



340B ESP Claim Level Data (CLD) Reporting Requirements

March 23, 2022

Gilead's letter to 340B covered entities explains that it is "making this change across [its] branded hepatitis C products because of the acute impact of duplicate discounts and diversion." 340B ESP supports this by combining claim level data (CLD) provided by 340B covered entities with Medicaid and commercial rebate data that payers provide to pharmaceutical manufacturers. Consequently, in addition to helping manufacturers determine if they have paid both a 340B discount and Medicaid rebate on the same prescription fill – federal law protects manufacturers from this practice; a duplicate discount finding may prompt Gilead Sciences to attempt to withhold the rebate payment to the state Medicaid program (or the 340B covered entity if the state Medicaid program disallows the practice or disputes the withheld rebate) – 340B ESP is also likely to be used by Gilead Sciences to look for Epclusa, Harvoni, Sovaldi, or Vosevi fills subject to up-front 340B discounts and back-end rebates to commercial or Medicare Part D payers, which is not prohibited by federal law. Should any "duplicate discounts" on commercial or Medicare Part D utilization be documented, it is unknown if or how manufacturers will seek to claw back revenue loss or what the potential impact will be on 340B covered entities.

Contract pharmacy based CLD elements being requested via 340B ESP and to be uploaded to the portal twice per month include:

- **Contracted Entity ID:** the 340B ID of the covered entity where the prescription originated. This is usually the 340B ID of the covered entity under which you registered.
- **Date of Service (aka Fill Date):** date on which the patient filled their prescription.
- **Date Prescribed:** date the prescriber wrote the prescription.
- **NDC:** the 11-digit National Drug Code which indicates the manufacturer, product, and the commercial package size.
- **Prescriber ID:** a unique, public ID for the prescribing physician. Accepted IDs include the NPI and DEA ID.
- **Prescriber ID Qualifier:** indicates the type of unique ID provided. A value of "01" indicates NPI, "12" indicates DEA.
- **Quantity:** the number of units in the prescription.
- **Rx Number:** the native (unmodified) prescription number for the prescription as generated by the pharmacy.
- **Service Provider ID:** a unique, public ID for the dispensing pharmacy. Accepted IDs include the NPI, DEA, NCPDP, and Medicaid ID.
- **Service Provider ID Qualifier:** indicates the type of unique ID provider. "01" for NPI, "05" for Medicaid, "07" for NCPDP, and "12" for DEA.
- **Wholesaler Invoice Number:** the invoice number assigned by the wholesaler for the replenishment order made by the 340B covered entity.

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CLD submission via 340B ESP will require covered entities (or their contract pharmacy claims administrators) to prepare and upload an Excel or CSV file with the required data elements. The CLD in the file is then “mapped” to the required data reporting elements in the 340B ESP dashboard.

As a reminder, 340B covered entities with contract pharmacies that exclusively serve uninsured patients – for example, ADAPs with direct purchase mechanisms for the full-pay medication programs, or sexually transmitted infection clinics – can submit an attestation form indicating they do not serve clients with any form of insurance, such as Medicaid, Medicare Part D, or a commercial plan. Upon completing the attestation, the 340B covered entity will be notified if they will be exempt from having to submit CLD for Gilead’s DAA products.

Consequently, NASTAD strongly recommends that 340B covered entities using contract pharmacies consult with legal counsel regarding the CLD reporting requirements and the 340B ESP terms of use agreements. Considerations to be addressed with legal counsel include whether the data requests violate HIPAA and/or other federal and state health information and data privacy laws; potentially constitutes breach of data privacy-based contractual arrangements with contract pharmacies, pharmaceutical benefit managers (PBMs), and others; the breadth and scope of the data elements to be provided; and/or the 340B ESP [Terms of Use](#), including a “royalty-free, perpetual, irrevocable license” to disclose and sub-license data the 340B covered entity submits.