June 3, 2019

Tammy R. Beckham, DVM, PhD
Director, Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
U.S. Department of Health and Human Services
330 C Street SW, Room L001
Washington, DC 20024
Attn: STD RFI
Submitted to: STDPlan@hhs.gov

Dear Dr. Beckham:

The Infectious Diseases Society of America (IDSA), HIV Medicine Association (HIVMA), National Coalition of STD Directors (NCSD), Treatment Action Group (TAG) and the Pediatric Infectious Diseases Society (PIDS) applaud HHS's effort to develop an STD Federal Action Plan and appreciate the opportunity to submit recommendations.

Our comments summarize issues that our members who are adult and pediatric ID and HIV providers, and public health professionals increasingly report as challenges to addressing the growing cases of STDs. Frequently cited issues include:

- the high costs of STD screenings and treatment;
- inconsistent access to benzathine penicillin G (BPG);
- poor access to healthcare for lower income individuals in non-Medicaid expansion states limited coverage of STD screening and treatment by some insurers; and
- insufficient attention and resources to STD prevention with young people and adolescents who account for half of new STD cases in the U.S.

In addition, stigma and discrimination, including by healthcare providers, remain sizeable barriers to thwarting better responses to the STD epidemic fueled by the intersecting HIV, viral hepatitis and opioid use disorder epidemics.

We are concerned that despite the HHS commitment to confront these epidemics recent policy proposals released by the administration will promote rather than reduce the stigma and discrimination that keeps marginalized populations from seeking preventive screenings and treatment. A prime example is the most recent proposed rule that would erode the Affordable Care Act Section 1557 Non-Discrimination provisions for LGBTQ individuals and women.

We framed our recommendations in response to the questions posed in the RFI and would welcome the opportunity to meet to elaborate on our recommendations.

1. How should the federal government address the rising rates of STDs?

The federal government has a significant role to play in responding to the STD epidemic as the progressively increasing incidence of new STD diagnoses continue to pose significant threats to public health in the U.S. This health crisis affects individual as well as public health and also contributes to antimicrobial resistance. We urge the federal government to:

- Fund STD prevention at a level commensurate to the scope of the epidemic. For Fiscal Year (FY) 2020, the Federal AIDS Policy Partnership recommended that STD prevention at the Centers for Disease Control and Prevention be funded at $227.3 million – an increase of $70 million over the FY 2019 funding level.
- Protect and expand access to healthcare coverage through the Medicaid program for low-income individuals to facilitate access to preventive and basic health care services.
- Commit to ending congenital syphilis by enhancing resources to strengthen the response with focused efforts to improve diagnosis and treatment of pregnant women and ensure prompt treatment of newborns in the ten states hardest hit by congenital syphilis. This should include activities consistent with WHO recommendations to achieve the goal of eliminating mother-to-child transmission of syphilis or congenital syphilis, with benchmarks and estimation of resources required to achieve this endpoint. Every case of congenital syphilis should be considered a sentinel public health event, including investigation of missed opportunities for diagnosis and treatment by healthcare providers.
- Support targeted interventions for adolescents through increased support for school-based health programs that include comprehensive LGBTQ inclusive sex education and incentivize states to adopt and support these programs.
- Develop and submit for endorsement STD screening measures to promote clinician screening and adherence to treatment guidelines. Once developed, add the STD measures to the list of voluntary Medicaid quality measures.
- Make STD screening a reportable Uniform Data System (UDS) measure for community health centers (CHCs) supported by the HRSA Bureau of Primary Health Care. Increasing measurement of STD screening across federal programs is important to incentivize providers and clinics to prioritize STD screening with their patients, including CHCs.
- Prevent future treatment shortages of BPG by taking all steps necessary to ensure that this crucial drug is available and affordable for all who need treatment for syphilis. Ensure transparent engagement with the manufacturer among Federal and local officials, advocates and professional organizations regarding supply issues and potential shortages.
- Support a robust STD research agenda that includes:
  - Development of rapid point-of-care diagnostics that can precisely target treatment and rule out other infectious processes:
    - Dual treponemal/non-treponemal point-of-care test for syphilis
    - Chlamydia
    - Gonorrhea including antimicrobial susceptibility testing of Neisseria gonorrhoeae
    - Mycoplasma genitalium;
  - Development of new antimicrobials or alternative agents for gonorrhea to reduce the threat of drug resistance infections;
  - Vaccine development for syphilis, gonorrhea and chlamydia;
  - Applying genomics to develop rapid diagnostics for STDs;
  - Using molecular epidemiology questions, such as the overlapping HIV/STI epidemics and detection of “hot spot” clusters as foci for intervention strategies to decrease transmission of HIV and STD;

- Evaluating methods to improve the delivery of STD prevention, screening and treatment in conjunction with Pre-Exposure Prophylaxis (PrEP) programs;
- Evaluating strategies to improve prevention, diagnosis and treatment for extragenital infections;
- Understanding the drivers for the resurgence of syphilis and possible correlates of protection from infection;
- Evaluating methods to optimize STD screening, e.g., pooled urine samples from clinics and STD screening opportunities during emergency room visits;
- Supporting implementation science research to identify best practices for integrating testing and treatment into primary care, exploring nontraditional locations and tracking of time from diagnosis to treatment for each STD.

2. **What strategies can be implemented by federal agencies to improve the efficiency, effectiveness, coordination, accountability, and impact of our national response to increasing rates of STDs for all priority populations?**

   Reducing the silos within public health programs and promoting integration of prevention and service delivery across public health programs. This is important to ensure that there are no wrong doors to accessing the prevention and treatment available for STDs, HIV, viral hepatitis and substance use disorders. Expanded access is important to diagnose and treat STDs earlier to improve individual health and to stop further transition. We recommend:

   - Fully integrating and reducing barriers to STD screening and treatment across federally funded clinical programs, including HIV prevention and care sites; syringe exchange services and substance use treatment programs; Title X funded-clinics, and community health centers.
   - Leveraging resources by integration across the action plans and strategies under development or revision to respond to the STD, HIV, viral hepatitis and opioid epidemics.

3. **What are the barriers to people getting the quality STD health services they deserve? What strategies can be implemented by federal agencies to overcome these barriers?**

   We summarize key barriers with recommendations for addressing them below.

   - **Barrier:** STD screening, particularly three-site testing of mouth, genital and urinary systems, and rectum for chlamydia and gonorrhea is not covered or not fully covered by some insurers due to the cost. Patients face high out-of-pocket costs that prevent them from seeking care.

     Recommendations:

     - Monitor and review the price of diagnostic assays for chlamydia and gonorrhea and take all steps necessary to ensure that these vital tests are available and affordable to allow healthcare providers outside of public health systems to increase diagnosis and treatment of STDs. Given the significance of STDs as a public health issue, and rising rates of antimicrobial resistance, the cost should not interfere with timely patient access, diagnosis and treatment.
     - Issue guidance on the importance of health insurer's covering extragenital three-site testing. STD screening should be covered as recommended by the Centers for Disease Control and Prevention in the most recent versions of the STD Treatment Guidelines and the CDC's Clinical PrEP Guidelines. Some insurers are only covering STD screening once per year for high-risk populations contrary CDC recommendations.

- Urge the U.S. Preventive Services Task Force (USPSTF) to review and update its recommendations for Chlamydia and Gonorrhea: Screening.
- Ensure that quarterly STD screening as recommended by the CDC is covered as part of the USPSTF's draft grade A recommendation for PrEP once the recommendation is finalized.
- Require increased transparency of lab costs and develop innovative strategies to lower lab costs for patients as part of the administration's efforts to lower healthcare costs. Providers are frequently unaware of the cost of labs to the patient since insurers negotiate directly with labs.

- **Barrier:** The cost of BPG is limiting the ability of clinics without 340B discount pricing to stock it and making it unaffordable for patients. In addition, reimbursement rates for the administration of BPG are lower than the actual cost resulting in a loss to the health care provider.

  Recommendations:

  - Ensure all healthcare providers, in public and private sectors, who treat STDs can purchase BPG under the authority of the 340B Drug Pricing Program.
  - Monitor the price, affordability and accessibility of BPG, including as part of the administration's efforts to lower drug costs.

- **Barrier:** It is difficult for providers outside of health departments to prescribe expedited partner therapy to facilitate STD treatment for the partners of their patients with STDs due to liability and third-party coverage issues.

  Recommendation:

  - Evaluate creative solutions to expand access to expedited partner therapy for the partners of patients being treated for STDs.

- **Barrier:** Community health centers are limited in their ability to treat STDs and provide PrEP due to requirements that they assume full care for patients. Patients seek treatment for STDs outside of their regular primary care setting to avoid potential stigma and discrimination from their primary care providers. Since CHCs are required to report on all measures for all patients, they are reluctant to provide STD or HIV prevention services to patients who will not seek them from their regular provider.

  Recommendation:

  - Provide guidance and allow greater flexibility for CHCs to serve patients in different ways and to reduce the administrative burden of providing STD and HIV prevention services to patients only seeking these services.

- **Barrier:** Lack of provider knowledge regarding the latest STI screening and treatment recommendations.

  Recommendation:

  - Provider education is urgently needed to reacquaint providers with STD symptoms, best screening practices, and appropriate treatment to allow for timely diagnosis and effective treatment across all HRSA programs and through the CDC's prevention training centers.

4. **How can federal agencies influence, design and implement STD-related policies, services and programs in innovative and culturally responsive ways for priority populations?**

   Redesigning prevention, care and service delivery options to meet better the needs of individuals seeking healthcare services is critical to reach populations who are not currently engaged in health care. Innovative models are evolving to improve the delivery of culturally competent care and the quality of care. We strongly recommend supporting demonstration projects to:

   - Evaluate and potentially expand access to fully integrated Internet-based STD screening services that can include home-based testing and electronic partner notification.[i]
   - Expand access to status neutral clinics that provide same day point-of-care screening and treatment at accessible locations and with flexible and convenient hours.[ii,iii]
   - Expand access to same-day STD screening with point-of-care tests and same day treatment across settings, including those serving younger adults and adolescents. One study conducted in an emergency room setting found that nearly 60 percent of adolescents did not fill their prescription for STD treatment.[iv]

5. **How can the federal government help to reduce STD-associated stigma and discrimination?**

   The federal government has a critical role to play in reducing the stigma and discrimination that continues to be a major impediment to addressing serious epidemics like we are experiencing with STDs, opioid use disorder, viral hepatitis and HIV. We strongly urge HHS and other federal agencies to be leaders in combating the misperceptions and personal biases that keep individuals from accessing services that promote good health for them and for their communities. We strongly urge the federal government to:

   - Discontinue policies that facilitate discrimination in health care settings and in other federal programs that serve populations at higher risk for STDs. Recent policies or proposed policies that impede public health by promoting stigma and discrimination include the:
     - HHS "Conscience Rule" that allows health care providers and healthcare entities to discriminate based on their religious beliefs[v];
     - proposed rule released by the Department of Housing and Urban Development that weakens non-discriminatory protections for individuals seeking shelter in federally funded facilities[vi]; and
     - proposed rule released by the Department of Health and Human Services that would rollback the ACA's non-discriminatory protections for LGBTQ patients and women[vii]; and
     - Department of Education's discontinuation of policies protecting transgender students[viii].

   - Increase access to culturally competent care such as that provided by status neutral point of care sites located outside of traditional health care and public health settings.
   - Support and promote comprehensive sexual health and sexual education.

Please contact the HIVMA Executive Director Andrea Weddle at aweddle@hivma.org or the IDSA Vice President for Public Policy and Government Relations Amanda Jezek at ajezek@idsociety.org to schedule a meeting to discuss our recommendations.

Sincerely,

Cynthia L. Sears, MD, FIDSA
President, IDSA

W. David Hardy, MD
Chair, HIVMA

Paul Spearman, MD
President, PIDS

David C. Harvey
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About Our Organizations

IDSA represents more than 11,000 physicians, scientists and other health care professionals who specialize in infectious diseases.

HIVMA is a professional association within IDSA that represents more than 5,000 HIV clinicians and researchers working on the front lines of the HIV, HCV and STD epidemics.

NCSD is a national public health membership organization representing health department STD directors, their support staff, and community-based partners across 50 states, seven large cities, and eight US territories.

PIDS has 1,100 members who are the core professionals advocating for the improved health of children with infectious diseases both nationally and around the world.

TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention a vaccine and a cure for HIV, tuberculosis and hepatitis C virus.

[i] Spielberg F, et al. Fully Integrated e-Services for Prevention, Diagnosis, and Treatment of Sexually Transmitted Infections: Results of a 4-County Study in California. American Journal of Public Health. Dec 2014: 104(12).

[ii] Myers, JE, et al. Redefining Prevention and Care: A Status-Neutral Approach to HIV. Open Forum for Infect Dis. 2018 May 2;5(6).

[iii] See the University of San Diego's *Good to Go* point of sale testing program. https://www.goodtogosd.com.

[iv] Lieberman, BA, A., et al. Frequency of Prescription Filling Among Adolescents Prescribed Treatment for Sexually Transmitted Infections in the Emergency Department. *JAMA Pediatrics*. Published online May 28, 2019.

[v] HHS. HHS Announces Final Conscience Rule Protecting Health Care Entities and Individuals. May 2, 2019. https://www.hhs.gov/about/news/2019/05/02/hhs-announces-final-conscience-rule-protecting-health-care-entities-and-individuals.html.

[vi] Office of Management and Budget. Revised Requirements Under Community Planning and Development Housing Programs (FR-6152). Online at: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=2506-AC53

[vii] **H**HS Proposes to Revise ACA Section 1557 Rule to Enforce Civil Rights in Healthcare, Conform to Law, and Eliminate Billions in Unnecessary Costs. May 24, 2019. Online at: https://www.hhs.gov/about/news/2019/05/24/hhs-proposes-to-revise-aca-section-1557-rule.html

[viii] NPR. The Education Department Says It Won't Act On Transgender Student Bathroom Access. February 12, 2018. Online at**:** https://www.npr.org/sections/ed/2018/02/12/585181704/the-education-department-says-it-wont-act-on-transgender-student-bathroom-access.