

December 29, 2021

Dear 340B Covered Entity Customer,

Beginning February 1, 2022, AbbVie will implement a 340B program integrity initiative designed to address persistent abuses caused by the unwillingness of covered entities and their contract pharmacies to provide sufficient claims data to prevent prohibited and improper duplicate discounting on AbbVie products. This initiative will *not* block access to 340B priced medicines for any covered entity of the 340B program and—critically—patients will continue to have uninterrupted access to AbbVie’s medicines.

AbbVie will request that hospital covered entities, but not federal grantee covered entities, take the reasonable step to register with 340B ESP™ and submit limited claims data on 340B contract pharmacy utilization. Hospital covered entities that do so (and all grantee covered entities) will continue to be able to use bill to/ ship to arrangements for AbbVie products with an unlimited number of contract pharmacies.

AbbVie supports the 340B program and is committed to the program’s goal of improving access to medicines for uninsured and vulnerable patients. However, in recent years, the 340B program has increasingly suffered from abuses that undermine that goal and call into question whether patients benefit from 340B discounts.

AbbVie’s 340B integrity initiative will continue to honor bill to/ ship to requests for contract pharmacies, provided that 340B hospital covered entities share claims data for 340B prescriptions of certain AbbVie medicines filled through contract pharmacies. As of February 1, 2022, AbbVie will decline to facilitate bill to/ ship to replenishment orders of 340B priced medicines to contract pharmacies for which claims data are not provided. Hospital covered entities without in-house outpatient pharmacies may designate one contract pharmacy and AbbVie will continue to facilitate bill to/ ship to orders of 340B priced drugs.

What is not changing? Patients will have uninterrupted access to AbbVie medicines. All covered entities will continue to have access to 340B priced drugs at locations properly registered as a 340B covered entity or child site on the HRSA database. Covered entities will be offered, and may purchase, as much AbbVie medicine at the 340B price as desired, provided it is shipped to the covered entity location.

What is changing for hospital covered entities? Hospital covered entity types will be asked to register with 340B ESP™, a web-based platform made available to covered entities at no cost, and submit requested claims data. AbbVie will use this claims data to identify ineligible or duplicate discounts. Starting February 1, 2022, 340B hospital covered entities that elect not to provide the required claims data for a contract pharmacy will no longer be eligible for the benefit of being able to place bill to/ ship to replenishment orders of 340B priced drugs for that contract pharmacy. Hospital covered entities that do provide the data, will be able to use an unlimited number of contract pharmacies of their choosing.

What is changing for federal grantee covered entities? There is **no change** for federal grantee covered entities, such as community health centers, federally-qualified health centers and Ryan White clinics. Federal grantee covered entities will continue to be eligible to place bill to/ ship to replenishment orders of 340B priced drugs for their contract pharmacies, even if such entities do not submit 340B claims data through 340B ESP™.

What do you need to do next? 340B hospital covered entities should register at www.340BESP.com and begin submitting the required 340B claims data by February 1, 2022.

AbbVie believes that for the 340B program to fulfill its important mission of improving access to medicines for uninsured and vulnerable patients, the program integrity challenges must be addressed. We look forward to working collaboratively with you to further strengthen the 340B program.

Best regards,



Chris Compisi
Vice President, US Market Access

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 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 data twice monthly. Once your account is set up, the claims upload process takes about 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.

FREQUENTLY ASKED QUESTIONS

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

Contract pharmacy claims uploaded by 340B covered entities will be used to identify and resolve ineligible Medicaid, Medicare Part D and commercial rebates and to determine eligibility for certain replenishment orders under the policy.

Q: Are all AbbVie products subject to its contract pharmacy policy?

The policy will be applied across the product portfolio. Initially, the contract pharmacy policy will apply to the list of products attached to this FAQ. AbbVie will inform covered entities when additional products are added and of other changes to the product list.

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

AbbVie requests that 340B hospitals register with 340B ESP™ and begin providing 340B claims data for contract pharmacy purchases by the required date. 340B hospitals that elect not to provide 340B claims data will no longer be able to place bill to/ ship to replenishment orders for AbbVie products dispensed through a contract pharmacy.

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

No. AbbVie is only requiring 340B hospital covered entities to provide 340B claims data on units dispensed by contract pharmacies. Covered entities do not need to provide 340B claims data for prescriptions filled in their own outpatient pharmacies.

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

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What if my covered entity does not have an outpatient pharmacy registered as a parent or child site on the 340B covered entity database?

If your covered entity chooses not to submit claims data and doesn't have an in-house outpatient pharmacy capable of dispensing 340B priced products, your entity may designate a single pharmacy location and AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs for that contract pharmacy. To make your contract pharmacy designation, please navigate to www.340BESP.com.

Q: If my organization does not provide 340B claims data by the required date, can it elect to do so at a later date and gain access to 340B pricing for contract pharmacies?

If an entity begins to supply data after February 1, 2022, it must provide data for contract pharmacy dispenses to eligible patients in the prior 45-day period. Once the required data submission has been made, AbbVie will facilitate bill to/ ship to contract pharmacy replenishment orders on product dispensed to eligible patients from and after the date of data submission as well as the prior 45-day period.

Q: What happens if a covered entity who is already registered on the platform misses a data submission date?

If you miss a data submission date, please submit your data as soon as you are able. If a covered entity is unable to provide required data in a timely manner, AbbVie may no longer facilitate bill to/ ship to contract pharmacy replenishment orders on 340B claims.

Q: How do I get my pharmacy/covered entity set up to meet the new requirements?

We do not anticipate any action being necessary on the part of contract pharmacies as this policy requires covered entities to submit data for its contract pharmacy utilization. Covered entities should register with the www.340BESP.com website and follow instructions to begin submitting data.

Q: Will I be able to register and begin submitting data prior to February 1, 2022?

The 340B ESP™ platform is available now for registration and submission of claims data. The registration process takes just a few short minutes and there is a dedicated support team there to help.

Q: What training and resources will be provided to covered entities to help with this transition?

Detailed information about how to use the 340B ESP™ platform can be found at www.340BESP.com/FAQS or email support@340BESP.com. The 340B ESP™ website includes video tutorials and frequently asked questions.

Q: My covered entity owns an outpatient pharmacy that is registered with HRSA as a contract pharmacy. Is this pharmacy subject to AbbVie's policy?

If a covered entity wholly owns or has common ownership with an outpatient pharmacy that is registered as a contract pharmacy for the covered entity, AbbVie will facilitate such covered entity's bill to/ ship to replenishment orders of 340B priced drugs for that contract pharmacy. To register such pharmacy, please contact support@340BESP.com.

Q: My covered entity has an in-house outpatient pharmacy that is capable of purchasing and dispensing AbbVie products, but I do not use it to dispense AbbVie products or prefer to utilize a contract pharmacy. Can I designate one contract pharmacy instead?

If you provide required 340B claims data for an applicable contract pharmacy, AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs for that contract pharmacy.

Q: If my covered entity has chosen not to submit claims data and is eligible to designate a single contract pharmacy, how does our entity make its designation?

Covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy under AbbVie's policy.

AbbVie 340B Contract Pharmacy Data Integrity Initiative Applicable Products

PRODUCT
ANDROGEL®
CREON®
DEPAKOTE®
DUOPA®
GENGRAF®
HUMIRA®
KALETRA®
K-TAB®
LUPRON®
MAVYRET®
NIASPAN®
NIMBEX®
NORVIR®
ORIAHNN®
ORLISSA®
RINVOQ®
SYNTHROID®
SKYRIZI®
SURVANTA®
TRICOR®
TRILIPIX®
ULTANE®
VIEKIRA PAK®
ZEMPLAR®