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Notice to 340B Covered Entities Regarding 340B Claims Data Submission Policy

Announced September 4, 2026

This notice is to inform 340B covered entities of a change to the terms of the federal 340B ceiling price offer on Johnson & Johnson ("J&J") covered outpatient drugs ("CODs").

Effective September 15, 2026, J&J's offer of 340B pricing on its CODs includes a requirement for a covered entity to submit to 340B ESP™ specified claims data for each 340B-eligible J&J COD dispense or administration in accordance with this policy. This requirement applies to all covered entity types[1] regardless of drug dispensing or administration location, inventory management system, or payer coverage. Subject to this requirement, J&J will continue to offer covered entities access to 340B pricing on its CODs up-front at the time of purchase. This policy supersedes the claims data submission provisions in the Johnson & Johnson Health Care Systems Inc. ("JJHCS") notice regarding 340B delivery limitations initially announced on February 15, 2023.

JJHCS has designed this policy to create no more than a minimal administrative burden on covered entities. The limited, commercially standard claims data requested under this policy must already be maintained in covered entities' auditable records to demonstrate compliance with 340B program requirements. Additionally, this data is often already being collected, maintained, and reported through covered entities' existing third-party payer and vendor relationships and provided to manufacturers in deidentified form under contract pharmacy policies, in-house pharmacy claims policies, and/or 340B/"maximum fair price" deduplication policies.

Based on JJHCS's experience, as described below, we have determined that collection of limited, commercially standard 340B claims data in accordance with this policy is necessary to identify and address 340B-related transactions that involve prohibited duplicate discounts and diversion. Such data will also inform JJHCS's approach to engaging in statutorily prescribed audits, administrative dispute resolution ("ADR"), and/or other program integrity activities. Without access to this data, JJHCS cannot effectively identify these prohibited transactions and tailor its program integrity activities to promote efficient oversight and dispute resolution.

- **Medicaid Duplicate Discounts**. Despite long-standing HRSA guidance aimed at preventing duplicate discounts in fee-for-service Medicaid, there has been no reliable solution for preventing duplicate discounts in Medicaid managed care – which covers approximately 80% of Medicaid beneficiaries. Each year since implementing our initial contract pharmacy claims data policy, JJHCS has identified persistently high volumes of duplicate discounts in Medicaid managed care. These duplicates have been identified using the limited 340B claims data JJHCS received via 340B ESP™ under our prior policy. Importantly, this claims data has represented a small subset of total 340B claims and thus has not provided JJHCS with information it needs to identify the full universe of Medicaid duplicate discounts.

- **"Maximum Fair Price" ("MFP") Duplicate Discounts**. Due to litigation, HRSA paused and ultimately abandoned its initial 340B Rebate Model Pilot Program ("Pilot"). The Pilot was the government-endorsed mechanism JJHCS planned to use to ensure compliance with the nonduplication requirements in the Inflation Reduction Act. In the absence of the Pilot, JJHCS has used an interim approach that endeavors to deduplicate "MFP" and 340B discounts on Part D-

[1] This requirement does not apply to AIDS Drug Assistance Programs listed as Ryan White Part B ADAP Rebate Option grantees in OPAIS.

eligible dispenses of J&J's selected drugs. This interim approach has not been sufficient to identify all prohibited 340B/"MFP" duplicate discounts and, to date, JJHCS has encountered significant covered entity and pharmacy resistance to requests to provide necessary and limited 340B claims data.

- **Diversion**. Through JJHCS's approved audits of covered entities and our review of 340B claims data we received via 340B ESP™ under our prior policy, we have identified numerous instances of diversion. These instances include, for example: (i) dispensing of 340B drugs from locations (including contract pharmacies) that are not listed as active 340B dispensing sites on OPAIS, and (ii) two (or more) covered entities claiming 340B replenishment on the same drug dispense. JJHCS requires access to limited 340B claims data provided in accordance with this policy to identify instances of potential diversion.

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 improve 340B Program integrity and compliance to help ensure the 340B Program's long-term sustainability.

COVERED ENTITIES MUST SUBMIT ALL 340B CLAIMS IN ACCORDANCE WITH THIS POLICY TO REMAIN ELIGIBLE TO RECEIVE 340B PRICING ON J&J CODs

- Each covered entity must submit limited 340B claims data in support of each 340B-eligible dispense or administration of all J&J CODs in accordance with this policy as a condition of J&J's offer of 340B pricing to the covered entity on future orders of J&J CODs[2].

  Covered entities will be required to submit limited pharmacy or medical claims data, as applicable, for each 340B-eligible J&J COD to the 340B ESP™ platform within 45 days of product dispense, unless the drug is a J&J COD for which claim data may be submitted within 60 days of product dispense/administration.[3]
- Each conforming 340B claim must correspond to a J&J COD dispense or administration to a patient of the covered entity at (i) a location of the covered entity registered and active in OPAIS[4], or (ii) the eligible contract pharmacy location designated by the covered entity in 340B ESP™ under JJHCS's Contract Pharmacy Designation Policy. The location must be active and eligible as of the date of service on the claim.

- For all data reported to 340B ESP™ under this policy, the covered entity must maintain the integrity of the data provided to third-party payers without appending or altering in any way the data in the underlying payer claim (e.g., Rx number on the 340B claim submitted to 340B ESP™ pursuant to this policy must identically match the Rx number of the corresponding claim submitted to the payer for reimbursement).

- Covered entities must ensure the continued accuracy of 340B claims data submitted to 340B ESP™. If information on a claim changes after the covered entity submits claims data to 340B ESP™, the covered entity is required to update the claim in 340B ESP™ as soon as the change is effectuated

[2] Excluding Miglustat (CoTherix, Inc.), VISTASEAL™, and all Patriot Pharmaceuticals, LLC drugs.
[3] J&J CODs for which claims data may be submitted within 60 days currently include the following: CARVYKTI®, DARZALEX®, DARZALEX FASPRO®, IMAAVY®, INLEXZO®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, PROCRIT®, REMICADE® (infliximab), RISPERDAL CONSTA®, RYBREVANT®, RYBREVANT FASPRO™, SIMPONI ARIA®, SPRAVATO®, STELARA® (ustekinumab), TALVEY®, TECVAYLI®, TREMFYA®, VELETRI®, YONDELIS®.
[4] 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.

in the covered entity's auditable records. If the 340B eligibility of a claim initially submitted to 340B ESP™ as a 340B claim subsequently changes, the covered entity should reverse the claim in 340B ESP™ by submitting the same 340B claims data with a negative unit amount.

NOTICES OF NON-COMPLIANCE

- Covered entities must register on 340B ESP™ within the first 45 days after the effective date of this policy in order to submit claims and receive notifications of non-compliance. The registration period will be available to covered entities after this time has elapsed; however, registration is required to submit claims data in accordance with this policy.

- Failure by a covered entity to provide timely, accurate, and complete data in accordance with this policy may result in JJHCS suspending the covered entity's access to 340B pricing on J&J COD orders placed during a period of non-compliance.

  JJHCS will provide covered entities at least two (2) notices of non-compliance and a notice of pricing suspension before suspending access to 340B pricing for failure to comply with this policy.

Notice	Timing of Notice
1st Notice of Non-Compliance	Upon J&J identification of non-compliance
2nd Notice of Non-Compliance	Sent after 1st notice if covered entity has not submitted claims to come into compliance with this policy
Notice of 340B Pricing Suspension	At least 5 business days prior to suspension of 340B pricing on J&J CODs

- The period of a 340B pricing suspension begins at least 5 business days after the final notice of non-compliance is sent to the covered entity and continues until the covered entity's submission of conforming claims data in accordance with this policy. 340B pricing will be restored within 10 business days following the receipt of claims data that brings the covered entity back into compliance with this policy.

- In order to receive timely notices of non-compliance, covered entities should ensure appropriate and up-to-date contact information is provided in 340B ESP™ for these notices.

- Neither J&J nor JJHCS will be responsible for a covered entity not receiving, or not timely receiving, notices of non-compliance because the covered entity has not registered for, or maintained appropriate contact information in, the 340B ESP™ platform.

Please see ATTACHMENT A for covered entity instructions for this policy.

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.

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 claim submission process and/or the 340B ESP™ platform, please contact support@340BESP.com.

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FREQUENTLY ASKED QUESTIONS

1. **Q: Which covered outpatient drugs are subject to J&J's 340B Claims Data Submission Policy?**

   A: Covered entities may access the complete list of NDCs subject to this policy through the 340B ESP Help Center. From the Help Center, select Claims & Data Submissions, then 340B ESP™ NDCs.

2. **Q: My covered entity is a grantee. Does this policy apply to grantees?**

   A: Yes. This policy applies to all covered entity types except AIDS Drug Assistance Programs listed as Ryan White Part B ADAP Rebate Option grantees in OPAIS.

3. **Q: My covered entity already is registered on the 340B ESP™ platform. Does my entity need to take action?**

   A: If your covered entity is already registered on 340B ESP™, you do not need to take any action to be able to begin submitting limited claims data in accordance with this policy.

4. **Q: My covered entity already participates in JJHCS' Contract Pharmacy Designation Policy. Does my covered entity continue to have a contract pharmacy designation?**

   A: Yes. All covered entities subject to JJHCS' Contract Pharmacy Designation Policy may continue to designate a contract pharmacy location in accordance with that policy, available at https://www.jnj.com/innovativemedicine/us/authorized-distributors/policies.

5. **Q: Does this notice apply to all utilization of J&J CODs or only to utilization dispensed by contract pharmacies?**

   A: This notice applies to all utilization of J&J CODs purchased at 340B pricing by a covered entity, regardless of drug dispensing or administration location, inventory management system, or payer coverage.

6. **Q: Who may submit claims data on behalf of covered entities?**

   A: Covered entities can submit data online through 340B ESP™ or via a direct data submission process with participating TPAs. For any additional information on data submissions, please contact support@340BESP.com.

7. **Q: How frequently may covered entities submit claims data to 340B ESP™?**

   A: There is no limitation on how frequently data may be submitted to 340B ESP™. Claims submitted by covered entities are expected to reflect a **final and complete determination of 340B eligibility** for the claim. JJHCS encourages covered entities to submit 340B claims as soon as possible following the dispense or administration of a J&J COD for a 340B eligible claim.

8. **Q. How should a covered entity handle changes in 340B eligibility of a claim?**

   A:. If the 340B eligibility of a claim initially submitted to 340B ESP™ as a 340B claim subsequently changes, the covered entity should reverse the claim in 340B ESP™ by submitting the same 340B claims data with a negative unit amount. Covered entities are responsible for ensuring that ESP submissions remain current and accurately reflect the final 340B eligibility determination.

9. **Q: How long after a J&J COD is dispensed or administered to a covered entity patient can 340B claims data be submitted to 340B ESP™?**

   A: Covered entities will be required to submit limited pharmacy or medical claims data, as applicable, for each 340B-eligible J&J COD to the 340B ESP™ platform within 45 days of product dispense, unless the drug is a J&J COD for which claim data may be submitted within 60 days of product dispense/administration.[5] However, JJHCS encourages covered entities to submit 340B claims data as soon as possible following the dispense or administration of a J&J COD in an eligible transaction.

10. **Q: How will covered entities identify eligible 340B claims?**

    A: JJHCS expects that covered entities will rely on usual processes consistent with the 340B statute to identify transactions that are 340B eligible. In other words, this policy should not impact the manner by which covered entities identify units eligible for 340B pricing.

11. **Q: Are covered entities located in certain states exempt from this 340B claims data submission policy?**

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

12. **Q: How can my covered entity receive more information about HIPAA compliance and data privacy?**

    A: Second Sight Solutions has provided information on its website under References & Resources and Frequently Asked Questions (FAQs) explaining how data uploaded to 340B ESP™ meets the definition of a de-identified data set under the Health Insurance Portability and Accountability Act ("HIPAA"). Covered entities should refer to this website for questions about HIPAA and data privacy.

13. **Q: How can covered entity submission of 340B claims data under this policy support dispensing entities with the IRA "MFP" effectuation Good Faith Inquiry process?**

    A: Submitting all 340B claims in a timely manner in accordance with this policy and optionally including the associated wholesaler invoice number on each 340B claim supports prompt and efficient resolution of "MFP" rebate claims that are ultimately determined to be non-340B eligible. When the invoice number is included at the time of initial claim submission under this policy, related good faith inquiries can often be resolved automatically. Once a dispensing entity submits a good faith inquiry through Beacon MFP, the system will automatically identify and evaluate claims associated with the invoice referenced in the inquiry.

[5] J&J CODs for which claims data may be submitted within 60 days currently include the following: CARVYKTI®, DARZALEX®, DARZALEX FASPRO®, IMAAVY®, INLEXZO®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, PROCRIT®, REMICADE® (infliximab), RISPERDAL CONSTA®, RYBREVANT®, RYBREVANT FASPRO™, SIMPONI ARIA®, SPRAVATO®, STELARA® (ustekinumab), TALVEY®, TECVAYLI®, TREMFYA®, VELETRI®, YONDELIS®.

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ATTACHMENT A

COVERED ENTITY INSTRUCTIONS FOR THIS POLICY

COVERED ENTITIES MUST REGISTER FOR AND SUBMIT CLAIMS TO 340B ESP™

J&J 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.

As a condition of J&J's offer of 340B pricing on its CODs, covered entities are required to submit claims data utilizing 340B ESP™ in accordance with this policy. Covered entities may register an account at www.340besp.com. Users that already have registered an account with 340B ESP™ can submit the specified 340B claims data by navigating to the Claims Data Submission tab.

The covered entity should register its parent entity, which will be responsible for submitting required claims data for all child sites. Separate child site registration is not necessary because all claims data and purchasing data is aggregated at the parent level.

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 (recommended at least 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 or email support@340BESP.com.

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COVERED ENTITIES MUST PROVIDE 340B CLAIMS WITH LIMITED FIELD REQUIREMENTS

Pharmacy Claim Data Elements: For J&J CODs dispensed through a pharmacy and reimbursed under the pharmacy benefit, a covered entity will be required to submit the pharmacy claim fields specified below.

Field Name	Description
Date of Service	Date the prescription was filled at the pharmacy
Date Prescribed	Date the physician wrote the prescription
Rx Number	The native (unmodified) prescription number for the prescription as generated by the pharmacy
Fill Number[6]	The code indicating whether the prescription is an original or a refill. For example, a value of 0 indicates that the prescription is the original dispense, whereas the value of 1 indicates the prescription has been refilled once.
National Drug Code (NDC-11)	NDC-11 of the product that was purchased by the covered entity
Quantity Dispensed	Number of units dispensed to the patient
Prescriber ID[6]	National provider identifier (NPI) of the prescriber that wrote the prescription
Service Provider ID	NPI of the pharmacy that filled the prescription
340B ID	The HRSA assigned parent 340B ID of the entity that designated the prescription as 340B
Rx Bank Identification Number (BIN)[6]	Bank identification number of the primary payer on the claim. NOTE: If an uninsured patient, a cash paying patient, or no charge to the patient, include CASH in this field.
Rx Processor Control Number (PCN)[6]	Processor control number assigned by the entity processing payment. NOTE: If an uninsured patient, a cash paying patient, or no charge to the patient, include CASH in this field.

[6] Currently an optional field in 340B ESP® for pharmacy claims but may be required at a future date pursuant to instructions provided in 340B ESP.

Medical Claim Data Elements: For J&J CODs dispensed or administered in an outpatient setting by a health care provider and reimbursed under the medical benefit, a covered entity will be required to submit the medical claims fields specified below.

Field Name	Description
Date of Service	Date on which the medication was administered to the patient
Claim Number	The claim number as assigned by the healthcare provider
Claim Line Number	The line number of the claim
National Drug Code (NDC-11)	NDC-11 of the medication administered to the patient
Quantity	Total quantity being submitted on medical claim (units billed).
Unit of Measure[7]	The unit of measure for the quantity submitted on medical claim. Either HCPCS code or UOM is required. If HCPCS code is not included, UOM is required, and it should be consistent with NCPDP units.
Rendering Physician ID[7]	NPI assigned to the provider who administered the medication to the patient. NOTE: If not available, leave blank.
Service Provider ID	NPI assigned to a pharmacy or facility where the patient received the medication administration. For example, this could be the NPI of a hospital outpatient surgery center or the NPI of an outpatient infusion center
340B ID	The HRSA assigned parent 340B ID of the entity that purchased the drug
Health Plan ID	The identifier code of the patient's primary health insurance plan as assigned by the health insurer. NOTE: If an uninsured patient, a cash paying patient, or no charge to the patient, include CASH in this field.
Health Plan Name	Name of the patient's primary health insurance plan. Examples include Medicare Part B, MediCal, Aetna POS, etc. NOTE: If an uninsured patient, a cash paying patient, or no charge to the patient, include CASH in this field.
HCPCS Code[7]	The five character HCPCS code for separately payable medications. This value may not exist for medications that are reimbursed as part of procedure (e.g., a blood thinner used as part of an outpatient procedure).
HCPCS Code Modifier[7] (Up to 4)	Modifier code associated with a separately payable medication with its own five character HCPCS code

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 claim submission process and/or the 340B ESP™ platform, please contact support@340BESP.com.

[7] Currently an optional field in 340B ESP™ for medical claims but may be required at a future date pursuant to instructions provided in 340B ESP.