



**March 29, 2023**

Dear 340B Covered Entity,

AbbVie is updating its 340B program integrity initiative. The updated initiative is designed to address persistent abuses of the 340B program, including diversion and inappropriate duplicate discounting. AbbVie's updated initiative will *not* block access to 340B priced medicines for any eligible covered entity and patients will continue to have uninterrupted access to AbbVie's medicines.

Effective April 17, 2023, AbbVie will decline to facilitate bill to/ ship to orders for all hospital covered entities for 340B-priced medicines. This limitation on bill to/ ship to orders in AbbVie's new policy is aligned to AbbVie's standard commercial sales conditions for non-340B customers. Accordingly, hospital covered entities will no longer be permitted to direct delivery of AbbVie's 340B priced medicines to contract pharmacies. AbbVie's 340B integrity initiative will continue to honor bill to/ ship to requests to contract pharmacies for grantee covered entities.

**What is not changing?** Patients will continue to have uninterrupted access to AbbVie medicines. All covered entities will continue to be able to purchase 340B priced medicines and have them delivered to 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. Grantee covered entities will still be permitted to utilize contract pharmacies.

**What is changing for *hospital covered entities*?** Starting April 17, 2023, except for the limited exceptions described below or in the attached FAQs, hospital covered entities will no longer be eligible to place bill to/ ship to replenishment orders of 340B priced medicines for contract pharmacies.

A hospital covered entity *without* an in-house outpatient pharmacy may designate one contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that, (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

**Even if your hospital covered entity had previously designated a contract pharmacy location under AbbVie's existing policy, you will need to access 340B ESP™ and designate one contract pharmacy location for AbbVie's updated policy. Please do so prior to April 9, 2023.** For details on accessing the exceptions to this policy, please see the attached FAQs.



**What is changing for *federal grantee covered entities*?** There is **no change** for federal grantee<sup>1</sup> 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.

AbbVie is committed to the intended purpose of the 340B program and 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.

Please reach out to [340bcommunications@abbvie.com](mailto:340bcommunications@abbvie.com) if you have questions about our updated policy. For assistance with using 340 ESP™, please contact [support@340BESP.com](mailto:support@340BESP.com).

Best regards,

A handwritten signature in blue ink, appearing to read 'C Compisi', is positioned above the printed name.

Chris Compisi  
Vice President, US Market Access

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<sup>1</sup> Grantees refers to entities eligible for the 340B program under 42 U.S.C. §256(b)(4)(A)-(K).

## FREQUENTLY ASKED QUESTIONS

### **Medicines Covered**

**Q: Which AbbVie medicines are subject to this updated contract pharmacy policy?**

The policy applies to the list of products attached to this FAQ. AbbVie will inform covered entities of any changes to the product list. Both the AbbVie policy and the up-to-date list of AbbVie products can be found on 340B ESP™ [www.340BESP.com](http://www.340BESP.com).

### **Exception for Certain Products**

**Q: Am I still able to designate a contract pharmacy location for AbbVie medicines subject to a limited distribution network if my covered entity in-house pharmacy is not in the limited distribution network?**

If your covered entity's in-house pharmacy is not within a limited distribution network for an AbbVie product, you may designate one of the specified contract pharmacy locations for receiving replenishment shipment of the product. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy location. Currently, this contract pharmacy designation is available for Duopa and Imbruvica. Please access 340B ESP™ at [www.340BESP.com](http://www.340BESP.com) and navigate to the Entity Profile tab to make your selection. **Even if you had previously selected a designated one contract pharmacy location for Duopa or Imbruvica under AbbVie's previous policy, your covered entity must still access 340B ESP™ and select one designated pharmacy location for the limited distribution products under this updated policy. Your designated pharmacy location for limited distribution products must be listed in 340B ESP™ by April 9, 2023 for the designation to take effect on April 17, 2023.** If you have questions about how to make this designation, please contact Second Sight Solutions at 888-398-5520 or [support@340BESP.com](mailto:support@340BESP.com).

### **Exception for Hospital Covered Entities *Without* an In-House Pharmacy**

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

If your covered entity does not have an in-house outpatient pharmacy capable of dispensing 340B priced products, your entity may designate a single contract pharmacy location and AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; *provided that*:

- (i) the covered entity registers with 340B ESP™ and submits limited claims data on 340B utilization for such contract pharmacy, and
- (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

**Q: How can my covered entity identify pharmacy locations within 40 miles of my parent hospital?**

340B ESP™ will maintain a list of pharmacies within a 40 mile radius of the parent hospital registered on the HRSA 340B OPAIS database.



**Q: What if I am unable to identify an eligible pharmacy location for my designation? For example, what if there is no pharmacy location within 40 miles of my covered entity's parent site?**

AbbVie is committed to ensuring that every covered entity has at least one pharmacy location where it can receive AbbVie's medicines at 340B prices. If you are unable to locate a pharmacy location within 40 miles, AbbVie will work with your covered entity to locate the nearest appropriate contract pharmacy location. Please reach out to 340 ESP™ if you encounter challenges in designating your one contract pharmacy location.

**Designation of Permitted Contract Pharmacy Locations**

**Q: If my covered entity is eligible to designate a contract pharmacy location because it does not have an in-house pharmacy, how does my 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](http://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 location under AbbVie's policy.

**The one contract pharmacy location must be listed in 340B ESP™ by April 9, 2023 for the designation to take effect on April 17, 2023. Even if your covered entity has designated an exception for one contract pharmacy location under AbbVie's previous policy or is submitting claims data for the desired location, you must still access 340B ESP™ and select your designated contract pharmacy location for this updated policy. Please do so prior to April 9, 2023.** If you fail to designate your one contract pharmacy location by April 9, 2023, you may still make a designation after such date, but the designated contract pharmacy location will not be eligible for 340B priced orders by the effective date of AbbVie's updated policy.

Once during each 12-month period following the effective date of this policy, a covered entity may designate a different contract pharmacy location. Please note that such designations may take up to 10 business days to become effective.

**Q: If I designate one contract pharmacy location to receive orders of medicines subject to this policy, should I also make a separate designation for a contract pharmacy location to receive AbbVie medicines subject to a limited distribution network?**

Yes, you should separately designate one contract pharmacy location to receive medicines subject to a limited distribution network. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy. Currently, this separate contract pharmacy designation is available for Duopa and Imbruvica.

Accordingly, this pharmacy designation may be in addition to the one permitted contract pharmacy designation for other AbbVie medicines. Please access 340B ESP™ at [www.340BESP.com](http://www.340BESP.com) to make this selection.

**Q: My covered entity is affiliated with an outpatient pharmacy that is registered with HRSA as a contract pharmacy. How will AbbVie's policy impact this pharmacy location?**

AbbVie will decline to facilitate bill to/ ship to orders for all contract pharmacies of hospital covered entities. Your covered entity should place orders for delivery to your covered entity's in-house pharmacy. Hospital covered entities that do not have an in-house pharmacy, may choose to designate



an affiliated contract pharmacy as its designated contract pharmacy location, provided it complies with the data submission and distance requirements described herein.

### **Claims Data Submission Requirements**

#### **Q: What are the requirements for submission of claims data?**

The claims data submission requirement applies to a hospital covered entity without an in-house pharmacy that designates one contract pharmacy location within 40 miles of the HRSA registered covered entity parent site. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines.

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. Please see 340B ESP™ at [www.340BESP.com](http://www.340BESP.com) for additional details on submitting claims data, including the limited set of required data fields.

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

Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates, including in Medicaid, Medicare Part D, TRICARE and commercial payer rebates, determine compliance with AbbVie's 340B integrity initiative and determine eligibility for placing certain replenishment orders under the policy.

#### **Q: What happens if my organization is unable to provide claims data in conformance with AbbVie's policy?**

Failure to provide claims data in conformance with the requirements of this policy may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient. AbbVie will provide covered entities a 60-day grace period from the effective date of this policy to start submitting claims data for the designated contract pharmacy location.

You can visit [www.340BESP.com/FAQs](http://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](http://www.340BESP.com/resources/webinars) or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on [www.340BESP.com](http://www.340BESP.com).

**AbbVie 340B Program Integrity Initiative Applicable Products**

<b>PRODUCT</b>
CREON®
DEPAKOTE®
DUOPA®
GENGRAF®
HUMIRA®
IMBRUVICA®
KALETRA®
K-TAB®
LUPRON®
MAVYRET®
NIASPAN®
NIMBEX®
NORVIR®
ORIAHNN®
ORILISSA®
RINVOQ®
SKYRIZI®
SURVANTA®
SYNTHROID®
TRICOR®
TRILIPIX®
ULTANE®
VIEKIRA PAK®
ZEMPLAR®
ACTONEL®
ACULAR®
ACULAR® LS
ACUVAIL®
ALOCRIAL®
ALPHAGAN® P
ANDRODERM®
ARMOUR® THYROID
ASACOL® HD
ATELVIA®
AVYCAZ®
BENTYL®
BOTOX®

PRODUCT
BYSTOLIC®
CANASA®
CARAFATE®
CELEXA®
COMBIGAN®
CONDYLOX®
CRINONE®
DALVANCE®
DELZICOL®
DURYSTA®
ESTRACE®
FETZIMA®
FML®
FML FORTE®
GELNIQUE®
GENERESS® FE
INFED®
KADIAN®
KYBELLA®
LASTACAFT®
LATISSE®
LEXAPRO®
LINZESS®
LO LOESTRIN® FE
LUMIGAN®
MINASTRIN® 24 Fe
MONUROL®
NAMENDA® / NAMENDA XR®
NAMZARIC®
OCUFLOX®
OXYTROL®
OZURDEX®
POLYTRIM®
PRED FORTE®
PRED MILD®
PYLERA®
QULIPTA®
RAPAFLO®
RECTIV®
REFRESH®

PRODUCT
RESTASIS®
SAPHRIS®
SAVELLA®
TAYTULLA®
TEFLARO®
UBRELVY®
URSO FORTE® / URSO 250®
VANIQA®
VIBERZI®
VIIBRYD®
VRAYLAR®
VUITY™
ZYMAXID®