



January 1, 2024

Update to Gilead's Contract Pharmacy Integrity Initiative

Dear 340B Covered Entity,

We are writing to provide an important update regarding Gilead's Contract Pharmacy Integrity Initiative. As you may know, Gilead launched its Contract Pharmacy Integrity Initiative in March 2022 to help improve transparency and address certain program integrity concerns, namely duplicate discounting and diversion of 340B-priced product distributed through contract pharmacies.

Pursuant to the Contract Pharmacy Integrity Initiative, Gilead requests that 340B covered entities provide claims level data for 340B-priced purchases of Gilead's branded hepatitis C products (Branded HCV Products) dispensed through contract pharmacies. Covered entities that elect not to provide this data are not eligible to purchase Gilead's Branded HCV Products at the 340B price for shipment to their contract pharmacies, except that covered entities that do not have an in-house pharmacy have the option to designate a single contract pharmacy location to dispense Branded HCV Products purchased at the 340B price.

Gilead's Contract Pharmacy Integrity Initiative applies only to Gilead's Branded HCV Products, which include Eplclusa® (sofosbuvir / velpatasvir), Harvoni® (ledipasvir / sofosbuvir), Sovaldi® (sofosbuvir), and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir). Gilead's Contract Pharmacy Initiative does not apply to the authorized generics of Eplclusa® and Harvoni® offered by our subsidiary, Asegua Therapeutics, or to products in any of Gilead's other therapeutic areas.

Gilead Contract Pharmacy Integrity Initiative Update

Over time, Gilead has seen duplicate discounts and diversion of our medicines distributed through contract pharmacies occurring with increased frequency. The transparency achieved through our Contract Pharmacy Integrity Initiative has enabled Gilead to reduce 340B duplicate discounting and diversion of Gilead's Branded HCV products through contract pharmacies. To further increase transparency and help improve the integrity of the 340B program, we are modifying the Contract Pharmacy Integrity Initiative in the following ways:

Effective January 30, 2024, Gilead will require covered entities to submit claims level data for Gilead's Branded HCV Products purchased at the 340B price and dispensed through contract pharmacies that are wholly-owned by the covered entity. These wholly-owned contract pharmacies that are currently designated in the 340B ESP™ will continue to be exempt from Gilead's Contract Pharmacy Integrity Initiative until January 30, 2024.

Covered entities that do not have an in-house pharmacy will continue to be able to designate a single contract pharmacy location to dispense Gilead's Branded HCV Products purchased at the 340B price. In these instances, the covered entity may choose to designate a wholly-owned contract pharmacy to serve as its single contract pharmacy location.

Covered entities may voluntarily submit claims level data for Gilead's Branded HCV Products purchased at the 340B price and dispensed through their in-house pharmacies or designated single contract pharmacy locations (where applicable).

Next Steps

We request that covered entities that wish to dispense Gilead's Branded HCV Products purchased at the 340B price through wholly-owned contract pharmacies register an account with [340B ESP™](#), an industry standard no-cost web-based claims verification platform, and begin submitting the required 340B claims data. Below are the registration details.

Please contact support@340Besp.com or 1-888-398-5520 with any additional questions. We appreciate your continued collaboration as we work together to improve the integrity of the 340B program.

Best regards,



Jason Krings
Vice President, Managed Markets Strategy & Operations

U.S. Prescribing Information for Epclusa® (sofosbuvir / velpatasvir), Harvoni® (ledipasvir / sofosbuvir), Sovaldi® (sofosbuvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), including **BOXED WARNINGS**, are available at www.gilead.com.

How to Register for 340B ESP™

Covered entities should register with 340B ESP™, a web-based platform made available to covered entities at no cost, and begin submitting the required 340B claims level data.

To get started with the 340B ESP™ platform, follow these three steps:

1. Go to www.340besp.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes about 15 minutes.
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 level data twice monthly. Once your account is set up, the claims upload process takes about 5 minutes.

You can also visit <http://www.340besp.com/FAQs> to learn more about 340B ESP™. For further help with registration, account setup, and data submission process you can access a repository of webinars at <http://www.340besp.com/resources/webinars> or call Second Sight Solutions at 888-398-5520.

Frequently Asked Questions

Which products does Gilead's Contract Pharmacy Integrity Initiative apply to?

- As before, this integrity initiative applies only to Gilead's branded hepatitis C products, which are Epclusa® (sofosbuvir / velpatasvir), Harvoni® (ledipasvir / sofosbuvir), Sovaldi® (sofosbuvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir). Gilead's Contract Pharmacy Integrity Initiative does not apply to the authorized generics of Epclusa® and Harvoni® offered by our subsidiary, Asegua Therapeutics, or to products in any of Gilead's other therapeutic areas.

What are the updates to Gilead's Contract Pharmacy Integrity Initiative? When will they take effect?

- Effective January 30, 2024, Gilead will require covered entities to submit claims level data for Gilead's Branded HCV Products purchased at the 340B price and dispensed through contract pharmacies that are wholly-owned by the covered entity. These wholly-owned contract pharmacies will continue to be exempt from Gilead's Contract Pharmacy Integrity Initiative until January 30, 2024.
- Covered entities may voluntarily submit claims level data for Gilead's Branded HCV Products purchased at the 340B price and dispensed through their in-house pharmacies or designated single contract pharmacy locations (where applicable).
- Hospital and grantee covered entities that provide applicable claims level data will be able to continue to use the contract pharmacies of their choice to dispense Branded HCV Products purchased at the 340B price.
- Covered entities that decide not to participate in Gilead's Contract Pharmacy Integrity Initiative, and do not have an in-house pharmacy, will have the option to designate a single contract pharmacy location to dispense Branded HCV Products purchased at the 340B price. In these instances, the covered entity may choose to designate a wholly-owned contract pharmacy to serve as its single contract pharmacy location.

What claims level data is requested?

- There is no change to the required claims data elements, which are: Rx Number, Prescribed Date, Fill Date, NDC, Quantity, Pharmacy ID, Prescriber ID, Wholesaler Invoice Number, and 340B Covered Entity ID.

How does this update impact contract pharmacies that are wholly-owned by a covered entity?

- Effective January 30, 2024, Gilead will require covered entities to provide claims data for Gilead's Branded HCV Products purchased at the 340B price and dispensed through wholly-owned contract pharmacies.
 - Covered entities that elect to provide relevant claims data for their wholly-owned contract pharmacies will be able to continue using bill to / ship to arrangements for Gilead Branded HCV Products, for an unlimited number of wholly-owned contract pharmacies.
 - Covered entities that elect not to provide relevant claims data for their wholly-owned contract pharmacies will no longer be eligible for bill to / ship to orders of Gilead's Branded HCV Products purchased at the 340B price.
 - Covered entities that do not have an in-house pharmacy will continue to be able to designate a single contract pharmacy location to dispense Gilead's Branded HCV Products purchased at the 340B price. In these instances, the covered entity may

choose to designate a wholly-owned contract pharmacy to serve as its single contract pharmacy location.

How does this impact covered entities with an in-house pharmacy?

- In-house pharmacies are not subject to this update. Covered entities may voluntarily submit claims level data for Gilead’s Branded HCV Products dispensed by their in-house pharmacies.

Does Gilead have plans to expand this initiative to other therapeutic areas?

- Gilead’s Contract Pharmacy Integrity Initiative currently only applies to our Branded HCV Products. Since launching the Contract Pharmacy Integrity Initiative in May 2022, Gilead’s focus has been in preventing the duplication and diversion of our Branded HCV Products.

How does my covered entity change its contract pharmacy designation?

- Changes to the single contract pharmacy designation can only be made by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make/change their contract pharmacy designation.

How does my covered entity ensure that its wholly-owned contract pharmacy locations are eligible for bill to / ship to orders of Gilead’s Branded HCV Products on (and after) January 30, 2024?

- For a covered entity’s wholly-owned contract pharmacy location to be eligible for bill to / ship to orders of Gilead’s Branded HCV Products on (and after) January 30th, the entity must register its wholly-owned contract pharmacy to submit claims data by January 19, 2024. After January 19, 2024, please allow 10 business days for bill to / ship to eligibility for contract pharmacy locations to take effect.

My covered entity would like to submit 340B claims for its contract pharmacies and continue dispensing Gilead’s Branded HCV Products purchased at the 340B price through contract pharmacies.

What does our entity need to do to begin submitting claims data?

- 340B covered entities that wish to submit claims data under Gilead’s policy can do so by registering an account at www.340besp.com. Users that have registered an account with 340B ESP™ can register contract pharmacies and begin submitting claims data for Gilead products by navigating to the Claims Data Submission tab. Gilead will process replenishment orders at 340B pricing for shipment to a covered entity’s pharmacy location(s) for prescriptions dispensed to eligible 340B patients within forty-five (45) days of each data submission to 340B ESP™. As a reminder, claims level data must be submitted to 340B ESP™ within forty-five (45) days of the dispense by the contract pharmacy. The required data elements are: Rx Number, Prescribed Date, Fill Date, NDC, Quantity, Pharmacy ID, Prescriber ID, Wholesaler Invoice Number, and 340B Covered Entity ID.

How can a covered entity register its contract pharmacy location(s) with 340B ESP™ if the contract pharmacy location(s) does not have data to submit because it has not dispensed Gilead branded hepatitis C products for the covered entity within the last 45 days?

- Covered entities registering a contract pharmacy that does not have data to submit because the contract pharmacy has not dispensed Gilead branded hepatitis C products for the covered entity within the last 45 days may attest for their intent to submit applicable 340B claims in the Entity Profile tab in 340B ESP™. After attesting, the covered entity must submit the applicable contract pharmacy 340B claims data within 45 days of applicable dispenses of Gilead branded hepatitis C products made by the contract pharmacy.