



30 Hudson Street
Jersey City, NJ 07302

October 1, 2024

**NOTICE TO 340B COVERED ENTITIES IN ALL STATES REGARDING
ORGANON'S 340B CONTRACT PHARMACY POLICY APPLICATION TO
CERTAIN FEDERAL GRANTEES,
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October 21, 2024

Dear 340B Covered Entities,

Organon supports the 340B program and its intended mission of supporting safety net providers in providing patients in need with access to medical care and medications. This letter is intended to provide you notice that Organon is updating its approach to the offering of 340B prices to certain Federal grantees transferring 340B drugs to contract pharmacies. This update is in addition to, and supplements, Organon's policy approach applicable to hospital covered entities (as previously detailed in the letter notice dated June 1, 2023).

Effective December 1, 2024, Organon will only provide products purchased at the 340B price to locations registered as 340B covered entities and will decline to facilitate Bill To/ Ship To orders for HRSA-Funded Health Center (CH) grantees, subject to the exceptions outlined below. For clarity, and in conformity with the 340B Office of Pharmaceutical Affairs definition, the CH covered entity type is inclusive of Community Health Centers (CHC) and those entity types formerly identified as a School Based Program (340S), Health Care for the Homeless Program (HO), Migrant Health Program (MH), and Public Housing Primary Care Program (PH).

Organon's updated policy will apply to CH covered entities/grantees. Federal grantees with entity types other than CH will continue to remain eligible for Bill To/ Ship To arrangements for Organon products at the 340B discounted price and do not need to submit 340B claims.

Any CH Federal grantee, regardless of whether it has an in-house pharmacy capable of dispensing 340B purchased drugs to its patients, may designate a single contract pharmacy location if the covered entity provides claims data for the designated single contract pharmacy through 340B ESP™.

Covered entities will have the following exemptions to the limited contract pharmacy approach, and continue to remain eligible for unlimited Bill To/ Ship To arrangements, according to state legislative requirements, as previously notified and summarized here:

- Covered entities located in Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, and Missouri, will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies provided that claims level data is submitted via 340B ESP for these pharmacies.
- Covered entities located in Arkansas, Kansas, Louisiana, Maryland, Minnesota, Mississippi, and Missouri that do not adhere to the 340B claims submissions requirement will be considered to be out of compliance, and the 340B discount for Organon products will no longer be permitted. 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.
- Covered entities located in West Virginia will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies with no claims submission requirements. Accordingly, there is no action required by covered entities in the state of West Virginia with respect to this policy.

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Organon will continue to utilize the 340B ESP™ platform to support this policy and receive claim submissions. While covered entities are not required to take any action regarding contract pharmacy designations, a registered account with Second Sight Solutions' 340B ESP™ platform is needed for claim submissions. Please refer to the Next Steps and FAQs on how to register an account. If you have any questions about this initiative, please contact 340B ESP™ at support@340BESP.com.

Covered entities must take action by November 15th, 2024, in order for contract pharmacy location designations to take effect on the effective date of this policy.

Organon is committed to ensuring that all 340B covered entities can purchase Organon products at the 340B discounted price. 340B covered entities newly included in this policy should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To/ Ship To orders in advance of the December 1, 2024 effective date. Please refer to the Next Steps and FAQs for more information.

Best Regards,

A handwritten signature in black ink that reads "Andrew Tedeschi".

Andrew Tedeschi
Head of US Market Access
and Account Management

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30 Hudson Street
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August 1, 2024

Dear 340B Covered Entities,

Organon supports the 340B program and its intended mission of supporting safety net providers in providing patients in need with access to medical care and medications. This letter is intended to provide you notice that Organon is altering its approach to the offering of 340B prices to covered entities located in Minnesota transferring 340B drugs to contract pharmacies.

Following our notification to you dated June 1, 2023, Organon will be implementing the changes described below related to its 340B contract pharmacy policy.

Effective August 1, 2024 and until further notice, Organon is adopting the following:

- Covered entities located in Minnesota will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies provided claims level data is submitted via 340B ESP for these pharmacies.
- If a Minnesota covered entity does not adhere to the 340B claims submissions requirement, the covered entity will be considered out of compliance and the 340B discount for Organon products will no longer be permitted. 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.

Organon will continue to utilize the 340B ESP™ platform to support this policy and receive claim submissions. While covered entities are not required to take any action regarding contract pharmacy designations, a registered account with Second Sight Solutions' 340B ESP™ platform is needed for claim submissions. Please refer to the Next Steps and FAQs below on how to register an account.

If you have any questions about this initiative, please contact 340B ESP™ at support@340BESP.com.

Best Regards,

Andrew Tedeschi
Head of US Market Access
and Account Management

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August 1, 2024

Dear 340B Covered Entities,

Organon supports the 340B program and its intended mission of supporting safety net providers in providing patients in need with access to medical care and medications. This letter is intended to provide you notice that Organon is altering its approach to the offering of 340B prices to covered entities located in Missouri transferring 340B drugs to contract pharmacies.

Following our notification to you dated June 1, 2023, Organon will be implementing changes described below related to its 340B contract pharmacy policy.

Effective August 28, 2024 and until further notice, Organon is adopting the following:

- Covered entities located in Missouri will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies provided claims level data is submitted via 340B ESP for these pharmacies.
- If a Missouri covered entity does not adhere to the 340B claims submissions requirement, the covered entity will be considered out of compliance and the 340B discount for Organon products will no longer be permitted. 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.

Organon will continue to utilize the 340B ESP™ platform to support this policy and receive claim submissions. While covered entities are not required to take any action regarding contract pharmacy designations, a registered account with Second Sight Solutions' 340B ESP™ platform is needed for claim submissions. Please refer to the Next Steps and FAQs on how to register an account.

If you have any questions about this initiative, please contact 340B ESP™ at support@340BESP.com.

Best Regards,

A handwritten signature in black ink that reads "Andrew Tedeschi".

Andrew Tedeschi
Head of US Market Access
and Account Management

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June 6, 2024

Dear 340B Covered Entities,

Organon supports the 340B program and its intended mission of supporting safety net providers in providing patients in need with access to medical care and medications. This letter is intended to provide you notice that Organon is altering its approach to the offering of 340B prices to covered entities located in Kansas, Maryland, Mississippi, and West Virginia transferring 340B drugs to contract pharmacies.

Following our notification to you earlier this year, Organon will be implementing changes described below related to its 340B contract pharmacy policy.

Effective June 6th, 2024 and until further notice, Organon is adopting the following:

- Covered entities located in Kansas, Maryland, and Mississippi will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies provided claims level data is submitted via 340B ESP for these pharmacies.
- If a Kansas, Maryland, or Mississippi covered entity does not adhere to the 340B claims submissions requirement, the covered entity will be considered out of compliance and the 340B discount for Organon products will no longer be permitted. 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.
- Covered entities located in West Virginia will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies with no claims submission requirements. Accordingly, there is no action required by covered entities in the state of West Virginia with respect to this policy.

Organon will continue to utilize the 340B ESP™ platform to support this policy and receive claim submissions. While covered entities are not required to take any action regarding contract pharmacy designations, a registered account with Second Sight Solutions' 340B ESP™ platform is needed for claim submissions. Please refer to the Next Steps and FAQs on how to register an account.

If you have any questions about this initiative, please contact 340B ESP™ at support@340BESP.com.

Best Regards,

Andrew Tedeschi
Head of US Market Access
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November 1, 2023

Dear 340B Covered Entities,

Organon supports the 340B program and its intended mission of supporting safety net providers in providing patients in need with access to medical care and medications. This letter is intended to provide you notice that Organon is altering its approach to the offering of 340B prices to covered entities located in Louisiana and Arkansas transferring 340B drugs to contract pharmacies.

Following our notification to you earlier this year, Organon will be implementing changes described below related to its 340B contract pharmacy policy.

Effective December 1st, 2023 and until further notice, Organon is adopting the following:

- Covered entities located in Arkansas and Louisiana will be able to place Bill To / Ship To replenishment orders through an unlimited number of contract pharmacies provided claims level data is submitted via 340B ESP for these pharmacies.
- If an Arkansas or Louisiana covered entity does not adhere to the 340B claims submissions requirement, the covered entity will be considered out of compliance and the 340B discount for Organon products will no longer be permitted. 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.

Organon will continue to utilize the 340B ESP™ platform to support this policy and receive claim submissions. While covered entities are not required to take any action regarding contract pharmacy designations, a registered account with Second Sight Solutions' 340B ESP™ platform is needed for claim submissions. Please refer to the Next Steps and FAQs on how to register an account.

If you have any questions about this initiative, please contact 340B ESP™ at support@340BESP.com.

Best Regards,

Andrew Tedeschi
Head of US Market Access
and Account Management

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June 1, 2023

Dear 340B Covered Entity,

Organon supports the 340B program and its intended mission of supporting safety net providers in providing patients in need with access to medical care and medications. This letter is intended to provide you notice that Organon is altering its approach to the offering of 340B discounts to contract pharmacies. This change is intended to help reduce diversion and inappropriate claims for discounts and rebates.

Effective July 1, 2023, Organon will only provide products purchased at the 340B price to locations registered as 340B covered entities and will decline to facilitate Bill To/ Ship To orders for all hospital covered entities, subject to the exceptions outlined below. Organon's updated policy will not apply to 340B pricing for 340B contract pharmacy locations for any 340B covered entity that is eligible for the 340B program through their grant status with HRSA or other eligible grants. Federal grantees will continue to remain eligible for Bill To/Ship To arrangements for Organon products at the 340B discounted price and do not need to submit 340B claims.

Any hospital covered entity, regardless of whether it has an in-house pharmacy capable of dispensing 340B purchased drugs to its patients, may designate a single contract pharmacy location if the covered entity provides claims data for the designated single contract pharmacy through 340B ESP™.

Organon is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that haven't already registered an account with 340B ESP™, can make their designation by visiting www.340besp.com/designations. If you have any questions about this initiative, please contact 340B ESP™ at support@340besp.com.

Covered entities must take action by June 16th, 2023 in order for contract pharmacy location designations to take effect on the effective date of this policy.

Organon is committed to ensuring that all 340B covered entities can purchase Organon products at the 340B discounted price. 340B covered entities should work with their contract pharmacy administrators and wholesalers to process any outstanding Bill To/ Ship To orders in advance of the July 1, 2023 effective date. Please refer to the Next Steps and FAQs for more information.

Best Regards,

Andrew Tedeschi
Head of US Market Access
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NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

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 ~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 on a twice monthly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520.

Frequently Asked Questions

Q: Which products are subject to Organon's policy?

A: Organon's contract pharmacy policy applies to all Organon products. Organon's policy letter can be found at www.340besp.com/resources and a list of applicable NDCs can be found at **What NDCs Do We Look For?:** <http://help.340besp.com/en/articles/4455011-what-ndcs-do-welook-for>.

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

A: A covered entity may elect to designate any contract pharmacy location registered on the HRSA OPAIS database, regardless of ownership interest, as its single contract pharmacy location so long as it complies with the claim submission requirements noted below.

- A 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 for delivery of 340B-priced drugs if the covered entity provides claims data for the designated single contract pharmacy.
- A covered entity that does have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location for delivery of 340B-priced drugs if the covered entity provides claims data for the designated single contract pharmacy.

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

A: Yes, under Organon's policy, a covered entity that has an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy for delivery of 340B priced drugs if the covered entity provides claims data for the designated single contract pharmacy.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A. No. Organon's policy allows 340B covered entities 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. Exceptions to this policy include: (i) Federal grantees with entity type other than HRSA-Funded Health Center (CH), which may continue to obtain products at the 340B price through multiple contract pharmacy locations, and (ii) covered entities located in states that have enacted legislation limiting restrictions.

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 as agreed to by Organon and the covered entity (e.g., 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 the single contract pharmacy designation can only 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 make their contract pharmacy designation.

Q. Is Organon 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 for a covered entity to designate it as its single contract pharmacy. This information is important for Organon to manage its process with its wholesalers. If a covered entity needs guidance or more information on how to get a HIN assigned to a contract pharmacy, please reach out to support@340BESP.com.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

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A: Organon will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to 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 for how to obtain a HIN.

Q. How does my HRSA-Funded Health Center (CH) covered entity ensure that its eligible contract pharmacy locations take effect on December 1st, 2024?

A. For a covered entity's eligible contract pharmacy location to take effect on December 1st, 2024, the entity must take action by November 15th, 2024. If your covered entity takes action after November 15th, please allow 10 business days for the eligible contract pharmacy location to take effect.

Q: My covered entity would like to submit 340B claims for its designated contract pharmacy to continue purchasing Organon products at the 340B price through this location. What does our entity need to do to begin submitting 340B claims?

A: 340B covered entities that wish to submit 340B claims for its designated contract pharmacy under Organon's 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 claims for Organon 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: Does Organon restrict Federal Grantees?

A: Beginning December 1st, 2024, Organon's policy will apply to HRSA-Funded Health Center (CH) entity types. For clarity, and in conformity with the 340B Office of Pharmaceutical Affairs definition, CH covered entities include Community Health Centers (CHC) and those entity types formerly identified as a School Based Program (340S), Health Care for the Homeless Program (HO), Migrant Health Program (MH), and Public Housing Primary Care Program (PH). Organon does not restrict access to 340B pricing for 340B contract pharmacy locations for any other Federal grantee.

Q: Is there a limitation on how far back replenishment orders can be placed and still receive 340B pricing once eligibility for our contract pharmacy designation has been processed by our wholesaler?

A: Contract pharmacy replenishment orders for covered entities registered with 340B ESP™ will be honored for prescriptions dispensed to eligible 340B patients within forty-five (45) days of each data submission to 340B ESP™.

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