



April 12, 2021



Dear [REDACTED],

I am writing to inform you that United Therapeutics Corporation (United Therapeutics) is implementing a new 340B program integrity initiative to address unlawful duplicate discounts, consistent with the United Therapeutics 340B contract pharmacy policy announced by letter to 340B covered entities dated November 18, 2020 and effective November 20, 2020. United Therapeutics strongly supports the 340B program and is committed to maintaining and strengthening its mission, and this initiative is designed to enhance that support. In practice, manufacturers continue to pay Medicaid rebates to states on prescriptions filled with 340B purchased drugs despite this being statutorily prohibited. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program. These program integrity issues have grown due to the expanded use of contract pharmacies, without sufficient transparency and oversight.

To address these issues, United Therapeutics is requiring all 340B covered entities to share claims data for 340B purchases of United Therapeutics products that are ordered through contract pharmacy arrangements. United Therapeutics will use these data to match against rebate claims it receives to ensure that it is not paying ineligible discounts. 340B covered entities that choose not to provide the required claims data will no longer be eligible to place Bill To / Ship To replenishment orders of certain United Therapeutics' 340B priced drugs for their contract pharmacies. All covered entities and their eligible patients will continue to have access to United Therapeutics' 340B priced drugs at locations properly registered as a 340B covered entity or child site on the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) database. This policy will apply to all United Therapeutics covered outpatient drugs, except for ADCIRCA (tadalafil).

What do you need to do next? This initiative is enabled through 340B ESP™, a Second Sight Solutions technology, and is made available to 340B covered entities at no cost. United Therapeutics requires all 340B covered entities with a contract pharmacy to register at www.340BESP.com and begin submitting the required 340B contract pharmacy claims data by May 13, 2021.

United Therapeutics has maintained a strong commitment to the 340B program since its inception. We also recognize that serious program integrity and transparency challenges must be addressed for the 340B program to continue its mission. That is why we are adopting the 340B ESP™ platform, and we look forward to working collaboratively with 340B covered entities to further strengthen the 340B program.

Best regards,

Kevin Gray, Senior Vice President
United Therapeutics Corporation

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple 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 ~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 data on a twice monthly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™.

For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. To learn more about how United Therapeutics is working to improve program integrity through 340B ESP™, please contact United Therapeutics directly at 340b@unither.com.

Q: How will United Therapeutics use the 340B claims data that covered entities provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid, Medicare Part D and commercial rebates. These data will not be used for any other purpose.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is United Therapeutics requiring 340B claims data for all United Therapeutics products?

A: No. United Therapeutics is only requiring data for United Therapeutics drugs commonly dispensed through pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. This program also does not apply to ADCIRCA (tadalafil). 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data by the required date?

A: United Therapeutics is requiring all 340B covered entities to register with 340B ESP™ and begin providing 340B contract pharmacy claims data by May 13, 2021. 340B covered entities that elect not to provide 340B contract pharmacy claims data will no longer be eligible to place Bill To / Ship To replenishment orders for United Therapeutics products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase United Therapeutics products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is United Therapeutics requiring data for pharmacies that are registered with HRSA as a covered entity?

A: No. United Therapeutics is only requiring data for 340B claims that originate from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable United Therapeutics to definitively identify duplicate Medicaid rebates along with other ineligible rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, Firefox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.