

Dear 340B Covered Entity:

We understand that you submitted a complaint notifying HRSA that you were unable to access 340B pricing. As we have indicated in prior communications, covered entities may access 340B pricing for Sanofi eligible products in one of three ways: (i) by having the product shipped to its in-house pharmacy; (ii) to the extent the covered entity lacks an in-house pharmacy, by designating one contract pharmacy; or (iii) by providing minimal, non-burdensome claims data for drugs provided to a contract pharmacy. Please see Next Steps and Frequently Asked Questions below for more information.

As we also indicated in prior correspondence, Sanofi's 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)

Other covered entity types need not register or provide the data we request.

If your entity does not fall within the above categories, you are exempt from Sanofi's integrity initiative, meaning that Sanofi does not place any conditions on your use of contract pharmacies.

We also want to remind you that Sanofi's 340B Program integrity initiative does not include physician administered drugs, meaning that Sanofi does not place any limitations on its provision of such drugs to contract pharmacies at 340B prices.

Finally, please note that vaccines are not and have never been subject to 340B discounts. Accordingly, Sanofi's integrity initiative has no effect on the prices at which covered entities may purchase vaccines.

If you have any further issues or questions, please contact us at [Sanofi340BOperations@Sanofi.com](mailto:Sanofi340BOperations@Sanofi.com).

We appreciate your cooperation in ensuring integrity in the 340B program through this initiative and value our relationship with you very much.

Sincerely,



Gerry Gleeson  
Head, US Market Access Shared Services

## 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](http://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.
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 on a bi-weekly basis. 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](http://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](mailto:Sanofi340BOperations@sanofi.com).

### **Q: How can I designate one contract pharmacy?**

**A:** Covered entities that lack an in-house pharmacy may designate one contract pharmacy to receive 340B priced drugs. In order 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: 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, Medicare Part D 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. 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 of Biomedical Informatics, Biostatistics, & Computer Science, 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](mailto:support@340besp.com) or complete the BAA request form at [www.340Besp.com/BAA](http://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. Additionally, vaccines are not and have never been subject to 340B discounts. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

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

**A:** At a minimum, covered entities 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, 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:** 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. In addition, those covered entities that lack an in-house pharmacy may also designate one contract pharmacy to receive 340B priced drugs. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through unlimited contract pharmacies.

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

**A:** The 340B ESP™ platform requires claims uploads 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: 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.