NCSD
National Coalition of STD Directors

Promoting Sexual Health Through STD Prevention

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Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
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October 6, 2025

Re: Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327
(Federal Register Document Number 2025-14955)

Dear Ms. Britton:

On behalf of the National Coalition of STD Directors (NCSD), I write to support the content of the referenced enrollment and re-certification requirements but also share concerns regarding the burden estimate included in this ICR. NCSD is a national public health membership organization representing and serving the nation's STI professionals, including our historic members—the sixty-five STD directors serving every state, the territories, and seven large cities—their staff, and more than 1,400 clinic members and 1,800 disease intervention specialists. As the voice of our membership, our mission is to advance equitable, effective STI prevention programs and services in all communities across the country.

NCSD membership makes up a vast majority of the Section 318 STD grantees in the 340B program and oversee a network of safety net subgrantees who address our nation's STI epidemics. Subgrantees are a vital part of our nation's STI clinical safety net, as many STD grantees do not provide services directly themselves but use their grant support to ensure a robust and effective safety-net in their jurisdiction.

Generally, NCSD supports the proposed 340B registration and recertification requirements for STD grantees and their subgrantees. However, the proposed ICR does not acknowledge a significant operational challenge that will impact implementation. Many STD subrecipient agencies do not currently have written agreements with the recipient agency that meet the proposed standards, or existing agreement will need to be re-written to include the information requested by the Office of Pharmacy Affairs. While we appreciate that these materials may be requested upon an audit, the statement that this new requirement "…will slightly increase the burden on covered entities" is incorrect and does not account for the realities of STD grantees, who will need to provide these agreements to their subrecipients. Materials requested in an audit may result in an audit finding but are not equivalent to a registration requirement. This requirement will be a new reporting requirement to HRSA, and as such, will require by some STD grantees a substantial investment of time.

Due to stringent governmental public health agency procurement and contracting requirements outside of the STD grantee's control, the process of establishing new written agreements or amending existing ones is often time-consuming and

administratively complex. Recipient agencies will require ample time to draft, negotiate, and finalize these agreements, both internally and in collaboration with their existing and prospective subrecipient partners. A new or updated "executed written subrecipient agreement" could take up to a year for STD grantees to provide to their subrecipient partners.

The time assessment for new STD registrations (1.25 hour per respondent) and STD re-certification (.25 hour per respondent) belittle the investment of time of the respondent's granting entity, which could take upwards of 10-20 hours over the course of a year to establish such an agreement, and could vary depending on the requirements of a governmental health department. Health Departments may also require a separate agreement per subrecipient, which will also increase the time burden for these new requirements.

NCSD appreciates OPA's request for additional information about STD subrecipients and agrees that, in the long run, these written agreements could streamline the verification process. As such, after the Office of Pharmacy Affairs implements these new requirements, NCSD requests that OPA consider shortening the time between 340B registration and 340B program effective date. These new registration requirements could also provide STD grantees another tool to outline their terms for grant support that provides access to the 340B program. The time burden for grantees will dominantly occur at the implementation of the requirement.

As a result, and to ensure a smooth transition that does not jeopardize program access or continuity of care, NCSD request that HRSA provide a one-year implementation period after the new 340B registration and/or recertification process is finalized. A more rapid timeline may result in numerous 340B covered entities being unable to recertify because they cannot meet the new criteria in time. This would have a significant and detrimental impact on public health efforts to respond to STIs. This is particularly true for local public health department STD clinics, which are often smaller, do not generate program income, and could not afford the Wholesale Acquisition Cost (WAC) for essential drugs like Bicillin L-A.

We appreciate HRSA's commitment to strengthening the 340B program and believe that with a postponed implementation timeline, these requirements will enhance accountability and effectiveness. NCSD stands ready to serve as a resource to you on this and other matters.

Sincerely,

Stephanie S. Arnold Pang
Senior Director, Government Relations and Programs