

Beginning mid-2020, pharmaceutical manufacturers started overcharging covered entities (CEs) on 340B drugs shipped to CE contract pharmacies. This chart serves as a summary and timeline of these manufacturer restrictions.

Updated July 12, 2024

| Manufacturer Name | Type of Restriction | Who it Applies to | Effective Date |
|-------------------|---|----------------------------|---|
| Eli Lilly | <p>Effective July 1, 2024, “Lilly will allow distribution of 340B ceiling-priced product directly to covered entities and their child sites only. Wholly-owned and affiliated contract pharmacies will no longer be eligible recipients for distribution or Bill To/Ship To replenishment orders.” Refusing 340B pricing for drugs dispensed at contract pharmacies; recent changes allow 340B pricing if CEs submit contract pharmacy claims data. Any covered entity that doesn’t have an in-house pharmacy can choose a single location contract pharmacy. UPDATE: Need to submit data to ESP to get 340B pricing at one contract pharmacy. All CE’s with or without an in-house patient pharmacy must designate one contract pharmacy location to bill to/ ship Lilly 340B priced drugs. Lilly recognizes all sites as one covered entity. CE’s must register one single contract pharmacy designation and voluntary data</p> | All covered entities (CEs) | <p>Most recent restriction: July 1, 2024 Older restrictions: November 16, 2023 September 1, 2020</p> |

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| | submission by November 13, 2023, via 340BESP.com | | |
| AstraZeneca | <p>Effective August 1, 2023, Refusing 340B pricing for drugs dispensed at contract pharmacies. May designate a single contract pharmacy but each parent site can have one pharmacy site for itself.</p> <p>UPDATE: Moves admin of 340B contract pharmacy program to 340B ESP. Covered entities without an on-site dispensing pharmacy will need to select a single contract pharmacy location using the 340B ESP portal.</p> | All CEs | <p>Updated restriction effective: August 1, 2023</p> <p>Original restriction: October 1, 2020</p> |
| Sanofi | <p>Effective July 1, 2024, “Covered entities will continue to be able to purchase Sanofi products at the 340B ceiling price when shipped to an in-house retail pharmacy at an address registered on the 340B covered entity database as a parent or child site. These entities will not be able to place 340B orders at any contract pharmacies.</p> <p>NEW for hospitals: Refusing to ship 340B-priced drugs to contract pharmacies regardless of data submission to 340B ESP. If a CE lacks an in-house, can select 1 contract pharmacy. Doesn’t affect CHCs.</p> | 5 CE types: Consol, CHC, CAH, DSH, RRC, SCH | <p>New Restriction Effective: July 1, 2024</p> <p>NEW for hospitals: Effective June 1, 2023</p> <p>October 1, 2020</p> |

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| | <p>Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that doesn't have an in-house pharmacy can choose a single location contract pharmacy. If submitting data to 340B ESP, can choose unlimited contract pharmacies.</p> <p>UPDATE: Must designate one single contract pharmacy and submit claims via 340B ESP to access 340B pricing at the designated contract pharmacy. No redesignation required but must submit claims data to retain access to 340B pricing at designated contract pharmacy. All sites together are considered one covered entity which includes covered entity's parent site, child sites, and associated sites. Covered entities within the consolidated health center program must redesignate their one contract pharmacy through 340B ESP platform to continue receiving access to 340B pricing at that contract pharmacy.</p> | | |
| Novartis | <p>Effective March 20, 2024, UPDATE: Will exempt arrangements by Arkansas hospital-covered entities with Arkansas-based community pharmacies from current contract pharmacy policy. effective March 20, 2024. Refusing 340B pricing for drugs shipped to contract pharmacies more</p> | Hospitals only | November 16, 2020 Withdrawal of AR Restrictions Effective March 20, 2024: |

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| | <p>than 40 miles away from hospitals' parent sites</p> | | |
| <p>Novo Nordisk</p> | <p>Effective: July 1, 2024. UPDATE: All covered entities can designate a maximum of two total contract pharmacies; however, Novo Nordisk must approve all designations. Grantee CEs can use an unlimited number of contract pharmacies if they provide claims data on a timely basis for 340B dispenses at that specific contract pharmacy via ESP. In order to have the CP designation effective in time for July 1, the designation must be submitted to the ESP platform by June 23, 2024. Novo Nordisk will continue to collect claims data to ensure proper use of the 340B program.</p> <p>Will <u>not allow</u> hospitals to get 340B-priced drugs to unlimited contract pharmacies even if submitting to 340B ESP.</p> <p>Previously, allowed hospitals to <u>designate two contract pharmacies to receive 340B drugs</u> (one specialty, one regular). Will allow contract pharmacy bill to/ship to designations (one retail and/or one specialty) for all hospital CEs <u>within Arkansas</u>. Will also bill to/ship to orders to an unlimited number of both wholly and non-wholly owned contract pharmacies within</p> | <p>All CEs</p> | <p>Newest Restrictions: Effective: July 1, 2024.</p> <p>January 1, 2021 <u>New restrictions effective July 1, 2023</u></p> <p>Withdrawal of AR Restrictions: Effective February 1, 2024</p> |

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| | Arkansas that provides claims level data associated with 340B dispenses made by those contract pharmacies. | | |
| United Therapeutics | <p>Phase 1: Orders for contract pharmacy drugs accepted only if CE made a “valid 340B purchase” during first three quarters of 2020.</p> <p>Phase 2: Then, refusing 340B pricing for drugs dispensed at all contract pharmacies, unless CE submits claims data.</p> | All CEs | <p>Phase 1: November 20, 2020</p> <p>Phase 2: December 1, 2021</p> |
| Boehringer Ingelheim | <p>Effective August 1, 2023, UPDATE: BI will no longer provide drugs at the 340B price on drug shipments to contract pharmacies. Any CE that doesn’t have an in-house pharmacy can choose one contract pharmacy receive 340B drugs located within 40 miles of the parent site; cannot be a central fill pharmacy. Any CE that doesn’t have an in-house pharmacy capable of dispensing specialty drugs may also designate one (1) specialty pharmacy from within BI’s network to only dispenses OFEV at the 340B price to its patients. CEs must take action by July 14, 2023, to either designate or re-designate the single contract pharmacy location.</p> <p>Will ship 340B drugs only to CEs and their child sites. Any covered entity that does not have an in-house pharmacy</p> | Hospitals, CHCs | <p>New restrictions: Effective August 1, 2023</p> <p>As of September 1, 2022: Includes health centers</p> <p>Original restrictions: August 1, 2021</p> |

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| | <u>can choose one contract pharmacy to receive 340B drugs.</u> | | |
| Merck | <p><u>Update:</u> Effective July 12, 2023 no longer restricts 340B drugs in Louisiana or Arkansas. An in-house pharmacy <u>can elect one contract pharmacy at a single location.</u></p> <p><u>NEW:</u> Will not allow multiple contract pharmacies to receive discounts even if CE submits data to 340B ESP. If a CE lacks an in-house pharmacy, can select 1 contract pharmacy within 40 miles of its parent site. Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted.</p> | Hospitals, CHCs | <p>Newest restrictions: Effective June 12, 2023</p> <p>Original restrictions: September 1, 2021 As of May 31, 2022: Includes health centers</p> |
| UCB | <p>Effective October 2, 2023 UPDATE: Contract Pharmacies that are owned by a CE or under common ownership by a CE Health system can be designated as a CE's single contract pharmacy but <i>will no longer be separately eligible to receive 340B pricing.</i> The single contract pharmacy location by CE without in-house pharmacy must be located within 40 miles of the CE parent site. 340B contracts administered by UCB wholesalers will no longer support provision of drugs purchased at the 340B discount price to contract pharmacies under UCB's prior policy after October 2, 2023.</p> | Hospitals only | <p>Newest restrictions: Effective October 2, 2023</p> <p>Original restrictions: December 13, 2021</p> |

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| | <p>Will provide 340B priced drugs to locations registered as 340B covered entities or child sites. Any covered entity that does not have an in-house pharmacy can elect one contract pharmacy at a single location.</p> | | |
| <p>Amgen</p> | <p>Effective March 19, 2024, Federal grantees will no longer be able to place bill to/ship to orders purchased at the 340B price for multiple contract pharmacies. Grantees must designate a contract pharmacy by March 5th. PHS contracts administered by Amgen wholesalers will no longer support the distribution of drugs purchased at 340B price to the 340B contract pharmacies after March 19.</p> <p><u>Update:</u> Conditions have been placed on 340B sales and deliveries to covered entity in-house pharmacies. A hospital must designate a pharmacy by March 27.</p> <p>If you do not have an in-house pharmacy, you can pick ONE contract pharmacy, AND you must share claims data AND the pharmacy must be within 40 miles of the parent.</p> <p>If you do have an in-house pharmacy, same rules (one pharmacy within 40 miles and must share data).</p> <p><u>UPDATE:</u> Contract pharmacy arrangements between 340B covered</p> | <p>Hospitals, grantees</p> | <p>Newest restrictions: Effective March 19, 2024</p> <p>Start of original restrictions: January 3, 2022</p> <p>Further restrictions: Effective April 11, 2023</p> <p>Withdrawal of AR Restrictions: Effective April 2, 2024</p> |

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| | entities in Arkansas and pharmacies in Arkansas are exempt from Amgen's 340B contract pharmacy policy. | | |
| AbbVie | <p>Effective May 1, 2024, <u>Update</u>: Adds Venclexta (an oral therapy to help fight certain blood cancers) to 340B list prohibited bill to/ship to orders for all hospital covered entities.</p> <p>Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy can elect one contract pharmacy at a single location.</p> | Hospitals only | <p>Newest Restrictions: Effective May 1, 2024</p> <p>Original restrictions: February 1, 2022</p> |
| Pfizer | <p>Effective November 1, 2023, <u>Update</u>: Adds 15 more medications to the limited contract pharmacy distribution . CEs that do not have an in-house pharmacy can make their single contract pharmacy designation by October 20, 2023, at 340besp.com.</p> <p>Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy can elect one contract pharmacy at a single location (single HIN)</p> | Hospitals only | <p>New Restrictions: Effective November 1, 2023</p> <p>Original restrictions: March 1, 2022</p> |

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| <p>Bristol Myers Squibb</p> | <p>Effective July 1, 2024, Refusing 340B pricing for “non-IMiD” (Immunomodulatory imide drug) products dispensed at contract pharmacies; modifying access to 340B pricing under IMiD limited distribution network. UPDATE: Covered Entities will need to submit claims data for one designated contract pharmacy for non-IMiDs. Redesignation must be submitted by 6/21/2024.</p> <p>Update: Arkansas-covered entities may use any contract pharmacies properly licensed by Arkansas State Board of Pharmacy to dispense 340B-eligible covered outpatient drugs. REMS requirements stay in place.</p> <p>Previously allowed up to 2 contract pharmacies (one for non-IMiDs, another for IMiDs).</p> <p>UPDATE: Will recognize up to three contract pharmacies (one for Non-IMiDs, one for IMiDs, and one for Camzyos) for each CE. Only one 340B purchase on a single eligible IMiD prescription allowed.</p> | <p>Hospitals for non-IMiDs; All CEs for IMiDs</p> <p>Update: All grantees Update: Arkansas covered entities</p> | <p>Newest Restriction: Effective July 1, 2024</p> <p>Withdrawal of AR Restrictions: Effective March 28, 2024</p> <p>Original restrictions: March 1, 2022; November 1, 2023</p> |
| <p>GlaxoSmithKline</p> | <p>Effective May 1, 2023 Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data</p> | <p>Hospitals, all grantees</p> | <p>Newest restrictions: Effective May 1, 2023</p> |

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| | <p>are not submitted. Any covered entity that does not have an in-house pharmacy may designate one contract pharmacy location (single HIN) to have drugs shipped to. Applies to all drugs (especially impacts inhalers and certain HIV drugs).</p> <p>UPDATE: Prohibition of unlimited contract pharmacies for all CE's. Claims data is no longer a requirement under GSK's policy. CEs without an in-house outpatient pharmacy must designate one contract pharmacy location. CE's unable to dispense specialty/oncology will restrict 340B pricing on of blood cancer products must designate one specialty pharmacy for each of GSK's limited pharmacy network products.</p> <p>Update: Restrictions extend to Ojjaara, a cancer drug.</p> <p>UPDATE: Effective November 1, 2023, covered entities in Arkansas and Louisiana will be able to get 340B-priced drugs at contract pharmacies.</p> | | <p>Original restrictions: April 1, 2022</p> |
| <p>Gilead</p> | <p>Effective May 2, 2022, Refusing 340B pricing for brand-name Hepatitis C drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location. Likewise, this update does not apply to</p> | <p>All CEs</p> | <p>May 2, 2022</p> |

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| | contract pharmacies that are wholly owned by a covered entity or health system. | | |
| Johnson & Johnson | <p>Effective March 7, 2023, <u>UPDATE:</u> J&J has placed conditions on 340B sales and deliveries to covered entity in-house pharmacies. A hospital must designate a pharmacy by February 26; they define outside pharmacy as “a Ship To location that is not part of the Bill To purchaser”; If you do not have an in-house pharmacy, you can pick ONE pharmacy, AND you must share claims data AND the pharmacy must be within 40 miles of the parent. If you do have an in-house pharmacy, same rules (one pharmacy within 40 miles and must share data). Can also select a single specialty pharmacy for specialty drugs.</p> <p>Refusing 340B pricing for drugs dispensed at contract pharmacies; specifically: immunosuppressants, monoclonal antibodies, blood thinners, and treatments for diabetes, cancer, HIV, mental disorders, pulmonary arterial hypertension, and chemotherapy-induced anemia. If they choose not to submit data, <u>may still designate a single contract pharmacy location</u> (single HIN).</p> | Hospitals only | <p>New restrictions: Effective March 7, 2023</p> <p>Original restrictions: May 2, 2022</p> |
| Exelixis | Effective July 1, 2024, <u>Latest Update:</u> Covered Entities may only utilize | Hospitals only; grantees exempt “until further notice” | New restrictions: |

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| | <p>contract pharmacy “Bill To/Ship To” arrangements that are with “affiliated contract pharmacies (wholly owned CPs & under common ownership)” of the covered entity. Federal grantees are exempt, but claims data must be submitted by June 21, 2024 for all contract pharmacy dispenses. A CE that does not have an in-house pharmacy or an affiliated contract pharmacy capable of dispensing 340B drugs may designate 1 contract pharmacy for delivery of 340B priced drugs Refusing 340B pricing for drugs dispensed at contract pharmacies, specifically Cometriq and Cabometyx (cancer drugs). If they choose not to submit data, may still designate a single contract pharmacy location (single HIN).</p> <p>UPDATE: Extends 340B restrictions to contract pharmacies that are wholly-owned or under common ownership with a covered entity.</p> | | <p>Effective July 1, 2024 Original restrictions: July 6, 2022</p> |
| Bausch Health | <p>Effective July 1, 2024, UPDATE: Will only ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or child site location affiliated with that covered entity. If CE doesnt have an in-house pharmacy capable of dispensing 340B purchased products, CE may designate one contract pharmacy located within 40 miles of the CE</p> | All CEs | <p>Newest Restrictions: Effective July 1, 2024 Original restrictions: August 1, 2022 Older restrictions: Effective June 26, 2023</p> |

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| | <p>parent site. Designations must be made through 340B ESP. Any CE that submits claims will not be eligible to continue to bill to/ship to replenishment orders for each of its contract pharmacies but will be limited to one designated contract pharmacy. PHS contracts administered by Bausch wholesalers will no longer support distribution of 340B purchased drugs to non-designated 340B contract pharmacies after June 30, 2024.</p> <p>Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy can elect one contract pharmacy at a single location (single HIN).</p> <p><u>UPDATE:</u> Extending its conditions on 340B pricing to contract pharmacies that are wholly owned or under common ownership with a hospital covered entity. Any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location within 40 miles of the covered entity.</p> | | |

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| <p>Biogen</p> | <p>Effective March 15, 2024: Exempts Arkansas Covered Entities using Arkansas contract pharmacies from previous restriction policy. Refusing 340B pricing for drugs, specifically Avonex and Plegridy (which treat multiple sclerosis), dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy can designate one contract pharmacy location (single HIN) to have drugs shipped to.</p> | <p>Hospitals only UPDATE: Exempts Arkansas covered entities</p> | <p>Withdrawal of AR Restrictions: Effective March 15, 2024</p> <p>Original restrictions: February 1, 2023</p> |
| <p>Bayer</p> | <p>Effective June 1, 2023 UPDATE: Hospitals that lack an in-house pharmacy can designate one contract pharmacy location within 40 miles of the hospital parent site. Bayer will no longer let hospitals place replenishment orders for multiple contract pharmacies in exchange for submitting 340B claims to 340B ESP for Bayer drugs. Hospitals may voluntarily provide claims data for their single designated contract pharmacy through 340B ESP. Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy can designate one contract</p> | <p>Hospitals only</p> | <p>New restrictions: Effective June 1, 2023</p> <p>Original restrictions: March 1, 2023</p> |

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| | <p><u>pharmacy (single HIN)</u> to have drugs shipped to. Drugs excluded from this restriction, for now, include: Adempas, Aliqopa, Jivi, Kerendia, Kogenate, Kovaltry, Kyleena, Lampit, Mirena, Skyla, Nubeqa, Xofigo.</p> | | |
| <p>EMD Serono</p> | <p>Effective October 1, 2023 <u>UPDATE:</u> Extending its restrictions to ALL medications. If a hospital CE is granted an exemption for its wholly/commonly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy, except with respect to 340B purchases of <i>Serostim</i>. 340B CEs that do not have an in-house pharmacy and have not already registered an account with 340B ESP™ www.340besp.com/designations. Refusing 340B pricing for drugs, specifically Refib (interferon beta-1a) and Gonal-f (follitropin alfa for injection), dispensed at contract pharmacies if 340B contract pharmacy claims data are not submitted. Any covered entity that does not have an in-house pharmacy can <u>designate one contract pharmacy location (single HIN)</u> to have drugs shipped to.</p> | <p>Hospitals only</p> | <p>New Restrictions: October 1, 2023</p> <p>Original restrictions: March 1, 2023</p> |

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| Organon | <p>Effective December 1, 2023, UPDATE: covered entities in Arkansas and Louisiana will be able to receive 340B-priced drugs to an unlimited number of contract pharmacies provided claims level data is submitted via 340B ESP for these pharmacies. Refusing 340B pricing for drugs dispensed at contract pharmacies if 340B contract pharmacy claims aren't submitted. Any covered entity that doesn't have an in-house pharmacy can <u>designate one contract pharmacy location (single HIN)</u> to have drugs shipped to.</p> | Hospitals only | <p>Newest Restrictions: December 1, 2023</p> <p>Original restrictions: July 1, 2023</p> |
| Teva | <p>Effective November 6, 2023 UPDATE: Austedo and Austedo XR product families are now a part of 340B Program Integrity Initiative. Refusing 340B pricing for drugs dispensed at contract pharmacies. Affected drugs include Copaxone, Ajoyv, and Treanda. Any covered entity that doesn't have an in-house pharmacy can <u>designate one contract pharmacy location (single HIN)</u> within 40 miles of its parent site to have drugs shipped to and must submit claims data. 340B discounted products will only be shipped to the in-house outpatient pharmacy. Designation of new pharmacy must be made by June 18, 2023.</p> | Hospitals only | <p>Newest restrictions: November 6, 2023</p> <p>Original restrictions: July 5, 2023</p> <p>Older restrictions: September 26, 2023</p> |

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| | <p>UPDATE: Effective September 26, 2023, allows shipment/delivery of 340B drugs to unlimited number of contract pharmacies in Arkansas; ended restrictions in Louisiana as well in July 2023.</p> | | |
| <p>Astellas</p> | <p>Effective: May 1, 2024, Update: Will no longer facilitate bill to/ ship to orders of Myrbetriq (treats overactive bladder) at the 340B discount price to contract pharmacies. Federal grantee covered entities are excluded from this policy change. Covered entities in Arkansas and Louisiana will be able to bill to/ ship to orders of Myrbetriq products at 340B discount price to an unlimited number of contracts pharmacies location within each respective state.</p> <p>Refusing 340B pricing, specifically for its prostate cancer drug Xtandi, to contract pharmacies. Any covered entity that doesn't have an in-house pharmacy can <u>designate one single contract pharmacy location (single HIN)</u> and must submit claims data.</p> <p>340B discounted products will only be shipped to the in-house outpatient pharmacy. Designation of new</p> | <p>Hospitals only</p> | <p>New Restriction effective: May 1, 2024</p> <p>Original restrictions: September 1, 2023</p> |

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| | <p>pharmacy must be made by August 18, 2023. Effective October 17, 2023, will facilitate orders of Xtandi products at 340B price to an unlimited number of contract pharmacies located within the states of Arkansas and Louisiana.</p> | | |
| Jazz Pharmaceuticals | <p>Effective October 9, 2023, Refusing 340B pricing specifically for Epidiolex products, dispensed at contract pharmacies. CE that has a contact pharmacy either wholly or commonly owned, must use wholly owned pharmacy as the single contract pharmacy or designate one contract pharmacy location by September 29, 2023 at 340B ESP.</p> | Hospitals only | October 9, 2023 |
| Incyte | <p>Effective October 16, 2023, Refusing 340B pricing for Opzelura dispensed at contract pharmacies. CE without an in-house outpatient pharmacy may designate one contract pharmacy location within 40 miles of CE parent site. CE without an in-house outpatient pharmacy, must designate one contract pharmacy location by October 6, 2023, at 340B ESP. If CE can't identify an eligible contract pharmacy, Incyte will</p> | Hospitals only | October 16, 2023 |

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| | work with CE to find a suitable alternative. | | |
| Eisai | Effective November 1, 2023 , Refusing 340B pricing for drugs dispensed at contract pharmacies. CE will no longer be able to place orders to bill to/ship to Eisai-covered outpatient drugs for delivery to CPs. CEs without an in-house outpatient pharmacy must designate one contract pharmacy location by October 22, 2023, at 340B ESP . | Hospitals only | November 1, 2023 |
| Sandoz | Effective December 1, 2023 , Covered entity hospitals must designate 1 contract pharmacy location within 40 miles of the CE parent for shipment of listed products at the 340B price . If CE lacks both in-house or wholly owned pharmacy, Sandoz and its vendor will work with CE to identify an appropriate contract pharmacy to dispense covered outpatient drugs. Visit 340besp.com to designate a single contract pharmacy before December 1, 2023. | Hospitals only | December 1, 2023 |

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| Takeda | <p>Effective January 22, 2024, Refusing 340B-priced drugs (<i>Entyvio Pen, Entyvio IV, Trintellix, Motegrity, Mydayis, Dexilant, Adderall XR, Pentasa, and Vyvanse</i>) to hospital covered entity contract pharmacies. Any CE without in-house pharmacy may designate a single independent contract pharmacy location OR its wholly owned contract pharmacy(ies) <i>within 40 miles of the CE parent site</i>, to get 340B priced products. CE's must provide claims data through 340B ESP for the designated single contract pharmacy or wholly owned contract pharmacy(ies) to receive 340B discounted pricing.</p> | Hospitals only | January 22, 2024 |
| Liquidia | <p>Effective April 1, 2024, Refusing 340B pricing of <i>Yutrepia (treprostinil)</i> at covered entity contract pharmacies. Any covered entity that does not have an in-house pharmacy may designate a single Accredo or Caremark/CVS Specialty contract pharmacy location. The covered entity must agree to provide claims data for the designated single contract pharmacy within 45 days of the date of dispense. The 340B ESP platform will be used to support this designation and claims submission.</p> | All CEs | April 1, 2024 |

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| Genentech | <p>Effective May 1, 2024, Will limit 340B priced drugs exclusively to a single contract pharmacy and locations registered as a 340B covered entity or child site with affiliated covered entity. This change is applicable to medicines adjudicated through a retail or specialty pharmacy and will not apply to <i>Hemlibra</i> and <i>Evrysdi</i>. Voluntary submission of claims is encouraged to support program transparency.</p> | Hospitals only | May 1, 2024 |
| Sumitomo Pharma | <p>Effective May 1, 2024, Will provide 340B price for APTIOM®, GEMTESA®, MYFEMBREE®, and ORGOVYX® brands exclusively to locations registered as a 340B covered entity. A contract pharmacy beyond the 40-mile radius may be used if the covered entity shows it either lacks an in-house pharmacy or there is no contract pharmacy capable of purchasing and dispensing the above drug within a 40-mile radius provided the contract pharmacy selected is not a centralized pharmacy replenishment facility or “central-fill pharmacy”. PHS contracts administered by SMPA wholesalers will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after April 30, 2024.</p> | All CEs | May 1, 2024 |

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| Vertex Pharmaceuticals | <p>Effective July 1, 2024, Will no longer facilitate “Bill To/Ship To” replenishment orders of Cystic Fibrosis products purchased at the 340B discount for hospital-covered entities for contract pharmacies. Hospitals are permitted to designate 1 single contract pharmacy location if CE doesn’t have an in-house outpatient pharmacy by June 17th, 2024 to dispense 340B priced covered outpatient drugs. As of July 1, 2024, This contract pharmacy policy does not apply to federal grantees or CEs registered in the OPAIS database located in Arkansas, Kansas, Louisiana, Maryland, Mississippi, or West Virginia.</p> | Hospitals only | July 1, 2024 |
| Sobi | <p>Effective July 1, 2024, Refusing to “Bill to/Ship To” replenishment orders of Doptelet, Kineret, and Vonjo to all covered entities’ contract pharmacies. Covered entities can designate 1 contract pharmacy within 40 miles of parent site if there is not an in-house pharmacy available. Designations must be made by June 21, 2024; no data submission required. Effective July 1, 2024, Sobi will ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or child site location affiliated with that covered entity.</p> | All CEs | July 1, 2024 |

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| Alkermes | <p>Effective July 22, 2024, Alkermes will <u>limiting</u> distribution of 340B-priced product to locations registered as a 340B covered entity (including its child sites) for dispensing through the CE's in-house pharmacy to its patients consistent with the 340B statute. CEs without an in-house pharmacy can designate one single contract pharmacy (registered in OPAIS database) to receive <u>Alkermes' products</u> purchased at 340B price. Contract Pharmacy designation must be made by June 21, 2024, and all child sites must use the parent site's contract pharmacy for distribution. Exceptions in AR, LA, and WV - may direct shipment of Alkermes' products purchased at 340B price to contract pharmacies within state and registered as a contract pharmacy of the said state's CE in OPAIS. Voluntarily submit claims data for all Alkermes' products purchased under the 340B program within 45 days after the dispense date via 340B ESP.</p> | All CEs | July 22, 2024 |

| Manufacturer Name | Type of Restriction | Who it Applies to | Effective Date |
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| Bausch + Lomb | Effective July 1, 2024 , Bausch & Lomb <u>will</u> ship products purchased at the 340B price exclusively to locations registered as a 340B covered entity or child site location affiliated with that covered entity. If CE doesn't have an in-house pharmacy capable of dispensing 340B purchased products, CE may designate one contract pharmacy located within 40 miles of the CE parent site. Designations must be made through 340B ESP. Any CE that submits claims will not be eligible to continue to bill to/ship to replenishment orders for each of its contract pharmacies but will be limited to one designated contract pharmacy. PHS contracts administered by Bausch wholesalers will no longer support distribution of 340B purchased drugs to non-designated 340B contract pharmacies after June 30, 2024. | All CEs | New Restriction: Effective July 1, 2024 |
| Viatrix | Effective August 1, 2024 , Viatrix will ship applicable products exclusively to locations registered in the 340B OPAIS database as a covered entity, a child site location, or as a contract pharmacy location. Viatrix will permit covered entities without an in-house pharmacy to designate a single contract pharmacy location to receive bill to/ship to orders of applicable products at the 340B price. Covered entities must designate their single contract pharmacy location | Hospitals, CHCs | New Restrictions Effective: August 1, 2024. |

| Manufacturer Name | Type of Restriction | Who it Applies to | Effective Date |
|--------------------------|---|--------------------------|-----------------------|
| | <p>via the 340B ESP platform. Designations must be made by July 19, 2024, in order for the designation to take effect on the effective date of this policy change. Viatris will permit covered entities to change their designation once every twelve months, or upon the expiration of the contract between the covered entity and single-designated contract pharmacy. This policy change will not apply to contract pharmacy arrangements in AR, LA, WV, MS, KS, MD, and MD.</p> | | |