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July 14, 2015

TO: Each Supervisor

FROM: Cynthia A. Harding, M.P.H. Cynthia A. Harding
Interim Director

SUBJECT: **HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) PROGRAM IMPLEMENTATION PLAN (Item 9, Board Agenda of June 9, 2015)**

This report responds to your June 9, 2015 Board motion requesting that the Department of Public Health (DPH) report back on the implementation of a Los Angeles County Pre-Exposure Prophylaxis (PrEP) Program for the prevention of HIV. This implementation plan outlines the populations targeted for this service; reviews critical program elements; describes the package of biomedical prevention services to be included; outlines the program's funding strategy; lists the timeline and milestones associated with the program; and reviews the monitoring and evaluation plan. In addition, DPH will be releasing a solicitation to community-based health care service delivery partners in the coming weeks to further expand the delivery of biomedical HIV prevention services, including PrEP.

Since 2010, DPH has supported the delivery of Post-Exposure Prophylaxis (PEP) services at two locations – the Los Angeles LGBT Center and the DHS-operated Oasis Clinic on the Martin Luther King, Jr. Campus. The expansion of safety net PrEP services is intended to enhance our local biomedical prevention portfolio and fully complement the delivery of PEP services.

BACKGROUND

PEP and PrEP are evidence-based biomedical interventions that are intended to prevent HIV infection among individuals who are HIV-negative. They differ in terms of the groups of persons for whom they are recommended as well as the nature of the interventions.

PEP is a preventive intervention for HIV-negative persons who have had an acute, known potential exposure to HIV (such as a needle stick or unprotected sexual activity) in which an individual takes anti-retroviral medicines as soon as possible (but no more than 72 hours) after potential exposure to HIV, to try to reduce the chance of becoming HIV-positive. Two to three drugs are usually prescribed, and they must be taken for 28 days. PEP has been recommended by the U.S. Public Health Service since 1996.

PrEP is a more recently introduced preventive intervention for HIV-negative individuals who have an ongoing high risk of HIV infection that requires taking a U.S. Food and Drug Administration-approved daily anti-retroviral therapy for an extended period of time. Studies have shown PrEP reduces HIV acquisition among sexually active HIV-negative persons, and when taken daily as directed can reduce the risk of HIV infection by as much as 96%. Research has shown that PrEP is most effective when it is part of a comprehensive HIV prevention program that includes routine medical care, risk reduction counseling, medication adherence support, and care coordination.

Biomedical interventions, including PrEP and PEP, are critical components of Los Angeles County's overall HIV prevention strategy that also includes HIV testing, treatment as prevention, behavioral interventions, condom use promotion, and STD screening and treatment. DPH has been working with a diverse set of HIV prevention program planners, public- and private-sector health care delivery partners, public and private health plans, other County Departments (e.g., the Department of Health Services (DHS) and the Sheriff's Department), the California HIV Research Program, local HIV prevention scientists, and a range of consumer groups, to ensure that Los Angeles County implements a robust, responsive local network of biomedical prevention services intended to reduce the number of new HIV infections in our communities.

DPH's expanded biomedical HIV prevention strategy includes the delivery of a full menu of PrEP-related services (described below), delivered by both public and private health care providers, financed principally by private health plans and public health plans and complemented by the investment of DPH resources to ensure PrEP and PEP access for high risk HIV-negative individuals who are uninsured and underinsured. This public/private partnership approach to PrEP service delivery will allow for maximum countywide reach and impact. Moreover, the co-location of both PrEP and PEP services will allow for significant programmatic efficiency (as both interventions are intended for groups at high HIV risk), and allow for the efficient investment of scarce public health resources. DPH estimates that between 6,000 and 9,000 Los Angeles County residents can benefit from biomedical HIV prevention services, most of whom could rely on private health plans, public health plans or Patient Assistance Programs for coverage. Conversely, a fraction of these Los Angeles County residents will rely on this County-supported biomedical HIV prevention program.

PREP PROGRAM IMPLEMENTATION PLAN

The DPH-led PrEP implementation plan includes five main components:

1. Increasing consumer knowledge about biomedical HIV prevention through culturally and linguistically-appropriate and responsive education and awareness activities, including through English and Spanish-language social marketing, social media, and the use of a dedicated web-site;
2. Increasing health care provider knowledge of and comfort with the delivery of biomedical HIV prevention through multiple training and technical assistance strategies, the use of local AIDS Education and Training Centers, the deployment of tools and resources through the dedicated web-site, and through partnerships with DHS and the Community Clinic Association of Los Angeles County;

3. Collaborating and coordinating with DHS to deploy PrEP services at select DHS sites, in specific sub-units of the Men's Central Jail, and potentially in Juvenile Hall and/or probation camps;
4. Deploying PrEP services at Ruth Temple Health Center and the North Hollywood Health Center, both DPH-operated Community Health Clinics, by September 2015; and
5. Releasing a competitive solicitation to procure additional community-based PrEP services (and co-located PEP services) and expand service delivery options for uninsured and underinsured County residents at high risk for HIV infection.

PROGRAM TARGET POPULATION

The epidemiology of new HIV cases in Los Angeles County indicates that 83% of new HIV infections are among men who have sex with men; the rate of HIV infection is 8 times higher among African-American women compared to White women; and more than 20% of male-to-female transgender persons are HIV-positive. Therefore, DPH recommends that PrEP services be targeted, but not exclusively available, to men who have sex with men (including young African-American and Latino men), African-American heterosexual women, and transgender women who have an elevated risk of contracting HIV.

Increased HIV risk factors include:

- Having an HIV-positive sex partner;
- Having a bacterial STD diagnosed in the past 12 months;
- Having a history of multiple sex partners of unknown HIV status;
- Women with a recent history of syphilis;
- Women who have a male partner who she highly suspects may be having sex with men, and;
- Having other risk factors that put individuals at high risk for HIV, including a history of sex work.

PROGRAM ELEMENTS AND ASSOCIATED GOALS

1. Training, Education and Social Marketing to Increase Consumer and Provider Knowledge about PrEP

DPH will implement a targeted social marketing campaign through the use of our existing Master Agreement Work Order (PH-002446 W-1) for HIV and STD Social Marketing/ Prevention with KCBS that includes posters, postcards, pamphlets and a dedicated website (www.getprepla.com) that is culturally and linguistically appropriate and that relies on community-based partners for focus-group testing, refinement, and distribution of these campaign materials.

DPH will increase PrEP and PEP provider knowledge by training County- and community-based health care delivery partners who meet the following criteria: 1) interested in providing PrEP and PEP services but need additional training and technical assistance before operationalizing biomedical prevention services, and 2) serve a high number of persons from the target populations. In the next few weeks, DPH will meet and collaborate with the Community Clinic

Association of Los Angeles County's Clinical Workgroup to address technical assistance needs among their providers as a precursor to a targeted provider training plan.

Separately, DHSP will invite the three local federally-funded AIDS Education and Training Centers (UCLA, USC and Charles Drew University) to prioritize the training of clinical providers over the next 12 months on PrEP service delivery using the DHSP-developed training curriculum.

2. Promote Access to High Quality Comprehensive Biomedical Prevention Services

DPH will actively promote the current Los Angeles County PrEP Provider Directory through our website, targeted education and outreach efforts, and a social marketing campaign. DPH's planned social marketing campaign in partnership with KCBS will ensure that populations at highest risk for HIV are aware of the benefits of PrEP, including in the geographic areas that shoulder the most HIV burden. Specific target populations for education and awareness campaigns will include gay and bisexual men, African-Americans, Latinos, and transgender persons. DPH will also promote an expanded list of PrEP and PEP options as local provider capacity evolves and new service delivery options become available.

DPH will continue to promote consumer knowledge of biomedical prevention services through the balance of the 2015 Gay Pride Event season (ending with Pasadena Pride on October 17th) and will partner with local organizations to extend the reach of outreach and education efforts. More specifically, DPH will partner with the Los Angeles County PrEP and PEP Workgroup, the City of West Hollywood, and the National Minority AIDS Council, among others, to inform a broad cross-section of potential PrEP and PEP users throughout Los Angeles County.

3. Deploy County-Operated Safety-Net PrEP services

By September 2015, DPH will deploy PrEP services at Ruth Temple Health Center and the North Hollywood Health Center – two DPH STD clinics located in highly HIV-impacted areas. While the initial objective will be to provide PrEP services at no cost to uninsured and underinsured individuals, the secondary objective will be to transition patients to a permanent primary care provider (who also offers PrEP) within 12 months of the initial visit. DPH and DHS have begun discussions to strengthen these referral pathways for uninsured PrEP patients and for those already obtaining primary care through DHS. Additional DPH service delivery sites will be considered over the next 12 months.

As a complement to DPH-delivered services, DHS will deliver PrEP services at multiple sites beginning in the next few months. As part of this strategy, DHS will migrate PrEP service delivery from a limited California HIV Research Program-funded demonstration project model to a more permanent PrEP service delivery model that is integrated into the scope of clinical services at select DHS sites. In fact, DHS has already taken steps to ensure access to PrEP for its empaneled primary care patients as well as for uninsured patients new to DHS. As currently described in DPH's Los Angeles County PrEP Provider Directory, patients at high risk for HIV who are assigned to DHS for their primary care are also instructed to talk to their primary care doctor about PrEP. PrEP was recently added to DHS' e-Consult system to ensure that DHS primary care clinicians have immediate access to medical consultation and guidance related to

PrEP initiation for DHS patients. Uninsured patients who are new to DHS are instructed in the Directory to visit a DHS Urgent Care Clinic to consult with a clinician about PrEP and initiate it, if appropriate.

DPH has recently completed preliminary discussions with the medical leadership of the Sheriff's Department, DHS, and Juvenile Court Health Services related to the feasibility of offering PrEP to high risk individuals in those settings. For LASD, there is general agreement that the K6G unit of Men's Central Jail may be best suited to launch an initial pilot program and should be a public health priority given the high proportion of HIV at-risk individuals housed in this unit. Further planning of jail-based PrEP services will be done in the context of the recent Board action that affects the structure of health services within the jail system.

Separately, Juvenile Court Health Services has also expressed interest in providing PrEP to detained youth who are at highest risk of HIV infection. This would be done in coordination and collaboration with DPH as well as community HIV clinics to develop a standardized youth-focused protocol to guide the delivery of PrEP for persons in custody, as well as to assist with case management to ensure linkage to community clinical care after release.

As a final element of County-supported PrEP services, DHSP will issue a competitive solicitation to identify between 3 and 5 community-based PrEP service delivery partners. Services will be targeted to the areas of Los Angeles County where HIV burden is highest and with a distribution pattern that best complements public-sector PrEP service delivery options.

PACKAGE OF BIOMEDICAL PREVENTION SERVICES

Effective delivery of PrEP and PEP must include a comprehensive prevention package for at-risk HIV-negative individuals that will not only increase the likelihood of individuals staying HIV negative but also result in better engagement in regular preventive health care services, linkage to appropriate social services, and better health outcomes. Several studies have confirmed that PrEP and PEP services are most effective when access to antiretroviral medication is supplemented by an HIV prevention package that also includes the following:

- Medical visits - six or more times a year;
- Laboratory tests (HIV, STD, Hepatitis, kidney function);
- STD treatment and recommended vaccinations (Hepatitis, Meningococcal);
- Care coordination and linkage to support services (e.g., mental health, substance abuse);
- Medication adherence support and education;
- Risk reduction counseling; and
- Benefits navigation (i.e., enrollment in health insurance)

FUNDING STRATEGY

DPH will rely on the investment of four distinct revenue streams to finance both newly expanded PrEP services and ongoing PEP services. These include three current and anticipated grants from the federal Centers for Disease Control and Prevention: 1) *HIV Prevention Cooperative Agreement (2012-2016)*; 2) *Improving Sexually Transmitted Disease Programs through*

Assessment, Assurance, Policy Development, and Prevention Strategies (AAPPS) (2014-2018); and 3) PS15-1506 *Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons (September 30, 2015 – September 29, 2018)*. More specifically, these grants will be used to cover costs associated with social marketing, provider training and education, dedicated outreach staff, benefits navigation, linkage to support services, risk reduction counseling services, adherence counseling services, program administration (including within DPH, DHS, and LASD), STD screening and treatment, data collection and reporting, and program evaluation.

Finally, DPH will invest approximately $1 million in Net County Cost funds (fourth revenue stream) managed by DHSP for critical PrEP and PEP-related expenses not covered by either public health plans, private health plans, the three federal grants listed above, or Patient Assistance Programs. These expenditures are within DPH's existing budget appropriation and will not require any additional Net County Cost. No federal Ryan White Program funds will be used to fund these PrEP and PEP services, as services for HIV-negative individuals cannot by law be funded through the Ryan White Program.

TIMELINE AND PROGRAM IMPLEMENTATION MILESTONES

March 2015	DPH and DHS jointly briefed Board Health Deputies and the Chief Executive Office on HIV Biomedical Prevention Framework, including local PEP Program update;
May 2015	DPH released Los Angeles County PrEP Provider Directory;
June 2015	Biomedical prevention-specific timeline website (www.getprepla.com) went live; PrEP and PEP education and outreach materials developed and disseminated;
June 2015	Updated PrEP and PEP Warm-line (213-351-7699) went live;
July 2015	DHS e-Consult system became available to provide clinical consultations related to PrEP;
July 2015	Anticipated release of competitive solicitation for community-based expanded PrEP service delivery;
Sept 2015	Anticipated start of PrEP services at North Hollywood and Ruth Temple Health Center;
Dec 2015	Anticipated start of contracts to deliver PrEP services with community-based partners;
June 2016	First Biomedical Prevention Progress Report issued to Board of Supervisors from DPH.

PROGRAM MONITORING AND EVALUATION

As part of the ongoing evaluation of biomedical HIV prevention services, including the expansion of PrEP services, DHSP will monitor the following programmatic benchmarks:

- Number of hits to DPH PrEP and PEP website and calls to PrEP and PEP warmline;
- Number of trainings provided to non-clinical providers about PrEP and PEP;
- Number of trainings provided to medical providers about PrEP and PEP;
- Number of medical providers in the PrEP and PEP Provider Directory;
- Number of Los Angeles County residents enrolled in PrEP stratified by health plan, geographic area, target population and service delivery site;
- Number of Los Angeles County residents enrolled in PEP by geographic area, target population and service delivery site;
- Cost per person served for both the PrEP and PEP programs;
- Number of community-based PrEP and PEP service delivery sites; and
- Number of persons enrolled in biomedical prevention services offered through the LASD, Juvenile Hall and probation camps.

In the first year of expanded PrEP programming, DPH staff will facilitate regular meetings with PrEP and PEP stakeholders to review programmatic accomplishments; identify programmatic opportunities for improvement; continually assess cultural and linguistic responsiveness; elicit feedback on social marketing efforts; and refine, improve and troubleshoot implementation issues related to community education, training, technical assistance, service access points, program website, program warm line and service quality. In addition, DPH staff will continually assess program-related expenditures and make adjustments as necessary congruent with need and demand.

The goal of the HIV biomedical prevention program described above, effectively utilizing PrEP and PEP, among a range of other HIV prevention tools, is to make a significant impact on the reduction of HIV incidence in Los Angeles County. I look forward to providing you reports on our progress in program implementation and increased access to HIV prevention services.

If you have any questions or would like additional information, please let me know.

CAH:mjp

c: Interim Chief Executive Officer
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