

Dear 340B Covered Entity,

In response to inquiries we have received about providing our 340B contract pharmacy claims data to certain drug manufacturers, we want to provide the following background and response.

We understand that two pharmaceutical manufacturers – Sanofi-Aventis US LLC (Sanofi) and Merck & Co. (Merck) – have recently sent letters to covered entities requesting 340B drug claims data on products dispensed by the covered entities' contract pharmacies. The letters are blanket requests for the covered entities to submit contract pharmacy claims data on a bi-weekly basis to an online site, 340B ESP. The stated purpose of collecting this data is not only to identify Medicaid duplicate discounts, but also duplicate discounts on Medicare Part D and commercial utilization.

The terms and conditions of the manufacturers' 340B ESP program raise numerous issues that a covered entity may want to consider before enrolling in the program. Among the issues are the following:

- As a general matter, no legal requirement exists requiring covered entities to provide data in the fashion requested and, as such, any provision of data would be on a voluntary basis.
- If provided at all, the data could reasonably be limited to claims data for 340B drugs billed to Medicaid fee-for-service. While there exists a statutory prohibition against duplicate discounts for Medicaid fee-for-service claims, the 340B statute does not protect manufacturers from paying duplicate discounts on drug claims submitted to Medicare Part D or commercial plans. Therefore, covered entities may want to consider whether they want to put their 340B discounts at risk by providing the data requested by manufacturers.
- Responding to the data request could create issues for covered entities under HIPAA and other federal and state health information and data privacy laws. For example, a covered entity may want to evaluate the de-identification standards being applied – and seek something in writing that indemnifies the covered entity for any failure to satisfy the stated de-identification standards. In addition, a covered entity may want to seek a written representation and indemnification regarding where the de-identification takes place. If de-identification is performed by a third party or by third-party software after it leaves the covered entity's firewall, a business associate agreement may be required with the third party.
- Responding to the data request could induce covered entities to breach contractual arrangements with their contract pharmacies, third party administrators, prescription benefit managers and others. Our agreement with you, for example, requires the confidentiality of data, pricing, and other information and prohibits disclosure to a third-party without prior written consent.

- Covered entities may want to review the terms and conditions required for enrollment in the manufacturers' programs. For example, it is our understanding that the manufacturers' vendor, 340B ESP, requires that covered entities certify that they have the contractual right and/or appropriate license to release the data. Covered entities may want to evaluate whether they are in a position to provide such certification.

340B Compliance and Release of Data

As your 340B administrator, our ultimate goal is to support your compliance with the 340B program consistent with the terms of our agreement. Although there is no legal requirement that a covered entity provide data in the fashion being requested, we understand that some covered entities may wish to provide the data on a voluntary basis where there exists a statutory prohibition against duplicate discounts. As such, CVS is willing to authorize a covered entity's disclosure of Medicaid fee-for-service claims to 340B ESP for the sole purpose of reviewing potential Medicaid duplicate discounts, provided the manufacturer is willing to enter into an appropriate nondisclosure agreement. If desired, CVS may also authorize release of managed Medicaid claims. CVS will work with covered entities to create a claims report that includes the limited data elements requested by 340B ESP.

As it is not a required element for 340B compliance, at this time CVS does not authorize a covered entity's disclosure of any other data to 340B ESP, including, but not limited to, Medicare Part D claims and commercial claims.

We are happy to provide you this overview information about the data requests, but please understand that we cannot provide you, the covered entity, legal or regulatory advice. We recommend that the covered entity consult with its own counsel when reviewing and weighing its options in this matter.

We would, of course, be willing to discuss in more detail if you have questions.

Regards,



Kenneth Bodmer
Vice President, Wellpartner,
a CVS Health company