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July 8, 2019

Captain Krista Pedley, PharmD Director, Office of Pharmacy Affairs Health Resources Services Administration 5600 Fishers Lane Rockville, Maryland 20857

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

Dear Captain Pedley--

The National Coalition of STD Directors (NCSD) appreciates this opportunity to provide comments on the Health Resources and Services Administration's (HRSA) data collection plans for covered entities in the 340B Drug Pricing Program administered by the Office of Pharmacy Affairs (OPA). As the executive director of NCSD, I am writing on behalf of our membership – the directors of the 65 STD programs across the country, which are directly funded by the Centers for Disease Control and Prevention (CDC) and participants in the 340B program.

In this Information Collection Request (ICR), HRSA proposes to collect certain information from "STD/TB Clinics." STD clinics receive their authority for the 340B program through the 318 program. HRSA has recently redefined which grants from the CDC confer eligibility under the 318 program to now include any CDC grant that uses the 318 statutory authority, a total of approximately 30 grants as of earlier this spring. Despite this ICR stating "any STD entity," we assume this pertains to all 318 entities.

This ICR requests that at the time of registration for the 340B program, any 318 covered entity provide its Notice of Funding Opportunity (NOFO) number, and describe the type and time period of in-kind funding the entity receives. We support the request for NOFO number, as this will provide clarity regarding which CDC NOFO is conferring the covered entity's eligibility, as well as encourage communication between the NOFO recipient and their 340B-eligible partners. As stated in the ICR, this information is already being collected upon 340B registration and recertification.

NCSD has concerns, however, regarding the requested in-kind donation information, particularly considering the additional 318 covered entities now with access to the 340B program. Providing the requested information regarding the type of in-kind donations received imposes an additional reporting and administrative burden on 340B 318 covered entities, for which OPA has provided no rationale.

NCSD requests that OPA clarify their purpose for seeking this data collection, and work with NCSD and other membership organizations that represent other 318 340B covered entities to provide additional information regarding in-kind contributions, should that be needed.

NCSD appreciates your attention to this matter. If you need additional information, please contact NCSD's director of policy and government relations, Stephanie Arnold Pang, at sarnold@nsddc.org or 202-715-3865.

Sincerely,

David C. Harvey Executive Director

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