

Notice to 340B and Non-340B End Customers Regarding Updates to 340B Delivery Limitations

February 15, 2023

This notice is to inform all end customers—both 340B customers and non-340B customers—of updates to Johnson & Johnson Health Care Systems Inc.’s (JJHCS) policy regarding Bill To/Ship To orders. Our updated policy will take effect on March 7, 2023. The updated policy will impact Bill To/Ship To orders involving contract pharmacies used by non-grantee 340B Covered Entities, subject to exceptions described below.¹ This policy supersedes the policy announced on March 21, 2022.

Except as permitted by this Policy, no end customer will be permitted to direct shipment or delivery of product to a Ship To location that is not part of the Bill To purchaser. The updated policy will apply to all end customers—both 340B and non-340B—and to all of the JJHCS products set out in Attachment A. All Johnson & Johnson companies participating in the 340B Program are subject to the policy.

Consistent with the 340B statute, JJHCS will continue to offer 340B covered outpatient drugs to all Covered Entities at the HRSA registered locations for those entities² or other locations designated in accordance with JJHCS’ policy as described further below. Subject to the exceptions described below that permit Bill To/Ship To transactions by 340B Covered Entities, customers may not direct delivery to contract pharmacies as Ship To locations.

JJHCS continues to be committed to the 340B Program and to supporting access to care for patients in need. We also believe it is important to further improve 340B Program Covered Entity and contract pharmacy integrity and compliance to ensure the 340B Program’s long-term sustainability. We believe that this policy will help to reduce diversion and inappropriate claims for discounts and rebates.

Effective March 7, 2023, JJHCS will implement the following requirements with respect to exceptions under this policy:

- If a non-grantee Covered Entity³ does not have an in-house pharmacy, such Covered Entity may designate a single contract pharmacy location registered on the HRSA OPAIS database for delivery of 340B-priced covered outpatient drugs listed on Attachment A if (i) the Covered Entity provides limited claims data with respect to that contract pharmacy location and (ii) that single contract pharmacy location is within 40 miles of the Covered Entity parent site.
- If a non-grantee Covered Entity does have an in-house pharmacy, that Covered Entity may designate a single contract pharmacy registered on the HRSA OPAIS database for delivery of 340B-priced covered outpatient drugs listed on Attachment A if (i) the Covered Entity provides limited claims data for both that contract pharmacy location and the in-house pharmacy and (ii) that single contract pharmacy location is within 40 miles of the Covered Entity parent site.

¹ Grantee Covered Entities may continue to use an unlimited number of contract pharmacies under our updated policy.

² Covered Entity registered locations include both the HRSA registered parent and child site locations.

³ Non-grantee covered entities are eligible to participate in the 340B program under 42 U.S.C. § 256(b)(4)(L)-(O).

- Covered Entities that receive grants from the Health Resources and Services Administration (HRSA) may continue to use an unlimited number of contract pharmacies, without providing limited claims data.⁴

In addition, for our pulmonary arterial hypertension covered outpatient drugs⁵ that are included in Attachment A, non-grantee Covered Entities may place orders for such drugs through a single specialty pharmacy location that is part of that limited distribution system, if they provide the requested limited claims data for this specialty pharmacy location. If a non-grantee Covered Entity chooses to participate in this exception, the entity must designate a single specialty pharmacy location approved for the limited distribution of Janssen PAH Products and provide the requested limited claims data. This specialty pharmacy location for PAH products may be in addition to a contract pharmacy designation for non-PAH products. Grantee Covered Entities may continue to order such drugs through a specialty pharmacy at any location that is part of our pre-existing limited distribution program⁶ for those drugs, without providing the requested limited claims data.

The updated policy will continue to include claims data submission requirements.⁷ Under the updated policy, a non-grantee 340B Covered Entity may elect to submit claims data for the one contract pharmacy location of their choice to be eligible to receive 340B discounts for certain products with a Ship To location of that contract pharmacy location. Claims must be submitted within 45 days of dispense to the patient. Claims submitted outside the 45-day window will be considered non-conforming claims. Further, only the contract pharmacy location associated with the submitted claims will be eligible for 340B discounts, not related or affiliate contract pharmacies.

Non-grantee Covered Entities must take action by February 26, 2023 (regardless of whether the Covered Entity is currently submitting limited claims data) in order for its eligible contract pharmacy location designation to take effect on the effective date of this policy update.

Under this updated policy, subject to the exceptions described above, wholesalers and distributors will be required to ensure that all end customers – 340B or non-340B – do not direct shipment or delivery to a Ship To location that is not part of the Bill To entity.

Instructions for how 340B Covered Entities may access these exceptions are provided in Attachment B to this notice.

This updated policy will apply to the JJHCS products listed in Attachment A to this notice, and to any newly introduced or other JJHCS covered outpatient drugs when added to Attachment A at a later date. **Wholesalers and distributors have been instructed to implement this policy beginning on March 7, 2023.**

Please contact us by email at 340B_JJHCS@its.jnj.com with any questions or with requests for additional information.

⁴ Grantee covered entities are eligible to participate in the 340B program under 42 U.S.C. § 256(b)(4)(A)-(K).

⁵ The following are our current PAH covered outpatient drugs included on Attachment A: Opsumit (macitentan), Tracleer (bosentan), Upravi (selexipag), and Veletri (epoprostenol).

⁶ HRSA has reviewed that program notice and posted it on its website, demonstrating that the program is permitted under applicable law and guidance. HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-11 (May 23, 2012) (stating “If OPA has concerns about the allocation plan, it will work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the HRSA/OPA website”).

⁷ This data will be used to identify duplicate discounts and diversion that we could not identify without this data.

ATTACHMENT A

All of the following products are subject to the updated policy effective March 7, 2023:

STELARA®
TREMFYA®
SIMPONI ARIA®
SIMPONI®
REMICADE®
XARELTO®
INVOKAMET®
INVOKAMET® XR
INVOKANA®
DARZALEX®
DARZALEX FASPRO®
ERLEADA®
INVEGA HAFYERA™
INVEGA SUSTENNA®
INVEGA TRINZA®
INVEGA®
OPSUMIT®
UPTRAVI®
TRACLEER®
VELETRI®
SYMTUZA®
PREZCOBIX®
PREZISTA®
ZYTIGA®
PROCRIT®
EDURANT®
ELMIRON®
TOPAMAX®
YONDELIS®
RYBREVANT®

Our policy will also apply to any newly introduced or other JJHCS covered outpatient drugs when added to this Attachment at a later date. As the list above may be updated from time to time, end customers may also access the complete list of NDCs by accessing [What NDCs do we look for? | 340B ESP - Help Center](#). See <http://help.340besp.com/en/articles/4455011-what-ndcs-do-we-look-for>.

ATTACHMENT B

INSTRUCTIONS FOR EXERCISING POLICY EXCEPTIONS

Instructions for Grantees

Grantees may continue to use an unlimited number of contract pharmacies, without providing limited claims data. Grantees may order and direct delivery of products as they did previously.

Instructions for Covered Outpatient Drugs Not on Attachment A

Covered Entities may continue placing Bill To/Ship To orders involving contract pharmacies, without providing limited claims data, for covered outpatient drugs not covered by the program (i.e., drugs not listed in Attachment A).

Instructions for Non-Grantees Submitting 340B Claims & Designating a Single Contract Pharmacy Location

Non-grantee 340B Covered Entities without an in-house pharmacy may designate a single contract pharmacy location registered on the HRSA OPAIS database if (i) the Covered Entity provides limited claims data with respect to that contract pharmacy location and (ii) that single contract pharmacy location is within a 40 mile radius of the Covered Entity parent site. Non-grantee Covered Entities with an in-house pharmacy may designate a single contract pharmacy location registered on the HRSA OPAIS database if (i) the Covered Entity provides limited claims data for both that contract pharmacy location and the in-house pharmacy and (ii) that single contract pharmacy location is within a 40 mile radius of the Covered Entity parent site.

For a non-grantee Covered Entity's eligible contract pharmacy location to take effect on March 7, 2023 (which is the effective date of this policy update), the non-grantee Covered Entity must take action by February 26, 2023 regardless of whether the Covered Entity is currently submitting limited claims data. Beginning on February 27, 2023, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

Non-grantee Covered Entities that elect to designate a contract pharmacy location and to submit claims data will utilize 340B ESP™. Non-grantee Covered Entities that wish to submit 340B claims can do so by registering an account at www.340besp.com. Users that have registered an account with 340B ESP™ can designate a contract pharmacy location by visiting <http://www.340besp.com/designations> and can submit the specified 340B claims data for Janssen by navigating to the Claims Data Submission tab. All 340B claims must be submitted within 45 days of the date of dispense in order for the contract pharmacy location to remain eligible to receive 340B purchased drugs. If purchases through this contract pharmacy location exceed claims submitted that are conforming to this policy, the contract pharmacy location is at risk of having eligibility to receive 340B purchased drugs removed.

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340besp.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes about 15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP™ and submit your 340B contract pharmacy claims data twice monthly. Once your account is set up, the claims upload process takes about 5 minutes. For further help with the registration, account setup, and data submission process you can contact Second Sight Solutions at 888-398-5520.

Instructions for PAH Products

Our pulmonary arterial hypertension (PAH) covered outpatient drugs,⁸ which are already subject to a limited distribution plan that has been reviewed and posted by HRSA, will continue to be available at the 340B price to all 340B Covered Entities that place orders through a single designated specialty pharmacy at a location that is part of that limited distribution system.⁹

Grantee Covered Entities may continue to place orders through a specialty pharmacy at any location that is part of that limited distribution system, without providing the requested limited claims data. Non-grantee Covered Entities may place orders for such drugs by designating a single specialty pharmacy location approved for the limited distribution of Janssen PAH Products, if they provide the requested limited claims data for the specialty pharmacy location. This specialty pharmacy location designation for PAH Products may be in addition to a contract pharmacy location designated for non-PAH Products. Users that have registered an account with 340B ESP™ can designate a single pharmacy location for PAH product orders by navigating to the Entity Profile tab. **For a non-grantee Covered Entity's eligible specialty pharmacy location to take effect on March 7, 2023, the entity must designate the single contract pharmacy location by February 26, 2023.** Beginning on February 27, 2023, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

⁸ The following are our current PAH covered outpatient drugs included on Attachment A: Opsumit (macitentan), Tracleer (bosentan), Upravi (selexipag), and Veletri (epoprostenol).

⁹ HRSA has reviewed that program notice and posted it on its website, demonstrating that the program is permitted under applicable law and guidance. HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-11 (May 23, 2012) (stating "If OPA has concerns about the allocation plan, it will work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the HRSA/OPA website").

Transition Instructions

In support of a smooth transition to our new policy, non-grantee Covered Entities should:

- Work with your contract pharmacy administrators and wholesalers to process any outstanding Bill To/Ship To orders in advance of the March 7, 2023 effective date.
- Continue to submit claims within 45 days of dispense to patient for current eligible contract pharmacy locations.

Please reach out to 340B_JJHCS@its.inj.com for policy questions or to support@340BESP.com for any assistance related to the claims submission process and/or the ESP portal.

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FREQUENTLY ASKED QUESTIONS

JJHCS is utilizing Second Sight Solutions' 340B ESP™ platform (www.340besp.com). 340B ESP™ is a web-based platform made available to Covered Entities at no cost, to make contract pharmacy designations and to submit the requested limited contract pharmacy claims data. JJHCS uses this data to identify duplicate discounts and diversion that we could not identify without this data.

Q: Which products are subject to JJHCS' policy?

A: Covered Entities may access the complete list of NDCs that may be subject to exemption requirements under JJHCS' policy at [What NDCs do we look for? | 340B ESP - Help Center](#). We have tried to limit the scope of our program to the areas where the duplicate discount and diversion risks are likely greatest.

Q: Does my Covered Entity need to submit limited claims data for products not covered by JJHCS' policy?

A: No, JJHCS' policy only requests limited claims data for the products subject to the policy, as listed in Attachment A. Covered Entities may continue to order product using Bill To/Ship To orders for those drugs not included on Attachment A.

Q: My Covered Entity is a grantee. In light of the updated policy, does my Covered Entity have to change the way we order 340B drugs for the contract pharmacies that we use?

A: No. As under our current policy, grantees are exempt from our updated policy, and they may continue to engage in Bill To/Ship To orders with contract pharmacies.

Q: How will the updated policy affect non-grantee Covered Entities without in-house pharmacies?

A: A non-grantee Covered Entity¹⁰ that does not have an in-house pharmacy may designate a single contract pharmacy location registered on the HRSA OPAIS database for purchases of covered outpatient drugs listed on Attachment A if (i) the Covered Entity provides limited claims data with respect to that contract pharmacy location and (ii) that single contract pharmacy location is within 40 miles of the Covered Entity parent site. To designate a contract pharmacy, you must list the contract pharmacy at 340B ESP™ by February 26, 2023 for the contract pharmacy location designation to take effect on March 7, 2023.

If you wish to change the pharmacy location that you have designated under this policy, you can do so once in any 12 month period, allowing 10 days for the change to take effect, with the understanding that the contract pharmacy must be listed on HRSA's database and be within 40 miles of your parent site location in order to access 340B pricing at the contract pharmacy location.

If you have not designated a single contract pharmacy location, you may designate one contract pharmacy location within 40 miles of the Covered Entity parent site by February 26, 2023 to access 340B pricing at that contract pharmacy location.

Limited claims data must be submitted within 45-days of dispense to the patient to access 340B pricing at the designated contract pharmacy location.

¹⁰ Non-grantee covered entities are eligible to participate in the 340B program under 42 U.S.C. § 256(b)(4)(L)-(O).

Q: How will the updated policy affect non-grantee Covered Entities with in-house pharmacies?

A: Non-grantee Covered Entities which do have an in-house pharmacy may designate one contract pharmacy location registered on the HRSA OPAIS database within 40 miles of the Covered Entity parent site by February 26, 2023 in order to access 340B pricing at the contract pharmacy location as of March 7, 2023. After February 26, 2023, please allow 10 business days for the eligibility to become effective. This designation can be done once in any 12 month period.

If a contract pharmacy is designated, limited claims data must be submitted for both the contract pharmacy location and the in-house pharmacy within 45-days of dispense to the patient to access 340B pricing at the designated contract pharmacy location.

Q: My non-grantee Covered Entity has designated a single contract pharmacy and now would like to submit 340B limited claims data for this contract pharmacy to continue purchasing Janssen products at the 340B price. What does our entity need to do to begin submitting 340B claims data?

A: Non-grantee 340B Covered Entities can submit claims by registering an account at www.340besp.com. Users that have registered an account with 340B ESP™ can begin submitting 340B limited claims data for JJHCS by navigating to the Claims Data Submission tab. 340B claims must be submitted within 45 days of the date of dispense in order for the contract pharmacy to remain eligible to receive 340B purchased drugs.

Q: My non-grantee Covered Entity already designated a single contract pharmacy location without submitting claims. Does my entity need to take action?

A: Yes, your non-grantee Covered Entity will need to make a designation at www.340besp.com/designations by February 26, 2023 in accordance with our policy, in order for the designation to be effective when our updated policy goes into effect on March 7, 2023. If you choose to make your designation after February 26, 2023, please allow up to 10 business days for the designation to take effect.

Q: What happens if my non-grantee Covered Entity does not provide 340B limited claims data?

A: If a non-grantee Covered Entity does not submit the requested 340B limited claims data required by JJHCS policy, the Covered Entity may lose the ability to access 340B pricing at the designated contract pharmacy location. In order to ensure non-grantee Covered Entities have time to establish an internal claims submission process, we will allow non-grantee Covered Entities to have 60 days after the effective date of this policy to begin submitting data. After May 6, 2023, if a non-grantee Covered Entity does not submit claims data, the non-grantee Covered Entity may not be able to access 340B pricing at the designated contract pharmacy location. Claims must be submitted within 45 days of date of dispense to the patient.

If you need any support with complying with this claims data requirement, please reach out to 340B_JJHCS@its.jnj.com for policy questions or to support@340BESP.com for any assistance related to the claims submission process and/or the ESP portal.

Q: Are the 340B claims data elements that JJHCS is requiring for an in-house pharmacy different from the 340B claims data elements that are provided for a contract pharmacy?

A: Non-grantee Covered Entities that have an in-house pharmacy and elect to designate a single contract pharmacy location are required to submit 340B claims data for both the designated contract pharmacy location and all in-house pharmacy locations. The claims data elements that JJHCS requires are exactly the same for in-house and contract pharmacy locations. Non-grantee Covered Entities should utilize 340B ESP for claims submissions for both types of pharmacies. These required fields are subject to change with notice via the ESP portal.

Q. My non-grantee 340B Covered Entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. Contract pharmacy locations are registered individually on the HRSA OPAIS database. Non-grantee 340B Covered Entities may designate a single contract pharmacy location that corresponds to a single contract pharmacy registration with HRSA.

Q: My non-grantee Covered Entity is designating a single contract pharmacy location for non-PAH Janssen covered outpatient drugs, but has a contract pharmacy arrangement with a different specialty contract pharmacy location in the PAH limited distribution network. Can my entity also designate this PAH specialty contract pharmacy location for PAH covered outpatient drug orders?

A. Yes. Our pulmonary arterial hypertension (PAH) covered outpatient drugs¹¹ which are already subject to a limited distribution plan¹² that has been reviewed and posted by HRSA, will continue to be provided at the 340B price to 340B Covered Entities that place orders through a specialty pharmacy at a location that is part of that limited distribution system. Non-grantee Covered Entities may designate a single specialty pharmacy location approved for the limited distribution of Janssen's PAH products by visiting www.340besp.com/designations, and provide the requested limited claims data with respect to such specialty contract pharmacy location. This specialty pharmacy location for PAH products may be in addition to a contract pharmacy designation for non-PAH products. Just for clarity, there is not a requirement to submit in-house pharmacy claims in order to qualify for this exception.

¹¹ The following are our current PAH covered outpatient drugs included on Attachment A: Opsumit (macitentan), Tracleer (bosentan), Upravi (selexipag), and Veletri (epoprostenol).

¹² HRSA has reviewed that program notice and posted it on its website, demonstrating that the program is permitted under applicable law and guidance. HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-11 (May 23, 2012) (stating "If OPA has concerns about the allocation plan, it will work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the HRSA/OPA website").

Q. My non-grantee Covered Entity previously had an exemption for a contract pharmacy that was wholly-owned by the Covered Entity. Will that contract pharmacy still have access to 340B pricing?

A. A non-grantee Covered Entity may elect to designate any contract pharmacy location registered on the HRSA OPAIS database that is within 40 miles of the Covered Entity's parent site as its single contract pharmacy location so long as it complies with the claim submission requirements noted above.

Q. How often can my non-grantee Covered Entity change its contract pharmacy designation?

A. Non-grantee Covered Entities may change their contract pharmacy designation once in any 12 month period (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q. How does my non-grantee Covered Entity change its contract pharmacy designation?

A. Changes to a contract pharmacy designation can be made by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to update their contract pharmacy designation.

Q. Is JJHCS requiring non-grantee Covered Entities to have a HIN registered for the contract pharmacy that they designate?

A. Yes, a contract pharmacy must have a HIN assigned to it in order for a non-grantee Covered Entity to designate it as its single contract pharmacy. This information is important for JJHCS to manage its process with its wholesalers.

Q. If the contract pharmacy my non-grantee Covered Entity wants to designate doesn't have a HIN, how does my entity get one?

A: If you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please contact support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions regarding how to obtain a HIN.