



September 4, 2020

Dear Covered Entity Partner,

Like many of you, we have more questions than clear answers regarding the various drug manufacturer announcements that have consumed 340B headlines over the past few weeks. We undeniably share your concerns.

Verity Solutions will continue to pay close attention to the situation and pass along relevant information to our Covered Entity partners. As part of that effort, this communication provides our interpretation of the information in the headlines, recommendations where appropriate, and response to the situation today.

SUMMARY TO DATE

Various stakeholders, primarily drug manufacturers, have issued communications over the past few weeks that either request or attempt to compel covered entities to provide varying levels of claims data as a condition of continued access to 340B drug pricing in the context of traditional contract pharmacy relationships, while others have indicated an intention to limit the use of contract pharmacies by Covered Entities altogether.

To date, manufacturers Lilly, Merck, Sanofi, AstraZeneca, and Novartis, and the technology company Kalderos have published letters aimed at Covered Entities and the benefits they receive from the 340B program. Most have taken somewhat different positions, which makes cohesive understanding more challenging.

OUR PERSPECTIVE AND RELATED CONSIDERATIONS

Verity Solutions encourages our Covered Entity customers to consult carefully with their legal counsel to determine how, if at all, to respond to these manufacturer mandates. It is also important to carefully review any related agreements you might have regarding data privacy and confidentiality conditions with other partners, including your contract pharmacies partners BEFORE deciding to share claims data or other confidential information as requested in the recent communications from manufacturers.

Advocate group 340B Health has encouraged its Covered Entity members to issue a response, even if it is an “opt-out” action, to demonstrate a good faith effort to acknowledge the request.

Supporting the interests of our Covered Entity customers in maximizing 340B benefits while always ensuring compliance with program requirements remains Verity Solutions’ priority #1. Verity has always and will continue to respect our customers’ data privacy concerns as well as our legal obligations as outlined in our Business Associate Agreements, which restrict our ability to share your data other parties.

Verity Solutions is working on various strategies to further enhance our software and optimally position our customer support to our Covered Entity partners as this situation continues to develop and unfold. These enhancements include:

- Updates to our software platform to support data extracts for Covered Entities who may decide to share data with the pharmaceutical manufacturers.
- Reporting enhancements to provide visibility of potential 340B savings loss due to the unfolding situation.
- Other means to provide visibility to drug pricing changes that might be triggered by manufacturer actions.

In the coming weeks, we will be communicating definitive product and feature enhancements to our Covered Entity customers.

In closing, we are aware of actions being taken by 340B advocate groups, including 340B Health, as the situation continues to develop, and we will continue to relay important information as we go forward.

Please feel free to raise any questions to your dedicated account manager who will ensure the proper subject matter expert engages and responds to your query.

SUMMARY OF MANUFACTURER COMMUNICATION TO DATE

- **Merck, Sanofi and Novartis** – Each has issued communications to 340B Covered Entities requesting submission all of contract pharmacy claims data related to the dispense of their respective products on a bi-weekly basis to the 340B ESP website powered by Second Sight Solutions and owned by the Berkeley Research Group.
 - Merck communicated a registration deadline of August 14th.
 - Sanofi and Novartis communicated a registration deadline of October 1st.
 - Claims to be reviewed for duplicate discounts for Medicaid (FFS and MCO), *Medicare Part D and Commercial Claims*.
 - Merck has asserted that if Covered Entities do not provide a “significant response” to this request, they may take further action to address 340B program integrity through “less collaborative and substantially more burdensome” actions. At this juncture, we have not seen any additional detail published.
 - Sanofi and Novartis have asserted that if Covered Entities do not opt-in, they will “no longer be eligible to place Bill To/Ship To replenishment orders” for their products dispensed through a contract pharmacy. At this juncture, we have not seen any additional detail published.

- After the August 14th deadline passed, 340B ESP sent out an invitation on August 17th for a training session the next day, August 18th. During this session, it was revealed that 340B ESP is requesting that ALL of a Covered Entity's contract pharmacy claims be uploaded and 340B ESP would pull out only those for the participating manufacturers. Verity Solutions believes there is more explanation and justification warranted on this topic. We remain waiting for additional details to become available.
- **Lilly and AstraZeneca** – Both manufacturers have asserted that they are implementing limited distribution of their 340B priced drugs to Covered Entities' contract pharmacies.
 - **Lilly** limited distribution of Cialis effective July 1, 2020 and will no longer sell this drug at 340B prices for shipment to contract pharmacies.
 - On September 1, 2020, Lilly communicated its intent to expand this limited distribution policy, effective immediately, to include all of their drugs with labeler codes 00002, 00077 and 66713 with an exception for their Insulins in specific circumstances.
 - **AstraZeneca**, starting October 1st, has indicated it will only ship to a Covered Entity's owned Outpatient Pharmacy. If a Covered Entity does not have one, then Astra Zeneca has indicated it will ship to only one contract pharmacy location per Covered Entity. To date, Astra Zeneca has not offered further clarification as to whether it intends to limit a Covered Entity's use of a single contract pharmacy to a single contract pharmacy licensed location or to all HRSA registered licensed locations of the contract pharmacy.
 - With respect to AstraZeneca, Verity Solutions believes additional clarification is in order concerning questions such as:
 - If the Covered Entity owns multiple outpatient pharmacies, can they all be included?
 - Does the letter's stipulation of "only 1 Contract Pharmacy" mean only one pharmacy, or only one pharmacy chain?
- **Kalderos Pay** – Technology company Kalderos has announced it will launch a new product module as of September 8 that Kalderos asserts has the ability to replace Covered Entity purchases at statutorily mandated discount prices with "rebates" to Covered Entities after purchase. To date, we are not aware of any decisions by a manufacturer or manufacturers to implement the Kalderos product.

For ongoing updates to our summary of manufacturer communications, visit [Verity Solutions News.](#)