



Notice Regarding Puma Biotechnology, Inc.'s 340B Contract Pharmacy Policy
(Effective January 1, 2026)

June 24, 2026

Dear 340B Covered Entity,

Puma Biotechnology, Inc. is providing notice of its new policy regarding its approach to 340B contract pharmacies, which will be effective **January 1, 2026**. This policy is applicable to all Puma products and extends to all covered entities participating in the 340B program. The objective of this policy is to ensure clarity and consistency in our approach to 340B contract pharmacy arrangements.

This notice applies to contract pharmacy orders only. Puma does not restrict orders placed by an eligible 340B covered entity for delivery to the covered entity's owned pharmacy. Nothing in this notice should be read to suggest that covered entities are restricted from placing orders for delivery to the covered entity itself.

Under Puma's policy, each covered entity may select and utilize one designated contract pharmacy within our specialty network to dispense 340B products (in addition to the covered entity-owned pharmacy, if applicable). The covered entity's designated contract pharmacy is required to be the dispensing site for all dispenses of Puma products to the covered entity's patients (other than those through the covered entity-owned pharmacy). Each specialty pharmacy in Puma's network is registered as a 340B contract pharmacy location in the Office of Pharmacy Affairs Information System (OPAIS) database. Covered entities that elect to utilize a network contract pharmacy will be required to provide specified claims-level data elements (CLDE) within 45 days of the date of dispensing from the designated contract pharmacy location, and the contract pharmacy relationship must be listed in the OPAIS database. These data elements are detailed in **Exhibit A** of this policy document and are crucial for Puma to effectively monitor and reconcile 340B transactions. Only one covered entity may claim the 340B discount on a given dispense. The data is only required for the 340B contract pharmacy dispenses, not any other dispenses or transactions.

Puma will be utilizing Kalderos' platform, Truzo, where covered entities can make designations and submit the required claims data. To designate a contract pharmacy and submit claims data, please go to <https://truzo.kalderos.com/request/signup>. Truzo offers technical assistance and customer service. If you need assistance, please visit the [Covered Entity Onboarding center](#) or contact the Kalderos covered entity concierge team at truzo-support@kalderos.com. With this new policy, Puma is dedicated to upholding the integrity of the 340B program, striving for transparency and adherence to its regulations.



This policy does not alter or expand Puma's limited distribution network of pharmacies and will not affect access to Puma products for any patient.



Puma 340B Contract Pharmacy Policy Update: Frequently Asked Questions (December 1, 2025)

General

1. *Which products are subject to Puma's Policy?*

This policy applies to all Puma NDCs. The details of the policy and products can be found at <https://gotruzo.com/manufacturer-policies/>.

Contract Pharmacy Designations

2. *How often can I update my Contract Pharmacy designation?*

Unless there is a material change to the eligibility status of a designated Contract Pharmacy, Covered Entities will be permitted to update their Contract Pharmacy designation annually, based on the initial date of designation. As a result, barring any change to the eligibility status of your designated Contract Pharmacy, you will be able to update your Contract Pharmacy designations on January 1, 2027 or one year from the initial designation, whichever is later.

In the event that something changes with the eligibility of your designated Contract Pharmacy, please contact Kalderos' Covered Entity concierge team for assistance at truzo-support@kalderos.com.

3. *Does Puma require designated contract pharmacies to have a HIN assigned?*

Yes. A 340B covered entity is responsible for obtaining and entering the HIN for the contract pharmacy within Puma's specialty network upon designation.

4. *How long does it take for my covered entity's designation of its single contract pharmacy location to take effect after January 1, 2026?*

The designation of an eligible contract pharmacy may not take effect until up to 10 business days following the designation. All pharmacy designations completed prior to the effective date will be active as of the effective date.

5. *I have an entity-owned pharmacy. Can my entity still designate a single contract pharmacy within Puma's specialty network?*

Yes, all covered entities can designate a single contract pharmacy within Puma's specialty network. The covered entities are required to submit claims for all 340B dispenses at the designated contract pharmacy.

6. *Can a child site designate a single contract pharmacy?*

No. All child sites must utilize the parent site's contract pharmacy.



7. *What do I need to do if I don't use a Contract Pharmacy?*

Nothing. No action is required.

Claims Data Submission

8. *When should I start submitting claims?*

Covered Entities are required to start submitting claims for the designated contract pharmacy on the effective date of the policy, which is January 1, 2026.

9. *How often will I need to submit claims?*

You can submit your claims at a cadence that works for you so long as it is within 45 days of the date of service of the claim.

To minimize the effort required to assemble the submission, we have found that most covered entities prefer to submit claims at least twice a month.

Truzo Fees

10. *Will I be charged any fees for using Truzo?*

No. There are no fees associated with your covered entity's use of Truzo.

Voluntary State Exemptions

11. *Is Puma voluntarily exempting any states from this policy and what are the exemptions?*

Covered entities located in the following states can designate unlimited contract pharmacies located within the state that are part of Puma's limited specialty pharmacy network. These designated contract pharmacies must be registered in HRSA OPAIS. Covered Entities located in these states must submit claims level data elements (CLDE) for their designated contract pharmacies.

- LA, MD, MN, MO, MS

Covered entities located in the following states can designate unlimited contract pharmacies located within the state that are part of Puma's limited specialty pharmacy network. These designated contract pharmacies must be registered in HRSA OPAIS. Covered entities located in these states can voluntarily submit claims level data elements (CLDE) for their contract pharmacy designations.

- AR, CO, HI, ME, ND, NE, NM, OK, OR, RI, SD, TN, VT, UT, WA, WV



Exhibit A: Required Claims Level Data Elements

Field #	Field Type	Field Name
1	Transaction Identifier	RXID
2	Transaction Identifier	Fill Number
3	Product Information	NDC11
4	Product Information	Quantity Dispensed / Administered
5	Product Information	Unit of Measure
6	Entity Identifiers	Ordering Physician NPI
7	Entity Identifiers	Submitter (340B ID)
8	Entity Identifiers	Submitter (NPI)
9	Entity Identifiers	Service Provider ID (NPI)
10	Transaction Dates	Date Written / Prescribed
11	Transaction Dates	Date of Service
12	PBM Information	BIN
13	PBM Information	PCN
14	PBM Information	GRP



Exhibit B: Puma Product List

NDC	Product
70437-0240-18	NERLYNX 40MG TABLETS 180CT BTL
70437-0240-33	NERLYNX 40MG TABLETS 133CT BTL