



340B HEALTH

Note: The Health Resources and Services Administration (HRSA) has made clear its position that pharmaceutical manufacturers may not impose restrictions on 340B pricing for drugs dispensed by a contract pharmacy to a covered entity's 340B-eligible patients. The agency has said the drug companies imposing such restrictions must immediately offer 340B pricing to covered entities through their contract pharmacy arrangements and repay covered entities for all past overcharges, warning them that failure to comply could result in civil monetary penalties for knowingly and intentionally overcharging covered entities. Manufacturers are legally challenging the agency's position in federal court. Three district courts have recently issued decisions on this issue, with two courts agreeing with HRSA that manufacturers cannot unilaterally impose conditions on 340B pricing and one court disagreeing with HRSA's position. Several manufacturers have filed appeals of the decisions agreeing with HRSA's position, and the government has appealed the court decision disagreeing with HRSA's position. 340B Health continues to advocate for drug companies to be held accountable for their illegal conduct and strongly encourages hospitals that are denied 340B pricing on eligible drugs for contract pharmacy to report the overcharges to HRSA using an [Apexus form](#) designed for such reporting. 340B Health has also developed a [template letter](#) that member hospitals can use to report overcharges to HRSA. We will inform member hospitals of any major developments regarding manufacturers' restrictive contract pharmacy policies.

Manufacturer Exceptions to Contract Pharmacy Restrictions

Updated January 19, 2022

- **Introduction**
 - Multiple manufacturers have implemented policies refusing to provide 340B pricing for drugs dispensed through contract pharmacies. The manufacturers have also provided exceptions that allow hospitals to receive 340B pricing for certain drugs or under certain circumstances or conditions. This document outlines some of those policies and exceptions and will be updated, as needed, to provide information about other companies and additional exceptions.
- **AbbVie**
 - Starting Feb. 1, 2022, AbbVie will no longer offer 340B discounts to hospitals on drugs dispensed at contract pharmacies unless the hospital submits contract pharmacy patient claims data using 340B ESP.
 - In a Dec. 29, 2021 [letter](#) to covered entities, AbbVie said it “will decline to facilitate bill to/ship to replenishment orders of 340B priced medicines to

contract pharmacies for which claims data are not provided” once the Feb. 1, 2022 policy takes effect.

- The policy initially applies to a list of two dozen AbbVie drugs that includes *Humira* (adalimumab), and the company indicated it could expand that list.
 - The policy will not apply to non-hospital 340B grantees.
 - The company says it will allow hospitals without in-house pharmacies that do not submit the claims data to designate a single contract pharmacy location to continue receiving 340B-priced drugs.
 - The policy also provides for an exemption for contract pharmacies wholly owned by hospitals or that have common ownership with a health system.
 - AbbVie directs hospitals to use the [340B ESP](#) platform to submit claims data.
 - Hospitals should be aware that using the ESP platform to submit claims data requires agreeing to its Terms of Use. 340B Health has raised several concerns with the platform’s Terms of Use. See below for more detail.
- Amgen
 - Amgen announced in an email to 340B hospitals that pharmacies registered as contract pharmacies no longer will be eligible for Bill To/Ship To replenishment orders at 340B pricing starting Jan. 3, 2022. The policy will not apply to non-hospital covered entities.
 - Hospitals that submit all contract pharmacy claims data through 340B ESP will continue to receive 340B pricing for Bill To/Ship To replenishment orders for their contract pharmacies.
 - The company said it will offer an exception for hospitals that do not have an in-house pharmacy capable of dispensing 340B purchased drugs to designate a single contract pharmacy location. Hospitals are to use the [340B ESP website](#) to designate the single contract pharmacy location to receive 340B drugs. For a hospital’s designation to take effect on Jan. 3, 2022, its contract pharmacy selection needs to be made by Dec. 10, 2021. Amgen indicated hospitals should allow 10 business days for designations made after Dec. 10, 2021 to take effect. A hospital may change its contract pharmacy designation once every 12 months from the date of first designation.
 - Amgen will also provide an exemption for contract pharmacies wholly owned by hospitals or that have common ownership with a health system. Hospitals granted this exemption may not designate “an independent contract pharmacy.” Hospitals must apply for the exemption using the [340B ESP website](#).
 - In an FAQ accompanying the announcement, Amgen said its policy “primarily applies to self-administered, pharmacy benefit Amgen products, specifically *Repatha*, *Enbrel*, *Otezla*, and *Aimovig*. The policy does not currently apply to medical benefit products and Amgen does not intend to change that in the future.”

- Hospitals should be aware that using the 340B ESP platform to submit claims data requires agreeing to Terms of Use. 340B Health has raised several concerns with the platform’s Terms of Use. See below for more details.
- AstraZeneca
 - AstraZeneca began refusing 340B pricing for products dispensed at contract pharmacies, effective Oct. 1, 2020. Some hospitals reported receiving a [notice](#) from AstraZeneca dated Sep. 14, 2020, stating that the company is only applying this new policy to certain AstraZeneca products, which are listed by NDC in an attachment to the notice.
 - AstraZeneca will permit 340B pricing through a single contract pharmacy for those hospitals that do not maintain their own on-site dispensing pharmacy.
 - Any hospital that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca at membership@astrazeneca.com to arrange for a contract pharmacy of its choice to be eligible to receive 340B pricing on behalf of the hospital.
 - 340B Health members have shared an [exception application form](#) that hospitals can send to membership@astrazeneca.com to apply for this exception. The application form grants AstraZeneca authority to impose and enforce requirements beyond federal rules prohibiting duplicate discounts and diversion:
 - Hospitals must comply with all requirements in the 340B statute for drugs purchased under the exception.
 - Hospitals must forgo all other discounts for the same products.
 - Hospitals must agree to repay AstraZeneca for discounts provided in “error.”
 - Hospitals must allow AstraZeneca and/or its auditor to have access to any information necessary for AstraZeneca to audit 340B purchases.
- Boehringer Ingelheim (BI) Pharmaceuticals
 - BI [announced](#) that it would refuse shipments to contract pharmacies for 340B purchased drugs for orders placed on or after Aug. 1, 2021. BI’s original notice indicated its policy applies to all BI products except those distributed through specialty pharmacies, which BI listed as OFEV, Gilotrif, and Praxbind. On Oct. 29, 2021, BI sent an [additional notice](#) to hospitals indicating that BI would begin refusing shipments of OFEV to contract pharmacies for 340B purchased drugs effective Dec. 1, 2021. This new policy does not apply to Gilotrif and Praxbind. BI’s contract pharmacy restrictions do not apply to non-hospital covered entities.
 - Hospitals can apply for two exceptions to the policy using 340B ESP:
 - Any hospital that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location to receive and dispense 340B purchased products. The 340B ESP website must be used to apply for this exception.

- If the hospital previously designated a contract pharmacy for BI's products and that contract pharmacy is not in BI's limited distribution network for OFEV, the hospital can designate one specialty pharmacy from within BI's limited distribution network for the sole purpose of distributing OFEV to its patients.
 - Contract pharmacies that are wholly owned by a 340B hospital, or under common ownership with a 340B health system, will remain eligible to receive "Bill To / Ship To" replenishment orders of 340B priced drugs. These pharmacies must be registered with HRSA as a contract pharmacy of their related 340B hospitals, and the 340B ESP website must be used to apply for this exception.
 - Any wholly owned contract pharmacies that have an approved wholly owned contract pharmacy exception for BI's primary care products will remain eligible to place Bill To/Ship To replenishment orders for OFEV at the 340B price and do not need to apply for an additional wholly owned contract pharmacy exception for OFEV.
- Hospitals are directed to contact support@340Besp.com with questions regarding the policy change.
- For a hospital's contract pharmacy designation to take effect on Aug. 1, 2021, its contract pharmacy selection must be made by July 16, 2021. For a hospital's OFEV contract pharmacy designation to take effect on Dec. 1, 2021, its contract pharmacy selection must be made by Nov. 12, 2021. After these dates, BI indicates a contract pharmacy selection will take up to 10 business days to take effect in wholesalers' systems.
- BI indicates they will allow hospitals to change its single contract pharmacy designation every 12 months from the date of first designation or more often if the relationship is terminated from OPAIS. Covered entities are only permitted to select one single contract pharmacy location and BI will not allow a hospital to designate all locations of the same contract pharmacy.
- Bristol Myers Squibb
 - Starting Mar. 1, 2022, Bristol Myers Squibb (BMS) will limit each 340B hospital without an in-house pharmacy to a maximum of two contract pharmacy locations for receiving 340B-discounted drugs — one for IMiDs (immunomodulatory drugs) and a second for other, non-IMiD products. BMS will not allow hospitals that have an entity-owned pharmacy capable of dispensing 340B-discounted drugs to designate a contract pharmacy to receive non-IMiD drugs purchased at the 340B price.
 - In an email sent to covered entities on Jan. 14, 2022, BMS said that starting Mar. 1, 2022 "BMS will recognize up to two designated 340B contract pharmacy locations per 340B hospital that lacks an entity-owned pharmacy. One for IMiDs, and a second for non-IMiD products." Under the new policy, hospitals that are not already part of the IMiD limited distribution network are allowed to designate one of the pharmacies already in the existing limited distribution

network for IMiDs as a contract pharmacy to access 340B pricing for those products. Hospitals that choose to access IMiDs at 340B prices at an IMiD-designated specialty contract pharmacy location will submit claim information to BMS directly. The IMiD products in the BMS portfolio are *Revlimid*, *Pomalyst*, and *Thalomid*, which the company assumed when it acquired manufacturer Celgene in Nov. 2019.

- Contract pharmacies that are wholly owned by a hospital also would be exempted from the restriction for non-IMiD products.
- Non-hospital covered entities without in-house pharmacies are similarly limited to one designated contract pharmacy already in the existing limited distribution network for IMiD products, but they can continue receiving non-IMiD drugs at 340B prices for distribution at an unlimited number of contract pharmacies.
- BMS directs hospitals to use the [340B ESP](#) website to designate IMiD and non-IMiD contract pharmacies to continue receiving 340B-discounted drugs after Mar. 1, 2022.
- Eli Lilly (Lilly)
 - Eli Lilly began refusing 340B pricing for three NDCs of the drug Cialis effective July 1, 2020. The company extended this policy to all Lilly products, effective Sep. 1, 2020.
 - Lilly is offering exceptions for hospitals without an in-house pharmacy, insulin products, “wholly owned contract pharmacies,” and, as of Dec. 16, 2021, hospitals that agree to submit contract pharmacy claims data using the 340B ESP platform.
 - Hospitals without in-house pharmacies can designate a single contract pharmacy to obtain 340B pricing for Lilly products. 340B Health members have shared an [exception application form](#) and an [updated exception application form](#) that hospitals can use to apply for this exception. The initial application form grants Lilly authority to enforce 340B provisions beyond those related to duplicate discounts and diversion:
 - Hospitals must comply with all requirements in the 340B statute for drugs purchased under the exception.
 - Hospitals must forgo all other discounts for the same products.
 - Hospitals must agree to repay Lilly for discounts provided in “error.”
 - Hospitals must allow Lilly and/or its auditor to have access to any information necessary for Lilly to audit 340B purchases.

Much of this language has been removed from the updated form. Based on conversations with members, Lilly’s initial application of this exception was limited. Some members reported that Lilly denied exception requests for hospitals with any in-house pharmacy listed as a ship to address on the Office of Pharmacy Affairs Information System (OPAIS), including pharmacies that provide drugs to the hospital’s outpatient settings. Some members have since reported that Lilly will now permit hospitals without an in-house retail pharmacy to designate one contract pharmacy to dispense retail outpatient prescriptions.

 - Lilly is also offering an [exception for some insulin products](#).

- To qualify for the exception a hospital submits claim documentation and agrees to the following conditions:
 - Point of sale price equals the 340B price.
 - No mark-up or fees of any kind were charged.
 - No insurer or payor was billed.
- Lilly directs hospitals interested in qualifying for the insulin exception to complete a [Contract Pharmacy Selection Form](#). The Contract Pharmacy Selection Form includes more detail about the specific claims level data a hospital will be required to submit to Lilly in order to be eligible for this exception.
- The third exception offered by Lilly applies to “wholly owned contract pharmacies,” which Lilly defines as contract pharmacies where both the covered entity and pharmacy are wholly owned by the same common parent entity.
 - The [form](#) to apply for this exception contains some of the same concerning provisions as the original exception form to designate one contract pharmacy when a hospital does not have its own in-house pharmacy.
 - Lilly also requests that a hospital submit an [Excel document](#) with information identifying the wholly owned contract pharmacies where the hospital would like this exception to apply.
- Under the fourth exception, covered entities can access 340B pricing for an unlimited number of contract pharmacy arrangements if they submit all contract pharmacy claims data using 340B ESP.
 - In a Dec. 16, 2021 [letter](#) to covered entities, Lilly said it will “permit 340B purchases by, and distribution through, an unlimited number of contract pharmacies, where the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders.”
 - Lilly directs hospitals interested in this exception to contact Second Sight Solutions, the vendor that operates ESP, at www.340BESP.com
 - Hospitals should be aware that using the ESP platform to submit claims data requires agreeing to its Terms of Use. 340B Health has raised several concerns with the platform’s Terms of Use. See below for more detail.
 - For hospitals that register and provide data for Lilly’s NDCs via ESP on or before Mar. 15, 2022, Lilly will honor contract pharmacy replenishment purchases for prescriptions dispensed to eligible 340B patients on or after Oct. 29, 2021. Replenishment orders for prescriptions dispensed prior to Oct. 29, 2021 will not be honored. Starting on Mar. 16, 2022, all contract pharmacy replenishment orders for all hospitals registered with ESP will be honored for prescriptions dispensed to eligible 340B patients within 45 days of each data submission to ESP.

- Hospitals wishing to work with Lilly on the first three exceptions or that have questions about any of the exceptions should contact 340B@Lilly.com.
- Merck
 - In Aug. 2021, Merck [notified](#) 340B hospitals that, beginning Sep. 1, 2021, Merck will no longer honor 340B discounts or chargebacks for contract pharmacy transactions for hospitals that do not provide data for all 340B contract pharmacy claims through 340B ESP. Merck's policy does not apply to federal grantee covered entities at this time.
 - Merck announced that any hospital that does not anticipate meeting the Sep. 1, 2021 deadline and that does not have an outpatient, on-site dispensing pharmacy can designate a single contract pharmacy site of its choice to be eligible to receive 340B pricing by contacting Second Sight Solutions, the vendor that operates 340B ESP, at www.340BESP.com. Merck directs hospitals to contact 340Bdata@Merck.com with any questions. Hospitals should be aware that using the 340B ESP platform to submit claims data requires agreeing to Terms of Use. 340B Health has raised several concerns with the platform's Terms of Use. See below for more details.
 - Merck previously requested that covered entities begin submitting 340B program claims data by Aug. 14, 2020. Merck's 2020 policy was voluntary for covered entities but Merck warned "[a]bsent significant cooperation from covered entities, Merck may take further action to address 340B program integrity." 340B Health prepared an [in-depth analysis](#) of Merck's initial request for submission of claims data through 340B ESP.
- Novartis
 - Novartis began refusing 340B pricing for drugs dispensed at contract pharmacies that are more than 40 miles away from the hospitals' parent sites, effective Nov. 16, 2020. The policy only applies to hospitals and does not limit the number of contract pharmacies dispensing 340B drugs within the 40-mile radius. Novartis directs hospitals to use the 340B ESP website to identify which contract pharmacies Novartis is permitting to dispense 340B drugs. However, Novartis does not require hospitals to submit data for 340B contract pharmacy claims using the 340B ESP platform in order to continue using contract pharmacies falling under this exception. Alternatively, hospitals can use publicly available tools such as Google Maps or MapQuest to estimate the distance between the parent location and the hospital's contract pharmacy locations to identify pharmacies that may be located outside of the 40-mile radius, though these estimations may differ from Novartis' calculations.
- Novo Nordisk
 - Novo Nordisk announced in a [notice](#) dated Dec. 1, 2020 that it will begin refusing to facilitate bill-to/ship-to distribution of their 340B products to contract pharmacies for 340B hospitals starting Jan. 1, effectively refusing 340B pricing for drugs dispensed at contract pharmacies. The policy does not apply to any non-hospital covered entities. The notice states that a 340B hospital without an "in-house" pharmacy capable of dispensing drugs to outpatients can designate a

single contract pharmacy location to which 340B drugs can be shipped. Based on conversations with members, Novo Nordisk's application of this exception is limited. Some members reported that Novo Nordisk has denied exception requests for hospitals with any in-house pharmacy listed as a ship-to address on OPAIS, including pharmacies that provide drugs to the hospital's outpatient settings. Hospitals are directed to submit questions about the policy to 340Binfo@novonordisk.com.

- Sanofi

- Sanofi began refusing 340B pricing for drugs dispensed at contract pharmacies for hospitals that do not submit data on 340B claims using the 340B ESP platform, effective Oct. 1, 2020. On Feb. 1, 2021, Sanofi announced its [policy](#) only applies to the following covered entity types: consolidated health center programs, critical access hospitals, disproportionate share hospitals, rural referral centers, and sole community hospitals. Sanofi also announced that, beginning Mar. 1, 2021, any provider participating in 340B as one of the five covered entity types listed above that does not have an in-house pharmacy location registered as a shipping address or child site may designate a single contract pharmacy for the entity and its child sites. Sanofi will provide 340B pricing for drugs purchased to be dispensed at this contract pharmacy regardless of whether the covered entity provides data using the 340B ESP platform. Sanofi directs covered entities that wish to qualify for this exception to inform Sanofi of its contract pharmacy selection by Feb. 22, 2021, using the 340B ESP platform in order for the designation to be effective by Mar. 1, 2021. Covered entities should be aware that using the 340B ESP platform to submit claims data requires agreeing to Terms of Use. 340B Health has raised several concerns with the platform's Terms of Use. See below for more detail.

- UCB

- UCB announced in a [notice](#) dated Nov. 22, 2021 that effective Dec. 13, 2021, it would provide its products purchased at the 340B price only to locations registered as a 340B covered entity or child site location. Contract pharmacies will no longer receive "Bill To / Ship To" replenishment orders of 340B priced drugs. UCB's restrictions on 340B pricing for contract pharmacy arrangements do not apply to any non-hospital covered entities.
- Hospitals can apply for two exceptions to the policy using 340B ESP:
 - Any hospital that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location to receive and dispense 340B purchased products. 340B ESP must be used to apply for this exception. Hospitals that have not already registered an account with 340B ESP may make their designation at www.340besp.com/designations. Hospitals should submit their contract pharmacy designation by Dec. 1 for the designation to be effective by Dec. 13, 2021. After Dec. 13, 2021, contract pharmacy designations may take 10 business days to become effective.

- Contract pharmacies that are wholly owned by a 340B hospital, or under common ownership with a 340B health system, may continue to receive “Bill To / Ship To” replenishment orders of 340B priced drugs. These pharmacies must be registered with HRSA as a contract pharmacy of their related 340B hospitals and 340B ESP must be used to apply for this exception at www.340besp.com/wholly_owned_application.
- United Therapeutics
 - United Therapeutics sent covered entities a [notice](#) dated Nov. 18, 2020 announcing it would implement a two-phase policy to restrict covered entities’ purchases of discounted 340B drugs for dispensing at contract pharmacies. Starting Nov. 20, 2020, United Therapeutics accepts orders for 340B drugs dispensed at a contract pharmacy only if the covered entity made a “valid 340B purchase” of one of the company’s covered outpatient drugs for that pharmacy during the first three quarters of 2020. For the first phase, United Therapeutics’ notice indicates that, if a covered entity does not have its own on-site pharmacy, the company will allow the covered entity to designate a single contract pharmacy to receive 340B orders. To apply for this exception, covered entities are directed to contact 340b@unither.com.
 - Under the second phase of its policy, United Therapeutics plans to refuse 340B pricing for drugs dispensed at all contract pharmacies unless the covered entity submits claims data for all 340B contract pharmacy orders of the company’s drugs. United Therapeutics initially planned to implement phase two beginning May 13, 2021, and provided more details on phase two in an [April 12, 2021 notice](#). This notice confirms that United Therapeutics will require covered entities to submit data using the 340B ESP platform in order to maintain access to 340B pricing through contract pharmacy once phase two begins. Covered entities should be aware that using the 340B ESP platform to submit claims data requires agreeing to Terms of Use. 340B Health has raised several concerns with the platform’s Terms of Use. See below for more detail. It is unclear if United Therapeutics will allow a covered entity without an on-site pharmacy to apply for the single contract pharmacy exception during the second phase.
 - The Apr. 12, 2021 notice says “This policy will apply to all United Therapeutics covered outpatient drugs, except for ADCIRCA (tadalafil). It is unclear how United Therapeutics intends for its policy to affect covered entities’ purchases of ADCIRCA (tadalafil). [ADCIRCA \(tadalafil\)](#) is a product marketed by United Therapeutics but manufactured by Eli Lilly and may be impacted by Lilly’s restrictions instead of United Therapeutics’ policy.
 - Subsequently, in a notice dated May 11, 2021, United Therapeutics announced that it was delaying implementation of phase two until Sep. 1, 2021. In a notice dated July 23, 2021, United Therapeutics further delayed implementation of phase two until Dec. 1, 2021.
- Hospital Considerations
 - **340B Health strongly recommends you consult with legal counsel regarding the legal implications of each manufacturer’s exception policy.**

- General Considerations: We have identified several questions and concerns hospitals may want to consider before entering into an agreement with any manufacturer or vendor working on behalf of a manufacturer:
 - Can multiple contract pharmacies participate under Lilly’s insulin exception?
 - How would a hospital operationalize exception policies?
 - Can a hospital change its designated contract pharmacy? If so, how often and what is the process for requesting a change?
 - Will the manufacturer require a hospital to sign a legally binding contract or other document to participate in the exception? If so:
 - Would this impact a hospital’s ability to further challenge the manufacturer’s refusal to offer 340B pricing?
 - Do these legal obligations apply only when purchasing through the contract pharmacy or apply to all hospital 340B purchases from the manufacturer?
 - Would the manufacturer require a hospital to share information that violates state or federal privacy laws or other state or federal laws?
 - Will participation require a hospital to breach other existing contractual obligations, such as to contract pharmacies, third-party administrators, or other vendors?
 - Will participation place any additional burdens or requirements on a hospital?
- 340B ESP: Use of the 340B ESP platform to submit contract pharmacy claims data requires hospitals to accept the service’s Terms of Use. The Terms of Use indicate that they create legally binding obligations on the covered entity and that, by accepting them, the user represents having the authority to enter into the agreement on behalf of the covered entity to provide covered entity claims data. 340B Health has expressed significant concerns with the Terms of Use, as outlined in our [analysis](#) of Merck’s request for hospitals to submit data using 340B ESP.
- 340B Health strongly opposes attacks by manufacturers on 340B hospitals and contract pharmacies and continues to request that the Department of Health and Human Services take enforcement action against manufacturers that refuse to offer 340B pricing for drugs dispensed by contract pharmacies.

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