

Notice to 340B Covered Entities Regarding 340B Contract Pharmacy Designations

Announced September 4, 2026

This notice is to inform 340B covered entities of Johnson & Johnson Health Care Systems Inc.'s ("JJHCS") policy regarding 340B contract pharmacies. This policy supersedes JJHCS's notice regarding 340B delivery limitations initially announced on February 15, 2023. This 340B Contract Pharmacy Designation Policy applies to all 340B covered entity types¹ purchasing Johnson & Johnson ("J&J") covered outpatient drugs ("CODs") found in ATTACHMENT B of this notice. As described below, grantee covered entities newly subject to this policy will have until October 20, 2026 to designate a contract pharmacy location to ensure the contract pharmacy is active when this policy becomes effective for these covered entities on November 3, 2026.

Consistent with the 340B statute and other applicable law, JJHCS offers covered entities 340B pricing on J&J CODs purchased by the covered entity for dispensing at the entity's active HRSA registered locations² and up to one (1) contract pharmacy dispensing location designated in accordance with JJHCS' policy, as described further below, and subject to JJHCS' 340B Claims Data Submission Policy announced on September 4, 2026.

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 help ensure the 340B Program's long-term sustainability. We believe this policy is necessary to identify and reduce prohibited diversion and duplicate discounts.

Effective September 15, 2026, JJHCS will implement the following requirements with respect to *hospital* covered entities under this policy:

- Regardless of whether a hospital covered entity has an in-house pharmacy, each hospital covered entity subject to this policy may designate a single contract pharmacy location actively registered in OPAIS as a contract pharmacy for delivery of 340B-priced J&J CODs if that single contract pharmacy location is within 40 miles of the covered entity parent site.
- For J&J's pulmonary arterial hypertension ("PAH") CODs that are included in this policy, each hospital covered entity may designate a single specialty pharmacy location approved for the limited distribution of PAH CODs.³ This pharmacy designation is separate from the pharmacy designation a covered entity may make for all other J&J CODs subject to this policy.
- Hospital covered entities that have already designated an eligible contract pharmacy and a specialty pharmacy for PAH CODs as part of the previous policy are not required to take any further action at this time.

Effective November 3, 2026, JJHCS will implement the following requirements with respect to *grantee* covered entities under this policy:

- Regardless of whether a grantee covered entity has an in-house pharmacy, each grantee covered entity subject to this policy may designate a single contract pharmacy location actively registered

¹ This notice does not apply to AIDS Drug Assistance Programs described at 42 U.S.C. § 256b(a)(4)(E).

² For purposes of this policy, Covered entity registered locations include only the covered entity's HRSA registered parent and child site locations, and any shipping addresses listed as active in OPAIS.

³ 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").

in OPAIS as a contract pharmacy for delivery of 340B-priced J&J CODs if that single contract pharmacy location is within 40 miles of the grantee site. Grantee covered entities have until October 20, 2026 to designate a contract pharmacy location in order for eligible contract pharmacy location designations to take effect on November 3, 2026.

- For J&J's PAH CODs that are included in this policy, each grantee covered entity may designate a single specialty pharmacy location approved for the limited distribution of PAH CODs.⁴ This pharmacy designation is separate from the pharmacy designation a covered entity may make for all other J&J CODs subject to this policy. Grantee covered entities have until October 20, 2026 to designate a single specialty pharmacy location approved for the limited distribution of PAH CODs⁴ in order for eligible contract pharmacy location designations to take effect on November 3, 2026.

For each order the covered entity places for 340B-priced J&J CODs on or after the applicable effective date specified above, the covered entity represents and warrants that:

- for each contract pharmacy arrangement: (i) the covered entity is responsible for and maintains title to the J&J CODs distributed to the contract pharmacy from the date of purchase until the date of final dispensing to the covered entity's eligible patients, and (ii) the contract pharmacy is operating as an agent of the covered entity;
- the 340B-priced J&J CODs being purchased are for dispensing or administration (or replenishment of J&J CODs dispensed or administered) to the covered entity's patients at the entity's active HRSA registered locations and/or the contract pharmacy dispensing location designated in accordance with this policy; and
- the covered entity and each contract pharmacy arrangement comply with all applicable laws, including the Drug Supply Chain Security Act.

JJHCS may take remedial action in the event of non-compliance with this policy, which may include limiting distribution of 340B-priced J&J CODs to locations not eligible to receive such products under this policy and reversing 340B chargebacks.

Instructions for how 340B covered entities may make a contract pharmacy designation in accordance with this policy are provided in ATTACHMENT A of this notice.

All Johnson & Johnson companies participating in the 340B Program are subject to this policy. JJHCS reserves the right to revise this policy at any time.

Wholesalers and distributors have been instructed to implement this policy effective as of the effective dates specified in this notice. This policy will also apply to newly introduced J&J CODs, and these new CODs will be added to the list of J&J CODs upon launch.

For policy questions, please contact us at <https://jnjit.appianportals.com/jj340BIQ> or by email at 340B_JJHCS@its.jnj.com. For any assistance related to the 340B ESPTM registration or contract pharmacy designation process, please contact support@340BESP.com.

⁴ 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").

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.

1. Q: Which J&J CODs are subject to JJHCS' policy?

A: Covered entities may access the list of CODs covered by this policy in ATTACHMENT B of this notice.

2. Q: Does my Covered Entity need to submit limited claims data for J&J CODs subject to this policy?

A: Please refer to JJHCS' 340B Claims Data Submission policy at <https://www.jnj.com/innovativemedicine/us/authorized-distributors/policies> for information regarding submission of claims data for J&J CODs.

3. Q: My Covered entity is a grantee. Is my Covered Entity subject to this policy?

A: Yes. Grantees are included in the scope of covered entities subject to this policy. Grantee covered entities may designate a contract pharmacy location within 40 miles of the grantee site as listed in OPAIS, through the 340B ESP™ platform. Please see ATTACHMENT A for further instructions on the designation process.

4. Q: How will the updated policy affect covered entities without in-house pharmacies?

A: A covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location actively registered in OPAIS as a contract pharmacy to receive 340B priced J&J CODs included in this policy if that single contract pharmacy location is within 40 miles of the covered entity parent site.

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.

5. Q: How will the updated policy affect covered entities with in-house pharmacies?

A: A covered entity that does have an in-house pharmacy may designate a single contract pharmacy location actively registered in OPAIS as a contract pharmacy to receive 340B priced J&J CODs included in this policy if that single contract pharmacy location is within 40 miles of the covered entity parent site.

6. Q: My covered entity already designated a single contract pharmacy location under JJHCS' prior Bill To/Ship To policy. Does my entity need to take action?

A: No. If your covered entity already had a designated contract pharmacy location under JJHCS's Bill To/Ship To policy, no further action is required.

- 7. Q: My 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 in OPAIS. 340B covered entities may designate a single contract pharmacy location that is within 40 miles of the Covered Entity's parent site that corresponds to a single contract pharmacy location actively registered in OPAIS as a contract pharmacy.

- 8. Q: My covered entity is designating a single contract pharmacy location for non-PAH J&J CODs, 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 COD orders?**

A: Yes. J&J's PAH CODs which are already subject to a limited distribution plan⁵ 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. Covered entities may designate a single specialty pharmacy location approved for the limited distribution of J&J's PAH CODs by visiting <http://www.340besp.com/designations>. This specialty pharmacy location for J&J's PAH CODs may be in addition to a contract pharmacy designation for J&J non-PAH CODs.

- 9. Q: My covered entity has one or more entity-owned/affiliated contract pharmacies. Will these contract pharmacies still have access to 340B pricing?**

A: A covered entity may elect to designate any contract pharmacy location as its single contract pharmacy location under this policy if it is actively registered in OPAIS and is within 40 miles of the covered entity's parent site. For clarity, an entity-owned/affiliated contract pharmacy will not be eligible if the contract pharmacy has not been designated (or is not eligible for designation) by the covered entity under this policy.

- 10. Q: Can my covered entity designate a central fill pharmacy or central receiving location as its contract pharmacy designation under this policy?**

A: No. The designated contract pharmacy must function as the dispensing pharmacy for patients whose prescriptions are filled at that location and may not serve as a central fill or central receiving site.

- 11. Q: How often can my covered entity change its contract pharmacy designation?**

A: 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 as reflected in OPAIS.

⁵ 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").

12. 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.

13. 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. This information is important for JJHCS to manage its process with its wholesalers.

14. 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.

15. Q: Are covered entities located in certain states exempt from this 340B Contract Pharmacy Designation policy?

A: If applicable, states will be exempted from this policy according to notifications provided to covered entities outside this policy.

ATTACHMENT A

INSTRUCTIONS FOR DESIGNATING A CONTRACT PHARMACY LOCATION

Instructions for J&J Covered Outpatient Drugs Not Included in This Policy

This policy is not applicable for any covered outpatient drug that is not included in the list of J&J CODs that can be found in ATTACHMENT B of this notice.

Instructions for 340B Covered Entities Designating a Single Contract Pharmacy Location

340B covered entities may designate a single contract pharmacy location actively registered in OPAIS as a contract pharmacy if that single contract pharmacy location is within a 40-mile radius of the covered entity parent site.

Grantee covered entities should designate their single contract pharmacy location in accordance with this policy by October 20, 2026. Beginning on October 21, 2026, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

Covered entities that elect to designate a contract pharmacy location will utilize 340B ESP™. Covered entities that wish to designate a contract pharmacy location 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>.

To get started with Second Sight Solutions' 340B ESP™ platform, follow these 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 designate a contract pharmacy location by navigating to <http://www.340besp.com/designations>. 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 CODs

J&J PAH CODs, 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.⁶

This specialty pharmacy location designation for PAH CODs may be in addition to a contract pharmacy location designated for non-PAH CODs. Users that have registered an account with 340B ESP™ can designate a single pharmacy location for PAH COD orders by navigating to the Entity Profile tab.

Grantee covered entities should designate their single contract pharmacy location in accordance with this policy by October 20, 2026. Beginning on October 21, 2026, please allow 10 business days from the date of designation for the eligible contract pharmacy locations to take effect.

For policy questions, please contact us at <https://jnjit.appianportals.com/jj340BIQ> or by email at 340B_JJHCS@its.jnj.com. For any assistance related to the 340B ESP™ registration or contract pharmacy designation process, please contact support@340BESP.com.

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”).

ATTACHMENT B

340B Contract Pharmacy Designation Policy Covered Outpatient Drugs

Johnson & Johnson Health Care Systems Inc.'s ("JJHCS") policy regarding 340B contract pharmacy designations effective September 15, 2026, will also apply to any newly introduced or other Johnson & Johnson ("J&J") covered outpatient drugs ("CODs") when added to this list at a later date.

This list may be updated from time to time. The applicable NDCs are listed on the next page of this notice.

J&J COD DIRECTORY	
<i>Alphabetical listing • Read each panel top-to-bottom, then left-to-right</i>	
J&J CODs	
CAPLYTA®	PROCIT®
DARZALEX®	REMICADE®
DARZALEX FASPRO®	RYBREXANT®
EDURANT®	RYBREXANT FASPRO™
ELMIRON®	SIMPONI®
ERLEADA®	SIMPONI ARIA®
ICOTYDE™	STELARA®
INVEGA®	SYMTOZA®
INVEGA HAFYERA™	TOPAMAX®
INVEGA SUSTENNA®	TRACLEER®[1]
INVEGA TRINZA®	TREMFYA®
INVOKAMET®	UPTRAVI®[1]
INVOKAMET® XR	ustekinumab (unbranded STELARA®)
INVOKANA®	VELETRI®[1]
OPSYNVI®[1]	XARELTO®
OPSUMIT®[1]	YONDELIS®
PREZCOBIX®	ZYTIGA®
PREZISTA®	
[1] J&J pulmonary arterial hypertension ("PAH") covered outpatient drug	

BRAND		NDC	BRAND		NDC	BRAND		NDC	BRAND		NDC
CAPLYTA®		72060011040	OPSUMIT®[1]		66215050115	SYMITUZA®		59676080030	VELETRI®[1]		66215040201
		72060012140			66215050130			50458063965			66215040301
		72060014240			66215081208			50458064065			50458057501
DARZALEX®		57894050505	OPSYNVI®[1]		66215081230	TOPAMAX®		50458064165		50458057710	
		57894050520			66215081410			50458064265		50458057718	
DARZALEX FASPRO®		57894050301			66215081430			50458064565		50458057760	
EDURANT®		59676027801	PREZCOBIX®		59676057530			50458064765		50458057810	
		59676028090			59676057830		66215010103		50458057830		
ELMIRON®		50458009801	PREZISTA®		59676056201	TRACLEER®[1]		66215010106		50458057890	
ERLEADA®		59676060012			59676056301			66215010203	XARELTO®		50458057910
		59676060430			59676056401			66215010206			50458057930
ICOTYDE™		57894020130			59676056501		66215023256			50458057989	
INVEGA®		50458055001	PROCRT®		59676056630	TREMIFYA®		57894064001		50458057990	
		50458055101			59676030201			57894064006		50458058010	
		50458055201			59676030301			57894064011		50458058030	
INVEGA HAFYERA™		50458061101			59676030401			57894065002		50458058090	
		50458061201			59676031001		57894065102		50458058451		
INVEGA SUSTENNA®		50458056001			59676031002		57894065104	YONDELIS®		59676061001	
		50458056101			59676031204		57894065122		ZYTIGA®		57894015012
		50458056201			59676032004		66215060206			57894019506	
		50458056301			59676034001		66215060214	END OF DIRECTORY			
		50458056401	REMICADE®	57894003001		66215060406					
INVEGA TRINZA®		50458060601	RYBREVANT®	57894050101		66215060606					
		50458060701	RYBREVANT FASPRO™	57894051001		66215060806					
		50458060801		57894051401		66215061006					
		50458060901		57894051501	UPTRAVI®[1]	66215061206					
INVOKAMET®		50458054060		57894052201			66215061406				
		50458054160	SIMPONI®	57894007001			66215061606				
		50458054260		57894007002		66215062820					
		50458054360		57894007101		66215071801					
INVOKAMET® XR		50458094001			57894007102		66215091014				
		50458094101	SIMPONI ARIA®	57894035001		66215091514					
		50458094201	STELARA®	57894005427	ustekinumab (unbranded STELARA®)	57894044001					
		50458094301		57894006002		57894044003					
INVOKANA®		50458014030		57894006003		57894044101					
		50458014090	57894006103	57894044401							
		50458014130	CONTINUED →		CONTINUED →						
		50458014190									

[1] J&J pulmonary arterial hypertension ("PAH") covered outpatient drug