NCSD
National Coalition of STD Directors

Promoting Sexual Health Through STD Prevention

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June 3, 2019

U.S. Department of Health and Human Services
Room L001, 330 C Street SW
Washington, DC 20024

RE: [Document no: 2019-09113] - Request for Information (RFI): Developing an STD Federal Action Plan

Dear Dr. Beckham,

The National Coalition of STD Directors (NCSD) respectfully submits these comments in response to document number 2019-09113 requesting comments from stakeholders to help inform development of the first-ever Sexually Transmitted Infections (STI) Federal Action Plan. We appreciate the opportunity to provide these comments at a time when STI rates are at record levels in the U.S.

As the national public health membership organization representing health department STD programs and their community-based partners across 50 states, seven large cities, and eight U.S. territories, NCSD is uniquely positioned to support the development of the first-ever STI Federal Action Plan. We submit these comments on behalf of our members and their partners, following a community input process with feedback from state and local or territorial health departments, STD program directors, health care providers, disease intervention specialists (DIS), community-based STD partners, and academic researchers.

STIs are at epidemic levels and continuing to rise. Data from the Centers for Disease Control and Prevention (CDC) tells us that between 2013 and 2017 syphilis cases increased 80 percent, gonorrhea cases increased 67 percent, and chlamydia cases increased 22 percent. Preliminary 2018 data from Florida, Mississippi, Missouri, Rhode Island, Tennessee, Washington state, and South Carolina show that STI rates continue to increase and will set a record for the fifth year in a row. These epidemics are creating a public health emergency with devastating health consequences in every corner of our nation, including

infertility, cancer, transmission of HIV, and infant and newborn death. These epidemics are so widespread and are increasing at such rapid rates that no one sector can stem the tide. All public and private stakeholder groups must play a role developing the action plan and in identifying and eliminating barriers to preventing, finding, diagnosing, and treating these diseases.

We believe this plan has been needed for some time, as was highlighted in the NCSD commissioned study by the National Academy of Public Administration titled "The Impact of Sexually Transmitted Diseases on the United States: Still Hidden, Getting Worse, Can be Controlled" which makes the case for a national strategy, and many other recommendations which we draw on in our comments. We encourage the Office of HIV/AIDS and Infectious Disease Policy (OHADIP) to review this study. A second phase of this study is now in the process and expected to be completed by November 2019. This second phase of work will focus on the "frontlines" of STD outbreaks including intergovernmental obstacles to program execution and conflicting policies and funding constraints.

Furthermore, a recent study by Treatment Action Group identifies the need for increased research, especially around novel treatment options and new prevention modalities including vaccine research which are highlighted in some of our comments below and in the report Gonorrhea, Chlamydia, and Syphilis Pipeline Report 2019.

NCSD submits these recommendations, with the expectation that the action plan will follow the format of similar federal plans, such as the National HIV/AIDS Strategy (NHAS), including principles, priorities, goals, action steps, and progress indicators to guide the national response to STIs. Therefore, NCSD's below comments follow the same format of NHAS, by numbering our goals 1-7, the action steps for each corresponding goal as 1.A for goal 1, 2.B for goal 2 etc., and sub steps as 1.A.1, etc.

NCSD believes that the below proposed indicators, goals, and steps should become part of the plans finalized indicators, goals, and steps.

Indicators:

While NCSD recommends the development of indicators to set priorities and to measure progress, we are mindful of the following challenges:

- Currently the data available to describe the STI epidemics, successful approaches, and best practices is limited and needs improvement. Data reporting is overly complex, inconsistent, and technologically challenged. While CDC collects and reports on STI rates via its annual surveillance report, legal authority for gathering and reporting the data rests with the states. Furthermore, some of the indicators listed below may not have available baseline data. As a result, this plan may need to implement a strategy for gathering and analyzing that data that has not previously reported and tracked.
- While CDC is the principal federal funder of STI prevention and control programs, it does not provide direct services. That responsibility lies with the states and local jurisdictions. As a result, there is wide variation across states and localities in how they address and fund efforts.
- As goals in this plan are implemented STI rates will most likely increase in the initial years, particularly as testing and screening is scaled-up. Therefore, it may take over ten years for some of these indicators to be achieved, unless significant new funding is infused into the current national STI prevention program.

NCSD is not aware that a firm timeframe has been determined by HHS staff for the STI Federal Action Plan. In providing indicators NCSD is presuming a ten-year timeframe similar to NHAS. NCSD believes that progress indicators for the action plan should be measurable, realistic, and achievable within this timeframe, or the final timeframe determined by HHS.

- *Increase condom use among individuals with multiple sexual partners who visit HIV, STI, or family planning clinics by 25 percent*
- *Increase syphilis, chlamydia, and gonorrhea screening of sexually active persons attending STI, family planning, school-based, and Ryan White clinics by 20 percent*

- *Increase the number of men who have sex with men, young people between the ages of 15-24, and women of childbearing age attending STD, HIV and family planning clinics who receive at least one test annually by ten percent*
- *Increase the number of people who are rescreened within 120 days for syphilis, chlamydia, and gonorrhea by 35 percent to reduce repeat infections*
- *Increase the percent of women who attend prenatal care who receive a repeat syphilis test in their third trimester to 70 percent*
- *Reduce the number of congenital syphilis cases among women attending prenatal care by 50 percent*
- *Increase HPV vaccination rates to 80 percent*

Goals:

Goal 1: Improving STI Prevention Efforts

Step 1.A: Increase STI Prevention Funding

- 1.A.1: Increase STI funding consistent with the scale of the STI Epidemic

Background: STI prevention funding has not increased in over 15 years, and this level funding has resulted in a 40 percent loss of purchasing power and millions of men, women, and children acquiring an STI. Without sufficient resources there is no chance that the STI Federal Action Plan will succeed. The CDC must be funded at $227.3 million for STIs in FY2021, an increase of $70 million.

- 1.A.2: Eliminate restrictions on the use of STI funds for screening, diagnosis and treatment:

Background: Although CDC is the principal funder of STI prevention, limited resources, if any, are devoted to funding services, leaving jurisdictions with limited resources to treat STIs after they are identified.

- 1.A.3: Provide incentives to encourage states and localities to increase funding for STI prevention, screening, diagnosis and treatment.

Background: Not all jurisdictions provide funding for STI prevention, screening, diagnosis and treatment. In fact, the majority of jurisdiction's STI funding is from the federal level.

- 1.A.4: Encourage flexibility of funding across programs such as HIV prevention, Ryan White, Title X, health programs directed toward adolescents, pregnant women and MSM to address the STI epidemic.

Background: Discreet funding streams create silos that inhibit the effective use of funds to increase STI prevention, screening and treatment. Artificial funding barriers and restrictions should be eliminated to promote service integration and expand STI testing and treatment.

- 1.A.5: Encourage and share condom best practices

Background: When used accurately and consistently condoms are one of the primary forms of protection against STIs. This plan should share best practice examples for free condom distribution in diverse venues.

Step 1.B: Support Biomedical Interventions for STI prevention and treatment

- 1.B.1: Invest in promising biomedical STI prevention and care interventions.

Background: Biomedical advances in HIV care and prevention have made it possible to plan for the elimination of HIV. Investment in promising biomedical STI prevention and care interventions may one day yield similar results. Opportunities include the following:

- Development of vaccines for chlamydia, gonorrhea, and syphilis
- Development of reliable Clinical Laboratory Improvement Amendments (CLIA) waived rapid tests for chlamydia, gonorrhea, and syphilis
- Testing and adoption of STI pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), such as the use of doxycycline
- Provision of incentives for pharmaceutical companies to develop new consumer-based tests and treatments

- Provision of incentives and innovative approaches to expand utilization of the HPV vaccine

Step 1.C: Reduce Stigma

- 1.C.1: Implement public awareness campaigns that use social media and targeted technology to change the narrative around STIs.

Background: Sexual health is a critical component of overall health and well-being, but most Americans have no idea that STIs can cause serious and long-lasting harm. Public awareness campaigns that use social media and targeted technology are essential to reach the widest possible audience with scientifically accurate, easy to understand information about how to prevent STIs. For example:

  - A national public health media campaign normalizing STI testing and treatment
  - Social media advertising to women of childbearing age about syphilis and where to be tested for free
  - A national initiative to educate providers on recommended screenings and treatments, emerging threats of antibiotic resistance, the importance of taking a sexual history, and prescribing PrEP

Step 1.D: Eliminate Congenital Syphilis

- 1.D.1 Designate $20 million for a special initiative within HHS to eliminate congenital syphilis.

Background: A completely preventable disease, congenital syphilis (CS), is a symptom of a failing public health system. Approximately 40 percent of the infants born with this disease die from it, and it results in significant health consequences for the infants who survive. Funding that focuses this funding on the states with the highest rates of congenital syphilis and assures that all jurisdictions are provided additional designated prevention funds can help to bend the curb on rising CS rates.

- 1.D.2: Work with public and private providers of maternity care to assure that all pregnant women are tested for syphilis at their first prenatal visit and again in the third trimester.

Background: Eight percent of CS cases in 2016 were due to women not being screened properly. The Centers for Disease Control and Prevention recommends syphilis screening at the first prenatal visit for all women and early in the third trimester and at delivery for women at high risk of infection.

- 1.D.3: Assure that all providers of maternity care are trained to recognize and treat syphilis in pregnant women.

Background: Eighteen percent of the CS cases in 2016 were due to improper treatment for CS after being screened. This is in large part to providers not being trained on proper treatment guidelines.

- 1.D.4: Assure that all payers provide payment for multiple syphilis testing and treatment as needed.

Background: Some insurance providers, including some state Medicaid plans, do not cover syphilis testing more than once a year, this can limit the number of times a individuals, including women, can be covered for syphilis testing in one year.

- 1.D.5: Initiate a public awareness campaign on the importance of prenatal care and syphilis testing for pregnant women.

Background: Thirty-four percent of CS cases were due to late or no prenatal care. A public awareness campaign about the importance of prenatal care and getting tested for syphilis during that check-up can help to get women into care and advocating for their health.

- 1.D.6: Recommend states implement policies in correspondence with CDC's guidelines for prenatal syphilis screening.

Background: Only seven states have statues or regulations that correspond to the CDC guidelines for prenatal screening. Therefore, providers are not always required to screen in the third, or even first trimester for syphilis.

Goal 2: Increasing STI Surveillance

Step 2.A: Improve Data

- 2.A.1: Provide financial and technical assistance to states and jurisdictions to enable them to upgrade their data infrastructure and data collection to make it more efficient and functional.

Background: Upgrading data collection, storage, and reporting will result in data that is timely and usable in identifying outbreaks and providing accurate information for program evaluation and planning.

- 2.A.2: Improve data sharing between HIV and STI systems

Background: Data sharing between STI and HIV systems helps to identify target populations for both STI testing and PrEP engagement, thereby benefitting continuity of prevention and care services.

- 2.A.3: Develop best practices for effective and efficient electronic laboratory reporting

Background: Accurate and timely STI data can help to identifying hotspots, prevent new STI cases, and monitor progress towards reducing new STI cases.

Goal 3: Improve and Expand STI Testing

Step 3.A: Support Innovative Activities for STI Testing and Treatment:

- 3.A.1: Develop and disseminate new, consumer-focused approaches to STI testing, including home testing, mobile apps, and telemedicine.

Background: Not every person will be able to go, or feel comfortable going, to a clinic for STI testing. New and innovative approaches for testing individuals outside the clinic setting will be necessary for reaching a broader population.

- 3.A.2: Expand the availability of express clinics

Background: Express clinics allow individuals to get tested, receive their results, and receive their prescription during a single visit, limiting the possibility of losing individuals to a follow-up visit.

- 3.A.3: Develop and implement point-of-care rapid STI testing and treatment

Background: Many individuals are lost to care when they are required to wait for test results before accessing treatment. The federal government should expand efforts to implement rapid point of care testing so that patients can receive treatment within the same visit. With the introduction of the rapid HIV test and the resulting significant increase in HIV testing in medical settings, we have all the information we need on how much rapid point of care tests for STIs will contribute to STI testing and treatment.

- 3.A.4: Develop and implement STI screening measures to provide positive incentives for clinicians to screen for STIs.

Background: Many clinicians do not screen and test for STIs during every visit, leaving many individuals unaware that they have, and can transmit an STI. The Centers for Medicare and Medicaid Services (CMS) should add screening measures the voluntary Medicaid quality indicators. The experience of adding chlamydia testing to the Healthcare Effectiveness Data and Information Set (HEDIS) should serve as an example of how these measures can increase STI testing.

Step 3.B: Utilize PrEP for STI Prevention:

- 3.B.: Use the provision of PrEP to increase STI testing.

Background: PrEP initiation and follow-up visits provide the perfect opportunity to increase STI testing to this population. All health care providers should be required to provide STI testing every three months for those on PrEP, as recommended by the CDC.

Step 3.C: Expand Extra-Genital Testing for STIs

- 3.C.1: Include three site testing as part of recommended STI testing guidelines

Background: Three-site testing of the mouth, genital and urinary systems, and rectum is a recommended practice, particularly as STIs in the mouth and rectum are more infectious and present no symptoms. To fully test for STIs all three sites must become a part of recommended guidelines. If this recommendation is to become a reality, payment from both public and commercial insurance must support this important change in STI testing.

Goal 4: Increase Access to STI Treatment and Care

Step 4.A: Improve Availability of Medications

- 4.A.1Take all steps necessary to prevent shortages of benzathine penicillin G (BPG).

Background: This crucial drug for treating syphilis must be available and affordable. The Federal government must engage with the manufacturer and other relevant groups to prevent any future drug shortages.

- 4.A.2: Increase availability of expedited partner therapy (EPT).

Background: Most states now have an EPT policy in place but continue to have challenges implementing the policy due to provider, insurance, and electronic barriers. The Federal government should provide guidance and protections for all pharmacies to dispense EPT to partners removing all barriers such as name, address, and date of birth (DOB) requirement for sex partners of infected patients. Additionally, liability coverage for

providers practicing at Federally Qualified Health Centers (FQHCs) should be altered to allow for the provision of EPT at FQHCs without additional liability coverage.

Goal 5: Achieve a More Coordinated Response to Rising STI Rates

Step 5.A: Support Better STI Coordination

- 5.A.1: Increase STI coordination, including testing and treatment, based on CDC guidelines across HHS funded service and prevention programs at the national, regional, and local levels.

Background: Several departments across HHS work to support STI prevention objectives, however, they do not always coordinate and provide clear and streamlined guidance.

- 5.A.2: Make STI screening a reportable Uniform Data System (UDS) measure for community health centers supported by HRSA's Bureau of Primary Health Care.

- 5.A.3: Increase STI screening among individuals seen by Ryan White Providers

Background: Increasing measurement of STI screening across federal programs is important to incentivize providers and clinics to prioritize STI screening with their patients including at CHCs and in the Ryan White system.

- 5.A.4 Provide positive incentives for increasing and reporting of STI screening across all HHS supported programs.

Background: STI prevention is not limited to one department; other departments have a responsibility to better respond to the STI epidemic. Below is a list of the HHS programs that must be included in expanding and coordinating an HHS response to the STI epidemics:

  - Health Resources and Services Administration (HRSA)

    - Bureau of Primary Health
    - HIV/AIDS Bureau
    - Maternal and Child Health Bureau
    - Office of Women's Health
- National Institutes of Health (NIH)
    - The National Institute of Allergy and Infectious Diseases (NIAID)
    - The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- Centers for Medicare and Medicaid Services (CMS)
- Substance Abuse and Mental Health Services Administration (SAMSHA)
- Indian Health Service (IHS)
- Food and Drug Administration (FDA)
- Office of the Assistant Secretary for Health
- Office of Population Affairs including Office of Adolescent Health

- 5.A.4: Support better coordination among all federal agencies with a role in STI prevention and control

  Background: Given the mission and reach of HHS, it must take the lead in any Federal response to the STI epidemics. However, a number of other Federal departments have a role in STI prevention and control—some of more than others. These agencies include the Department of Defense, the Department of Veterans Affairs, the Department of Justice (Federal Bureau of Prisons), and the Department of Agriculture (the WIC program).

Step 5.B: Remove Payment Barriers

- 5.B.1: Work with CMS and private insurers to eliminate payment barriers.

Background: With the implementation of the Affordable Care Act, many more Americans have insurance coverage for STI diagnosis and treatment through commercial insurance or Medicaid. This patchwork of coverage presents significant challenges and opportunities such as:

- **Reimbursement Issues-** CDC recommends STI testing every three-six months for individuals at high risk. Some insurers, however, only cover STI screening once a year. If providers are only paid to test their patients for STIs once a year, then testing every 3 months for people on PrEP will not take place. And extra genital screening will not take place if these tests are not covered both by private insurance and by Medicaid.
- **Billing-** Developing a successful revenue generation program, especially in a public health department environment, can be very challenging. Tool kits, training, and technical assistance must be expanded and maintained to assure that STI programs are maximizing revenue from insured patients and that public funds are being used to assure services to the millions of Americans who remain uninsured or underinsured.
- **Medicaid-** Because Medicaid is the largest insurer, begin with Medicaid. Create an STI initiative to identify and eliminate all payment barriers for STIs in all 50 states and territories.

Goal 6: Identify and Expand Innovative Research and Approaches to STI Testing and Treatment

Step 6.A: Improve Options for Extragenital Testing

- 6.A.1: Get FDA approval for nucleic acid amplification testing (NAAT) for extragenital testing.

Background: CDC recommends using NAATs for extragenital screening in MSM. The FDA, however, currently has not cleared NAAT for extragenital testing. The FDA should work to expedite this approval.

Step 6.B: Prevent Drug-Resistant Gonorrhea

- 6.B.1: Identify new antibiotics for gonorrhea.

Background: Gonorrhea is currently facing antibiotic resistance. NIH must invest heavily in identifying a new treatment for gonorrhea before the U.S begins to see gonorrhea treatment failures.

Step 6.C: Support a robust research/evaluation agenda

- 6.C.1: Identify biological, programmatic, and behavioral approaches to combating the STI epidemics.

Background: The STI field has been without the identification of new approaches to combatting the STI epidemics for years. Identifying new approaches to combatting these epidemics can help to identify new and innovative approaches to prevention and treatment.

Goal 7: Reduce Disparities in STI Testing and Treatment

Step 7.A: Increase STI services in Communities Most at Risk

- 7.A.1: Use data to calculate areas with highest risk populations.

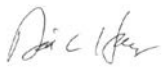
Background: STIs are more prevalent in some segments of the population than in others. Limited or no health care coverage is correlated with higher STI rates, as are low income and other social determinants of health. The Federal government should use epidemiological data to calculate where the highest risk populations are for STIs and target funding and resources toward prevention and treatment in those areas.

- 7.A.2: Support school-based health programs.

Background: Young people between the ages 15-24 make up more than half of new STI cases. To increase access to services the federal government should support and incentivize states to adopt school-based health programs, including medically accurate and comprehensive sex education.

Thank you again for the opportunity to provide comments on the development of this important action plan. If you have any questions about our comments, I would welcome an opportunity to discuss them with you. Please contact me at 202.842.4660 or via email at dharvey@ncsddc.org.

Sincerely,



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