

NOTICE TO 340B COVERED ENTITIES REGARDING UPDATES TO SANDOZ INC.

6/3/2024

Dear Covered Entity Customer

I am writing to inform you of changes to Sandoz, Inc. ("Sandoz") contract pharmacy policy under the 340B Program that became effective December 1, 2023.

Effective July 1, 2024, Sandoz is updating the list of products included in our contract pharmacy policy under the 340B Program to include Zarxio. Please refer to Attachment A for an updated product listing. Please note that Sandoz will no longer be providing additional notification for product changes to our contract pharmacy policy. Please visit www.340BESP.com for a current list of applicable NDC's included in Sandoz's contract pharmacy policy under the 340B Program as this list may be updated from time to time.

If you have questions regarding these changes, please contact support@340Besp.com.

Thank you

Angulo
Rafael

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ou=GX, serialNumber=940774,
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Rafael Angulo

Head, Revenue Finance, Government Pricing

11/1/2023

Dear Covered Entity Customer,

I am writing to inform you of a change in Sandoz policy regarding eligibility to receive products at the 340B price through a contract pharmacy arrangement. Sandoz is doing so to help prevent the benefits of the 340B program from being inappropriately captured by contract pharmacies at the expense of patients, and to help maintain the integrity of the 340B program and thereby its sustainability. Specifically, effective December 1, 2023, Sandoz will ship 340B products exclusively to locations registered as a 340B covered entity or its child site and certain contract pharmacy locations designated in accordance with Sandoz's contract pharmacy policy, as described below.

CONTRACT PHARMACY POLICY

Effective December 1, 2023, Sandoz will ship the drug and biological products listed in Attachment A and purchased at the 340B price exclusively to locations registered as a 340B covered entity or child site location, subject to the limited exception described below. The list of products in Attachment A may be updated periodically, and any updates will be published through Sandoz's vendor, 340B ESP™.

Although Sandoz historically has voluntarily acted consistently with agency guidance pertaining to bill to / ship to 340B purchases involving pharmacies registered in the 340B contract pharmacy database, it will no longer do so beginning December 1, 2023, except as provided herein.

- **340B covered entity hospitals.** ¹ A 340B covered entity hospital will be allowed to designate one contract pharmacy location as eligible for 340B pricing with respect to the products listed in Attachment A (as updated), if both of the following criteria are met by that contract pharmacy location:
 - (1) The contract pharmacy location is within 40 miles of the covered entity parent site location. If a covered entity both lacks an in-house outpatient pharmacy or a wholly-owned pharmacy and is unable to identify a contract pharmacy location within 40 miles, Sandoz and its vendor will work with the covered entity to identify an appropriate contract pharmacy location to dispense covered outpatient drugs to the covered entity's patients.
 - (2) The covered entity submits specified 340B claims data to the 340B ESP™ platform with respect to the contract pharmacy location. Covered entities can access the 340B ESP™ platform at www.340besp.com to designate a single contract pharmacy location, and to submit the claims data for that pharmacy location. In addition, a list of National Drug Codes (NDCs) applicable to this policy can be found at www.340besp.com.

¹ Covered entity hospitals located in Arkansas and Louisiana are not covered by this policy at this time.

Note that a covered entity's in-house pharmacies and any wholly-owned pharmacies are not affected by this policy.

- **340B covered entity grantees.** 340B covered entity grantees are excluded from the above policy.

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Sandoz is utilizing the 340B ESP™ platform to support both the facilitation of the contract pharmacy designations and the collection of the 340B claims data. 340B covered entities that have not already registered an account with 340B ESP™ can do so by visiting www.340bbsp.com/designations. Those that have already registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab.

In support of a smooth transition to our new policy, we recommend working with any contract pharmacy administrators and wholesalers to process any outstanding bill to / ship to replenishment orders in advance of December 1, 2023. 340B contracts administered by our wholesalers will no longer support distribution of 340B purchased drugs to 340B contract pharmacies outside of our contract pharmacy policy after December 1, 2023.

If you have questions regarding Sandoz's contract pharmacy policy, please contact us at support@340Bbsp.com.

Best regards,

Angulo Rafael

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Rafael Angulo
Head, Revenue Finance, Government Pricing

Attachment A (Updated June 3, 2024)

NDC	Brand	Material Description
61314032601	ZARXIO	ZARXIO 48MIU/0.8ML 1LISY BI US
61314031801	ZARXIO	ZARXIO 30MIU/0.5ML 1LISY BI US
61314031810	ZARXIO	ZARXIO 30MIU/0.5ML 10LISY V1 US
61314032610	ZARXIO	ZARXIO 48MIU/0.8ML 10LISY V1 US
61314045436	HYRIMOZ	HYRIMOZ 80MG/0.8ML 3LISY PE BI US
61314045468	HYRIMOZ	HYRIMOZ 80MG/0.8ML 3LISY BI US
61314045420	HYRIMOZ	HYRIMOZ 80MG/0.8ML 2LISY PE BI US
61314051736	HYRIMOZ	HYRIMOZ 80+40MG 3KIT MP PE BI US
61314053164	HYRIMOZ	HYRIMOZ 80+40MG 2KIT MP BI US
61314047320	HYRIMOZ	HYRIMOZ 40MG/0.4ML 2LISY PE BI US
61314047364	HYRIMOZ	HYRIMOZ 40MG/0.4ML 2LISY BI US
61314047664	HYRIMOZ	HYRIMOZ 20MG/0.2ML 2LISY BI US
61314050964	HYRIMOZ	HYRIMOZ 10MG/0.1ML 2LISY BI US
61314032764	ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ 40MG/0.4ML 2LISY US
61314032720	ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ 40MG/0.4ML 2LISY PE US
00781300107	OMNITROPE	OMNITROPE IJ 5MG/1.5ML 1X1CARTRIDGE BX
00781300407	OMNITROPE	OMNITROPE IJ 10MG/1.5ML 1X1CARTRIDGE BX
00781400436	OMNITROPE	OMNITROPE 8X5.8MG/VL+8XBZOH/WFI SOL KT
00078068361	ARRANON	ARRANON 250MG/50ML 1LIVI US
00078072210	AZOPT	AZOPT SUSP 1% 10ML LDP US
00078072215	AZOPT	AZOPT SUSP 1% 15ML LDP US
00078084101	CILOXAN	CILOXAN OINTMENT 0.3% 3.5G 1EOIN US
00078085526	CIPRO HC	CIPRO HC SUSP 0.2%+1% 10ML LDP US
00078086225	DUREZOL	DUREZOL 0.05% 5ML 1EMU US
00078050315	EXELON	EXELON 13.3MG/24H 30TTS US
00078050115	EXELON	EXELON 4.6MG/24H 30TTS US
00078050215	EXELON	EXELON 9.5MG/24H 30TTS US
00078038205	FOCALIN	FOCALIN 10MG 100TAB US
00078038005	FOCALIN	FOCALIN 2.5MG 100TAB US
00078038105	FOCALIN	FOCALIN 5MG 100TAB US
00078043105	FOCALIN XR	FOCALIN XR 10MG 100PRCH US
00078049305	FOCALIN XR	FOCALIN XR 15MG 100PRCH US
00078043205	FOCALIN XR	FOCALIN XR 20MG 100PRCH US
00078060805	FOCALIN XR	FOCALIN XR 25MG 100PRCH US
00078043305	FOCALIN XR	FOCALIN XR 30MG 100PRCH US
00078060905	FOCALIN XR	FOCALIN XR 35MG 100PRCH US
00078043405	FOCALIN XR	FOCALIN XR 40MG 100PRCH US
00078043005	FOCALIN XR	FOCALIN XR 5MG 100PRCH US
00078067201	HYCAMTIN	HYCAMTIN 0.25MG 10HGC US
00078067301	HYCAMTIN	HYCAMTIN 1MG 10HGC US
00078035415	LESCOL XL	LESCOL XL 80MG 30TAB US
00078036405	LOTREL	LOTREL 10+20MG 100HGC BO US

00078037905	LOTREL	LOTREL 10+40MG 100HGC BO US
00078040505	LOTREL	LOTREL 5+10MG 100HGC BO US
00078040605	LOTREL	LOTREL 5+20MG 100HGC BO US
00078077101	MAXITROL	MAXITROL 0.1% 3.5GM OIN US
00078043561	RECLAST	RECLAST 5MG/100ML 1LIVI US
00078044005	RITALIN IR	RITALIN IR 10MG 100TAB BO US
00078044105	RITALIN IR	RITALIN IR 20MG 100TAB BO US
00078043905	RITALIN IR	RITALIN IR 5MG 100TAB BO US
00078042405	RITALIN LA	RITALIN LA 10MG 100PRCH US
00078037005	RITALIN LA	RITALIN LA 20MG 100PRCH US
00078037105	RITALIN LA	RITALIN LA 30MG 100PRCH US
00078037205	RITALIN LA	RITALIN LA 40MG 100PRCH US
00078094640	TRAVATAN Z	TRAVATAN Z SOL .004% 2.5ML LDP US
00078094625	TRAVATAN Z	TRAVATAN Z SOL .004% 5ML LDP US
00078036542	VIVELLE-DOT	VIVELLE DOT 0.025MG/1D 8TTS US
00078034342	VIVELLE-DOT	VIVELLE DOT 0.0375MG/1D 8TTS US
66758014683	VIVELLE-DOT	VIVELLE DOT 0.0375MG/1D 8TTS US
00078034442	VIVELLE-DOT	VIVELLE DOT 0.05MG/1D 8TTS US
00078034542	VIVELLE-DOT	VIVELLE DOT 0.075MG/1D 8TTS US
00078034642	VIVELLE-DOT	VIVELLE DOT 0.1MG/1D 8TTS US

Frequently Asked Questions

Q: Which products are subject to Sandoz's contract pharmacy policy?

A: Sandoz's contract pharmacy policy applies to Hyrimoz, Adalimumab-adaz, Omnitrope, Arranon, Azopt, Ciloxan, Cipro HC, Durezol, Exelon, Focalin (XR), Hycamtin, Lescol XL, Lotrel, Maxitrol, Reclast, Ritalin (IR & LA), Travatan Z, and Vivelle-Dot, as listed in Attachment A. The list of products in Attachment A may be updated periodically, and any updates will be published through Sandoz's vendor, 340B ESP™.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system. Is this pharmacy subject to Sandoz's contract pharmacy policy?

A: No. A contract pharmacy that is wholly owned by the covered entity is not subject to Sandoz's contract pharmacy policy at this time.

Q. My covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different Accredo pharmacy locations). Can my covered entity designate all locations of the same pharmacy?

A. No. Sandoz's contract pharmacy policy allows certain 340B covered entities to designate only a single eligible contract pharmacy location in addition to covered entity in house pharmacies and wholly-owned pharmacy locations. Contract pharmacy locations are registered individually in the HRSA OPAIS database, and, under Sandoz's contract pharmacy policy, 340B covered entities are permitted to designate only a single contract pharmacy location that corresponds to a single contract pharmacy registration with HRSA.

Q. How often can my covered entity change its contract pharmacy location designation?

A. Covered entities may change their contract pharmacy location designation once every twelve (12) months (starting from the date of first designation) or when a designated contract pharmacy location is terminated from the HRSA OPAIS database.

Q. How does my covered entity change its contract pharmacy location designation?

A. 340B covered entities can designate a single contract pharmacy location every twelve (12) months or when a designated contract pharmacy location is terminated from the HRSA OPAIS database. Changes to the designation of a single contract pharmacy location can be made only by visiting www.340Besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy location designation.

Q. Is Sandoz requiring covered entities to have a HIN registered for the contract pharmacy location that they designate?

A. Yes, a contract pharmacy location must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy location. This information is needed so that Sandoz can manage its process with its wholesalers.

Q. If the contract pharmacy location that my covered entity wants to designate does not have a HIN, how does it obtain one?

A: Sandoz will not register a HIN on your behalf. If you need information on how to obtain a HIN, please reach out to support@340besp.com. If you try to designate a contract pharmacy location without a HIN, the 340B ESP™ system will notify you of the HIN requirement and provide instructions on how to obtain a HIN.

Q. How does my covered entity ensure that its eligible contract pharmacy location designation takes effect on December 1, 2023?

A. For a covered entity's eligible contract pharmacy location designation to take effect on December 1, 2023, the covered entity must designate by 11/17/2023. After 11/17/2023, please allow 10 business days for the designation to take effect.

Q. How long does it take for my covered entity's eligible contract pharmacy location designation to take effect after 11/17/2023?

A. After 11/17/2023, please allow 10 business days for the designation to take effect.