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October 6, 2025

VIA EMAIL: paperwork@hrsa.gov

HRSA Information Collection Clearance Officer
Health Resources & Services Administration
US Department of Health & Human Services
5600 Fishers Lane
Room 14NWH04
Rockville, MD 20857

RE: Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327—Revision

Dear Clearance Officer:

Johnson & Johnson Health Care Systems Inc. ("J&J") submits the following comments and recommendations in response to the proposed information collection request titled, "Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program," OMB No. 0915-0327-Revision, published in the *Federal Register* on August 7, 2025 (the "ICR").

At Johnson & Johnson, we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges.

J&J is strongly committed to the original intent of the 340B Program and believes transparency and increased accountability in the program will improve access to more affordable outpatient medicines for low-income and vulnerable patients. All Americans—employers, taxpayers, patients, and state and local governments—pay a price for expanded and uncontrolled 340B spending, either through higher premiums or lost tax revenue. The 340B Program must be modernized and refocused on low-income and vulnerable patients and true safety-net providers caring for them. J&J has recommended common-sense measures to improve transparency and accountability in 340B, such as provisions that would require providers to identify 340B-eligible prescriptions to eliminate the waste and abuse of prohibited duplicate discounts.

Below, we offer comments and recommendations on the following two components of the ICR:

1. 340B Registration and Recertification for Sexually Transmitted Disease (STD) and Tuberculosis (TB) Grantees

2. 340B Registration, Recertification and Change Requests for Shipping Address

We also offer an additional recommendation related to contact information for covered entity authorizing officials and primary contacts listed in OPAIS.

340B Registration and Recertification for Sexually Transmitted Disease (STD) and Tuberculosis (TB) Grantees

In the ICR, HRSA is "requesting that STD and TB grantees provide supporting documentation to demonstrate 340B eligibility pursuant to section 340B(a)(4)(K) of the PHS Act during initial registration as well as during recertification if requested to ensure compliance." This documentation "will include a copy of the federal grant notice of award that identifies the grantor, grant number, period of funding, and recipient information." Subgrantees "will also need to provide a copy of the executed written subrecipient agreement that includes the name and address of the recipient and subrecipient, the grant and notice of funding opportunity number, and the terms and conditions of support."

J&J appreciates HRSA's inclusion of these requirements in the ICR to improve program integrity. While these requirements are necessary to fulfill the Secretary's oversight obligations under the 340B statute,[1] we underscore that they are not alone sufficient to satisfy those obligations. Indeed, the absence of required statutory safeguards has led to a concerning proliferation of abusive arrangements involving "in-kind" STD subgrantees. J&J has become aware of a growing number of arrangements where for-profit private physician practices exclusively providing rheumatology, dermatology, or other health care services wholly unrelated to STD treatment have purchased millions of dollars' worth of J&J's 340B-priced non-STD drugs based merely on the practice receiving small quantities of "in-kind" items, such as condoms or marketing materials, and potentially providing a cursory sexual health screening. These abusive arrangements have been detailed in lawsuits brought by several pharmaceutical manufacturers in federal court.[2] To be clear, these arrangements threaten the integrity, safety-net focused mission, and long-term sustainability of the entire 340B Program.

J&J urges HRSA to take additional actions set forth below to end this blatant misuse of the 340B Program.

1. *HRSA should fully implement and enforce the statutory certification requirements in section 340B(a)(7)*

STD grantees are subject to unique 340B eligibility criteria relative to other grantees because they receive federal grant funds indirectly from state or local governments that receive such funds from the federal government. Congress recognized that the 340B eligibility criteria for STD subgrantees pose a heightened risk of abuse and, therefore, imposed additional requirements applicable to these entities in the 340B statute.[3] Section 340B(a)(7) directs the Secretary to establish "a process for the certification of" STD subgrantees that apply for 340B participation, and the Secretary must make these "criteria for certification" available to manufacturers.[4]

Additionally, the certification process "shall include a requirement that an entity applying for certification…submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the

[1] *See, e.g.*, 42 U.S.C. § 256b(a)(7).
[2] *See* Complaint, *Amgen v. Kennedy*, No. 1:24-cv-03571 (D.D.C. Dec. 20, 2024); Complaint, *Genentech v. Kennedy*, No. 1:25-cv-00290 (D.D.C. Jan. 31, 2025).
[3] These requirements also apply with respect to TB grantees and certain HIV clinics. J&J's concerns, as expressed in this section of our letter, relate to recent and ongoing conduct by STD subgrantees. J&J is not presently aware of comparable conduct by these other entity types; however, any such conduct would raise similar concerns.
[4] 42 U.S.C. § 256b(a)(7)(A), (C).

validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices."[5] And the annual recertification process for STD subgrantees "shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities."[6]

To J&J's knowledge, HRSA has never made its certification criteria available to manufacturers. Nor has HRSA otherwise disclosed the steps it has taken (if any) to verify the eligibility of STD subgrantees or to require the submission of purchase information on an ongoing basis. Therefore, in addition to the actions described in the ICR, HRSA should fully implement the statutory certification requirements in section 340B(a)(7). HRSA should also inform all relevant stakeholders, including drug manufacturers, of the actions HRSA takes to implement these requirements.

2. *HRSA should rescind any guidance purporting to confer 340B eligibility on an STD entity based solely on the entity's receipt of "in-kind contributions" or its receipt of grant funds or "in-kind contributions" from another subgrantee*

One of the 15 distinct categories of safety-net health care providers eligible to participate in the 340B Program includes, in relevant part, "[a]n entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases)…through a State or unit of local government…."[7] The phrase "under section 247c of this title" refers to Section 318 of the Public Health Service Act, which authorizes the Secretary to make "grants" to states, local governments, and other entities for prevention, control, and treatment of sexually transmitted diseases.

Despite a clear requirement in the 340B statute that an STD subgrantee must receive "funds" from a state or unit of local government to be eligible for 340B Program participation, HRSA, through a "Frequently Asked Question" or "FAQ" posted on its website, has impermissibly broadened this requirement to include entities that receive only "in-kind contributions" purchased with Section 318 grant funds.[8] This FAQ contained no analysis of the relevant statutory provisions and was issued without notice-and-comment rulemaking, or – more fundamentally – any consideration of whether HRSA has authority to announce this seemingly binding requirement in the first place (it does not).[9] We also understand that HRSA has

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[5] *Id.* § 256b(a)(7)(B).
[6] *Id.* § 256b(a)(7)(E).
[7] *Id.* § 256b(a)(4)(K).
[8] *See* https://www.hrsa.gov/opa/faqs. Relevant FAQ reads as follows: Question: "Can the receipt of in-kind contributions through section 317 or 318 of the Public Health Service Act (PHSA) qualify an entity for participation in the 340B Drug Pricing Program? What are in-kind contributions for purposes of 340B Program eligibility?" Answer: "An entity receiving in-kind contributions through section 317 or 318 may qualify for the 340B Drug Pricing Program provided all the remaining 340B requirements are met. Qualifying in-kind contributions must be paid for by section 317 or 318 grant funds to qualify a site as 340B eligible. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program. A grantee should contact the granting agency project officer to determine if the in-kind service meets the agency's definition of in-kind."
[9] Notably, HRSA lacks general rulemaking authority over the 340B program, and its enumerated regulatory authority does not include covered entity eligibility requirements. *See PhRMA v. HHS*, 42 F.Supp.3d 28 (D.D.C. 2014). The D.C. District Court has previously held that "[t]he rulemaking authority granted HHS by Congress under the 340B program has…been specifically limited, and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program." The Court clarified that "[w]ithin section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."

conferred 340B eligibility on STD subgrantees that have received federal grant funds only from other subgrantees (*i.e.*, sub-subgrantees) rather than from state or local governments.

Given HRSA's departure from the plain text of the 340B statute and failure to follow appropriate administrative procedures, HRSA should (i) rescind the FAQ and any other guidance that purports to allow 340B Program participation based solely on an entity's receipt of "in-kind contributions," or its receipt of grant funds or "in-kind contributions" from another subgrantee, and (ii) clarify that 42 U.S. Code section 256b(a)(4)(K) requires that an entity receive a non-nominal amount of "funds" (*i.e.*, cash) under a relevant federal grant directly from a state or unit of local government.

3. *HRSA should clarify that STD subgrantees, may not purchase 340B drugs that do not relate to the treatment of sexually transmitted diseases*

Under HRSA's 1996 patient definition guidance, an individual is a "patient" of an STD subgrantee for purposes of the 340B Program "only if…the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding…has been provided to the entity."[10] Additional HRSA guidance states that "STD (318 grantee) clinics that participate in the 340B Program may purchase 340B drugs (including prescribed contraceptives) for grantee patients *that meet the patient definition criteria*," and that an STD clinic "may purchase and dispense any 340B drugs associated with a service for which the covered entity is responsible, including contraceptives, to that patient, *to the extent it aligns with [the] patient definition and is consistent with the scope of the grant*."[11]

Construing a "patient" of an STD subgrantee to include only an individual receiving STD treatment comports with the text of the 340B statute, which provides that a person "is…a patient of the entity" "*[w]ith respect to* [a] covered outpatient drug."[12] This construction is also consistent with the statute's structure and purpose. The 340B statute permits STD subgrantees to obtain discounted drugs to further the purpose of the relevant federal grants – *i.e.*, "treatment of sexually transmitted diseases."[13] Permitting STD subgrantees to obtain 340B discounts on drugs that have no nexus to STD treatment furthers abuse of the 340B Program for the benefit of profit-seeking entities while doing nothing to advance the purpose of the underlying federal grants or the interests of individuals these grants are intended to benefit.

To stem this abuse, HRSA should expressly state that STD subgrantees may not purchase 340B drugs that do not relate to the treatment of sexually transmitted diseases.

340B Registration, Recertification and Change Requests for Shipping Address

In the ICR, HRSA is "providing additional clarification for covered entities to complete the shipping address section in 340B OPAIS to improve transparency and assist in determining the exact shipping address location and relationship to the covered entity. The information collected will help determine whether the shipping address is a pharmacy, health care delivery site, or other receiving location."

[10] 61 Fed. Reg. 55156, 55157-58 (Oct. 24, 1996).
[11] HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs (emphases added).
[12] 42 U.S.C. § 256b(a)(5)(B).
[13] *Id.* § 256b(a)(4)(K).

J&J supports HRSA's efforts to clarify the shipping address fields in OPAIS. In furtherance of this goal, we encourage HRSA to take the following actions:

First, HRSA should clearly define a new category of pharmacy – "covered entity-owned or affiliated pharmacy" – in the OPAIS user guide[14] and other guidance. Currently, we understand that covered entities may take different approaches to listing their owned and affiliated pharmacies in OPAIS. To ensure consistency and improve transparency, HRSA should define a new category of pharmacy that includes:

- pharmacies that are owned by the covered entity but not a legal part of the covered entity, and thus do not meet HRSA's current OPAIS user guide definition of an in-house pharmacy, and
- pharmacies under common ownership with the covered entity, such as pharmacies owned by the covered entity's affiliated health system, which a covered entity might not currently treat as contract pharmacies.

If HRSA were to create this new pharmacy category, we note that conforming updates to the definitions of "contract pharmacy," "in-house pharmacy," and/or "shipping address" may be required to avoid ambiguity and overlap. As noted, clearly defining all of these terms for OPAIS reporting purposes would improve transparency and consistency for the benefit of all 340B stakeholders.

Second, HRSA should add standard shipping address categories in OPAIS (through a drop-down menu) and require covered entities to assign the relevant category to each shipping address listed in their OPAIS record. Shipping address categories should include the following: covered entity health care delivery site, covered entity-owned or affiliated pharmacy, in-house pharmacy, third-party receiving facility, and covered entity central distribution facility.

To account for situations where a covered entity clinic site is located at the same address as a pharmacy or other facility, HRSA should require covered entities to list each site, pharmacy, or facility as a separate shipping address in OPAIS. For each shipping address, the covered entity should be required to: (i) describe the site, pharmacy, or facility located at that address using the standard categories described above, and (ii) provide the associated National Provider Identifier ("NPI").

Contact Information for Covered Entity Authorizing Officials and Primary Contacts

While not expressly contemplated in the ICR, we encourage HRSA to require covered entities to report up-to-date email addresses for their authorizing officials and primary contacts at least annually and to provide manufacturers access to this information in OPAIS. Currently, manufacturers can only access the phone number and mailing address of covered entity authorizing officials and primary contacts in OPAIS. While important, these modes of communication are not always the most effective or efficient. Collecting these email addresses and making them available to manufacturers through OPAIS would provide another option for manufacturers to efficiently and accurately contact covered entity personnel. We appreciate the sensitivity of email addresses and understand the likely desire to limit their broad dissemination. To address these valid concerns, HRSA could limit access to these email addresses to only authorized OPAIS users.

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[14] HRSA, 340B OPAIS User Guide, https://www.hrsa.gov/sites/default/files/hrsa/opa/public-user-guide.pdf.

J&J appreciates HRSA's attention to these comments and recommendations and welcomes further discussion as appropriate. Please do not hesitate to contact us with any questions or if additional information would be helpful.

Sincerely,

Corbin Santo
Senior Counsel

cc: Chantelle Britton, Director, HRSA Office of Pharmacy Affairs