



Dear 340B Covered Entity,

As an entity who is new to the 340B program or who did not previously have contract pharmacy arrangements, I am writing to inform you that Sanofi has a 340B program integrity initiative to address duplicate discounts. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. However, we are concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program.

To resolve these issues, Sanofi requires 340B covered entities to register at www.340BESP.com and submit claims data for 340B prescriptions of Sanofi products filled through their contract pharmacies. Sanofi uses this data to match against rebate claims it receives to ensure it is not paying ineligible rebates or discounts.

Our integrity initiative includes only the following categories of covered entities that have historically accounted for a significant share of contract pharmacy dispensing, and therefore duplicate discount risk, for Sanofi's products:

- Consolidated Health Center Programs (CH)
- Critical Access Hospitals (CAH)
- Disproportionate Share Hospitals (DSH)
- Rural Referral Centers (RRC)
- Sole Community Hospitals (SCH)

Sanofi is requiring entities in the above categories who are new to this policy to register at www.340BESP.com and to complete their claims data submission prior to the first day of next quarter. Other covered entity types need not register or provide the data we request.

340B covered entities that fall within one of the five (5) categories listed above, but do not have an in-house pharmacy location registered on the OPAIS covered entity database as a shipping address or child site, may designate a single contract pharmacy at www.340BESP.com for this purpose. Sanofi will provide 340B pricing at that designated contract pharmacy in this circumstance, irrespective of whether the covered entity provides the data Sanofi is requesting.

Sanofi has maintained a strong commitment to the 340B program since its inception. We also recognize that for the 340B program to continue in its mission, serious program integrity and transparency challenges must be addressed. That is why we adopted our integrity initiative and we look forward to working with 340B covered entities to further strengthen the 340B program.

Government reports and our own experience show that our duplicate discount concerns are well-founded. Despite the legal ban on forcing pharmaceutical manufacturers to double pay Medicaid

rebates and 340B discounts on the same drug,¹ duplicate discounting on Medicaid claims has continued to occur. Over 30% of Health Resources and Services Administration (HRSA) audits of covered entities in 2018 and 2019 found Medicaid duplicate discounting, and government reports have repeatedly documented this ongoing concern.² Likewise, in a limited scope test that analyzed three years of Medicaid rebates from five states for three Sanofi products, we identified over \$16M in 340B duplicate discounts. Further, government reports have found that contract pharmacies have unfortunately hindered efforts to prevent duplicate discounts.³ Between 2010 and 2019, the number of 340B contract pharmacies has grown 1,700 percent to about 23,000.⁴ This rapid growth in contract pharmacy arrangements has only reinforced the need for our initiative.

Sanofi's integrity initiative complies with the 340B statute and our agreement with the Department of Health and Human Services, 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."⁵ We continue to offer all of our drugs to all 340B covered entities. At most, if a covered entity included in our initiative refuses to provide the requested data, we will restrict the entity's use of contract pharmacy arrangements, but these entities will remain eligible to ship 340B-priced drugs to their own facilities and, if they lack an in-house pharmacy, to a single-designated contract pharmacy (as noted above). Additionally, Sanofi will offer 340B pricing on a non-discriminatory basis through an unlimited number of contract pharmacy arrangements if a covered entity provides the modest data Sanofi requests, which are identical to data already submitted by contract pharmacies to other third parties and by insurers to manufacturers for rebate purposes, to prevent duplicate discounts.

Please understand that we have designed our initiative so as not to burden covered entities. Our data submission portal is user-friendly, and as noted above, the required information is no different than what manufacturers require of insurance companies when paying rebates. The required information is the NCPDP standard for prescription claims. These data are generated by the pharmacy and submitted to insurance companies and, in the case of 340B contract pharmacies, to the third-party administrators that identify 340B eligible claims. Moreover, we do not request data on physician-administered drugs or drugs dispensed by covered entities' own facilities. Our approach also avoids burdensome and ineffective manual data exchanges.

Even more importantly, patients will not be affected by our initiative. Government Accountability Office reports have found that contract pharmacies often do not give discounts to patients and that in-house pharmacies (to which we in all circumstances will continue to sell 340B drugs)

¹ 42 U.S.C. § 256b(a)(5)(A)(i).

² See, e.g., GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (June 2018), <https://www.gao.gov/assets/700/692697.pdf> (hereinafter, "Oversight of Contract Pharmacies Needs Improvement"); GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 (January 2020), <https://www.gao.gov/assets/710/703966.pdf> (hereinafter, "Oversight of MDRP Intersection Needs Improvement"); OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (February 4, 2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

³ *Id.*

⁴ GAO, Oversight of MDRP Intersection Needs Improvement, at 2.

⁵ 42 U.S.C. § 256b(a)(1).

are significantly more likely to pass along drug cost savings to patients.⁶ Given these findings and the ubiquity of duplicate discounts, we are hopeful that all stakeholders invested in the success and purpose of the 340B Program will work together on what we believe is a shared goal of improving 340B Program integrity. Eliminating duplicate discounts ultimately will free resources to be focused where they belong: on reducing patients' out-of-pocket costs.

We appreciate your cooperation in this initiative and value our relationship with you very much.

Sincerely,

Gerry Gleeson
Vice President and Head, U.S. Market Access Shared Services
Sanofi U.S.

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. You will receive a two-factor verification code that is sent directly to your cell phone. As part of your initial registration, you will also receive a one-time authentication code via email. You can enter the code provided in the email or enter the unique authentication code provided in this email.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data once every two weeks. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q. My covered entity excludes Medicaid patients from our contract pharmacy utilization and/or my state has a Medicaid carve out that excludes these patients from 340B. Do I still need to submit data to Sanofi through 340B ESP?

A: Yes. This initiative is to address duplicate Medicaid rebates as well as ineligible rebates paid to commercial and Medicare Part D payers. Sanofi utilizes the claims data provided by 340B covered entities to address these duplicate discounts. All forms of duplicate discounts impair the sustainability of the 340B Program, so all must be addressed.

⁶ GAO, Oversight of Contract Pharmacies Needs Improvement, at 30 and n. 46.

The 340B statute permits this approach because Sanofi will continue to offer 340B pricing to covered entities outside contract pharmacy arrangements, regardless of whether data is provided.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: The required claims data elements include prescription number, prescribed date and date of service (fill date). Aren't those data elements considered PHI?

The prescription number, prescribed date and date of service (or fill date) are de-identified through a HIPAA compliant hashing process known as SHA-3 hashing. An additional layer of security called a "salt" is applied prior to any data being uploaded to 340B ESP™. This process was granted an Expert Determination by Dr. Brad Malin, a professor at Vanderbilt University Medical Center, indicating that it meets the definition of a De-Identified Data Set under HIPAA and does not contain PHI. Additional information on this expert determination may be requested by contacting Second Sight Solutions at 888-398-5520.

Q. My covered entity requires that we enter into a Business Associate Agreement (BAA) with Second Sight Solutions prior to submitting data. How do I initiate that process?

Second Sight Solutions does make a standard BAA available to 340B covered entities that require a BAA to be in place prior to submitting data. To request a BAA, you can email support@340besp.com or complete the BAA request form at www.340Besp.com/BAA.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What types of covered entities are included in Sanofi's integrity initiative?

A: Our integrity initiative includes only the following categories of covered entities that have historically accounted for a significant share of contract pharmacy dispensing, and therefore duplicate discount risk, for Sanofi's products:

- Consolidated Health Center Programs (CH)
- Critical Access Hospitals (CAH)
- Disproportionate Share Hospitals (DSH)
- Rural Referral Centers (RRC)
- Sole Community Hospitals (SCH)

Q: How do I know which NDCs to submit into the 340B ESP™ platform?

A: At a minimum, covered entities included in our compliance initiative must upload data for all Sanofi NDCs that are not physician-administered drugs. Sanofi NDCs have the following NDC "labeler code" values at the beginning of their NDC numbers: 00024, 00039, 00068, 00075, 00088, 00310, 00597, 00955, 58468 and 72733. Alternatively, a covered entity could upload a broader set of data, and the system will share with Sanofi only data on Sanofi's NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: In general, 340B covered entities included in our compliance initiative that elect not to provide 340B claims data cannot place 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. However, any 340B covered entity included in our compliance initiative that does not have an in-house pharmacy location registered on the covered entity database as a shipping address or child site of the covered entity

may designate a single contract pharmacy. A qualifying covered entity may choose a single contract pharmacy for the covered entity and its child sites and Sanofi will provide 340B pricing in this circumstance, irrespective of whether the covered entity provides the data Sanofi requests. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site, regardless of whether data is provided.

Q: How do I designate a single contract pharmacy?

A: To designate a contract pharmacy, a covered entity must first register at <https://www.340besp.com/>. After registering and logging in to its account, the covered entity may designate its single contract pharmacy in the Entity Profile tab. This designation will be made for the parent 340B ID and will apply to any child sites. Please note that a contract pharmacy must have an assigned HIN for the wholesaler to process 340B transactions for Sanofi drug products. Covered entities that designate a contract pharmacy without a HIN will be notified of this requirement and provided additional information on how to assign a HIN for their contract pharmacy.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts. We disagree with the HHS Office of General Counsel's advisory opinion on contract pharmacy arrangements.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads once every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: How many days from the date of a drug's dispense does my covered entity have to submit the corresponding claims data?

A: Covered Entities participating in the 340B Integrity Initiative must submit claims data within 45 days of the eligible claim's date of service. If a claim is submitted more than 45 days after the claim's date of service, the applicable drug dispense will not be eligible for 340B pricing. Where a particular drug requires longer than 45 days to trigger a replenishment order, the covered entity will still receive 340B pricing on the applicable drug dispense if the corresponding claims data is submitted within 45 days of the eligible claim's date of service.

Q: My covered entity is unable to produce claims data without first having access to 340B pricing. What should I do?

A: If you are unable to produce claims submissions prior to gaining access to 340B pricing, registered users may attest their intent to submit claims and participate in the 340B program integrity initiative from your Entity Profile in the 340B ESP platform. After attesting your intent to submit 340B claims data via 340B ESP™, you will be given access to pricing at an unlimited number of contract pharmacy locations. Claims must be received by Sanofi via 340B ESP™ within 45 days of attesting in order to maintain access to 340B pricing at your contract pharmacy locations.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.