients. This information can be used by covered entities to further strengthen their audit processes and compliance controls.

Our initiative complies with the 340B statute and Pharmaceutical Pricing Agreement (PPA), which require that Sanofi "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[8] Simply put, Sanofi will continue to offer all of its drugs to all 340B covered entities. At most, if a covered entity refuses to provide the claims data described above, we will restrict the entity's use of contract pharmacy arrangements, but these entities will remain eligible to purchase at 340B prices for shipment to their own facilities.

AHA's letter argues that Sanofi is out-of-compliance with HRSA's guidance regarding contract pharmacy arrangements. Specifically, AHA references a passage of this guidance that provides that "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."[9] Contrary to what AHA asserts, Sanofi will continue to sell its drugs at the 340B price. Even covered entities that do not provide the required data will remain able to purchase 340B drugs for shipment to the covered entity itself. The 340B statute supports this approach. Because the statute includes detailed eligibility requirements for 340B covered entities and a prohibition on duplicate discounts, the 340B statute supports manufacturers' right to require covered entities to provide the data necessary to ensure compliance with these limitations, especially because duplicate discounts otherwise will continue unchecked. Moreover, the 340B statute does not address contract pharmacy arrangements, nor does it grant HRSA authority to issue binding rules in this area.[10] These considerations give manufacturers discretion to adopt their own reasonable approaches.

---

[8] 42 U.S.C. § 256b(a)(1); Pharmaceutical Pricing Agreement Addendum, https://www.hrsa.gov/sites/default/files/opa/manufacturers/ppa_addendum.pdf.

[9] 75 Fed. Reg. 10272, 10278 (March 5, 2010).

[10] PhRMA v. United States Dep't of Health & Human Servs., 43 F. Supp. 3d 28, 42 (D.D.C. 2014) (explaining that HHS has only "specifically delineated" rulemaking authorities, none of which apply here).

We agree with AHA that HRSA guidance provides that covered entities remain responsible for ensuring the compliance of their contract pharmacies. We read this guidance, however, as expressing HRSA's expectation that covered entities will not offload this responsibility to their contract pharmacies. It does not, nor could it, bar manufacturers from reasonably collecting information to protect themselves from duplicate discounts that, as noted, remain a significant problem under the 340B Program.

Finally, AHA's letter expresses concern that our compliance initiative will launch during the COVID-19 pandemic. Please know that Sanofi understands well the challenges posed by this pandemic as we carry out multiple research and development initiatives to fight the disease, and as we engage in the daily business of making and delivering medicines for patients. We want to assure HHS that we would not implement our initiative if we believed it would hamper the fight against COVID-19. However, because our initiative will create only a minor data sharing obligation for 340B covered entities and strengthen the 340B Program, this initiative will not impair our common fight against the pandemic.

Thank you for your leadership in national public health during this critical time. Please contact me at 202-585-3085 with any questions you may have. At your request, we would be pleased to discuss this issue with you further.

Sincerely,

Adam Gluck
Head, U.S. and Sanofi Genzyme Corporate Affairs
Sanofi U.S.

CC: Deputy Director Herzog, Office of Pharmacy Affairs, HRSA