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October 6, 2025

VIA E-MAIL TO PAPERWORK@HRSA.GOV

HRSA Information Collection
Clearance Officer
Room 14NWH04
5600 Fishers Lane
Rockville, MD
20857

Re: **Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program,**
OMB No. 0915–327—Revision

Dear Director Button:

UCB, Inc. (UCB) is a global biopharmaceutical company focused on innovating new medicines to treat chronic, severe diseases in neurology and immunology. We are more than 9,000 people globally, inspired by patients and driven by science. Our foundational commitment to crafting sustainable solutions and delivering medicines that aim to improve lives is at the core of all that we do, as we live our purpose each day. Since 1928, we have brought together the expertise, talent, tools, and scientific ingenuity needed to pursue what's right for people living with severe disease and for society. UCB is committed to ensuring that all patients have affordable access to the right medicine at the right time, regardless of age, ethnicity, geography, or economic circumstance. Patients are at the heart of everything we do at UCB, from where we invest our research dollars to how we engage with other stakeholders to bring new therapies to market. Every day, we work to ensure that patients have the best individual experience, while promoting access to high-quality, coordinated, affordable care and equitable access to medicines for all patients.

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UCB welcomes this opportunity to respond to the request for comment from the Health Resources and Services Administration (HRSA) on the necessity and utility of proposed information collection for various aspects of 340B enrollment and certification of eligibility by covered entities.[1] Below, we provide comments on HRSA's proposal to require entities seeking to register as sexually transmitted disease (STD) grantees under Section 340B(a)(4)(K) to submit certain information "during initial registration as well as during recertification if requested."[2] This information includes documentation of a federal grant award for STD grantees and, "[i]f the entity is a subgrantee," a written copy of a "subrecipient agreement."[3] While UCB applauds HRSA's interest in "enhanc[ing] program integrity,"[4] and views these proposals as a good first step, the proposed changes fall short of ensuring that STD grantees are certified and recertified in a manner consistent with statutory requirements.

As an initial matter, UCB notes that Section 340B requires the Secretary to "develop and implement a process for the certification of" STD grantees and to "make available to all manufacturers of covered outpatient drugs a description of the criteria for [their] certification."[5] To date, however, HRSA has yet to make any certification criteria available to manufacturers. As a starting point, HRSA should comply with this mandatory statutory requirement.

Furthermore, based on the data requested in its recent information collection request, it appears that HRSA is not employing adequate criteria to ensure that all entities registered as STD grantees are in fact eligible under the statute. Indeed, we note several examples where HRSA's certification and recertification process for STD grantees falls short.

First, HRSA's request that "[i]f the entity is a subgrantee" it must provide documentation of a "subrecipient agreement" ignores that Section 340B does not include subgrantees in the list of eligible covered entities. Rather, an entity may qualify only if it receives "funds . . . through a State or unit of local government."[6] This provision accordingly requires such an entity to establish its eligibility by receiving funds directly from state and local public health agencies or other governmental units. It does not authorize such a grantee to pass on 340B eligibility even further down the chain, by transferring a portion of its own grant funds to other "sub-subgrantee" providers. Interpreting the statute that way would effectively rewrite the text, conferring eligibility on providers that "receiv[e] funds . . . through a State or unit of local government or through a subgrantee."

Rewriting the statute that way would give a covered entity the power, by choosing other providers on which to bestow a share of its grant funds, to create brand new covered entities. Congress has never allowed covered entities to unilaterally create other independent covered entities. Allowing a subgrantee to pass on 340B eligibility by transferring grant funds to other entities also has no limiting principle or logical stopping point. It would allow a pool of grant funds to be transferred from provider to provider to provider—all of which could declare themselves covered entities on the ground that the funds at one point passed, however distantly, through a state agency. The care

[1] *See* 90 Fed. Reg. 38,167 (Aug. 7, 2025)
[2] *Id.* at 38,168
[3] *Id.*
[4] *Id.*
[5] 42 U.S.C. § 256b(a)(7)(A), (C)
[6] *Id.* § 256b(a)(4)(K)

and precision with which Section 340B identifies and defines the list of eligible covered entities underscores that Congress never intended to create such a perpetually cascading authorization structure.

UCB therefore urges HRSA to modify its information collection request accordingly to make clear that only entities receiving funds through a State or unit of local government—rather than through another covered entity—may qualify as eligible STD grantees.

Second, Section 340B limits eligibility to "entit[ies] receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases)."[7] The plain meaning of "funds" is "money, often money for a specific purpose."[8] Thus, only entities that receive money, not those that receive goods, qualify as covered entities under this statutory definition.

This plain meaning is supported by the fact that the cross-referenced provision, Section 247c, authorizes States and units of local government to receive "grants,"[9] a term that likewise refers only to "an amount of money."[10] States and units of local governments receive money as grant recipients under Section 247c; and when they transmit a portion of that money to an STD clinic, the recipient may become "[a]n entity receiving funds under section 247c."[11] The associated reference to "grants" thus reinforces the monetary meaning of "funds."

The cross-referenced provision also expressly distinguishes "grants" from "supplies or equipment," by authorizing the Secretary to "reduce [a] grant by the fair market value of any supplies or equipment furnished to such recipient."[12] The provision thus makes clear that a "grant" is distinct from in-kind contributions of supplies or equipment, and also "show[s] that Congress knows how" to refer to in-kind contributions in the context of federal public health grants when it intends to do so.[13]

HRSA has expressed a contrary view in guidance on its website, which states that "the receipt of in-kind contributions" can qualify a recipient as a 340B-eligible STD grantee.[14] This statement is at odds with the text of the 340B statute, as an entity receiving only in-kind contributions for STD treatment does not receive "funds" through a State or local unit of government.[15] HRSA should therefore require entities seeking eligibility as STD grantees to confirm that they have received "funds" (*i.e.*, money), rather than goods or other in-kind remuneration.

Third, to qualify and maintain eligibility as a covered entity under Section 340B, an entity must "meet[] the requirements described in paragraph [(a)](5)" relating to program compliance.[16] Under paragraph (a)(5), "a covered entity shall not resell or otherwise transfer [any covered outpatient]

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[7] *Id.*
[8] Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/funds.
[9] 42 U.S.C. § 247c(b)-(d).
[10] Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/grant.
[11] 42 U.S.C. § 256b(a)(4)(K).
[12] *Id.* § 247c(e)(4).
[13] *Pereida v. Wilkinson*, 592 U.S. 224, 232 (2021).
[14] HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs.
[15] 42 U.S.C. § 256b(a)(4)(K).
[16] *Id.* § 256b(a)(4).

drug to a person who is not a patient of the entity."[17] An entity that transfers drugs to non-patients does not "meet[] the requirements described in paragraph [(a)](5)"—and thus does not qualify as a covered entity.[18] Therefore, to establish its eligibility for purposes of certification and recertification as an STD grantee, an entity must submit information demonstrating that it does not transfer 340B drugs to non-patients.

Of particular relevance, HRSA's longstanding guidance provides that an individual is a "patient" of an STD grant recipient for purposes of program eligibility "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."[19] Construing "patient" of an STD subgrant recipient to include only an individual receiving STD treatment also comports with the statute's text, structure, and purpose. Section 340B allows STD subgrantees to obtain reduced-price drugs to facilitate the purpose of those federal grants: namely, "treatment of sexually transmitted diseases."[20] Permitting STD grantees to obtain 340B-priced drugs with no nexus to STD treatment advances neither the purpose of the federal grants nor the interests of the individuals whom the grants seek to benefit. Instead, it encourages abuse of the 340B program.

Therefore, under Section 340B's definition of "patient," if an entity has been certified as 340B-eligible based on its receipt of STD grant funds, but the entity provides 340B-priced medicines to individuals who are not receiving STD treatment (or the 340B-priced medicines are not used or indicated for treating STDs), the entity has "transfer[ed] [a covered outpatient drug] to a person who is not a patient of the entity."[21] Such an entity no longer satisfies the statutory definition of what "the term 'covered entity' means,"[22] and should thus be ineligible to participate in the 340B program.

The 340B statute thus imposes an affirmative obligation on HRSA to ensure that an entity applying for certification or recertification submits information necessary to assess whether the entity's 340B-priced purchases comply with statutory eligibility criteria, including paragraph (a)(5)'s prohibition on transferring covered drugs to non-patients.[23] Indeed, the 340B statute expressly requires HRSA to "evaluat[e] the validity" of each entity's drug purchases before HRSA certifies or recertifies a covered entity.[24] HRSA should accordingly require an entity seeking certification or recertification to submit information about its purchases to allow the agency to evaluate whether the entity has transferred 340B-priced medicines to individuals who are not receiving STD treatment within the scope of the relevant grant.

Finally, the information collection request states that entities must "provide supporting documentation to demonstrate 340B eligibility . . . during initial registration as well as during

[17] *Id.* § 256b(a)(5)(B).
[18] *Id.* § 256b(a)(4).
[19] 61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996); *accord* HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs (STD grantees may purchase 340B drugs in connection with a service "to the extent it aligns with [the] patient definition and is consistent with the scope of the grant.").
[20] 42 U.S.C. § 256b(a)(4)(K).
[21] *Id.* § 256b(a)(5)(B).
[22] *Id.* § 256b(a)(4).
[23] *Id.* § 256b(a)(7).
[24] *Id.* § 256b(a)(7)(B), (E).

recertification if requested to ensure compliance."[25] This approach of making the submission of information optional for certifying and recertifying entities does not accord with statutory requirements.

The 340B statute provides that the Secretary "shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities."[26] The word "'shall'" has "an unmistakably mandatory character."[27] The statute thus makes clear that HRSA should require an entity seeking certification and recertification to submit the information necessary to evaluate the entity's eligibility, including purchase information, each time the entity is certified or recertified.

In conclusion, UCB offers these comments in the hope that HRSA will take the above steps to strengthen the process for verifying the eligibility of entities seeking to certify and recertify as STD grantees. UCB respectfully submits that the suggestions proposed above are necessary to ensure program integrity and prevent abuse of the 340B program by entities that do not meet the statutory criteria. If you have any questions, please contact Douglas Helling, Head of Global Market and Pricing Legal at UCB, at Douglas.Helling@ucb.com or (770) 970-8363.

[25] 90 Fed. Reg. at 38,168.
[26] 42 U.S.C. § 256b(a)(7)(E).
[27] *Hewitt v. Helms*, 459 U.S. 460, 471 (1983).