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Notice to 340B and Non-340B End Customers Regarding Bill To/Ship To Orders

March 21, 2022

This notice is to inform all end customers—both 340B customers and non-340B customers—of updates to the policy of Johnson & Johnson Health Care Systems Inc. (JJHCS) regarding Bill To/Ship To orders. JJHCS' updated policy will take effect on May 2, 2022. The updated policy will impact 340B Bill To/Ship To orders involving contract pharmacies used by non-grantee Covered Entities, subject to multiple exceptions described below.

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 this policy and the 340B statute, JJHCS will continue to offer 340B covered outpatient drugs to all Covered Entities at the HRSA registered locations for those entities¹ or other locations designated in accordance with JJHCS' policy as described further below. Subject to the multiple, expansive 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.

Both in the non-340B and 340B context, JJHCS has long attempted to control diversion and inappropriate claims for discounts and rebates by requiring end customers to only buy product for their "own use" and seeking to prohibit the transfer of purchased drugs outside of the applicable class of trade. 340B Covered Entities, despite that practice, have enjoyed preferential treatment allowing them to engage in contract pharmacy transactions that have permitted 340B Covered Entities, in Bill To/Ship To arrangements, to direct delivery to contract pharmacy Ship To locations.

JJHCS is committed to the 340B Program and to supporting access to care for patients in need. We also are committed to continuing to offer 340B discounts to Covered Entities on all of JJHCS' covered outpatient drugs. At the same time, we see a clear need to require end customers, in Bill To/Ship To arrangements, to be prohibited from directing shipment or delivery to Ship To locations that are not a part of the Bill To entity, subject to the exceptions described below. We believe that this policy will help to reduce diversion and inappropriate claims for discounts and rebates, regardless of the nature of the purchase or the end customer involved.

¹ Covered Entity registered locations include both the HRSA registered parent and child site locations.

We believe that this policy will also improve 340B Program integrity and compliance. The government itself has repeatedly expressed concerns about diversion and duplicate discounts involving contract pharmacies. Unfortunately, despite years of efforts by JJHCS and other stakeholders to address 340B Program integrity and compliance concerns, the program has been seriously challenged by contract pharmacy transactions that are not required by or consistent with the statute. In addition, we are disappointed that contract pharmacy transactions direct 340B discounts to large, for-profit entities—while failing to extend meaningful discounts to patients.

To date, JJHCS has been voluntarily recognizing chargebacks for 340B discounts for unlimited contract pharmacy transactions and permitting Covered Entities to direct deliveries to Ship To locations that are not a part of the Bill To entity. Under the updated policy, subject to the exceptions described below, 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.

Despite our concerns, a series of broad exceptions will allow 340B Covered Entities to engage in Bill To/Ship To orders. First, Covered Entities that receive grants from the Health Resources and Services Administration (HRSA)² may continue to use an unlimited number of contract pharmacies, without providing limited claims data, even when they purchase covered outpatient drugs on Attachment A. Second, for covered outpatient drugs listed on Attachment A, non-grantee 340B Covered Entities³ may continue to use an unlimited number of contract pharmacies if they elect to provide the requested limited claims data.⁴ Third, if non-grantees choose not to provide limited claims data, they still may designate a single contract pharmacy location for purchases of covered outpatient drugs listed on Attachment A, if they lack an in-house pharmacy and that contract pharmacy is registered on the HRSA database. Fourth, for all such covered outpatient drugs, Covered Entities may place Bill To/Ship to orders for not-for-profit contract pharmacies wholly-owned by the Covered Entity and located within the same parent or child site as the Bill To location, without supplying the requested limited claims data. Finally, all Covered Entities will be permitted to direct Bill To/Ship To orders to an unlimited number of contract pharmacies for covered outpatient drugs not listed on Attachment A.

In addition, for our pulmonary arterial hypertension covered outpatient drugs that are included in Attachment A,⁵ 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 program,⁶ without providing the requested limited claims data. Non-grantee Covered Entities may place orders for these drugs through a specialty pharmacy at any location that is part of that limited distribution system, if they provide the requested limited claims data. Non-grantee Covered Entities that elect

² Grantee covered entities are eligible to participate in the 340B program under 42 U.S.C. § 256(b)(4)(A)-(K).

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

⁴ This data will be used to identify duplicate discounts and diversion that we could not identify without this data.

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”).

not to provide the requested limited claims data for these drugs may designate a single specialty pharmacy location that is part of our pre-existing limited distribution system.

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 May 2, 2022.

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

ATTACHMENT A

All of the following products are subject to the Bill To/Ship To Policy effective May 2, 2022:

STELARA®
TREMIFYA®
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®

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

Non-grantee 340B Covered Entities may continue to use an unlimited number of contract pharmacies if they provide specified, limited claims data on contract pharmacy transactions for drugs covered by the program (which are listed in Attachment A). Covered Entities that elect to submit their 340B claims will be allowed to continue Bill To/Ship To orders for those contract pharmacy locations for which it submits data. Such Covered Entities will submit their 340B claims through 340B ESP™ for utilization dispensed through contract pharmacies. 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 begin submitting the specified 340B claims data for Janssen 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 location to remain eligible to receive 340B purchased drugs.

For a Covered Entity's eligible contract pharmacy locations to take effect on May 2, 2022, the entity must submit 340B claims by April 18, 2022. Beginning on April 19, 2022, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

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 Designating a Single Contract Pharmacy if You Lack an In-house Pharmacy

If non-grantee Covered Entities choose not to provide the requested limited claims data, they still may designate a single contract pharmacy location if they lack an in-house outpatient pharmacy and the contract pharmacy location is registered on the HRSA database. 340B Covered Entities that want to designate a contract pharmacy location and haven't already registered an account with 340B ESP™ can make their designation by visiting <http://www.340besp.com/designations>. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab. For a Covered Entity's eligible contract pharmacy location to take effect on May 2, 2022, the entity must designate the contract pharmacy by April 18, 2022. Beginning on April 19, 2022, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

Instructions for PAH Products

Our pulmonary arterial hypertension (PAH) covered outpatient drugs,⁷ 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 specialty pharmacy at a location that is part of that limited distribution system.

- Grantees 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 through a specialty pharmacy at any location that is part of that limited distribution system, if the Covered Entity provides the requested limited claims data.
- Non-grantee Covered Entities that elect not to submit the specified, limited claims data may designate a single specialty contract pharmacy location approved for the limited distribution of Janssen's PAH products by visiting www.340besp.com/designations.

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 Covered Entity's eligible contract pharmacy location to take effect on May 2, 2022, the entity must designate the contract pharmacy by April 18, 2022. Beginning on April 19, 2022, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

⁷ The following are our current PAH covered outpatient drugs included on Attachment A: Opsumit (macitentan), Tracleer (bosentan), Uptravi (selexipag), and Veletri (epoprostenol).

Instructions for Placing Bill To/Ship To Orders for Wholly-Owned, Not-For-Profit Contract Pharmacies at the Same Site

A Covered Entity may place Bill To/Ship To orders for not-for-profit contract pharmacies wholly-owned by the Covered Entity and located within the same parent or child site as the Bill To location. Covered entities need not provide limited claims data for such contract pharmacies. These pharmacies and the locations must be registered with HRSA. To apply for this wholly-owned contract pharmacy exemption, please visit http://www.340besp.com/wholly_owed_application. For a Covered Entity's eligible contract pharmacy location to take effect on May 2, 2022, the entity must designate the contract pharmacy by April 18, 2022. Beginning on April 19, 2022, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

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In support of a smooth transition to our new policy, Covered Entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To/Ship To orders in advance of the May 2, 2022 effective date.

If you have questions regarding these instructions, please contact support@340besp.com.

FREQUENTLY ASKED QUESTIONS

JJHCS is utilizing Second Site 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 will use 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. Does my Covered Entity have to change the way we order 340B drugs for the contract pharmacies that we use?

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

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

A: 340B Covered Entities that wish to submit 340B limited claims data under JJHCS' policy can do so 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: What happens if my non-grantee Covered Entity does not provide 340B limited claims data by the required date?

A: We encourage you to consider submitting the limited claims data requested. If a Covered Entity elects not to submit the requested 340B limited claims data on its contract pharmacy transactions, the Covered Entity will have the option to designate a single contract pharmacy if it doesn't have an in-house pharmacy capable of dispensing 340B purchased products. Your entity may also apply for an exemption to use not-for-profit contract pharmacies wholly-owned by the Covered Entity and located within the same parent or child site as the Bill To location.

Q: My Covered Entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to JJHCS' policy?

A: Covered Entities may place Bill To/Ship To orders involving not-for-profit contract pharmacies wholly-owned by the Covered Entity and located within the same parent or child site as the bill to location. Orders involving such contract pharmacies need not supply limited claims data. These pharmacies and their locations must be registered with HRSA. To apply for this wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application.

Q: My non-grantee Covered Entity has an in-house pharmacy that is capable of purchasing and dispensing covered outpatient drugs, but my entity doesn't use it to dispense Janssen drugs. Can my entity designate one contract pharmacy instead?

A: No. Assuming your Covered Entity elects not to provide the requested limited claims data, it must use the in-house pharmacy capable of dispensing 340B covered outpatient drugs to eligible patients and cannot designate a contract pharmacy instead. We encourage you to consider the other available exceptions described above. If you agree to provide limited claims data, for instance, your entity could use an unlimited number of contract pharmacies.

Q: My non-grantee Covered Entity already designated 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 drugs,⁸ which are already subject to a limited distribution plan that has been reviewed and posted by HRSA, will continue to be provided at the 340B price to all 340B Covered Entities that place orders through a specialty pharmacy at a location that is part of that limited distribution system. Covered Entities that do not submit the requested claims data may designate a single specialty contract pharmacy location approved for the limited distribution of Janssen's PAH products by visiting www.340besp.com/designations.

Covered Entities that do not submit the requested claims data are permitted to designate (i) one PAH in-network specialty contract pharmacy location for PAH covered outpatient drugs and (ii) for all other Janssen covered outpatient drugs, another contract pharmacy location, if they decline to provide the requested limited claims data, lack an in-house pharmacy, and that contract pharmacy and location are registered on the HRSA database.

For a Covered Entity's eligible contract pharmacy location to take effect on May 2, 2022, the Covered Entity must designate the specialty contract pharmacy location by April 18, 2022. Beginning on April 19, 2022, please allow 10 business days for the designation to take effect.

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

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. If your Covered Entity supplies the requested limited claims data, there is no need to designate any contract pharmacy locations. If your Covered Entity chooses not to provide limited claims data, JJHCS' policy allows qualifying 340B Covered Entities (i.e., Covered Entities without an in-house pharmacy) to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B Covered Entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA. Separate, additional exceptions include those pertaining to grantees, not-for-profit contract pharmacies wholly-owned by the Covered Entity and located within the same parent or child site as the bill to location, and a specialty pharmacy location that is part of the limited distribution system for the PAH products, as described above.

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

A. Covered Entities may change their contract pharmacy designation once every twelve (12) months (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 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 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 Covered Entity to designate it as its single contract pharmacy or to apply for a wholly owned contract pharmacy exemption. This information is important for JJHCS to manage its process with its wholesalers.

Q. If the contract pharmacy my 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.

Q. How does my Covered Entity ensure that its eligible contract pharmacy location takes effect on May 2, 2022?

A. For a Covered Entity's eligible contract pharmacy locations to take effect on May 2, 2022, the entity must designate or submit 340B claims by April 18, 2022. Beginning on April 19, 2022,

please allow 10 business days from the day on which you make your designation for the eligible contract pharmacy location to take effect.

Q. How long does it take for my Covered Entity's eligible contract pharmacy location to take effect after May 2, 2022?

A. Covered Entities can take action to comply with Janssen's policy after it goes into effect on May 2, 2022. After April 19, 2022, please allow 10 business days from the day on which you make a designation for the eligible contract pharmacy location to take effect.