



March 15, 2022

Update: Gilead to Implement 340B Claims Verification for Branded Hepatitis C Products

Dear 340B Covered Entity,

We recognize the important role of the 340B Federal Drug Pricing Program in providing medicines for individuals with low incomes. The 340B program has grown rapidly in recent years, and a well-documented lack of oversight has elevated concerns among stakeholders about the program's integrity and sustainability.

Gilead Contract Pharmacy Integrity Initiative

To help improve transparency, Gilead is requesting that 340B covered entities provide claims level data for prescriptions of Gilead's branded hepatitis C products dispensed from contract pharmacies, as of May 2, 2022. This includes data for prescriptions of Epclusa® (sofosbuvir / velpatasvir), Harvoni® (ledipasvir / sofosbuvir), Sovaldi® (sofosbuvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir). The integrity program does not apply to authorized generics of Epclusa® and Harvoni® offered by our subsidiary, Asegua Therapeutics.

Covered entities that provide claims level data, will be able to continue to use the contract pharmacies of their choice. Covered entities that decide not to participate in this integrity program, and do not have an in-house pharmacy, will have the option to select a single contract pharmacy location.

Why We Are Making This Change

We are making this change across our branded hepatitis C products because of the acute impact of duplicate discounts and diversion. The claims level data being requested is similar to the data Gilead receives from other purchasers and payers and is tailored to minimize burdens on covered entities while mitigating duplicate discount and diversion concerns.

Over time, Gilead has seen duplicate discounts and diversion of our medicines distributed through contract pharmacies occurring with increased frequency. This means that multiple discounts have been improperly applied to the same single bottle of Gilead medicine, and/or that discounts are being claimed on bottles dispensed to individuals who are not patients of a 340B covered entity. Sharing of claims level data with manufacturers is a necessary step toward achieving greater transparency in the 340B program and will help Gilead address duplicate discounts and diversion while also bolstering the integrity and sustainability of the program.

Next Steps

To prepare for this transition, we kindly request that you register your account with [340B ESP™](#), an industry standard no-cost web-based claims verification platform and begin submitting the required data as of May 2, 2022 (registration details below). Following this date, covered entities that elect not to participate will no longer be eligible for bill to / ship to orders of 340B-priced HCV drugs for contract pharmacies. Any covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location. Likewise, this update does not apply to contract pharmacies that are wholly owned by a covered entity or health system.

We believe this initiative is a necessary step toward improving the transparency of the 340B program and we understand that implementing a new process impacts your organization. We hope this letter provides as much advanced notice as needed to allow for planning and preparation.

Please contact support@340besp.com or **1-888-398-5520** with any additional questions. We appreciate your continued collaboration as we work together to expand access to our medicines for all those who could benefit, in a transparent and sustainable way.

Best regards,

A handwritten signature in black ink, appearing to read "Jason Krings".

Jason Krings
Vice President, Managed Markets

U.S. Prescribing Information for EPCLUSA, HARVONI, SOVALDI and VOSEVI, 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 as of May 2, 2022.

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?

- This update applies to Gilead's hepatitis C products, Eplclusa® (sofosbuvir / velpatasvir), Harvoni® (ledipasvir / sofosbuvir), Sovaldi® (sofosbuvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir). It does not apply to authorized generics of Eplclusa® and Harvoni® offered by our subsidiary, Asegua Therapeutics. Covered entities may access the complete list of NDCs at 340B ESP – Help Center.

What data are requested?

- As of May 2, 2022, covered entities will be required to submit claims level data on 340B contract pharmacy utilization. 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.
- Covered entities that elect to participate and provide data will be able to continue using the bill to / ship to arrangements for Gilead HCV products, for an unlimited number of contract pharmacies.
 - For a covered entity's eligible contract pharmacy locations to take effect on May 2, 2022, the entity must designate or submit claims level data by April 22, 2022. After April 22, 2022, please allow 10 business days for the eligible contract pharmacy locations to take effect.
- Covered entities that elect not to provide the data will no longer be eligible for bill to / ship to orders of 340B-priced drugs for their contract pharmacies after May 2, 2022.
 - Covered entities can take action to participate after May 2, 2022. After May 2, 2022, please allow 10 business days for the eligible contract pharmacy locations to take effect.
- If a covered entity elects not to participate, and it does not have an in-house pharmacy, the covered entity will have the option to select a single contract pharmacy location.
- Covered entities may continue to dispense 340B product from its wholly owned contract pharmacies so long as they are registered with HRSA as a contract pharmacy and are designated in the 340B ESP™ platform.

How do I submit claims level data?

- Covered entities submit claims level data by registering an account at www.340besp.com.
- Users that have registered an account with 340B ESP™ can begin submitting claims for Gilead by navigating to the Claims Data Submission tab.
- To get started with the 340B ESP™ platform, follow these three steps:
 - 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.
 - 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.
 - 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.

How does this impact contract pharmacies that are wholly owned?

- Contract pharmacies that are wholly owned by the covered entity are not subject to this update. The covered entity may continue dispensing 340B product from its wholly owned pharmacies so long as the pharmacies are registered with HRSA as a contract pharmacy and are designated in the 340B ESP™ platform. A wholly owned pharmacy may be designated at: www.340besp.com/wholly_owned_application.

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

- In-house pharmacies are not subject to this update. If a covered entity has an in-house pharmacy, then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Can I register all locations of the same pharmacy chain?

- If contract pharmacy claims level data is not provided, 340B covered entities without an in-house pharmacy may designate a single contract pharmacy location through which they will access 340B discounts.
- Contract pharmacy locations are registered individually on the HRSA 340B Office of Pharmacy Affairs Information System database. Therefore, 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.
- Covered entities that participate and submit claims level data may continue to dispense 340B product from an unlimited number of contract pharmacies.

Can I change the contract pharmacy designation?

- Covered entities can elect a single contract pharmacy every twelve (12) months, by visiting www.340besp.com/designations.

What is Gilead's policy regarding the timeframe for placing a replenishment order for Gilead's branded hepatitis C products at 340B pricing for dispensing through my contract pharmacy?

- Effective June 22, 2022, Gilead will process replenishment orders at 340B pricing for shipment to a covered entity's contract pharmacy location(s) registered with 340B ESP™ for prescriptions dispensed to eligible 340B patients within forty-five (45) days of each data submission to 340B ESP™.

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 as it has not dispensed Gilead branded hepatitis C products on behalf of the covered entity within the last 45 days?

- Covered entities registering a contract pharmacy that does not have data to submit as the contract pharmacy has not dispensed Gilead branded hepatitis C products on behalf of 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 is requested to submit the contract pharmacy 340B claims data within 45 days of applicable dispenses of Gilead branded hepatitis C products made on behalf of the covered entity.