AGENDA

ASSEMBLY BUDGET SUBCOMMITTEE NO. 1

ON HEALTH AND HUMAN SERVICES

ASSEMBLYMEMBER TONY THURMOND, CHAIR

MONDAY, APRIL 18, 2016

2:30 P.M. - STATE CAPITOL ROOM 127

ITEMS TO BE HEARD

ITEM	DESCRIPTION	
4265	**DEPARTMENT OF PUBLIC HEALTH**	
	OFFICE OF HEALTH EQUITY	
ISSUE 1	OFFICE OF HEALTH EQUITY OVERVIEW AND MEMBERS' PROPOSALS	2
	CENTER FOR ENVIRONMENTAL HEALTH	
ISSUE 2	MEDICAL MARIJUANA BUDGET CHANGE PROPOSAL	7
	CENTER FOR INFECTIOUS DISEASES	
ISSUE 3	AIDS DRUG ASSISTANCE PROGRAM (ADAP) ESTIMATE	10
ISSUE 4	INFECTIOUS DISEASES: TIMELY OUTBREAK DETECTION BUDGET CHANGE PROPOSAL	13
ISSUE 5	INCREASED ACCESS TO HIV PRE-EXPOSURE PROPHYLAXIS (PREP) BUDGET CHANGE PROPOSAL	16
ISSUE 6	RICHMOND LABORATORY CAPITAL OUTLAY REAPPROPRIATION	18
ISSUE 7	INFECTIOUS DISEASE STAKEHOLDER PROPOSALS – PART 1	20
ISSUE 8	INFECTIOUS DISEASE STAKEHOLDER PROPOSALS – PART 2	25
0530	**CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**	
ISSUE 9	INFECTIOUS DISEASE INTERAGENCY TASK FORCE STAKEHOLDER PROPOSAL	28
4265	**DEPARTMENT OF PUBLIC HEALTH**	
	CENTER FOR HEALTHCARE QUALITY	
ISSUE 10	LICENSING AND CERTIFICATION PROGRAM ESTIMATE	30
ISSUE 11	TIMELY INVESTIGATIONS OF CAREGIVERS BUDGET CHANGE PROPOSAL	41
ISSUE 12	LICENSING AND CERTIFICATION PROGRAM QUALITY IMPROVEMENT PROJECTS BUDGET CHANGE PROPOSAL	43
ISSUE 13	LONG-TERM CARE OMBUDSMAN FUNDING STAKEHOLDER PROPOSAL	45
0530	**CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**	
ISSUE 14	CALQUALITYCARE.ORG STAKEHOLDER PROPOSAL	48

ITEMS TO BE HEARD

4265 DEPARTMENT OF PUBLIC HEALTH

OFFICE OF HEALTH EQUITY

ISSUE 1: OFFICE OF HEALTH EQUITY OVERVIEW AND MEMBERS' PROPOSALS

PANELISTS

- **Marina Augusto**, Chief Community Development & Engagement Unit, Office of Health Equity, Department of Public Health
- **Reginald Byron Jones-Sawyer, Sr.**, Member, California State Assembly
- **Rob Bonta**, Member, California State Assembly
- **Nora Campos**, Member, California State Assembly
- **Cheryl Brown**, Member, California State Assembly
- **Koffi Kouassi**, Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

OVERVIEW

The DPH Office of Health Equity (OHE) provided the following overview/update on the activities and accomplishments of the OHE:

California Reducing Disparities Project (CRDP) *is funded at $60 million through the Mental Health Services Fund.*

a) Approximately $57 million in contracts and grants will be awarded in the next two months.

b) In February, the California Department of Public Health (CDPH) announced the intent to award one contract for a Statewide Evaluator and four contracts for Technical Assistance Providers; these contracts are expected to be executed in the next month.

c) It is anticipated that the intent to award 33 pilot project grants will be announced in May 2016. The pilot projects will evaluate evidence-based practices for mental health interventions within communities.

d) One remaining solicitation for Education, Outreach, and Awareness in the amount of $3 million will be issued in the fall of 2016.

The Health in All Policies Task Force *was charged by Executive Order (S-04-10) in 2010 to identify priority programs, policies, and strategies to improve the health of Californians while also advancing the goals of the Strategic Growth Council (SGC). The Task Force consists of representatives from 22 State agencies, departments, and offices, who contribute their time to this initiative of improving health, equity, and sustainability.*

a) Health in All Policies staff continues to convene multiagency working groups on a wide range of topics, including active transportation, community greening and parks, and the links between land use, schools, and health.

b) The Task Force is also pleased to have a new working group and action plan that coordinates multiple agencies around work to prevent violence and increase community resilience factors.

c) In response from departments who sit on the task force, the Task Force is convening cross-agency and cross-departmental conversations on equity. The goal is to build the capacity of government agencies to promote equity across multiple sectors and to learn from each other's equity initiatives.

The Climate Change and Health Team

a) The team completed the Public Health Chapter of the statewide climate change adaptation plan called the Safeguarding California Implementation Plan, now publicly released through the Natural Resources Agency (see http://resources.ca.gov/docs/climate/safeguarding/Safeguarding%20California-Implementation%20Action%20Plans.pdf)

b) The team is working closely on the AB 32 Scoping Plan update led by the Air Resources Board. This is the long-term plan for how California will reduce greenhouse gas emissions 40% below 1990 levels by 2030. The Climate Change and Health Team is providing input, data, and tools to embed public health co-benefits in most of the sectors' chapters, and helping to write the Public Health Analysis chapter.

c) The team continues to coordinate the quarterly Public Health Workgroup of the Climate Action Team. The April 19th meeting will be on identifying locations at risk of and planning for extreme heat.

Portrait of Promise: The California Statewide Plan to Promote Health and Mental Health Equity

CDPH OHE has continued the public launch of this legislatively-mandated Strategic Plan to promote health and mental health equity. Now CDPH OHE is sharing the plan with stakeholders around the state and engaging them with implementation of strategic priorities.

PROPOSALS

Strong California

The "Strong California" budget proposal has been submitted to the Subcommittee by Assemblymember Reginald Jones-Sawyer Sr. and Assemblymember Rob Bonta. The Strong California budget proposal proposes $25 million in grants to qualified nonprofit organizations to support efforts around: 1) access to health care *($8 million);* 2) trauma informed care *($8 million)*; 3) healthy living *($6 million);* and 4) health education *($3 million)*. The proposal is aimed at reducing the impacts of health disparities for boys and young men of color. Under this proposal, the California Department of Public Health's Office of Health Equity will administer the funding. Eligible organizations are nonprofit, community-based organizations with a proven track-record of improving outcomes for boys and men of color.

The authors of this proposal state that our state's future growth depends on its young people having a fair chance to thrive and succeed. According to the 2010 Census, over 70 percent of Californians under the age of 25 identify as people of color, and this number is expected to grow. Within this demographic, a disproportionate number of California's boys and young men of color – primarily African American, Latino, Native American, and Southeast Asian males - experience underperforming schools, disadvantaged neighborhoods, poor health, inadequate social support, and limited job opportunities.

With support from several philanthropic partners, youth and community leaders in 15 cities throughout California participate in local campaigns to improve outcomes for boys and men of color. Collectively, these leaders are known as the Alliance for Boys and Men of Color. This statewide network seeks to ensure boys and men of color are: physically and mentally healthy; live in safe neighborhoods; succeed in school and work; and possess the knowledge, skills, and leadership capacity to contribute to their families, communities, and the state's social and economic well-being.

Strong California is meant to enhance these efforts by strengthening the ability of nonprofit organizations working in communities to partner with agencies, deliver critical services, and support systems reform. The authors hope that by leveraging partnerships with qualified non-profit organizations with strong ties to boys and men of color throughout the state's diverse communities, California can ensure that millions of Californians are prepared to succeed.

Select Committee on the Status of Girls and Women of Color Proposal

Assembly Select Committee on the Status of Girls and Women of Color Co-Chairs Assemblymember Nora Campos and Assemblymember Cheryl Brown propose $100 million in grants for qualified non-profit organizations. These funds would be used to support (1) general and reproductive healthcare, (2) high school retention rates and STEM pathways to success, (3) homelessness and poverty reduction, (4) social support systems for working women, and (5) human trafficking prevention and recovery support systems for survivors.

Under this proposal, the California Department of Public Health, Office of Health Equity, would be responsible for administering this funding, and identifying eligible organizations that are non-profit, community-based, with a proven track record of improving outcomes for girls and women of color. No more than 2 percent of this grant funding may be used for administration of the fund or other key non-direct service activities associated with the fund.

Research shows that a disproportionate number of California's girls and women of color - primarily African American, Latino, Native American, and Southeast Asian – experience limited access to general and reproductive healthcare, increased high school drop-out rates, limited acceptance into STEM programs, higher rates of homelessness and poverty, shortages in social support systems, and increased human trafficking victimization with limited recovery resources. These young women also experience limited access to entrepreneurship training, and face challenges when seeking educational opportunities and careers in business.

Strong California is meant to strengthen the ability of non-profit organizations working in communities to partner with state agencies, deliver critical services. This includes promoting access to general and reproductive healthcare, improving high school retention, providing access to STEM education, reducing poverty and homelessness, and increasing anti-Human Trafficking efforts and support systems for survivors.

The $100 million will be allocated as follows: 1) General and Reproductive Healthcare; 2) High School Retention Rate and STEM Pathways to Success; 3) Homelessness and Poverty Reduction; 4) Social Systems for Working Women; and 5) Trafficking Prevention and Recovery Support Systems.

Early Mental Health Initiative Proposal

Assemblymember Bonta requests $6 million to restore the Early Mental Health Initiative (EMHI) through the Department of Public Health.

According to Assemblymember Bonta, for 20 years, the EMHI Matching Grant Program was a highly successful state program that provided matching grants to Local Education Agencies (LEAs) to provide school-based mental health support to young pupils experiencing mild to moderate school adjustment difficulties. EMHI supported Primary Intervention Programs consisting of one-on-one services or services delivered in small groups to address social skills, anger management, friendship groups, or topic-specific issues such as bullying or divorce; and, indirect services such as parent and teacher services and classroom curricula.

EMHI served over 15,000 children per year and its services were in great demand. Despite its success and the demand for services, the program was defunded in 2012. Additionally, with the dissolution of the Department of Mental Health, its oversight and agency was eliminated, effectively ending the program.

The Centers for Disease Control’s (CDC) Adverse Childhood Experiences (ACE) study indicates that childhood exposure to abuse, neglect, and other traumatic experiences has lifelong health impacts. Left unaddressed, ACEs expose children to toxic stress,

keeping them in a constant state of fight-or-flight and taking years off their lives and damaging their health. Bonta states that restoring and expanding the EMHI Program is a significant step towards addressing the harmful and long-lasting effects of ACEs, and will give children a better shot at success.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to provide an overview of the Office of Health Equity and for the Assemblymembers to present their proposals:

Staff Recommendation: Staff recommends no action at this time.

CENTER FOR ENVIRONMENTAL HEALTH

ISSUE 2: MEDICAL MARIJUANA BUDGET CHANGE PROPOSAL

PANELISTS

- **Miren Klein,** Assistant Deputy Director, Center for Environmental Health, Department of Public Health
- **Koffi Kouassi**, Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

DPH requests 37.0 positions and $12 million in funding from the Medical Marijuana Regulation and Safety Act Fund to be phased in between fiscal years 2015- 16 to 2018-19 to begin the implementation of the mandated provisions specified in Chapter 689, Statutes of 2015 (AB 266), Chapter 688, Statutes of 2015 (AB 243), and Chapter 719, Statutes of 2015 (SB 643).

Specifically, this request includes:

YEAR	# OF POSITIONS	$ RESOURCES
2015-16	6.0	$457,000
2016-17	8.0	$3,438,000
2017-18	2.0	$2,520,000
2018-19	21.0	$5,658,000

BACKGROUND

In 1996, voters approved the Compassionate Use Act (CUA), which allows patients and primary caregivers to obtain and use medical marijuana, as recommended by a physician, and prohibits physicians from being punished or denied any right or privilege for making a medical marijuana recommendation to a patient. In 2003, SB 420, Chapter 875, Statutes of 2003, established the Medical Marijuana Program (MMP), which allows patients and primary caregivers to collectively and cooperatively cultivate medical marijuana. It also established a medical marijuana card program for patients to use on a voluntary basis.

Passed in 2015, AB 266 established the Medical Marijuana Regulation and Safety Act (Act) for the licensure and regulation of medical marijuana. Also passed in 2015, AB 243 and SB 643, in conjunction with AB 266, established the regulatory framework to regulate the cultivation, sale, testing, manufacturing and transportation of medical cannabis in California. AB 243 requires the licensing authorities to establish a scale of application, licensing, and renewal fees, based upon the cost of enforcement. All fees collected are to be deposited into the new Medical Marijuana Regulation and Safety Act

Fund (Fund). In order to begin implementation of the bills, AB 243 authorized the Director of Finance to provide an initial operating loan from the General Fund or a Special Fund of up to $10 million and appropriates that money to the California Department of Consumer Affairs.

The departments impacted by these bills are the California Department of Consumer Affairs (DCA), the California State Board of Equalization (BOE), the California Department of Food and Agriculture (CDFA), the California Department of Industrial Relations (DIR), the California Department of Pesticide Regulations (DPR), State Water Resources Control Board (SWRCB), and the Department of Public Health (CDPH). The administration of the Medical Marijuana Regulation and Safety Act will include the following roles:

- Department of Consumer Affairs will establish the Bureau of Medical Marijuana Regulation (The Bureau) to administer, enforce, create, issue, renew, discipline, suspend, and or revoke licenses for the transportation, storage unrelated to manufacturing activities, and sale of medical marijuana within the state. The Bureau will issue licenses to distributors, transporters, and dispensaries.

- California Department of Public Health is required to adopt and enforce regulations for the licensing structure for cannabis manufacturers and the licensing and registration of testing laboratories which will require the establishment of new program staff within CDPH. CDPH is also required to develop standards for the production and labeling of all edible medical cannabis products and will work with CDFA on the development of a database that will be used to store and share relevant information on licensees and the tracking and tracing of regulated commodities.

- California Department of Food and Agriculture is required to create, issue, and suspend or revoke cultivation licenses. CDFA is required to promulgate regulations governing the licensing of indoor and outdoor cultivation sites, develop standards for the use of pesticides in cultivation, and maximum tolerances for pesticides and other foreign object residue in harvested cannabis and create an electronic database containing the electronic shipping manifests. Not later than January 1, 2020, CDFA, in conjunction with the Bureau, shall make available a certified organic designation and organic certification program for medical marijuana. In consultation with the Board of Equalization, CDFA is required to adopt a system for reporting the movement of commercial cannabis and cannabis products.

- Department of Pesticide Regulations is required to provide guidance, in absence of federal guidance, on whether the pesticides currently used at most cannabis cultivation sites are actually safe for use on cannabis intended for human consumption. DPR, in consultation with CDFA, shall develop standards for the use of pesticides in cultivation, and maximum tolerances for pesticides and other foreign object residue in harvested cannabis. DPR, in consultation with the SWRCB, shall promulgate regulations that require that the application of

pesticides or other pest control in connection with the indoor or outdoor cultivation of medical cannabis meets standards.

The Act requires a distributor to ensure that a random sample of the medical cannabis or medical cannabis product is tested prior to distribution. Since this industry is currently unregulated, the number of dispensaries, manufacturers, growers, and potential testing laboratories is unknown. There are varying numbers of estimated medical marijuana dispensaries from different published websites ranging anywhere from 500 to 4,000. Based on the number of dispensaries and the potential demand for testing, CDPH estimates that the number of testing laboratories that will seek licensure and registration in California could be approximately 100 testing laboratories.

The main functions DPH will have include:

1. ***License Medical Marijuana Manufacturers***. Establish new regulatory program to annually licensing medical marijuana manufacturers and conduct investigations and inspections of manufacturers. Develop standards, regulations, and procedures governing a variety of manufacturing activities such as transportation processes and quality control procedures, as well as standards for production and labeling of all edible marijuana products. Work with CDFA on developing a data system to share information on licensees.

2. ***License and Register Medical Marijuana Testing Laboratories***. Establish new regulatory program to (1) annually license and register marijuana testing laboratories, (2) conduct research on marijuana product safety and survey other states' regulations and requirements, (3) develop and validate standard methods for testing medical marijuana including for potential contaminants, and (4) serve as a reference laboratory for medical marijuana manufacturing enforcement. Develop and enforce licensing fee program for testing laboratories. Work with CDFA to develop a data system to store and share information on licensed laboratories.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH present this proposal.

Staff Recommendation: Staff recommends no action at this time.

CENTER FOR INFECTIOUS DISEASE

ISSUE 3: AIDS DRUG ASSISTANCE PROGRAM (ADAP) ESTIMATE

PANELISTS

- **Karen Mark, MD,** Chief, Office of AIDS, Center for Infectious Diseases, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

The proposed 2016-17 ADAP budget includes total funding of $330.2 million, a $66.3 million decrease from the 2015 Budget Act, and a $13.1 million increase over the revised current year estimate of $317.1 million. The decrease primarily reflects savings resulting from the implementation of the Affordable Care Act (ACA), which has led to caseload shifting to comprehensive coverage through either Covered California or Medi-Cal.

BACKGROUND

ADAP pays for HIV/AIDS drugs for individuals who could not otherwise afford them. Drugs on the ADAP formulary slow the progression of HIV disease, prevent and treat opportunistic infections, and treat the side effects of antiretroviral therapy. Specifically, ADAP is made up of the following two services:

1) Medication Program. This pays the prescription costs for drugs on the ADAP formulary (either the full cost of medications or co-pays and deductibles) for the following groups:

    a) ADAP-only clients, for whom ADAP pays 100 percent of the prescription drug costs as these clients do not have a third-party payer;
    b) Medi-Cal share of cost clients, for whom ADAP pays 100 percent of the prescription drug costs up to the client's share of cost amount;
    c) Private insurance clients, for whom ADAP pays prescription drug co-pays and deductibles; and
    d) Medicare Part D clients, for whom ADAP pays the Medicare Part D drug co-pays and deductibles.

2) Insurance Assistance Program. This pays for private health insurance premiums or Medicare Part D premiums, for eligible clients with the following three types of health insurance:

    a) Non-Covered California private insurance;
    b) Private insurance purchased through Covered California; and
    c) Medicare Part D.

Funding Source	2015-16 Budget	2015-16 Estimate	2016-17 Proposed
General Fund	$0	$0	$0
Federal Funds – Ryan White	$109.9	$138.1	$94.0
Rebate Fund	$268.4	$178.1	$236.2
Reimbursements from Medicaid Waiver (Safety Net Care Pool)	$18.2	$0.9	$0.0
Total Expenditures	**$396.5**	**$317.1**	**$330.2**

Estimated ADAP Clients by Coverage Group		
Coverage Group	**2015-16**	**2016-17**
ADAP-only	12,404	11,419
Medi-Cal	191	174
Private Insurance	8,497	9,192
Medicare	8,706	8,615
TOTAL	**29,798**	**29,400**
Insurance Assistance Programs		
OA-HIPP	1,047	895
OH-HIPP Covered California	2,019	3,074
OA-Medicare Part D	634	626
TOTAL	**3,700**	**4,595**

Current Year and Budget Year Changes. Compared to the 2015 Budget Act, estimated expenditures for current year will be $317.1 million, which is a $79.4 million decrease. OA projects expenditures of $330.2 million in 2016-17, which a $66.4 million decrease compared to the 2015 Budget Act.

According to OA, these decreases are mainly due to ADAP clients continuing to transition from ADAP to Medi-Cal or enrolling directly in Medi-Cal, and ADAP clients continuing to transition to private health insurance.

ADAP Rebate Fund. Drug rebates constitute a significant part of the annual ADAP budget. This special fund captures all drug rebates associated with ADAP, including both mandatory (required by federal Medicaid law) and voluntary supplemental rebates (additional rebates negotiated with drug manufacturers through the ADAP Taskforce).

Federal HRSA Maintenance of Effort (MOE) for Ryan White CARE Act. The federal Health Resources and Services Administration (HRSA) requires states to have HIV-related non-HRSA expenditures. California's HRSA match requirement for the 2015 federal Ryan White Part B grant year (04/01/2015-03/31/2016) is $65,519,485.

Payment of Out-of-Pocket Medical Costs through OA-HIPP. As part of the 2014 budget, the Legislature adopted trailer bill language that allows OA-HIPP to pay for out-of-pocket medical expenses. OA anticipates this to begin in the spring of 2016.

ADAP Modernization. SB 75 (Committee on Budget and Fiscal Review), Chapter 18, Statutes of 2015, updated financial eligibility criteria for ADAP and the Office of AIDS Health Insurance Premium Payment program to consider family size and to increase the income limit of $50,000 for these programs, which is estimated to be 447 percent federal poverty level (FPL) to 500 percent FPL or $58,350 for a single individual and $98,950 for a three-person household. OA estimates that this change will cause an additional 306 clients to enroll in 2015-16 and another 151 clients in 2016-17.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present the ADAP estimate and respond to the following:

1. Please describe significant trends in the ADAP budget.

2. Please describe the status of the various augmentations made to the Office of AIDS in the 2014 and 2015 Budget Acts.

3. Please provide an update on the implementation of 2014 trailer bill language to pay out-of-pocket medical costs through OA-HIPP.

4. Please provide an overview of the trends in HIV rates specific to racial, ethnic, and age disparities.

Staff Recommendation: Staff recommends holding open the ADAP estimate until after the release of the May Revision, in order to consider updates and changes.

ISSUE 4: INFECTIOUS DISEASES: TIMELY OUTBREAK DETECTION BUDGET CHANGE PROPOSAL

PANELISTS

- **Gil Chavez, MD,** Deputy Director, Center for Infectious Diseases, DPH
- **Koffi Kouassi**, Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

DPH, Center for Infectious Diseases, Division of Communicable Disease Control requests $1.6 million General Fund expenditure authority for FY 2016-17, $2.1 million General Fund expenditure authority for FYs 2017-18 and 2018-19, and 14.0 permanent positions, to provide support to protect California from infectious diseases through increased disease surveillance and laboratory capacity. The 14.0 positions will be phased in over the 2016-17 fiscal year.

BACKGROUND

Infectious disease laboratories including the Viral and Rickettsial Disease Laboratory and the Microbial Disease Laboratory in the Division of Communicable Disease Control, play three unique and critical functions: (1) detecting and confirming outbreaks (e.g., measles, salmonellosis, and drug resistant tuberculosis outbreaks); (2) monitoring and identifying emerging pathogens (e.g., Ebola, acute flaccid myelitis, middle-eastern respiratory virus, and novel influenza viruses); and (3) providing situational awareness and actionable intelligence to local partners (e.g., plague and norovirus outbreaks). In addition, CDPH epidemiologists rely upon accurate and timely laboratory data and information to identify the source of outbreaks, evaluate disease transmission patterns, and conduct surveillance to monitor and control epidemics.

The infectious disease laboratories provide high quality diagnostic testing for rare diseases, which offers valuable information to local public health departments, health care providers, and patients. The laboratories have a critical role as they work in close collaboration with many CDPH disease control programs and local public health departments to provide laboratory support, technical assistance, and research for the development and maintenance of high quality local laboratory services. For counties without available public health laboratory services, CDPH infectious disease laboratories function as the reference and local public health laboratory. Unlike commercial laboratories or smaller local public health laboratories, the scope of the CDPH infectious laboratories differs as they provide a full, statewide testing menu on all 88 mandated reportable diseases that require laboratory confirmation. The infectious disease laboratories currently receive $16 million in General Fund and $2.9 million in Federal Funding to support 73.1 positions.

During the last decade, CDPH's infectious disease laboratories have faced new challenges posed by emerging and re-emerging infectious diseases, changing laboratory technology, and new federal regulatory and biosafety requirements. Workload in the laboratories has increased dramatically; due to outbreaks and new infectious disease threats, viral disease testing has more than doubled in the past four years. Over the same time period, the number of specimens submitted for testing to identify foodborne disease outbreaks has increased by more than 30 percent. This substantial increase in workload has impaired the ability of the laboratories to address other important laboratory challenges and to complete all needed testing in a timely manner. For example, the laboratories were unable to carry out 18 percent of the total viral disease testing submitted to CDPH in 2014-15. Furthermore, roughly half (49 percent) of all the antimicrobial resistance testing submitted to the infectious disease laboratories for drug resistant gonorrhea, highly drug resistant organisms in health care facilities, and drug resistance in outbreaks was not completed due to insufficient capacity during the same time period. In addition, the laboratory was unable to carry out testing for respiratory viruses in 75 percent of the respiratory samples submitted.

Demands on the laboratories have increased as new infectious diseases have emerged to pose threats to public health. For example, Ebola virus, Middle Eastern Respiratory Syndrome, Coronavirus, and novel influenza viruses have required the CDPH infectious diseases laboratories to develop and deploy new laboratory tests to local public health laboratories. In addition to the emerging and re-emerging infectious diseases, there are vaccine-preventable agents, bacterial toxins, bioterrorism, and pandemics that also pose a threat to public health and require CDPH laboratories to develop more accurate and efficient diagnostic methods that improve capacity and readiness. The Department's laboratories need to develop and support statewide capacity for rapid detection of emerging diseases to enable effective public health response.

New molecular technologies, such as whole genome sequencing, are being introduced in public health laboratories at a rapid pace. Whole genome sequencing technology allows more rapid and accurate identification, characterization and genotyping of microbial pathogens. The federal Centers for Disease Control and Prevention (CDC) is leading a national strategic initiative to implement whole genome sequencing for bacterial, mycobacterial, and fungal pathogens. The CDC has identified foodborne bacterial pathogens, Mycobacterium tuberculosis and Neisseria gonorrhoeae as the highest priority for implementation of whole genome sequencing. This new technology will improve the timeliness of outbreak investigations and enhance control measures. The CDPH infectious disease laboratories have fallen behind a number of other state public health laboratories in the introduction of whole genome sequencing in routine laboratory practice due to high capital costs and the need for specialized personnel. This capacity is needed to support work of local public health laboratories and CDPH's disease control programs.

A critical gap exists in the state's ability to protect California residents from foodborne illnesses. Laboratory testing of foodborne pathogens is critical for identification of foodborne outbreaks. State regulations require that diagnostic laboratories submit isolates of common foodborne pathogens (including Salmonella, Escherichia coli, and Listeria) to public health laboratories for strain typing. In 2014-15, the laboratory was

unable to type 20 percent of foodborne disease specimens submitted for testing. One important element of outbreak detection is timeliness. Delays in strain typing can lead to delays in outbreak detection and delays in implementing steps to remove contaminated food from the food supply. In addition, the CDC's national foodborne pathogen system (PulseNet) is beginning to introduce new technologies based on gene sequencing to replace the current typing method. The Department's infectious disease laboratories need to direct resources to implement and test these new technologies. Meanwhile, the current legacy testing technologies must be sustained during the multi-year transition, further straining existing resources.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to present this proposal.

Staff Recommendation: Staff recommends holding this item open.

ISSUE 5: INCREASED ACCESS TO HIV PRE-EXPOSURE PROPHYLAXIS (PREP) BUDGET CHANGE PROPOSAL

PANELISTS

- **Gil Chavez, MD,** Deputy Director, Center for Infectious Diseases, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

DPH proposes to expend $2.625 million ($1.35 million local assistance and $1.275 million state operations) in fiscal year 2015-16 and $3.5 million ($1.8 million local assistance and $1.7 million state operations) federal funds in 2016-17, and requests the addition of 5.0 permanent positions, to implement a three-year Centers for Disease Control and Prevention (CDC) grant awarded to CDPH on September 3, 2015; the grant is entitled Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men and Transgender Persons.

BACKGROUND

The CDPH Office of AIDS (OA) is funded by the CDC to provide HIV prevention services in California in order to achieve the three primary goals of the National HIV/AIDS Strategy: 1) reduce the number of people who become infected with HIV; 2) increase access to care and improve health outcomes for people living with HIV; and 3) reduce HIV-related health disparities. California ranks second only to Florida in the annual number of newly diagnosed HIV infections, and ranks second only to New York in the number of persons living with HIV infection.

The HIV Prevention Program provides CDC-funded services to the CDC-defined California Project Area. The California Project Area includes all California local health jurisdictions except the Los Angeles County Metropolitan Statistical Area, which includes the cities of Long Beach and Pasadena, and the San Francisco County Metropolitan Statistical Area, which includes the counties of San Mateo and Marin. These jurisdictions receive direct CDC funding. OA uses CDC funding to provide HIV prevention funding to the 18 remaining local health jurisdictions that represent 93 percent of the HIV prevalence in the California Project Area.

The HIV Prevention Program currently receives approximately $16 million annually in CDC cooperative agreement funding to provide the CDC-required activities of targeted HIV testing, linkage to HIV care, partner services, transmission prevention activities focused on HIV-positive persons, condom distribution, and routine, opt-out HIV testing in healthcare settings. The HIV Prevention Program currently has 24.0 authorized positions.

OA also receives $8 million annually in General Fund local assistance and state operations funding for HIV prevention activities, including:

1. HIV Prevention Demonstration Projects pursuant to Chapter 40, Statutes of 2014 ($2,850,000 local assistance and $150,000 state operations)

2. State Syringe Exchange activities ($2,882,000 local assistance and $118,000 state operations)

3. Pre-Exposure Prophylaxis (PrEP) Navigator Services ($1,764,000 local assistance and $236,000 state operations).

CDPH will use both the new CDC grant funding addressed in this proposal and the ongoing $2 million state General Fund for PrEP Navigator Services to increase knowledge, awareness, and uptake of PrEP among Californians at highest risk for HIV acquisition. As specified in SB 75, Chapter 18, Statutes of 2015, the state General Fund dollars will be used to fund a PrEP Navigator Services Program, including local assistance funding disseminated through a competitive Request for Applications process to an entity in any county if that county meets certain specified eligibility criteria. By contrast, the CDC requires the federal grant funding addressed in this proposal be disseminated by the department to only four CDC-designated local health jurisdictions: San Diego, Orange, Alameda, and Riverside. The funded activities must meet CDC's specific requirements, including focusing on the target population of men who have sex with men and transgender persons at high risk for HIV infection, development and distribution of educational resources for clinical and non-clinical providers, and development of a training program for patient navigators who will assist patients with accessing PrEP in the eligible communities.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to present this proposal and to respond to the following:

Please describe how the PrEP funding in the 2015 Budget Act has been implemented.

Staff Recommendation: Staff recommends no action at this time.

ISSUE 6: RICHMOND LABORATORY CAPITAL OUTLAY REAPPROPRIATION

PANELISTS

- **Timothy Bow**, Chief, Program Support Branch, Administration Division, DPH
- **Koreen Hansen**, Principal Program Budget Analyst, Department of Finance
- **Matthew Lea,** Junior Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

This Capital Outlay Budget Change Proposal requests to reappropriate $3,799 million from a Capital Outlay Project approved in Fiscal Year 2015-16 to upgrade the California Department of Public Health (CDPH) Bio-Safety Level 3 (BSL-3) certified Viral and Rickettsial Disease Laboratory. The upgrades were needed to ensure that CDPH retains its BSL-3 Certification from the Federal Center for Disease Control and Prevention and National Institutes of Health.

In 2015, the administration requested, and the final budget included, a one-time capital outlay of $4,333,000 General Fund for a construction project at the DPH Viral and Rickettsial Diseases Laboratory (VRDL) in Richmond California in order to meet current guidelines for Bio-Safety Level 3 (BSL-3) laboratory requirements set by the federal Centers for Disease Control (CDC) and National Institutes for Health (NIH).

BACKGROUND

The VRDL in Richmond is a secure facility with six laboratories, approximately 400,000 square feet of offices, a warehouse, and an animal care facility. The laboratories are used by various DPH programs for review and analysis of communicable disease agents, environmental toxins, and other disease-related agents.

When the VRDL was constructed in 2000, it became a BSL-3 certified lab, and met the BSL-3 requirements established by the CDC and NIH at that time. Therefore, the lab was and is qualified to handle select BSL-3 agents and viruses, such as hantavirus, poxviruses, novel influenza, Middle East Respiratory System (MERS), Severe Acute Respiratory System (SARS), and West Nile Virus. However, in 2006, in response to the Avian flu threat, the CDC and NIH implemented enhanced BSL-3 requirements for BSL-3 laboratories. In response to these enhanced requirements, the state appropriated resources to allow DPH to contract with an engineering firm to conduct an evaluation of the VRDL to identify upgrades needed to meet the enhanced requirements. This engineering firm identified the following infrastructure upgrades needed to meet the new requirements:

- Unidirectional shower with in/out capabilities
- Pass-through autoclave sterilizer
- Equipment decontamination area

- Upgraded High-Efficiency Particulate Absorption filtration of the exhaust side of the Heating Ventilation and Air Conditioner (HVAC) system
- Positive sealing dampers on the HVAC system and through-wall ports for the safe gaseous decontamination for the laboratory
- Electronic monitoring systems within the HVAC system
- Mechanical/Valve Room changes to support the laboratory

The engineering firm identified the following infrastructure changes needed to meet the new requirements:

1. Expansion of the VRDL BSL-3 suite from 1,210 to approximately 2,000 square feet;

2. Modifications to the HVAC mechanical and other related building operating systems to provide enhanced filtering capabilities;

3. Deconstruction of some existing walls; and

4. Construction of new walls to create new containment area(s).

After this engineering contract produced working drawings and recommendations in 2006, actual construction of the project was put on hold due to the state's fiscal crisis. This request is to continue this project that began in 2006, by updating the working drawings to reflect current construction and Americans with Disabilities Act statutes, and then to proceed with actual construction

After the enactment of the FY 2015-16 budget, CDPH engaged the services of the Department of General Services (DGS) Real Estate Services Division (RESD) to manage the project and in July 2015 CDPH transferred $534,000 into the DGS Architectural Revolving Fund (ARF) to fund the Working Drawing (WD) Phase of the project. Originally, the DGS schedule was to proceed into the Construction phase in April/May 2016, which would then allow CDPH to transfer the remaining ($3,799 million) funds into the Architectural Revolving Fund (ARF). However, in August 2015, the State Fire Marshal's (SFM) Office redirected all SFM resources to addressing California fires throughout the state and suspended all reviews of construction plans, drawings, and documents. This effectively caused a 3-4 month delay in the project. The project's construction phase has been delayed to occur after July 2016. As a result, this request is to reappropriate the remaining funds ($3,799 million) for construction to FY 2016-17.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present this proposal.

Staff Recommendation: Staff recommends holding this item open.

ISSUE 7: INFECTIOUS DISEASE STAKEHOLDER PROPOSALS – PART 1

PANELISTS

- **Courtney Mulhern-Pearson**, MPH, Director of State and Local Affairs, San Francisco AIDS Foundation
- **Emalie Huriaux**, MPH, Director of Federal & State Affairs, Project Inform, Chair, California Hepatitis Alliance
- **Gil Chavez, MD,** Deputy Director, Center for Infectious Diseases, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSALS

California HIV Alliance Proposals:

1. **Cost Sharing – Eliminate cost-sharing for individuals enrolled in the AIDS Drug Assistance Program with annual incomes between 400 percent and 500 percent of the Federal Poverty Level.**

This proposal is to change the AIDS Drug Assistance Program guidelines to eliminate any copay requirement, an administrative change that can be made using existing federal and rebate funds and would not require any state General Fund, according to the Alliance. Currently, the AIDS Drug Assistance Program serves individuals with incomes up to 500 percent of the Federal Poverty Level, or about $58,350 for a single individual. However, individuals with incomes between 400 percent and 500 percent of the Federal Poverty Level are required to pay a copay to access the benefit. Advocates state that the copay calculation is cumbersome and hard to administer, and the copay amounts can be quite high, making the program inaccessible for many clients who fall in this narrow income bracket.

2. **Out-of-Pocket Costs – Allow the Office of AIDS' Health Insurance Premium Payment Program to cover premiums, copays, coinsurance, and deductibles incurred by all eligible people living with HIV/AIDS in California.**

The Alliance proposes to expand the Office of AIDS' Health Insurance Premium Payment Program, or OA-HIPP, to cover premiums, copays, coinsurance, and deductibles incurred by all eligible people living with HIV/AIDS in California, including (but not limited to) people with employer-based and family or dependent health coverage. OA-HIPP currently covers only eligible clients with non-Covered California private health insurance, private health insurance purchased through Covered California, and Medicare Part D. The expansion would allow OA-HIPP to pay the premiums and other out-of-pocket costs associated with medical services for all eligible individuals, thereby improving individual health outcomes and dramatically reducing risk of new infections. The federal Health Resource Services Administration has encouraged

the payment of these costs to allow more people living with HIV to access comprehensive and secure coverage. Advocates state that this proposal can be implemented using existing federal and rebate funds and would not require state General Fund.

3. **PrEP Affordability – $1 million State General Fund – Create a PrEP affordability program to cover PrEP-related copays, coinsurance, and deductibles incurred by all individuals accessing PrEP in California with annual incomes below 500 percent of the Federal Poverty Level.**

We propose the development of a PrEP affordability program to cover PrEP-related copays, coinsurance, and deductibles incurred by all individuals accessing PrEP in California with annual incomes below 500 percent of the Federal Poverty Level. Because the cost of the medication is generally covered by public and private health insurance plans and other patient assistance programs, the PrEP affordability program would primarily cover PrEP-related clinical ancillary costs including (but not limited to) HIV and sexually transmitted infection screening, treatment for sexually transmitted infections, medical monitoring, assorted labs, and counseling. However, if an individual uses all available patient assistance programs and still has out-of-pocket costs for the medication, the PrEP affordability program would also cover these remaining costs (essentially operating as a payer of last resort for the medication). New York, Washington, and Colorado have already implemented programs to reduce cost-sharing and improve access to PrEP.

PrEP is an HIV prevention strategy that involves taking a daily pill to reduce the risk of infection. PrEP is a key component of the National HIV/AIDS Strategy as well as California's response to the HIV epidemic. However, PrEP use among Californians at-risk for HIV remains extremely low and costs associated with use of PrEP is one of the primary barriers to PrEP access. A 2015 survey of gay and bisexual men by the California HIV/AIDS Research Program found that only 1 in 10 respondents had ever used PrEP. Latino and black respondents were less likely to have used PrEP than their white counterparts. In addition, over half of all respondents indicated that they would not be able to afford PrEP.

Project Inform and California Hepatitis Alliance Proposals:

1. **$100,000 to CDPH to purchase 41,666 doses of Hepatitis B Vaccine (HBV) vaccines (at $2.40 per dose) for distribution to local health jurisdictions to vaccinate at-risk adults.**

The CDC recommends vaccination for persons at risk for infection by sexual exposure, persons at risk for infection by percutaneous or mucosal exposure to blood, and others. The CDC also recommends vaccination for all adults receiving services in the following settings:

- STD clinics
- HIV counseling, testing, and treatment facilities
- Health care settings targeting services to men who have sex with men
- Drug use prevention and drug treatment facilities

In 2013, HBV coverage (≥3 doses) among adults in the United States was poor:

- 25.0% for adults aged ≥19 years
- 32.6% among adults aged 19–49 years
- 16.1% among adults aged ≥50 years.
- Overall vaccination coverage decreased compared with 2012 among adults aged ≥19 years by 2.1 percentage points.
- Among adults aged 19–49 years, vaccination coverage was lower for blacks (30.5%) and Latinos (23.7%) compared with whites (35.2%), but higher for Asians (39.3%).

There are significant vaccination disparities among foreign-born populations in the United States. Access to low-cost or free vaccinations are especially important for this population because of limited economic resources and high rates of uninsurance, particularly among the 2.67 million undocumented immigrants in California. Foreign-born individuals may be eligible for low-cost public health programs providing vaccinations in certain communities, but factors such as limited local health department funding for vaccinations, language barriers, or immigrants' lack of awareness of their eligibility for these programs may restrict their use. In 2011, more than 25% of the foreign-born population of the United States lived in California.

From 2007-2010, the state received funds from the CDC to purchase doses of HBV. During that time, local health jurisdictions and community based organizations provided >100,000 doses of HBV to at-risk adults. Those funds came from a vaccine manufacturer rebate that is now gone. Advocates state that it was an effective program and the loss of funding has left a gap that has not been filled.

2. **$600,000 to the CDPH Office of AIDS to purchase 33,333 rapid Hepatitis C Vaccine (HCV) antibody test kits (at $18/kit) to distribute to community-based testing programs to test at-risk individuals.**

Advocates state that they will work with the Office of AIDS (OA) and the Adult Viral Hepatitis Coordinator (housed in the STD Branch) to determine the best method to disseminate test kits to community-based programs with a focus on serving low-income communities, primarily reaching those who are currently not enrolled in Medi-Cal or other health insurance or who are disconnected from primary care services.

In addition to identifying new cases of chronic HCV infection, and enrolling patients in healthcare and follow-up, testing emphasizes prevention of transmission from an infected person to uninfected persons. Not every person identified with HCV will need immediate treatment, but everyone has the right to know their status so they can then take steps to take care of themselves and protect others.

3. **$500,000 to CDPH to support an additional 25 to 30 trainings (at $18,000 per training for a minimum of 8 and maximum of 16 trainees per training based on current CDPH estimate) for non-medical personnel to become certified to perform rapid HCV and rapid HIV testing in community-based settings and to provide capacity-building assistance to community-based organizations**

starting or scaling up HIV and/or HCV testing programs. Of this, 10% ($50,000) is to be allocated for capacity building for community-based organizations that are starting new HIV and/or HCV testing programs or existing testing programs that are scaling up their efforts.

Currently, CDPH-OA contracts with a training organization to conduct trainings for non-medical personnel to become certified to perform rapid HCV and rapid HIV testing in community-based settings. Advocates propose an additional 15 trainings (or equivalent number of training seats, 120-240 seats) through the provision of these funds, to be prioritized for the training of personnel in counties not currently funded by OA, as well as counties that have no or limited access to community-based HCV testing or that can identify a need for scaling up HCV testing. The proposal includes an additional 10 trainings (or equivalent number of training seats, 80-160) through the provision of these funds be prioritized for the training of personnel in OA-funded counties, or personnel in Los Angeles County, who do not have access to the Los Angeles County trainings. Although Los Angeles and San Francisco are counties directly funded by CDC and provide their own trainings with that funding, advocates have identified significant training access challenges for programs in Los Angeles. This proposal would target at least 10% of this allocation to new testing sites or programs with a plan to expand existing HCV and HIV testing services.

4. $*200,000 to the Office of AIDS for technical assistance to local governments and to increase the number of syringe exchange and disposal programs throughout California and the jurisdictions in which syringe exchange and disposal programs are authorized.*

Due to overwhelming consensus among public health and medical experts that syringe exchange programs reduce the rates of HIV, HBV, and HCV, and assist persons in accessing drug treatment and medical care, the U.S. Congress recently lifted the longstanding ban on the use of federal funds to support syringe exchange and disposal programs, now allowing for federal dollars to be used to support all aspects of these programs, except for the actual purchase of syringes. In addition, the CDPH-OA now supports a syringe exchange and disposal supply clearinghouse, providing supplies to authorized programs throughout the state, as approved through the 2015 Budget Act.

Syringe exchange and disposal programs are extremely cost effective. The average cost to cure one person living with HCV, given new price discounts and market competition, is approximately $40,000, and may be decreasing due to new competition in the market. Data have shown that each person living with HCV who injects drugs is likely to infect approximately 20 other people. The lifetime costs of treating one person for HIV is $412,000. The lifetime cost to prevent one HIV infection through syringe exchange and disposal programs is estimated to be $4,800-$14,500. Thus, the impact of averting new HCV and HIV infections through support for syringe exchange and disposal programs is exponential.

Despite these significant changes in funding, local governments and community-based organization have yet to expand availability. Advocates state that dedicated technical assistance is needed to address areas of greatest need and risk, and jurisdictions that

have authorized syringe exchange and disposal programs need to scale up and expand existing efforts to maximize their effectiveness. In addition, many areas of the state have no authorized programs (e.g., Modesto, Riverside, San Bernardino, Ventura) and have a growing population of people who inject drugs who require services to prevent the spread of infectious diseases and other drug-related harms. Advocates explain that capacity-building assistance is essential to help scale up syringe exchange and disposal services, so that California avoids an HIV and HCV outbreak similar to what occurred in Indiana and avoids the HBV and HCV outbreaks that are recently identified in parts of Appalachia.

Currently there are 37 legally authorized syringe exchange and disposal programs operating in California. They provide a wide range of services in addition to providing sterile injection equipment and disposal options, including HIV testing and risk-reduction counseling, overdose prevention education, and referrals to additional services such as drug treatment, mental health, and housing.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the stakeholder panelists to present these proposals.

Staff Recommendation: Staff recommends no action on these proposals at this time.

ISSUE 8: INFECTIOUS DISEASE STAKEHOLDER PROPOSALS – PART 2

PANELISTS

- **Charity Dean**, MD, Health Officer of Santa Barbara County, President, California Tuberculosis Controllers Association, Health Officers Association of California
- **Katya Ledin**, PhD MPH, Director, Napa-Solano-Yolo-Marin County Public Health Laboratory, Health Officers Association of California
- **Gil Chavez, MD,** Deputy Director, Center for Infectious Diseases, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSALS

Health Officers Association of California (HOAC) Proposals:

Tuberculosis (TB) Elimination
HOAC proposes an augmentation to CDPH Tuberculosis Control Branch of $10,000,000 to assure that every California jurisdiction receives funding to implement recent innovations in TB prevention, which are essential elements to achieve TB elimination by 2040.

A recently released DPH report on TB in California states:

> "At the current rate of decline, TB will not be eliminated from California until 2116. Nearly ten percent of TB cases continue to die each year, and TB is diagnosed in a young child every week. Continuing our efforts to identify and successfully treat active TB cases in California is important to prevent transmission and the most severe outcomes. However, this strategy alone may not be sufficient to increase the decline in TB. In order to reach the goal of TB elimination (<1 case per million population) by 2040, the TB community now must expand our focus to preventing TB."

California has over 2,000 new cases of tuberculosis each year, reports the most tuberculosis cases in the United States, and has nearly twice the national case rate. It is believed that there are another 2.5 million Californians with TB infection, though undiagnosed and inactive. Finding and treating those with TB infection would stop the transmission of TB before it starts. However, TB funding is limited and current funding to local health jurisdictions goes to support identification and treatment of suspected and confirmed active TB disease cases, not undiagnosed, inactive cases.

HOAC states that an augmentation to CDPH Tuberculosis Control Branch of $10,000,000 will assure that every California jurisdiction receives funding to implement recent innovations in TB prevention, which are essential elements to achieve TB elimination by 2040. HOAC proposes that CDPH award funds to help all 61 local health jurisdictions to identify high-risk TB populations and get them tested and treated. A

minimum of $150,000 per jurisdiction will assure all areas have resources to pursue prevention activities in at-risk communities through education, training, and provision of new diagnostic tests and treatment options.

HOAC states that elimination of TB will save vital funds in California, both privately and in Medi-Cal. If $10 million is invested annually in testing and treating tuberculosis infection, after only a 5 year investment, the $50 million will not only be returned but there will be an additional $1.6 million accrued in medical savings. This is a conservative estimate, and does not include the value of lives saved, employment losses averted, the quality of life for Californians who do not develop tuberculosis disease and public health costs averted. In 2014, Medi-Cal spent an estimated $19.9 million on treatment of TB disease in California, according to HOAC.

Lab Aspire

HOAC proposes an augmentation of $1.2 million to establish the Lab Aspire Program, to be housed at the CDPH State Laboratory Director's office. Six assistant lab directors will be funded on a yearly basis, allowing a rotating cohort to provide experience to the maximum number of qualified participants. The budget for this proposal also covers administration costs at CDPH, and much-needed updates to laboratory equipment. This investment would be limited to assistant lab directors to be employed in local public heath labs. These individuals will be eligible for a five-year commitment of funds, thus allowing them to accrue the state certification and subsequent four years of laboratory experience required to become public health lab directors.

The California Public Health Laboratory Network is made up of the state laboratory and 34 local public health laboratories working in conjunction with hospital and commercial laboratories throughout the state. Public health labs perform the vital task of identifying specific strains of bacteria such as *E coli* to help pinpoint the source of a foodborne illness outbreak. Good lab work can prevent a serious outbreak.

HOAC reports that there is a severe shortage of trained, qualified public health lab directors. Sixteen labs have only part-time directors at present, and 22 labs have directors who plan to retire within the next five years. Current regulations require public health lab directors to hold a doctorate degree, board certification, California Public Health Microbiologist certification, and have at least four years of experience in a public health laboratory. There are simply not enough individuals in the state of California or nationwide who meet these requirements.

To address this problem, a program called Lab Aspire was created in 2006 to provide educational support for Ph.D. candidates interested in becoming public health laboratory directors. Lab Aspire was a collaboration between UCLA, UC Davis, UC Berkeley, the California Association of Public Health Laboratory Directors, and the California Conference of Local Health Officers. During its six years of funding, Lab Aspire produced 5 public health lab directors and 1 assistant public health lab director. Eighteen trainees were in the pipeline to become public health lab directors. However, funding for this program was eliminated in 2012 due to state budget shortfalls.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the stakeholder panelists to present these proposals.

Staff Recommendation: Staff recommends no action on these proposals at this time.

0530 CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY

ISSUE 9: INFECTIOUS DISEASE INTERAGENCY TASK FORCE STAKEHOLDER PROPOSAL

PANELISTS

- **Anne Donnelly**, Director of Health Care Policy, Project Inform, California HIV Alliance
- **Yang Lee**, Principal Program Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

The California HIV Alliance and the California Hepatitis Alliance propose $500,000 General Fund to create a health care and prevention interagency task force, convened by the California Health and Human Services Agency, to create strategic action plans that will better integrate public health efforts and health care delivery to address the interrelated epidemics of HIV, hepatitis C, and sexually transmitted infections, as well as drug user health and the opioid epidemic.

BACKGROUND

This funding would establish an interagency taskforce that would set direction for coordinated action at the state level in meeting the health care and prevention needs of people living with or at risk for HIV, HCV, STIs and for people who use drugs. The goal of the taskforce is to improve health outcomes for people living with these conditions and to reduce new infections. The task force will be convened by the Health and Human Services agency and membership of the task force will include, but not be limited to, representatives from Department of Health Care Services, Department of Public Health, Department of Corrections and Rehabilitation, and Covered California as well as medical and non-medical providers, and consumer advocates. It is essential that representatives include members from communities disproportionately affected by these conditions, including but not limited to, communities of color, youth, women, transgender individuals, men who have sex with men and people who use injection drugs. Initial and ongoing responsibilities of the task force would include, but are not limited to:

- Assessment of state program alignment with the objectives of existing federal or state action plans, such as the National HIV/AIDS Strategy;

- Assessment of any California strategies that are aimed at enhancing positive health outcomes and eliminating or mitigating new infections;

- Creation of strategic action plans for each condition, developed with appropriate stakeholder feedback, that promote evidence-based, high-impact health care and prevention strategies, and measurable objectives/targets and evaluation metrics, including improved health outcomes and reduced condition-related deaths, disparities, and new infections/occurrences where appropriate in each of the areas outlined above. These action plans should be submitted to the Legislature and available to the public;

- Creation of recommendations and strategies to increase coordination and collaboration, including data sharing and care quality measures, between and among departments and entities to effectively leverage and, where appropriate, integrate public health efforts with health care delivery systems in California to address these serious health issues. Recommendations and strategies should be reported to the Legislature and available to the public;

- Creation of recommendations on how to leverage state investments and federal investments with already existing efforts to strategically address these inter-related conditions to improve individual and population health outcomes particularly in underserved communities, move toward ending HIV and HCV disease, greatly decrease the incidence of STIs, and decrease fatal overdose in California; and

- Report out any successes and barriers to implementation and recommendations on next steps.

The taskforce will meet quarterly, for a minimum of two years, convening additional work groups as necessary. The taskforce is authorized to accept federal funds, gifts, donations, grants, or bequests for all or any of its purposes.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests Anne Donnelly to present this proposal.

Staff Recommendation: Staff recommends no action on this proposal at this time.

4265 DEPARTMENT OF PUBLIC HEALTH

CENTER FOR HEALTHCARE QUALITY

ISSUE 10: LICENSING AND CERTIFICATION PROGRAM ESTIMATE

PANELISTS

- **Jean Iacino**, Deputy Director, Center for Healthcare Quality, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

Licensing & Certification (L&C) Program Estimate

The Governor's budget proposes a 1.7 percent increase to L&C funding for 2015-16, and funding of $264.2 million for 2016-17, a 7 percent increase over current year, as shown in the chart below:

L&C Program Funding & Positions (Dollars in Thousands)			
Funding Source	**2015-16 Budget Act**	**2016-17 Proposed**	**Budget Act to Budget Year Change**
General Fund	$3,700	$3,703	$3 (0.1%)
Federal Funds	$91,781	$95,091	$3,220 (3.5%)
Internal Departmental Quality Improvement Account	$2,292	$2,304	$12 (0.5%)
State Health Facilities Citation Penalty Account	$2,144	$2,144	$0 (0%)
Federal Health Facilities Citation Penalty Account	$973	$973	$0 (0%)
Reimbursements	$15,130	$16,421	$1,291 (8.5%)
L&C Program Fund	$134,334	$147,218	$12,884 (9.6%)
Less GF Transfer	-$3,700	-$3,700	$0 (0%)
Internal Health Information Integrity Quality Improvement Account	$25	$0	$-25 (-100%)
Total Funds	**$246,769**	**$264,154**	**$17,385 (7.0%)**
Field Positions – Health Facilities Evaluator Nurses	600.2	600.2	0.0 (0.0%)
Field Positions – Other	446.1	448.1	2.0 (0.4%)
Headquarters Positions	251.0	251.0	0.0 (0.0%)
Total L&C Positions	**1,297.3**	**1,299.3**	**2.0 (0.2%)**

The Governor's budget includes the following estimates for L&C accounts:

L&C Accounts *(In Thousands)*			
	State Health Facilities Citation Penalties Account	**Federal Health Facilities Citations Penalties Account**	**Internal Departmental Quality Improvement Account**
Beginning Balance	$7,957,000	$7,487,000	$17,859,000
Revenues	$2,425,000	$2,004,000	$4,217,000
Expenditures	$3,337,000	$973,000	$2,304,000
Fund Balance	**$7,045,000**	**$8,518,000**	**$19,772,000**

State Health Facilities Citation Penalties Account - Used primarily to pay for temporary managers and/or receivers for SNFs. Funds ($1.2 million) from this account are also used to support the Department of Aging's Long Term Care Ombudsman programs.

Federal Health Facilities Citations Penalties Account - Used to fund innovative facility grants to improve the quality of care and quality of life for residents of SNFs or to fund innovative efforts to increase employee recruitment or retention subject to federal approval.

Internal Departmental Quality Improvement Account - Used to fund internal L&C program improvement efforts. Funded by administrative penalties on hospitals.

Health Facility License Fees

Existing statute requires the L&C Program to annually publish a Health Facility License Fee Report (DPH Fee Report) by February of each year. The purpose of this annual DPH Fee Report is to provide data on how the fees are calculated and what adjustments are proposed for the upcoming fiscal year.

Licensing fee rates are structured on a per "facility" or "bed" classification and are collected on an initial license application, an annual license renewal, and change of ownership. The fees are placed into a special fund—the Licensing and Certification Special Fund.

The fee rates are calculated as follows:

- Combining information on projected workload hours for various mandated activities by specific facility type (such as skilled nursing home, community-based clinic, or hospital).
- Calculating the state workload rate percentage of each facility type in relation to the total state workload.
- Allocating the baseline budget costs by facility type based on the state workload percentages.
- Determining the total proposed special fund budget cost comprised of baseline, incremental cost adjustments, and credits.
- Dividing the proposed special fund cost per facility type by the total number of facilities within the facility type or by the total number of beds to determine a per facility or per bed licensing fee.

License Fees by Facility Type			
	Fee Per Bed or Facility	FY 2015-16 Fee Amounts	FY 2016-17 Proposed Fee Amounts
Acute Psychiatric Hospitals	Bed	$319.90	447.86
Adult Day Health Centers	Facility	$4,997.90	6,241.53
Alternative Birthing Centers	Facility	$2,380.19	2380.19
Chemical Dependency Recovery Hospitals	Bed	$229.52	321.33
Chronic Dialysis Clinics	Facility	$2,862.63	3,407.02
Community Clinics	Facility	$862.03	1,206.84
Congregate Living Health Facilities	Bed	$374.40	524.16
Correctional Treatment Centers	Bed	$688.44	963.82
District Hospitals Less Than 100 Beds	Bed	$319.90	447.86
General Acute Care Hospitals	Bed	$319.90	447.86
Home Health Agencies	Facility	$2,761.90	2761.90
Hospices (2-Year License Total)	Facility	$2,970.86	2970.86
Hospice Facilities	Bed	$374.40	524.16
Intermediate Care Facilities (ICF)	Bed	$374.40	524.16
ICF - Developmentally Disabled (DD)	Bed	$696.48	975.07
ICF - DD Habilitative	Bed	$696.48	975.07
ICF - DD Nursing	Bed	$696.48	975.07
Pediatric Day Health/Respite Care	Bed	$180.49	252.69
Psychology Clinics	Facility	$1,771.99	2,480.79
Referral Agencies	Facility	$2,795.53	3,728.78
Rehab Clinics	Facility	$311.22	435.71
Skilled Nursing Facilities	Bed	$377.77	527.51
Surgical Clinics	Facility	$2,984.40	4,178.16
Special Hospitals	Bed	$319.90	447.86

Data Source: FY 16-17 Licensing Fees Chart

BACKGROUND

The California Department of Public Health's (DPH) Licensing and Certification Program (L&C) is responsible for regulatory oversight of licensed health facilities and health care professionals to ensure safe, effective, and quality health care for all Californians. L&C fulfills this role by conducting periodic inspections and compliant investigations of health facilities to ensure that they comply with federal and state laws and regulations. L&C licenses and certifies over 7,500 health care facilities and agencies in California, such as hospitals and nursing homes, in 30 different licensure and certification categories.

The federal Centers for Medicare and Medicaid Services (CMS) contracts with L&C to evaluate facilities accepting Medicare and Medicaid (Medi-Cal in California) payments to certify that they meet federal requirements. L&C evaluates health care facilities for compliance with state and federal laws and regulations, and it contracts with Los Angeles County to license and certify health care facilities located in Los Angeles County.

L&C's field operations are implemented through district offices, including over 1,000 positions, throughout the state, and through the contract with Los Angeles County.

In addition, L&C oversees the certification of nurse assistants, home health aides, hemodialysis technicians, and the licensing of nursing home administrators.

Long-Standing Problems with L&C

There have been long-standing concerns about the L&C program. Multiple recent legislative oversight hearings, an audit released by the California State Auditor in October 2014, and media reports have highlighted significant gaps in state oversight of health facilities and certain professionals that work in these facilities.

CMS Concerns

On June 20, 2012, CMS sent a letter to DPH expressing its concern with the ability of DPH to meet many of its current Medicaid survey and certification responsibilities. In this letter, CMS states that its analysis of data and ongoing discussions with DPH officials reveal the crucial need for California to take effective leadership, management, and oversight of DPH's regulatory organizational structure, systems, and functions to make sure DPH is able to meet all of its survey and certification responsibilities.

The letter further states that "failure to address the listed concerns and meet CMS' expectations will require CMS to initiate one or more actions that would have a negative effect on DPH's ability to avail itself of federal funds." In this letter, CMS acknowledges that the state's fiscal situation in the last few years, and the resulting hiring freezes and furloughs, has impaired DPH's ability to meet survey and certification responsibilities.

As a result of these concerns, CMS set benchmarks that DPH must attain and is requiring quarterly updates from DPH on its work plans and progress on meeting these benchmarks. The state was in jeopardy of losing $1 million in federal funds if certain benchmarks were not met. (Ultimately, $138,123 in federal funding was withheld.)

State Auditor Concerns

In October 2014, the State Auditor released a report regarding the L&C program. The findings from this report include:

- DPH's oversight of complaints processing is inadequate and has contributed to the large number of open complaints and entity reported incidents. For example, the Auditor found more than 11,000 complaints and entity-reported incidents open for an average of nearly a year.
- DPH does not have accurate data about the status of investigations into complaints against individuals.
- DPH has not established formal policies and procedures for ensuring prompt completion of investigations of complaints related to facilities or to the individuals it certifies.
- DPH did not consistently meet certain time frames for initiating complaints and ERIs.

Hospital Complaint Investigations & Staffing Ratios

While the focus of recent audits, reports and media coverage has been on nursing homes, DPH acknowledges that they also face a backlog of complaint investigations

that are hospital-based. Moreover, DPH explains that DPH only investigates a hospital's compliance with statutorily-required staffing ratios when they receive a complaint about the hospital. DPH stated last year that the staffing/resources requested last year would address the full spectrum of workload and backlogs within L&C, including complaint investigations for both nursing homes and hospitals. DPH also states that these resources will enable L&C to do licensing surveys of hospitals every three years, as is statutorily-required.

Budgets Address Problems. The 2014-15 and 2015-16 budgets took actions to address these concerns.

2014-15 Budget. The Legislature adopted trailer bill language that required L&C to:

- Report metrics, beginning October 2014 and on a quarterly basis, on: (1) investigations of complaints related to paraprofessionals certified by DPH; (2) long-term care health facility complaints, investigations, state relicensing, and federal recertification surveys; and (3) vacancy rates and hiring within L&C.
- Report by October 2016 the above information for all facility types.
- Assess the possibilities of using professional position classifications other than health facility evaluator nurses to perform licensing and certification survey or complaint workload by December 1, 2014.
- Hold semiannual meetings, beginning August 2014, for all interested stakeholders to provide feedback on improving the L&C program to ensure that Californians receive the highest quality of medical care in health facilities.
- See the following website for the publication of this data: http://www.DPH.ca.gov/programs/Pages/CHCQPerformanceMetrics.aspx

2015-16 Budget. The 2015-16 budget included:

- ***Workload***. An increase of $19.8 million in 2015-16 for 237 positions (123 positions became effective July 1, 2015 and 114 positions will begin on April 1, 2016), and an increase in expenditure authority of $30.4 million in 2016-17 from the L&C Special Fund to address the licensing and certification workload.
- ***Quality Improvement Projects***. An increase of $2 million in 2015-16 from the Internal Departmental Quality Improvement Account to implement quality improvement projects.
- ***Los Angeles County Contract***. An increase in expenditure authority of $14.8 million from the L&C Special Fund to augment the Los Angeles County contract to perform licensing and certification activities in Los Angeles County.
- ***Los Angeles County Contract Monitoring***. An increase of $378,000 from the L&C Special Fund and three positions, to provide on-site oversight and perform workload management, training, and quality improvement activities to improve the efficiency and effectiveness of the Los Angeles County contract licensing and certification activities.

- ***Complaint Investigation Timelines***. The Legislature adopted trailer bill language to establish timeframes to complete complaint investigations at long-term care facilities. This language requires the department to do the following:

  - For complaints that involve a threat of imminent danger or death or serious bodily harm that are received on or after July 1, 2016, the department must complete the investigation within 90 days of receipt. This time period may be extended up to an additional 60 days if the investigation cannot be completed due to extenuating circumstances. If there is an extension, the department must notify the facility and the complainant in writing of this extension and the extenuating circumstances and document the extenuating circumstances in its final determination. Any citation issued as a result of the complaint investigation must be issued and served within thirty days of the completion of the complaint investigation.
  - For all other categories of complaints received on or after July 1, 2017, the department must complete the investigation within 90 days of receipt. This time period may be extended up to an additional 90 days if the investigation cannot be completed due to extenuating circumstances. If there is an extension, the department must notify the facility and the complainant in writing of this extension and the extenuating circumstances and document the extenuating circumstances in its final determination. Any citation issued as a result of the complaint investigation must be issued and served within thirty days of the completion of the complaint investigation.
  - For all complaints received on or after July 1, 2018, the department must complete the investigation within 60 days of receipt. This time period may be extended up to an additional 60 days if the investigation cannot be completed due to extenuating circumstances. If there is an extension, the department must notify the facility and the complainant in writing of this extension and the extenuating circumstances and document the extenuating circumstances in its final determination. Any citation issued as a result of the complaint investigation must be issued and served within thirty days of the completion of the complaint investigation.
  - Report on an annual basis (in the Licensing and Certification Fee report) data on the department's compliance with these new timelines.
  - Beginning with the 2018-19 Licensing and Certification November Program budget estimate, the department must evaluate the feasibility of reducing investigation timelines based on experience implementing the timeframes described above.
  - States the intent of the Legislature that the department continues to seek to reduce long-term care complaint investigation timelines to less than 60 days with a goal of meeting a 45-day timeline.

- Notification for Hospital Complaints. The Legislature adopted trailer bill language to require the department to notify hospitals and complainants if there are extenuating circumstances impacting the department's ability to meet complaint investigation timelines. This notification would include the basis for the extenuating circumstances and the anticipated completion date.

- Long-Term Care (LTC) Ombudsman Program. The Legislature directed $1 million (one-time) from the State Health Facilities Citation Penalties Account to the LTC Ombudsman Program at the Department of Aging in 2015-16 and adopted trailer bill language to increase the L&C fee for skilled nursing facilities to generate $400,000

to support the LTC Ombudsman Program on an ongoing-basis. This increase in funds would be used to support skilled nursing facility complaint investigations and quarterly visits.

Report on the Use of Non-Registered Nurses in L&C Regulatory Activities. As noted above, SB 857 required DPH to provide a report to the Legislature assessing the possibilities of using professional position classifications other than registered nurses (RNs) to perform licensing and certification survey or complaint investigation workload in order to help evaluate if using different position classifications would help the program recruit and retain staff and address concerns with L&C. This report was due December 1, 2014 and was just received on February 22, 2016. According to the report, DPH found the following:

Importance of Using RNs as Surveyors. The department believes RNs possess the technical, professional, and clinical expertise needed to appropriately evaluate patient care and safety, assess health facility operations in a highly regulated environment, interpret regulations, interact with patients and facility staff, and apply the clinical judgment needed to perform licensing and certification surveys and complaint investigations. This includes serious patient care events that occur in health care settings, and the potential for those events to lead to situations that cause or are likely to cause serious injury or death (immediate jeopardy).

In the department, RNs normally investigate a complaint or ERI. Most complaint and ERI investigations involve clinical or clinically-related questions and issues. The investigations are multifaceted and include medical record reviews, interviews, and observations related to the allegations in the complaint or ERI. These activities include interviews with facility clinicians and patients whose physical and mental condition may be clinically compromised.

Using RNs allows the survey staff to respond to shifting circumstances that may occur during the course of an investigation. During a survey or an investigation, a surveyor may identify a patient safety issue that requires them to stop what they are doing to investigate, or an investigation may require more clinical judgment than was initially anticipated. Because RNs are competent to perform any survey task, they have the ability to fulfill any role on the survey team at any time. This allows the department to address shifting and immediate workload demands. Further, the increasing level of acuity of residents in general acute care hospitals and skilled nursing facilities requires a higher level of clinical skill among surveyors. Filling most surveyor positions with RNs reflects the nature of the department's workload, and the requisite background required to perform capably as a surveyor in all relevant situations.

Potential for Using Licensed Vocational Nurses (LVNs) to Perform Surveys or Complaint Investigations. In the past, the department has hired LVNs in the health facilitator evaluator (HFE) I classification to perform survey and investigation work. This is the only classification in the HFE series performing survey and investigation work for which an LVN could meet the minimum qualifications. The current minimum qualifications for the HFET and the HFE I is a four-year degree in specified medical fields. Each two years of LVN experience can substitute for one year of education.

Thus, an LVN would require eight years of experience to meet the minimum qualifications. When the pending HFE reclassification proposal becomes effective, the HFET and HFE I classifications will be eliminated.

Using information from the Department of Consumer Affairs, the department determined that approximately 130,339 LVNs are licensed in California, compared with over 500,000 RNs licensed in California. Given the education or experience requirements needed in addition to an LVN license, the lack of an appropriate civil service classification, and the small number of LVNs compared with RNs, the department determined that limiting the applicant pool to LVNs would likely not yield enough viable candidates to result in a notable impact on workload.

Potential for Using Other Classifications to Perform Medical Information Breach Investigations. The department had approximately 5,100 medical information breach cases pending investigation as of June 30, 2015. Medical breach investigations represent about 10 percent of the total annual complaints/ERIs received.

Currently, the department uses HFENs as the primary investigators of medical information breaches. However, this type of investigation does not require the clinical expertise of an RN. Since July 1, 2014, the department has had a small staff of non-RNs investigating medical information breaches. Expanding this investigative staff with Associate Governmental Program Analysts (AGPAs) or Special Investigators may be an effective way to relieve some workload from HFENs, enabling them to focus their clinical expertise on survey and other complaint/ERI investigation work. The applicant pool for AGPAs and SIs is substantial. The AGPA classification is the journey-level analyst civil service classification used by departments statewide and the SI classification is also used statewide.

In December 2015, using existing position authority, the department initiated a pilot program that will use 13 AGPAs or SIs spread across the six regions of the state to investigate medical information breaches. These AGPAs or SIs will address medical breach investigation workload in each of the 14 district offices and Los Angeles County but will not be physically located in every district office. The department proposes a three-year pilot to allow time to recruit and train the AGPAs or SIs and collect sufficient data to assess this model's effectiveness, as well as feasibility of expanding the program. The department will periodically provide updates in its November estimates on the pilot's progress.

Update on L&C's Efforts to Hire Nurse Surveyors. Since July 1, 2015, CHCQ has hired 108 Health Facilities Evaluator Nurses (HFENs), and 72 HFENs have separated from CHCQ. As of January 26, 2016, CHCQ has 70.5 vacant HFEN positions. CHCQ estimates there will be a turnover rate of approximately 20 percent in 2015-16, which is similar to past trends. CHCQ has worked closely with the department's Human Resources Branch (HRB) to improve efforts to hire L&C HFEN applicants. CHCQ funded a new position in HRB dedicated to work only on CHCQ personnel activities including pre-screening of applicants to ensure they meet minimum qualifications.

In order to fill the new HFEN positions, CHCQ sent contact letters to everyone on the HFEN certification list in July 2015 (approximately 600 letters). As a result, CHCQ received more than 175 applications between July and October. In November 2015, CHCQ sent approximately 1,500 contact letters to HFEN candidates, and has since received more than 300 applications. In August 2015, CHCQ also mailed over 500,000 post cards advertising HFEN positions to every registered nurse in California.

To ensure consistency and standardization among district offices, CHCQ established a fixed set of questions for all district offices to use for HFEN interviews. In addition, CHCQ encouraged district offices to partner with other closely located offices to conduct joint interviews. CHCQ designed these coordinated interviews to improve "customer service" for applicants and to reduce prior inefficiency where an individual received multiple interview requests from district offices because they indicated a willingness to work in several offices in their application.

CHCQ continues to gather feedback from the district offices to improve the hiring process. There are currently 32 pending offers to HFEN candidates. CHCQ is continuing to work on filling the remaining support and supervisory positions that were established July 1, 2015. CHCQ received 14 health facility evaluator II supervisor positions and currently has 12 vacancies. CHCQ received 14 program technician II positions and currently has 9 vacancies. CHCQ is currently and continuously reviewing applications and interviewing for HFENs and other positions.

Update on L&C's Oversight of the Los Angeles County Contract. As noted above, the 2015-16 contained funding and positions to improve the state's oversight of the Los Angeles County Contract. According to DPH, over the past 18 months, CHCQ has significantly increased its monitoring of Los Angeles County's (LAC's) work performance. Below are some of the actions CHCQ has undertaken:

- Developed specific workload tracking worksheets to ensure compliance with contracted work as established in the new three-year contract.

- Dedicated one Field Operations Branch Chief whose primary function is to oversee LAC performance.

- Hired a former L&C district manager as a retired annuitant to conduct ongoing oversight and monitoring of the Los Angeles County contract performance through onsite monitoring, statistical data analysis, and audit review of required federal and state survey workload, as well as, assessment of proper assignment of scope and severity, triaging, timeliness and completion of complaints and entity reported incident (ERI) investigations.

- Established the LA County Monitoring Unit (LACMU) and hired a HFE nurse supervisor with 2 HFEN nurse surveyors to conduct concurrent onsite quality review of the federal recertification survey process through a defined State Observation Survey Analysis (SOSA) process. [A SOSA survey is where one of DPH's trained HFENs observes an entire recertification survey to ensure proper

survey protocols are used. The SOSA surveyor relays observations to LAC supervisors on areas needing improvement.]

- As of January 2016, conducted 11 SOSA surveys at selected skilled nursing facilities within the four LA District Offices and identified problems with the survey process involving sample selection, general investigation, and deficiency determination. The results from the SOSA surveys were shared with the LA County Health Facilities Inspection Division (HFID) managers and supervisors. CHCQ identified a need for additional training and developed a corrective action plan. CDPH and the federal Centers for Medicare and Medicaid Services will conduct a joint training in April 2016 to improve process and quality review outcomes.

- Conducted quality review and evaluation of complaints and ERI investigations by implementing quality improvement (QI) studies to review prioritization of complaints, investigative process, and principles of documentation.

- Developed and implemented a review tool, "Supervisor Worksheet for Complaint/ERI investigation by Surveyors," to document LAC supervisors review and discussion with survey staff of deficiency findings and citations.

- Conducted quality assurance audits on compliance with the abbreviated survey process, allegation prioritization, and standard level of review for principles of documentation for; intermediate care facilities, end stage renal disease facilities, and home health agencies.

- Conducted bi-monthly calls with individual LAC program managers to discuss work performance and enforcement actions.

- Conducted bi-monthly calls with the Health Facilities Inspection Division (HFID) branch chief, assistant branch chief and program managers to discuss ongoing operational issues and monitoring activities.

- Documented non-compliance with Licensing and Certification's policies and procedures, and requested a corrective action plan to address the problem and ensure compliance.

- Required LA County HFID supervisors and managers to participate in monthly District Administrators and District Managers (DA/DM) conference calls and required LAC managers to attend in-person, quarterly DA/DM meetings.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present an overview of the L&C program and estimate, and respond to the following:

1) Please provide an update on L&C's efforts to hire and retain nurse surveyor staff.

2) Please provide an update on L&C's oversight of the Los Angeles County contract.

3) Please provide an update on L&C's status in regard to meeting the new complaint timeframe requirements that are effective July 1, 2016.

4) Please provide a summary of the findings from the report on using classifications other than HFENs to perform L&C workload.

Staff Recommendation: Staff recommends holding this item open to allow for further consideration and public input.

ISSUE 11: TIMELY INVESTIGATIONS OF CAREGIVERS BUDGET CHANGE PROPOSAL

PANELISTS

- **Jean Iacino**, Deputy Director, Center for Healthcare Quality, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

The DPH, Center for Health Care Quality, Professional Certification Branch, requests an additional $2.5 million in expenditure authority from the State Department of Public Health Licensing and Certification Program Fund in fiscal year 2016-17 to convert 18.0 two-year limited-term positions approved in fiscal year 2014-15 to permanent positions, and to fund 2.0 additional positions for the Office of Legal Services, for a total of 20.0 positions to improve the timeliness of investigations of complaints against caregivers. The two positions for the Office of Legal Services will provide the Professional Certification Branch with house counsel and litigation support during investigations and criminal convictions, and represent DPH at administrative appeal hearings.

BACKGROUND

The Professional Certification Branch is responsible for the certification of nurse assistants, home health aides, hemodialysis technicians, and the licensure of nursing home administrators. It is also responsible for the investigation of allegations involving health care professionals and the enforcement of disciplinary actions. There are over 200,000 active certified nurse assistant, home health aide, and certified hemodialysis technicians, and over 400,000 inactive applicants and certificate holders (hereinafter referred to collectively as caregivers). These caregivers provide approximately 80 percent of direct patient care activities for dally living in skilled nursing facilities licensed by DPH, and may also provide direct care in residences through licensed home health agencies.

The Professional Certification Branch is composed of three sections: 1) the Aide and Technician Certification Section; 2) the Criminal Background Section; and 3) the Investigation Section. The Aide and Technician Certification Section certifies caregivers and maintains a registry of certified caregivers. The Criminal Background Section retrieves and analyzes criminal offender record information received from the California Department of Justice. The Investigation Section investigates all complaints/allegations of unprofessional conduct against these caregivers. Federal and state laws require investigation of complaints against caregivers.

The Professional Certification Branch receives approximately 1,200 complaints annually alleging wrongdoing by caregivers, and as of December 31, 2015 had 160 open complaints from prior fiscal years and 538 from the current fiscal year, for a total

pending of 698. Furloughs, vacancies, and outdated processes initially led to the number of open complaints in previous years. As a result of audits in 2013 and 2014 and internal and consultant-driven business process reviews, the Professional Certification Branch has instituted a number of business process improvements. These improvements include:

- Redirected two positions to create a more robust management team.
- Filled 18.0 two-year limited-term positions received in fiscal year 2014-15.
- Developed "on-boarding" training for new employees.
- Automated business processes.
- Piloted a "hearing team" of analysts to develop skills representing Public Health at administrative appeal hearings.
- Created and enhanced existing tracking documents and tools used to capture and monitor data and identify trends.
- Published quarterly statistical information on the Internet.
- Began strategically documenting policies and procedures.
- Enhanced communication and information sharing efforts with the California Departments of Justice and Social Services, and the California State Long-Term Care Ombudsman Program.

These improvements enabled staff to complete Investigations of all pending complaints received prior to January 1, 2014, while continuing to assess and address current complaints based on severity. As of December 31, 2015, 2 complaints remain of the 1,169 received in fiscal year 2013-14.

The Professional Certification Branch has statutory authority to take administrative action against certificate holders and applicants due to criminal convictions and substantiated complaints. As the Professional Certification Branch completes investigations more timely, the number of investigations resulting in administrative actions will increase. Applicants or certificate holders may appeal these administrative actions. Analysts represent the Department at administrative appeal hearings, while attorneys often represent appellants. Administrative Law Judges increasingly require DPH analysts to provide complicated legal briefs, and require them to respond to questions of evidence and legal issues at hearings.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to present this proposal.

Staff Recommendation: Staff recommends no action at this time.

ISSUE 12: LICENSING AND CERTIFICATION PROGRAM QUALITY IMPROVEMENT PROJECTS BUDGET CHANGE PROPOSAL

PANELISTS

- **Jean Iacino**, Deputy Director, Center for Healthcare Quality, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

DPH requests expenditure authority of $2 million in 2016-17 from the Internal Departmental Quality Improvement Account to execute two contracts to implement recommendations from the Hubbert Systems Consulting report. One contract will support the redesign of the Central Applications Unit IT systems, and the other will support the redesign of the Health Facilities Consumer Information System.

BACKGROUND

The Center for Healthcare Quality (Center) is responsible for regulatory oversight of licensed health care facilities and health care professionals to ensure safe, effective, and quality health care for all Californians. The Center fulfills this role by conducting periodic inspections and complaint investigations of health care facilities to ensure they comply with federal and state laws and regulations. The Center is primarily funded by a grant from the federal Centers for Medicare and Medicaid Services (CMS) and by licensing fees paid by health care facilities. The Center licenses and certifies over 7,500 health care facilities and agencies in California in 30 different licensure and certification categories.

Chapter 605, Statutes of 2008 (SB 541) established the Internal Departmental Quality Improvement Account. The account is funded by administrative penalties Public Health imposes against health facilities for violations that meet the definition of Immediate Jeopardy of death or serious harm to a patient. As required by statute, the Center has used the funds to contract, develop, and maintain program quality improvement activities.

In a June 20, 2012 letter, CMS required DPH to "conduct a comprehensive assessment of Public Health's entire survey and certification operations at not only its headquarters but also at each of the District Offices and the offices covered by its contractual agreement with Los Angeles County. The assessment must identify concerns, issues, and barriers related to Public Health's difficulty in meeting performance expectations."

The Center contracted for this assessment and received the contractor's final report in August 2014. The report contained 21 recommendations to "allow for meaningful, measurable improvements in the Center's performance." The Center created a plan to implement the 21 recommendations, and is tracking the progress made toward fully implementing the recommendations.

In fiscal year 2014-15, the Center received expenditure authority of $1.4 million from the Internal Departmental Quality Improvement Account and used these funds to hire consultants from The Results Group to conduct business process reengineering projects for its Central Applications Unit and Professional Certification Branch. The Center also contracted with a project manager and change consultant to facilitate and coordinate the multi-year implementation of the Hubbert Systems Consulting's 21 remediation recommendations.

The 2015 Budget Act includes $2 million in expenditure authority from the Internal Departmental Quality improvement Account for the Center to execute two contracts in 2015-16 to further implement recommendations from the Hubbert Systems Consulting's report. One contract will evaluate the Center's recruitment efforts, and design and implement a comprehensive recruitment plan. The other contract will evaluate the Center's employee onboarding and employee retention efforts, and implement changes to existing onboarding and retention practices as necessary.

The Center's authorized and actual expenditures have consistently been significantly less than the revenues received. As a result, the Internal Departmental Quality Improvement Account fund balance has continued to increase. As of December 2015, the Internal Departmental Quality Improvement Account fund balance is near $16 million.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to present this proposal.

Staff Recommendation: Staff recommends no action at this time.

ISSUE 13: LONG-TERM CARE OMBUDSMAN FUNDING STAKEHOLDER PROPOSAL

PANELISTS

- **Leza Coleman,** Executive Director, California Long-Term Care Ombudsman Association
- **Jean Iacino**, Deputy Director, Center for Healthcare Quality, DPH
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

The California Long-Term Care Ombudsman Association (CLTCOA) proposes $3.6 million General Fund for the Long Term Care Ombudsman Program, located in the Department of Aging. The Subcommittee already heard this proposal on April 13, 2016, however it is also included on this agenda because it suggests potential funding from the Department of Public Health.

BACKGROUND

CLTCOA provides the following justification for this proposal:

> "[CLTCOA] requests an allocation that conforms to the unanimous and bipartisan actions of the 2015-2016 Budget Conference Committee recommendation of an additional $5 million in General Fund support for the Long Term Care Ombudsman Program, which was then passed by both houses of the Legislature. While the program is most grateful for the $1.4 million continuing appropriation included in the 2015 approved budget, we request that the Legislature's intent be fully actualized and sustained through an on-going $3.6 million allocation to the Long Term Care Ombudsman Program."

In 2015-16, $2.4 million in additional funds were allocated to provide increased support for the Long-Term Care (LTC) Ombudsman Program. Local Ombudsman programs received $1 million from the General Fund, on-going, for the first time since FY 2007-08. They also received an additional $400,000 from the California Department of Public Health, Licensing and Certification Program Fund, as a direct result of an on-going increase in the Skilled Nursing Facility Bed Fee. An additional $1 million was allocated to local Ombudsman programs from the State Health Facilities Citation Penalty Account on a one time basis. Local Ombudsman programs used this funding for expenditures that are one-time in nature, e.g., long delayed equipment purchases, reimbursement of volunteer mileage, volunteer recognition activities, and infrastructure improvements such as increased Internet bandwidth for local Ombudsman program offices.

This additional funding has directly led to increased LTC Ombudsman visits to facilities and assistance to residents. Comparing second quarter FY 2015-16 to second quarter FY 2014-15, the following occurred:

- **27.3% increase in the number of information and consultation sessions with individuals** – during these sessions, Ombudsman representatives provide information about long-term care and answer questions about residents' rights and other issues that residents, family members, and friends may be concerned about, often empowering residents, families, and friends to resolve issues on their own;

- **13.9% increase in the number of residential care facilities receiving at least one visit each quarter, not in response to a complaint** -- during these unannounced, non-complaint related visits, Ombudsman representatives meet with residents, inform residents of their rights, and build relationships of trust;

- **6.2% increase in the number of skilled nursing facilities receiving at least one visit each quarter, not in response to a complaint** – during these unannounced, non-complaint related visits, Ombudsman representatives meet with residents, inform residents of their rights, and build relationships of trust;

- **13.6% increase in the number of consultations to facilities** – these consultations can resolve issues before they even become complaints;

- **17.8% increase in the number of paid staff** – these are staff positions that are working in facilities and responding to resident complaints (27 positions);

- **54.4% increase in the number of training sessions for Ombudsman staff and volunteers** – a significant increased investment in well-trained existing and new Ombudsman representatives

This proposed increased funding will enable the program to:

- Conduct vital unannounced monitoring visits to all long-term care facilities in California;
- Recruit, supervise and train volunteer Ombudsmen;
- Investigate more complaints per year.

Since this elimination, Ombudsman representatives have worked tirelessly to secure alternative funding, streamline services and create more efficient systems. Total allocated local funding for the LTCOP in 2016 stands at $7.29 million compared to $11.2 million in FY 2007-08. In response to cuts in funding, California's local LTCOPs were forced to reduce operating hours and scale back services. Since the cuts to their budget, the local LTCOPs have had to greatly reduce the number of long-term care facilities they visit quarterly. There were 5,206 facilities in California that did not receive regular quarterly visits from an Ombudsman in FY 2014/15. This left approximately 100,000 residents in those facilities without an advocate and at increased risk of

suffering from abuse and neglect. CLTCOA states that the requested funding will allow the LTCOP to once again meet their federal and state mandates, and will be an important first step to rebuilding the State's commitment to protecting vulnerable residents of LTC facilities.

The Assembly Aging and Long-Term Care Committee Chair Assemblywoman Cheryl Brown has also written in support of this request.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests Leza Coleman to present this proposal and requests DPH or DOF to respond to the following:

1. What is the balance in the State Facilities Citation Account? What have the balances been, roughly, over the past few years?
2. What is this funding for, per statute? Has the funding ever been used for this purpose?
3. Has DPH ever taken receivership of a facility? How many times? How much does this typically cost?
4. What else have these funds been used for? How much of this funding typically rolls over to the General Fund each year?
5. Is this revenue increasing?
6. Given that statute expresses legislative intent that the Quality Accountability Fund serve as an increasing funding source for the Ombudsman Program, for what reasons has this not occurred?

Staff Recommendation: Staff recommends no action at this time.

0530 CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY

ISSUE 14: CALQUALITYCARE.ORG STAKEHOLDER PROPOSAL

PANELISTS

- **Leslie Ross**, PhD, CalQualityCare.org, PI/Project Director, University of California San Francisco
- **Yang Lee**, Principal Program Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

UC San Francisco requests $500,000 on-going for the Office of Patient Advocate (within the Health and Human Services Agency) to manage and maintain the CalQualityCare.org website. Stakeholders propose that the funding to operate this website be generated through a fee on the facilities that are covered by the website. The specific formula for setting the fees is still being developed and will be addressed through proposed trailer bill.

BACKGROUND

The www.calqualitycare.org website provides important, objective information to consumers about the quality of long term care facilities, including skilled nursing facilities, assisted living or hospice facilities. The website, which is administered by the University of California, San Francisco, has almost 400,000 hits annually, and gives consumers access to publicly available data to help them make placement decisions. Since 2002, the $500,000 annual cost of the website has been supported by the California Health Care Foundation (CHCF), but on-going funding will not be available after August 2016. California Health Policy Strategies is working with CHCF and UCSF to identify sustainable funding options to maintain the website, and provided the following information:

- As California's population ages, demand is increasing for long term care services and supports. Each year over 600,000 consumers receive care in a skilled nursing facility, assisted living or hospice facilities. Deciding which facility best meets a consumer's needs is a challenging task. The CalQualCare.org website makes it easy for consumers to learn how these long term care facilities compare on the basis of location, quality ratings, staffing, and cost.

- Since 2002 the California HealthCare Foundation (CHCF) has partnered with and funded the Department of Social and Behavioral Sciences at the University of California, San Francisco (UCSF-SBS) to develop a resource for consumers on long-term care providers throughout the State. The UCSF-SBS team collects the

data from state and federal sources, as well as from recognized accrediting organizations. On the website, consumers can search for the providers that are closest to them, and then make a comparison based on the data.

- Data elements include:

  - Provider characteristics (e.g., location, size, ownership);
  - Ratings – nursing facilities, home health, hospice, intermediate care facilities for the developmentally disabled;
  - Staffing (number and type)
  - Quality of Facility (deficiencies, complaints)
  - Quality of Care (e.g., pressure ulcers, infections)
  - Costs and Finances.

- The website receives almost 400,000 hits annually, and provides a unique source of information to consumers, family members, hospital discharge planners, managed care organizations, Coordinated Care Initiative (CCI) care managers, and others concerned with the quality of out-of-home placement care.

- The CalQualCompare.org website provides California consumers with the most comprehensive and inclusive compilation of available data. This includes information on state citations and quality comparisons, staff salaries, finances, and costs – data not available on the federal website. The California website also includes information on an array of other long-term care service and supports including, congregate living health facilities, hospice, assisted living, continuing care retirement communities, adult day care, adult day health care, and intermediate care for the developmentally disabled (ICF/DD).

STAFF COMMENTS/QUESTIONS

The Subcommittee requests Dr. Ross to present this proposal.

Staff Recommendation: Staff recommends no action at this time.

4265 DEPARTMENT OF PUBLIC HEALTH

CENTER FOR HEALTH STATISTICS AND INFORMATICS

ISSUE 15: STATE AGENCIES: COLLECTION OF DATA (AB 532) BUDGET CHANGE PROPOSAL

PANELISTS

- **Tony Agurto**, Assistant Deputy Director, Center for Health Statistics and Informatics, Department of Public Health
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

The DPH, Center for Health Statistics and Informatics (CHSI) requests expenditure authority of $236,000 for 2016-17 and $234,000 for 2017-18 from the Health Statistics Special Fund (Fund 0099) to comply with the new mandate to acknowledge individuals with multi-race and multi-ethnic backgrounds and to tabulate the data for both single and multiple designations in reports provided to other state departments created by Chapter 433, Statutes of 2015 (AB 532).

BACKGROUND

The State Registrar operates within CHSI under the authority of the Health and Safety Code The State Registrar is responsible for registering each live birth, fetal death, death, and marriage that occurs in California, and for providing certified copies of vital records to the public. The State Registrar is also required by law to permanently preserve vital records and to prepare and maintain a comprehensive and continuous index of all registered certificates For birth, death, and fetal death, this is completed through the registration of vital events via web-enabled registries.

CDPH is responsible for monitoring and improving the health of Californians. The issuance of death and birth certificates is a key process in generating data required by both the federal Centers for Disease Control and Prevention (CDC) and CDPH to monitor the health of the population. California operates electronic birth, death and fetal death registration systems. Today, data on over 99 percent of these vital events is captured electronically at the time of registration. These systems enable CDPH to turn vital record data into actionable public health information.

CHSI provides custom data files derived from these systems to the following types of end users:

- Local public health departments for public health purposes;
- CDPH programs;
- Other local, state, and federal government entities;
- Qualified researchers; and
- Public requesters, including the media.

The CHSI Public Policy and Research Branch leads the planning efforts and enterprise initiatives in Health Information Technology and Health Information Exchange adoption; coordinates the development of policies related to informatics and data sharing; enhances programs, services, and communications with current and emerging technologies that can be shared at the state and local levels; increases internal coordination with respect to use and management of data and information; and identifies opportunities to consolidate, coordinate, and integrate informatics-related programs and services.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to present this proposal.

Staff Recommendation: Staff recommends no action at this time.

ISSUE 16: END OF LIFE OPTION ACT (AB X2 15) BUDGET CHANGE PROPOSAL

PANELISTS

- **Tony Agurto**, Assistant Deputy Director, Center for Health Statistics and Informatics, Department of Public Health
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

The DPH, Center for Health Statistics and Informatics (CHSI) requests expenditure authority of $323,000 from the Health Statistics Special Fund (Fund 0099) for 2016-17, $245,000 for 2017-18 and annually thereafter, and 2.0 permanent positions to meet the new mandate to establish the End of Life Option Act program as specified in Assembly Bill X2-15. This funding will enable DPH to create a secure database to implement and administer the program and provide staffing for the required confidential program management and reporting duties.

BACKGROUND

The State Registrar operates within CHSI under the authority of the Health and Safety Code. The State Registrar is responsible for registering each live birth, fetal death, death, and marriage that occurs in California. CHSI prepares and publishes de-identified public health data collected from registered certificates to its website and reports this data to various state and federal agencies.

The End of Life Option Act establishes a new program within CDPH, and allows terminally ill adults seeking to end their life to request aid-in-dying drug from their attending physician. Consistent with other states operating similar programs, CDPH proposes locating this new program within CHSI. CHSI will be responsible for receiving forms specified in statute, tabulating reported data, and preparing an annual statistical report. CHSI staff are well-versed in the protection of highly confidential data, and have management staff with the necessary expertise to oversee the data collection and reporting required by this legislation.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present this proposal.

Staff Recommendation: Staff recommends no action at this time.

ISSUE 17: LESBIAN, GAY, BISEXUAL, AND TRANSGENDER DISPARITIES REDUCTION ACT (AB 959) BUDGET CHANGE PROPOSAL

PANELISTS

- **Tony Agurto**, Assistant Deputy Director, Center for Health Statistics and Informatics, Department of Public Health
- **Kimberly Harbison**, Staff Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

PROPOSAL

The DPH, Center for Health Statistics and Informatics (CHSI), requests an additional one-time expenditure authority of $125,000 for fiscal year 2016-17 from the Health Statistics Special Fund to modify existing birth and fetal death registration systems and meet the new mandate to collect voluntary self-identification information pertaining to sexual orientation and gender identity as specified in the Lesbian, Gay, Bisexual, and Transgender Disparities Reduction Act (Chapter 565, Statutes of 2015 (AB 959)).

BACKGROUND

By statute, the Director of DPH is the State Registrar and operates under the authority of the Health and Safety Code. The State Registrar is responsible for registering each live birth, fetal death, death, and marriage that occurs in California, and for providing certified copies of vital records to the public. For birth, death, and fetal death, this is completed through the registration of vital events via web enabled registries.

DPH is responsible for monitoring and improving the health of Californians. The issuance of death and birth certificates is a key process in generating data required by both the Centers for Disease Control and CDPH to monitor the health of the population. California operates electronic birth, death, and fetal death registration systems. Data on over 99 percent of these vital events is captured electronically at the time of registration. These systems enable CHSI to turn vital record data into actionable public health information.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present this proposal and respond to the following:

Staff Recommendation: Staff recommends no action at this time.

LABORATORY FIELD SERVICES

ISSUE 18: LABORATORY FIELD SERVICES OVERSIGHT

PANELISTS

- **Paul Kimsey**, Deputy Director, Center for Health Statistics and Informatics, Department of Public Health
- **Koffi Kouassi**, Finance Budget Analyst, Department of Finance
- **Meredith Wurden**, Fiscal and Policy Analyst, Legislative Analyst's Office
- **Public Comment**

BACKGROUND

On September 10, 2015, the State Auditor released a report on DPH's Laboratory Field Services (LFS) program. In this audit, the State Auditor found that LFS is "still not performing the oversight activities with which it has been entrusted and that its management of its responsibilities is inadequate." Specifically, it found that LFS:

- Only inspects about half of California labs, and it has not established a process to ensure that it becomes aware, in a timely manner, when out-of-state labs that are licensed in California fail required proficiency testing.

- Does not yet investigate all complaints against labs and has issued only a small number of lab sanctions in the past seven years; despite the number of labs it oversees.

- Made an unauthorized fee increase in January 2014 that resulted in labs overpaying the fee by more than $1 million, and since 2008 it has collected more than $12 million in lab fees that it has not spent.

- Has missed opportunities to more effectively use its limited personnel by partnering with other organizations that could help it meet its workload obligations under state law.

To address these findings, the State Auditor recommends to eliminate the state's redundant oversight of labs (as federal requirements are similar to state requirements) and to ensure labs do not pay unnecessary or duplicative fees. The State Auditor recommends that the Legislature do the following:

- Repeal existing state law requiring that labs be licensed or registered by Laboratory Services and that Laboratory Services perform oversight of these labs. Instead, the state should rely on the oversight the federal government provides.

- Repeal existing state law requiring labs to pay fees for state-issued licenses or registrations.

Concerns Regarding Laboratory Personnel Licensing. In addition to the issues identified by the State Auditor, concerns have been raised that LFS's regulation of laboratory personnel is cumbersome and outdated, and is preventing qualified individuals from working in labs. DPH has been working on regulations to update this program since 2008. DPH anticipates promulgating these regulations two to three years from now. These regulations deal with the training, licensure or certification, and work scope of clinical laboratory personnel in 22 licensure categories and 10 trainee license categories, and the training and work scope of unlicensed laboratory personnel. The new regulations set and update requirements of education, training, and examination for initial licensure and renewal of licensure. They also set and update requirements for department approval of examinations, training programs, and continuing education programs for clinical laboratory personnel.

LFS, within DPH, is responsible for overseeing clinical laboratories (labs) that analyze human specimens such as blood, tissue, and urine. Medical professionals use these analyses to make diagnoses and prescribe treatment. LFS' oversight responsibilities cover both labs located within California and labs located outside of the state that test specimens originating from within California. The state currently has licensed approximately 2,800 labs and registered approximately 19,300 labs; the complexity of the tests the labs perform dictates whether they require licensing or registration. LFS' oversight responsibilities include inspecting licensed labs once every two years and periodically verifying the accuracy and reliability of their tests through a process called *proficiency testing*. It must also investigate complaints against both licensed and registered labs and may issue sanctions when it finds that a lab is out of compliance with state laws or regulations. All licensed labs must pay Laboratory Services an annual fee based on the volume of tests they perform, while registered labs must pay an annual flat fee.

In addition to licensing labs, LFS certifies and/or licenses the personnel who work in labs, including phlebotomists, cytotechnologists, medical laboratory technicians, clinical laboratory scientists trainees, clinical laboratory scientists, public health microbiologists, and clinical laboratory directors.

AB 1774 (Bonilla) has been introduced to repeal the laws requiring a clinical laboratory to be licensed and inspected by the department, including the licensing fee, as recommended by the State Auditor. Consequently, it appears that the issues regarding the licensure of labs could be addressed in the near future.

However, efforts to timely address the concerns regarding the licensure of laboratory personnel remain outstanding. Given DPH's past difficulties in promulgating regulations and the fact that DPH began work on these regulations in 2008, it is likely that the state is years away from modernizing its laboratory personnel licensure/certification program.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to provide an overview of laboratory field services and to respond to the following:

1. Please provide an overview of this issue and DPH's corrective actions to address the State Auditor's findings.

2. Are there risks in not having finalized the regulations regarding laboratory personnel?

3. What steps has DPH taken to expedite the promulgation of the regulations related to laboratory personnel licensure/certification? Has DPH considered sponsoring a bill to modernize this program?

Staff Recommendation: Staff recommends no action at this time.