



August 28, 2024 Update – New Attachment A

Dear 340B Covered Entity,

AbbVie's initiative is designed to address persistent abuses of the 340B program, including diversion and inappropriate duplicate discounting. AbbVie's initiative does *not* block access to 340B priced medicines for any eligible covered entity and patients will continue to have uninterrupted access to AbbVie's medicines. Under the initiative, AbbVie declines 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 current policy is aligned with AbbVie's standard commercial sales conditions for non-340B customers. Accordingly, hospital covered entities are not 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.

Patients continue to have uninterrupted access to AbbVie medicines. All covered entities are able to purchase 340B priced medicines for delivery to locations properly registered as a 340B covered entity or child site on the HRSA database. Grantee covered entities will still be permitted to utilize contract pharmacies.

What is AbbVie's policy for hospital covered entities? Except for the limited exceptions described below or in the attached FAQs, hospital covered entities are not 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.

What is AbbVie's policy for *federal grantee covered entities*? There is **no change** for federal grantee¹ 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.

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



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 if you have questions about our updated policy. For assistance with using 340 ESP™, please contact support@340BESP.com.

Best regards,

Carter Dutch

Carter Dutch
Vice President, US Market Access

FREQUENTLY ASKED QUESTIONS

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.

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. This contract pharmacy designation is available for Duopa, Imbruvica, and Venclexta. Please access 340B ESP™ at www.340BESP.com and navigate to the Entity Profile tab to make your selection. If you have questions about how to make this designation, please contact Second Sight Solutions at 888-398-5520 or support@340BESP.com.

Q: Does my covered entity have an “in-house pharmacy”?

An “in-house pharmacy” is any type of pharmacy—including but not limited to specialty pharmacy, retail pharmacy, central fill pharmacy, etc.—that (i) is 100% owned by your covered entity, (ii) is appropriately licensed or authorized by the applicable state, (iii) can dispense the list of products attached to this FAQ; and (iv) is not listed as a contract pharmacy for your covered entity on OPAIS.

It does not include a pharmacy partially owned by your covered entity, a pharmacy owned by an entity other than your covered entity, including a parent or affiliated entity other than your covered entity. Merely listing a non-entity owned pharmacy (i.e., a contract pharmacy) as a ship to address on OPAIS does not confer entity-owned status on the pharmacy. AbbVie may require eligibility information, such as auditable records, to confirm 100% ownership by your covered entity.

For purposes of clarity, if your covered entity has an “in-house pharmacy” as explained above, the entity **may not** designate a contract pharmacy.

Q: What if my covered entity does not have an in-house 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 covered outpatient drugs, your covered entity may designate a single contract pharmacy location. AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; *provided that*:

- (i) your covered entity registers with 340B ESP™ and completes the attestation;
- (ii) your covered entity provides AbbVie with appropriate documentation subject to AbbVie's sole discretion to support that your covered entity does not have an in-house pharmacy capable of dispensing 340B priced products;
- (iii) your covered entity submits limited claims data on 340B utilization for such contract pharmacy (see below for more details), and
- (iv) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

Q: Can child sites also designate a single contract pharmacy?

No. A child site must utilize the parent site's contract pharmacy designation. AbbVie considers all sites together as one covered entity, inclusive of the parent and child sites, listed on the HRSA database.

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.

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 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.

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.

Please note that designating a contract pharmacy does not in any way eliminate the program eligibility requirements and provide access to pricing to entities or individuals that do not meet the terms of this initiative. Covered entities are responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations.

Q: Does my covered entity need to have a HIN registered for the contract pharmacy that they designate?

Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for AbbVie to manage its process with its wholesalers. If you try to designate a contract pharmacy location that does not have a HIN in 340B ESP™, the system will provide guidance on how you can register the pharmacy for a HIN. If you have previously registered a contract pharmacy without a HIN, 340B ESP™ will notify you if such information needs to be updated. If you have questions, please reach out to support@340BESP.com.

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, Imbruvica and Venclexta. 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 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.

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 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.

Q: May a covered entity designate a single contract pharmacy 'replenishment' location, include dispensing activity from several other non-designated contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?

No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and location. All dispensing to eligible patients must occur at the properly designated contract pharmacy location(s), and 340B priced drugs will be shipped directly to that location either by AbbVie or an authorized distributor.

Q: May my covered entity tally dispensing activity from non-designated contract pharmacy locations and/ or a non-eligible pharmacy locations and place subsequent orders to be shipped to a different, single designated contract pharmacy or covered entity in-house location?

No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and physical location, and 340B dispensing activity must occur at this location in order for the location to receive 340B priced drugs. Covered entities may not resell or otherwise transfer 340B covered outpatient drugs to a person who is not a patient of the covered entity.

Q: What if two covered entities attempt to order a 340B priced drug to replace the same prescription number or unit dispensed?



Multiple 340B requests on a single prescription (same prescription ID number) or unit will not be allowed. AbbVie will honor the first 340B discount request received and deny all subsequent requests.

Q: Is there a time limitation on when replenishment orders can be placed to my designated contract pharmacy?

If the contract pharmacy has submitted claims data within 45 days of the date of dispensation by the contract pharmacy, AbbVie will process the contract pharmacy's replenishment order.

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. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

Attachment A
State Policies

Arkansas: AbbVie's 340B program integrity initiative does not apply to covered entities in Arkansas.

Minnesota: AbbVie's 340B program integrity initiative does not apply to covered entities in Minnesota.

Mississippi: AbbVie's 340B program integrity initiative does not apply to covered entities in Mississippi.

Missouri: AbbVie's 340B program integrity initiative does not apply to covered entities in Missouri.

AbbVie 340B Program Integrity Initiative Applicable Products

PRODUCT
ANDROGEL®
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

PRODUCT
ATELVIA®
AVYCAZ®
BENTYL®
BOTOX®
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®

PRODUCT
POLYTRIM®
PRED FORTE®
PRED MILD®
PYLERA®
QULIPTA®
RAPAFLO®
RECTIV®
REFRESH®
RESTASIS®
SAPHRIS®
SAVELLA®
TAYTULLA®
TEFLARO®
UBRELVY®
URSO FORTE® / URSO 250®
VENCLEXTA®
VIBERZI®
VIIBRYD®
VRAYLAR®
VUITY™
ZYMAXID®