Senate Budget and Fiscal Review—Mark Leno, Chair

SUBCOMMITTEE NO. 3 Agenda

Senator Holly J. Mitchell, Chair
Senator William W. Monning
Senator Jeff Stone

Thursday, March 3, 2016
9:30 a.m. or upon adjournment of session
State Capitol - Room 4203

Consultant: Michelle Baass

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0530 CALIFORNIA OFFICE OF HEALTH INFORMATION INTEGRITY (CALOHII)

Issue 1: Restructure the California Office of Health Information Integrity

Budget Issue. CalOHII requests a reduction of five positions and operating expenses for a net reduction of $1.4 million ($1.3 million General Fund). Based on a zero base budget analysis, CalOHII requests to reduce its staffing and amend its statutory obligations. CalOHII will continue to serve as the state's authority on the Health Insurance Portability and Accountability Act (HIPAA) matters, but will reduce the scope of its activities to updating statewide HIPAA policy and monitoring progress of HIPAA impacted and covered departments.

The Administration also proposes trailer bill language to implement these changes.

Background. The Health Insurance Portability and Accountability Act (HIPAA) of 2001, established CalOHII and specified the office's responsibilities and authority, including:

- Statewide leadership, coordination, policy formulation, direction, and oversight responsibilities for HIPAA implementation by impacted state departments;
- Authority relative to state entities to establish policy, provide direction to state entities, monitor progress, and report on HIPAA implementation efforts; and,
- Responsibility for determining which provisions of state law concerning personal health information are preempted by HIPAA for state agencies.

The federal government continues to update existing HIPAA regulations periodically. The federal government utilizes HIPAA to govern the privacy and security requirements associated with its efforts to promote nationwide adoption of health information technology (HIT) and promote health information exchange (HIE). Because HIT and HIE are in the early stages of implementation, it is expected the federal government will be issuing and modifying HIPAA rules for years to come.

CalOHII is responsible for planning, policy articulation, education, monitoring, tracking, and evaluation of HIPAA implementation as a whole. Successful implementation requires close coordination and communication between CalOHII and HIPAA-impacted departments. CalOHII interprets HIPAA for all HIPAA-impacted entities and works with individual departments to ensure that HIPAA is implemented uniformly across the departments.

According to the Administration, now that CalOHII and the other HIPAA-impacted departments have established HIPAA programs, the purpose of CalOHII's activities has shifted to a "maintenance and operation" mode. Consequently, a review of the positions, funding, and workload revealed that CalOHII activities can focus on monitoring of departments and periodic updates to statewide HIPAA policy, thereby, allowing for a reduction in positions and operating expenses.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested CalOHII to respond to the following:

1. Please provide an overview of this issue.
2. Please describe why the Administration feels confident that the state will remain HIPAA compliant given the proposed reduction in staff and operating expenses.

0530 OFFICE OF THE PATIENT ADVOCATE

Issue 1: Complaint Data Reporting Project

Oversight Issue. The Office of Patient Advocate (OPA) is responsible for collecting, analyzing, and reporting complaint data from the Department of Managed Health Care (DMHC), Department of Insurance (CDI), Department of Health Care Services (DHCS), and Covered California. The first complaint data report was due to the Legislature on July 1, 2015. This report has not yet been finalized or made public.

Background. SB 857 (Committee on Budget and Fiscal Review), Chapter 31, Statues of 2014 revised the responsibilities of OPA to: (1) clarify that OPA is not the primary source of direct assistance to consumers; (2) clarify OPA's responsibilities to track, analyze, and produce reports with data collected from calls, about problems and complaints by, and questions from, consumers about health care coverage received by health consumer call centers and helplines operated by other departments, regulators or governmental entities; (3) require OPA to make recommendations for the standardization of reporting on complaints, grievances, questions, and requests for assistance; and (4) require OPA to develop model protocols, in consultation with each call center, consumer advocates and other stakeholders that may be used by call centers for responding to and referring calls that are outside the jurisdiction of the call center or regulator.

SB 857 requires OPA to collect, analyze, and report complaint data from the Department of Managed Health Care (DMHC), Department of Insurance (CDI), Department of Health Care Services (DHCS), and Covered California. OPA requests to convert the limited-term position previously approved by the Legislature to a permanent position to support this workload.

Subcommittee Staff Comment and Recommendation—Hold Open. At the request of the Brown Administration, the requirement that OPA be a single point of entry for consumer assistance and inquiries with its own 1-800 number for all health care consumer entries was repealed. This was based on the assertion that existing consumer assistance help lines such as the Department of Managed Health Care and the Department of Health Care Services' Managed Care Ombudsman Program were more than adequate and another line would be redundant. In exchange, the OPA responsibilities as an oversight agency were expanded. As part of this agreement, OPA was required to conduct this complaint data report as a baseline in order to make recommendations for improvements and uniformity among systems; and for the legislature, the public, and advocates to have a more robust picture of the adequacy of existing help lines. The fact that the report is more than six months overdue is a major breach of this agreement. It is also makes it impossible to accomplish the intended purpose of the legislation (i.e., assess adequacy of the help lines and make improvements).

It is recommended to hold this item open to explore potential remedies or sanctions if the report is not immediately forthcoming.

Questions. The Subcommittee has requested OPA to respond to the following:

1. Please provide an update on the status of the complaint data report due July 1, 2015. When do you expect finalizing and releasing the report?

2. What lessons did OPA learn in developing the report that will improve the process for future years?

0530 OFFICE OF SYSTEMS INTEGRATION (OSI)

Issue 1: MEDS Modernization Multi-Departmental Planning Team

Budget Issue. OSI requests 18.0 positions and $3.7 million to provide dedicated staffing and resources required for the agency-wide planning effort for Medi-Cal Eligibility Data System (MEDS) Modernization. See table below for details on the funding components of this request.

MEDS FY 2016-17 BCP Request			Department		
Line Items	PYs	Total Project	DHCS	OSI	CDSS
Total Staffing (includes Staff OE&E)	**18.0**	**$2,567,021**	**$2,542,021**	**$1,961,021**	**$249,000**
Core Planning Staff (10.0 PY, 1.0 Redirected, 1.0 DHCS Transfer)	10.0	$1,587,346	$1,587,346	$1,587,346	$0
Program/Stakeholder Staff (6.0 PY)	6.0	$745,448	$720,448	$139,448	$249,000
DHCS (3.0 PY)		$357,000	$357,000	$0	$0
CDSS (2.0 PY)		$249,000	$224,000	$0	$249,000
OSI (1.0 PY)		$139,448	$139,448	$139,448	$0
Direct Administrative Services (2.0 PY)	2.0	$234,227	$234,227	$234,227	$0
Total Other OE&E		**$1,172,787**	**$1,172,787**	**$597,000**	**$0**
Indirect Administrative Services		$575,787	$575,787	$0	$0
Facilities		$597,000	$597,000	$597,000	$0
Subtotal (BCP Requests)			**$3,714,808** [2]	**$2,558,021**	**$249,000**
Consultant Contracts		$2,914,665	$2,914,665	$2,914,665	$0
Subtotal (DHCS Local Assistance)		**$2,914,665**	**$2,914,665**	**$2,914,665**	$0
Total Project Costs	**18.0**	**$6,654,473** [1]	**$6,629,473**	**$5,472,686** [3]	**$249,000** [4]

[1] Total Project Funding of $6,654,473 for FY2016-17 consists of $6,629,473 (DHCS Total = BCP & L.A.) and $25,000 (CDSS 10% GF)

[2] BCP amount requested for DHCS.

[3] BCP amount requested for OSI. Expenditure Authority only.

[4] BCP amount requested for CDSS. (10% GF and 90% Reimbursement from DHCS.)

According to OSI, the requested positions include a variety of project management (PM), technical and program resources necessary to ensure that the modernized system is designed not only to be technically sound, but to best facilitate a health and human services system that can most effectively meet the needs of the client. These positions would be used to support the the planning phase, which consists of:

- Establishing formal Project Steering and Executive Steering Committees (governance)
- Initiating and managing stakeholder engagement
- Developing all required PM plans and associated artifacts
- Completing documentation of the current business and technical environment

- Conducting organizational readiness assessments
- Assessing readiness gaps and developing a mitigation plan
- Developing high-level business and technical requirements
- Assessing alternatives for future state business processes
- Conducting market research
- Assessment of viable alternatives for system modernization

Background. DHCS is the single state agency responsible for the administration of California's Medicaid Program known as Medi-Cal, which provides health care services to more than 12 million beneficiaries. Since 1983 DHCS has maintained the current MEDS system to support key programmatic functions both internally and externally for its critical partners. Today the system is used for a variety of eligibility, enrollment and reporting functions specific to Californians receiving Medi-Cal benefits. MEDS and its related subsystems have been designed over many years to capture client information from a variety of different sources. Key stakeholders that manage the beneficiary eligibility data include the three consortia (LEADER, C-IV, and CalWIN) representing all 58 counties, state and federal partners, and Covered California.

MEDS also serves as the "system of record" and houses eligibility information for numerous publicly subsidized health care and human services programs. Programs managed within the DHCS leveraging the system include Every Woman Counts, Child Health and Disability Prevention, Breast and Cervical Cancer Treatment, Family Planning Access Care and Treatment, and Cancer Detection. Programs managed within the California Department of Social Services leveraging the system include California Work Opportunity and Responsibility to Kids (CalWORKS), CalFresh (Supplemental Nutritional Assistance Program), Cash Aid Program for Immigrants, In-Home Supportive Services (IHSS) and Refugee Cash Assistance. In addition to the state managed programs, multiple programs at the local level also leverage the system such as the County Medical Services Program (CMSP), County Welfare and Tribal Temporary Assistance for Needy Families. MEDS data is also used in a wide variety of administrative functions and purposes such as accounting, reporting, and legislation and budget development and research. Access to the MEDS database is currently provided to over 35,000 distinct end-users in the administration of the state's health and human services programs.

According to OSI, supporting this mission-critical system on outdated technology, with a declining workforce of those skilled in the technology, has created significant risk to the DHCS and its critical partners. In addition, federal rules have been released that require states to modernize their eligibility determination systems to meet the standards of the Medicaid Information Technology Architecture (MITA) in order to maintain enhanced federal financial participation (FFP).

On July 1, 2015, the California Department of Technology (CDT) implemented a Stage/Gate Model for IT project approval process that consists of four stages and gates. Each stage requires specific deliverables and approvals prior to moving into the next stage. The four stages take a project from concept through contract award which ultimately results in formal project approval. According to OSI, this approach to planning for MEDS Modernization addresses the following issues surrounding this large and complex IT project:

- Enterprise Approach and Stakeholder Involvement: Ensures that common business needs are addressed in a consistent and collaborative manner. Supports full inclusion and collaborative decision making on informed investment decisions through a formal governance body. Prevents a siloed approach that results from stakeholders operating independently and duplicating efforts in a parallel manner. Lack of critical partners early in project planning is regularly identified as a key reason for large IT project delays, cost overruns, and even failure. Identifying the program and business needs up-front, and designing the IT system to meet those needs is widely considered best practice, but requires an up-front dedication of resources from all partners to ensure that planning is done properly. This request is specifically intended to meet that critical need.

- Project Approval Life Cycle: Ensures experienced PM and leadership is provided to all participating departments throughout the stage/gates of the new project approval life cycle. Given the newness of the stage/gate process, having experienced, dedicated PM to guide the project through will be critical to maintaining the schedule and subsequently best positioning the project best for control agency support and approval.

- Federal Funding Availability: Through leveraging enhanced FFP, departments will benefit from federal funds available which minimizes the impact on the General Fund.

- Sustaining enhanced FFP: Proper planning and implementation of MEDS Modernization will ensure that future MEDS maintenance and operations costs will continue to be reimbursed at the enhanced FFP of 75% federal and 25% state, as the state will comply with MITA standards.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested OSI to respond to the following:

1. Please provide an overview of this issue.

Issue 2: eWIC Management Information System Project

Budget Issue. OSI requests $4.1 million in expenditure authority and 19.5 permanent positions for the new Women, Infants and Children (WIC) Management Information Systems (eWIC MIS) project. The California Department of Public Health (DPH), as the single State entity responsible for the federally-funded WIC Program, is proposing to contract with the OSI to assume management of the eWIC MIS Project including completing the system acquisition and managing the project through successful completion of statewide implementation. DPH will fund the project with 100 percent federal funding and has submitting a separate BCP to request the necessary appropriation authority.

In addition, because completion of the eWIC MIS project is a critical component of meeting the federal mandate for California to issue WIC food benefits via Electronic Benefit Transfer (EBT) by October 1, 2020, DPH intends to redirect some existing positions and funding to OSI in the current year to begin its work.

Background. The United States Department of Agriculture's Special Supplemental Nutrition Program for WIC is a federally-funded nutrition education and supplemental food program established in 1972 under Public Law 92-433. DPH administers the WIC Program in California, contracting with 84 local agencies throughout California (in all 58 counties) to provide WIC services at over 650 sites, with approximately 1.4 million participants served on a monthly basis.

The federal Healthy, Hunger-Free Kids Act of 2010 requires all states to migrate from a WIC paper-based food benefits delivery system to an EBT system by 2020. Without an EBT system automating WIC benefits by October 1, 2020, California will not be in compliance with federal law, which may jeopardize millions of dollars in federal funding for the California WIC Program. DPH performed a detailed analysis that revealed the current WIC MIS was outdated and not EBT-compliant; therefore, DPH received both federal and state approvals to begin the procurement to solicit bids and contract for the services of a design, development, and implementation systems integrator. DPH also contracted with the OSI (via an interagency agreement) to leverage the new California EBT Services Contract to automate the issuance of WIC food benefits via the California EBT system.

The new eWIC MIS must be fully operational in California before WIC food benefits can be issued via EBT. In its June 2015 eWIC MIS Project Status Report, the California Department of Technology (CDT) gave the project an overall rating of "Yellow" (which indicates a project is slipping). This report also identified other possible delays that will likely cause the project to slip even further behind schedule. With the approaching federal deadline of October 1, 2020, DPH decided to leverage OSI's experience and have OSI manage the project. This would include the OSI assuming responsibility for completing the procurement; entering into a contract with the successful system integrator; managing design, development, testing, pilot, and statewide implementation activities; being responsible for contract and financial management; and providing other needed services.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested OSI to respond to the following:

1. Please provide an overview of this issue.

4265 DEPARTMENT OF PUBLIC HEALTH

Issue 1: Overview

The Department of Public Health (DPH) delivers a broad range of public health programs. Some of these programs complement and support the activities of local health agencies in controlling environmental hazards, preventing and controlling disease, and providing health services to populations who have special needs. Others are solely state-operated programs, such as those that license health care facilities.

According to the DPH, their goals include the following:

- ✓ Achieve health equities and eliminate health disparities.
- ✓ Eliminate preventable disease, disability, injury, and premature death.
- ✓ Promote social and physical environments that support good health for all.
- ✓ Prepare for, respond to, and recover from emerging public health threats and emergencies.
- ✓ Improve the quality of the workforce and workplace.

The department comprises seven major program areas. See below for a description of these programmatic areas:

(1) Center for Chronic Disease Prevention and Health Promotion – This center works to prevent and control chronic diseases, such as cancer, cardiovascular diseases, asthma, adverse pregnancy outcomes, and diabetes; to reduce the prevalence of obesity; to provide training programs for the public health workforce; to prevent and control injuries, violence, deaths, and diseases related to behavioral, environmental, and occupational factors; to promote and support safe and healthy environments in all communities and workplaces; and to prevent and treat problem gambling.

(2) Center for Environmental Health – This center works to protect and improve the health of all California residents by ensuring the safety of drinking water, food, drugs, and medical devices; conducting environmental management programs; and overseeing the use of radiation through investigation, inspection, laboratory testing, and regulatory activities.

(3) Center for Family Health – This center works to improve health outcomes and reduce disparities in access to health care for low-income families, including women of reproductive age, pregnant and breastfeeding women, and infants, children, and adolescents and their families.

(4) Center for Health Care Quality – This center regulates the quality of care in approximately 8,000 public and private health facilities, clinics, and agencies throughout the state; licenses nursing home administrators, and certifies nurse assistants, home health aids, hemodialysis technicians, and other direct care staff.

(5) Center for Infectious Disease – This center works to prevent and control infectious diseases, such as HIV/AIDS, viral hepatitis, influenza and other vaccine preventable illnesses, tuberculosis, emerging infections, and foodborne illnesses.

(6) Center for Health Statistics and Informatics – This center works to improve public health by developing data systems and facilitating the collection, validation, analysis, and dissemination of health information.

(7) Public Health Emergency Preparedness – This program coordinates preparedness and response activities for all public health emergencies, including natural disasters, acts of terrorism, and pandemic diseases. The program plans and supports surge capacity in the medical care and public health systems to meet the needs during emergencies. The program also administers federal and state funds the support DPH emergency preparedness activities.

Summary of Funding for the Department of Public Health. The budget proposes expenditures of about $3 million ($130 million General Fund) for the DPH as noted in the Table below and 3452 positions. Most of the funding for the programs administered by the DPH comes from a variety of federal funds, including grants and subventions for specified areas (such as emergency preparedness, and Ryan White CARE Act funds). Many programs are also funded through the collection of fees for specified functions, such as for health facility licensing and certification activities. Several programs are funded through multiple sources, including General Fund support, federal funds, and fee collections.

Table: DPH Budget Overview

Fund Source	**2014-15**	**2015-16**	**2016-17**	**BY to CY**
	Actual	**Revised**	**Proposed**	**Change**
General Fund	$117,688,000	$129,352,000	$130,170,000	$818,000
Federal Trust Fund	$1,594,040,000	$1,755,820,000	$1,685,024,000	($70,796,000)
Special Funds & Reimbursements	$1,004,560,000	$1,090,276,000	$1,148,356,000	$58,080,000
Total Expenditures	**$2,716,288,000**	**$2,975,448,000**	**$2,963,550,000**	**($11,898,000)**
Positions	**3271.1**	**3377.1**	**3452.2**	**75.1**

Subcommittee Staff Comment. This is an informational item.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide a brief overview of DPH's programs and budget.

Issue 2: Oral Health Program

Oversight Issue. The 2014 budget included $474,000 ($250,000 General Fund and $224,000 in reimbursements, federal funds from the Department of Health Care Services) to establish a State Dental Director, add an epidemiologist, and provide related consulting services to re-establish a statewide oral health program. DPH proposed to develop a Dental Burden of Disease (Burden) report which would help identify dental health issues, disease burden, facts and figures of dental disease, and capacity to address the burden. The Burden report would be the foundation for the development of the State Dental Plan (Plan). The Plan would serve as the roadmap for California's short-term, intermediate, and long-term priorities, goals, and objectives to address dental disease burden and prevention. At the time, DPH proposed the following implementation timeline:

- By October 2014, establish DPH's Dental Team (State Dental Director, epidemiologist, and develop and execute consulting contracts).
- By December 2014, establish an Advisory Committee and Coalition.
- By December 2014, establish the Dental Program Website.
- By March 2015, publish the Dental Burden of Disease Report.
- By June 2015, publish the State Dental Plan.

This timeline and these activities to re-establish and reinvigorate the DPH's efforts on oral health have been delayed due to difficulties in hiring a State Dental Director. Almost a year later than originally proposed, on August 3, 2015, Dr. Jay Kumar was appointed as the State Dental Director. The delayed appointment of a State Dental Director deferred completion of the Dental Burden of Disease Report and the State Dental Plan. These documents are expected to be finalized almost a year from which originally proposed. An updated timeline is provided on the next page.

California Oral Health Program Timeline, as of February 9, 2016

Objectives and Activities	Status as of 4/14/15	Status as of 2/9/16
Program Leadership Establish Dental Leadership Team: July 2015		
1.1.a Recruit, hire and orient Dental Director	1/31/15	Completed 8/3/15
1.1.b Recruit, hire and orient Epidemiologist	Completed	Completed
1.1.2 Develop and execute two contracts (Cal EIS Fellow, California State University	Completed	Completed
1.1.3 Orient Cal EIS Fellow	Completed	Completed
1.1.4 Oversee administrative and fiscal activities	Ongoing	Ongoing
Partnerships and Coalition Establish Advisory Committee & Coalition: Sep. 2015		
2.1.1 Convene Dental Program Advisory Committee	6/30/15	Completed 8/27/15
2.1.2 Participate in Chronic Disease Branch Communications, Health Care Systems/Community Prevention Workgroups	Ongoing	Ongoing
2.1.3 Participate in Chronic Disease Branch Evaluation, Surveillance and Epidemiology Workgroups	Ongoing	Ongoing
2.1.4 Convene first Coalition Meeting	9/30/15	Completed 1/28/16
2.1.5 Convene an ongoing Coalition Workgroup to develop the State Dental Plan	9/30/15	Ongoing
2.1.6 Convene second Coalition Meeting	2/29/16	05/30/16
2.1.7 Develop and implement a Dental Program Communications Strategy	Completed 9/30/15	Will be updated 8/01/16
Capacity Assessment & Dental Program Website Establish Website: June 2015		
3.1.1 Assess current resources and strategies in dental policy, care systems, community prevention and communications	Ongoing	Ongoing
3.1.2 Assess current resources and strategies in dental surveillance/epidemiology	Completed	Completed
3.1.3 Create Dental Program website, with information resources	Completed	Completed
3.1.4 Finalize Capacity Report (result of assessments)	9/30/15	Completed 9/30/15
State Dental Plan Publish State Dental Plan by June 2016		
4.1.1 In conjunction with Coalition members, develop a Dental State Plan Framework	9/30/15	Completed 10/5/15
4.1.2 In conjunction with Coalition members, develop a Draft Dental State Plan	2/29/16	04/30/16
4.1.3 Finalize Dental State Plan	6/30/16	06/30/16
4.1.4 Implement plan, including benchmarks and evaluation measures		Ongoing
Surveillance/Epidemiology Publish Dental Burden Report: June 2015		
5.1.1 Assess current data sets	Completed	Completed
5.1.2 Analyze data and write narrative	Completed	Completed
5.1.3 Develop a Draft Dental Burden of Disease Report	Completed	Completed
5.1.4 Finalize Dental Burden of Disease Report	6/30/15	Under review

Evaluation **Develop Dental Program Evaluation Methods: June 2016**		
6.1.1 Develop a Dental Program Logic Model	4/30/15	Completed 4/30/15
6.1.2 Develop Dental Program Performance Measures	4/30/15	Completed 4/30/15
6.1.3 Track Dental Program Performance Measures and write Report	Ongoing	Ongoing
6.1.4 Report on Dental Program Performance Measures	6/30/16 & Ongoing	6/30/16 & Ongoing

Subcommittee Staff Comment and Recommendation—Oversight Item. As noted above, the core activities of this program have been delayed. This means that the implementation of innovative policies and strategies to improve the state's oral health condition are postponed.

DPH's Oral Disease Burden Report should contain delineated information about the Medi-Cal program, so that the state can understand how Medi-Cal enrollees' oral health conditions compare to the other California residents. It will be important for the State Dental Director and the Oral Health Program to proactively work with Medi-Cal's Denti-Cal program given that Medi-Cal serves about a third of the state's population.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an update on the Oral Health Program and highlight key accomplishments in the last year.

2. Is DPH's Oral Health Program working with the Department of Health Care Services (DHCS) to identify dental health issues, disease burden, facts and figures of dental disease, and capacity to address the burden related to the Medi-Cal program? Please explain.

3. How are you working with DHCS regarding the 1115 Waiver Renewal Application: Medi-Cal 2020's Dental Transformation Initiative? Please provide specifics.

4. Subcommittee staff requested a copy of the dental program performance measures (that were completed on April 20, 2015) and has not yet received them. What is the status of providing this information to the Subcommittee?

Issue 3: Laboratory Field Services – State Auditor's Report

Oversight Issue. 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 it 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.

Background. 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.

Subcommittee Staff Comment—Oversight Item. 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.

Questions. The Subcommittee has requested DPH 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?

Issue 4: Richmond Laboratory: Viral Rickettsial Laboratory Enhanced Upgrade

Budget Issue. DPH requests to reappropriate $3.8 million from a Capital Outlay Project approved in 2015-16 to upgrade the DPH's Bio-Safety Level 3 (BSL-3) certified Viral and Rickettsial Disease Laboratory. The upgrades were needed to ensure that DPH retains its BSL-3 Certification from the Federal Center for Disease Control and Prevention (CDC) and National Institutes of Health (NIH). According to DPH, the reappropriation is needed due to the project's delays that were beyond DPH or the Department of General Services' (DGS) control.

Background. At the time of construction (2000), the Richmond Campus VRDL laboratory was designed to meet the existing BSL-3 requirements as determined by the CDC and NIH. In response to world health concerns, in 2006 the CDC/NIH implemented enhanced requirement for BSL-3 certified laboratories. In response to the required BSL-3 enhancements, in 2015-16, DPH was funded with a $4.3 million Capital Outlay Project to upgrade the VRDL.

Below are the phases and funding allocation for this project:

Phase	Authority
Working Drawings	$534,000
Construction – A&E	$351,000
Construction – Contract	$2,796,000
Construction – Contingency	$196,000
Construction – Other	$456,000
Total	**$4,333,000**

After the enactment of the 2015-16 budget, DPH engaged the services of DGS to manage the project and in July 2015 DPH transferred $534,000 to DGS to fund the working drawing phase of the project.

Originally, the DGS schedule was to proceed into the construction phase in April/May 2016, which would then allow DPH to transfer the remaining ($3.8 million) funds to DGS. However, in August 2015, the State Fire Marshall'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 ($3.8 million) for construction to 2016-17.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide a brief overview of this request.

Issue 5: Timely Infectious Disease Outbreak Detection and Disease Prevention

Budget Issue. DPH requests $1.6 million General Fund in 2016-17, $2.1 million General Fund in 2017-18 and 2018-19, and 14.0 permanent positions, to provide ongoing support to protect California from infectious diseases through increased disease surveillance and laboratory capacity. The 14.0 positions will be phased-in.

According to DPH, this requested investment in the infectious disease laboratories will increase DPH's ability to address the emerging public health challenges presented by microbes that cannot be cured with available antibiotics, to provide laboratory testing for newly emerging infectious disease threats, to implement new technologies, and to improve the timeliness and completeness of outbreak detection in the state. DPH indicates it needs additional staffing resources and modernized equipment in the infectious diseases laboratories. As a result of new challenges, the laboratories are unable to meet the current needs of state and local disease control activities. Specifically, the laboratories are unable to provide timely testing of foodborne pathogens to identify and investigate outbreaks, to complete viral disease testing, to provide antimicrobial resistance testing to monitor the emergence of resistance and efforts to control resistance, and to fully implement new technologies that are becoming the national standard such as whole genome sequencing.

Requested Positions:

Position	Duties
4.0 - Public Health Microbiologist II	Increase foodborne pathogen testing, verify and validate molecular diagnostic tests and perform antimicrobial resistance testing and viral testing.
3.0 - Public Health Microbiologist Specialists	Increase foodborne pathogen testing, and carry-out quality assurance activities.
1.0 - Research Scientist II	Coordinate testing and reporting for emerging viruses.
5.0 - Research Scientist III	Increase foodborne pathogen testing, perform antimicrobial resistance testing, evaluate and introduce new technologies for antimicrobial resistance testing and genotyping. Carry out viral testing. Prepare technical reports and documents for informing and educating healthcare professionals and local public health staff.
1.0 -Research Scientist Supervisor I	Oversee foodborne pathogen testing, processing and reporting of antimicrobial resistance testing, and supervise research scientists, public health microbiologists and laboratory technicians.

Background. Infectious disease laboratories including the Viral and Rickettsial Disease Laboratory and the Microbial Disease Laboratory in DPH's 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, DPH 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 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 DPH 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, DPH 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 DPH 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.

According to DPH, during the last decade DPH'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 DPH 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 DPH 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 DPH laboratories to develop more accurate and efficient diagnostic methods that improve capacity and readiness. DPH's laboratories need to develop and support statewide capacity for rapid detection of emerging diseases to enable effective public health response.

According to DPH, new molecular technologies, such as whole genome sequencing, are being introduced in public health laboratories at a rapid pace. This new technology will improve the timeliness of outbreak investigations and enhance control measures. The DPH 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 DPH's disease control programs.

Additionally, DPH cites that 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 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.

According to DPH, these additional requested resources will enable it to address some of the current gaps in infectious disease laboratory capacity. Specifically, the funds requested in this BCP will enable DPH to:

- Test additional foodborne specimens in the state to identify additional foodborne outbreaks and prevent the spread of foodborne illness. These resources should be sufficient to close the current gap in foodborne testing of approximately 1,000 specimens per year.

- Establish a reference public health antimicrobial susceptibility testing unit.

- Introduce molecular tests for rapid confirmation of drug resistant organisms, and expand the use of new molecular test technology to expedite outbreak investigations.

- Enhance the Infectious Diseases Laboratory customer service system by integrating specimen tracking and result reporting into electronic systems, increasing the laboratory's ability to respond to surges and outbreaks, supporting regulatory compliance, and improving turn-around-time for testing results.

- Increase core capacity for viral testing, including the development of molecular testing on vaccine preventable diseases and surge testing for statewide outbreaks of public health concern. These resources will enable the laboratory to enhance viral testing during outbreaks to reduce the number of viral tests that are not completed and carry out more effective public health response.

Difficulties Recruiting and Retaining Laboratory Personnel. The department plans a phased-in approach to hiring the 14 positions due to the difficulties in hiring laboratory personnel and the high turnover in these positions. DPH indicates that from 2012 to 2015, there were approximately 19.0 permanent separations from laboratory positions at within the Division of Communicable Disease Control, which include transfers to other state departments, departures to private industry, and retirements. Several factors contribute to the high turnover rate: more competitive salaries are offered in the private sector and local public health laboratories within the Bay Area, and the relatively small pool of individuals who meet entry level qualifications to perform the specialized laboratory testing makes them highly sought after candidates for other positions.

Subcommittee Staff Comment and Recommendation—Hold Open. It is unclear that even with the proposed phased-in approach to hiring these positions, if the state will be successful in recruiting and retaining laboratory personnel, microbiologists in particular. For this reason, it is recommended to hold this item open as discussions continue on potential alternatives to ensure timely infectious disease outbreak detection and disease prevention.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

2. Please describe the changes DPH has implemented to address the difficulties in recruiting and retaining laboratory personnel.

Issue 6: Oversight of Licensing and Certification (L&C) Program

Background. The California Department of Public Health's (DPH) Center for Health Care Quality's (CHCQ)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, including those conducted by Senate Budget and Fiscal Review Subcommittee No. 3, 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.

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[1] 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. See below for information on this report.

1 SB 857 (Committee on Budget and Fiscal Review), Chapter 31, Statutes of 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. In order to begin the on-site oversight immediately, the department plans to administratively establish three positions in 2014-15.

  - **Complaint Investigation Timelines.** The Legislature adopted trailer bill language[2] 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

2 SB 75 (Committee on Budget and Fiscal Review), Chapter 18, Statutes of 2015

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 Hosptial 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[3] 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.

3 According to DPH, the proposed HFE classification series revision comprehensively addresses compaction, recruitment, and entrance requirements for the various classifications. The proposal requires all persons in the HFE series to possess a valid RN license, adjusts salary ranges to incorporate past pay differentials for various HFE classes to address salary equity and recruitment issues, eliminates the HFET and HFE I classifications, and creates a new, non-clinical classification series to perform the body of work currently performed by those classifications. The proposal is currently under review with the affected unions. When DPH obtains union concurrence, CalHR will calendar the reclassification proposal for State Personnel Board review.

- **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.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions continue on this program. It appears that L&C is making progress in hiring staff to meet the requirements of the 2015-16 budget and has taken steps to improve the state's oversight of the Los Angeles County contract.

As noted above, last year's budget included a one-time $1 million augmentation to the LTC Ombudsman Program using funds from the State Health Facilities Citation Account. This account still maintains a $7 million fund balance. The Legislature may want to consider providing another one-time augmentation to the LTC Ombudsman Program. As discussed last year, it is reasonable to assume that the ombudsman program's presence and advocacy on behalf of skilled nursing facility (SNF) residents improves quality of life for these residents and improves a SNF's compliance with state and federal laws.

Questions. The Subcommittee has requested the L&C Program to respond to the following:

1. Please provide a brief summary of the L&C estimate.

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

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

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

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

Issue 7: L&C: Program Quality Improvement Projects

Budget Issue. DPH requests expenditure authority of $2 million from the Internal Departmental Quality Improvement Account to execute two contracts to implement program improvement recommendations. DPH will allocate $1.5 million to the redesign of the Centralized Applications Unit (CAU) IT systems, and $500,000 to the Health Facilities Consumer Information System (HFCIS) redesign.

DPH proposes to redesign the Central Applications Unit IT systems. This project would entail replacing substantially paper-based processes with information technology solutions that will allow recording and tracking of multi-level facility ownership structures, as well as on-line applications and reporting features. This redesign will also enable the center to be compliant with Affordable Care Act requirements, while also improving the quality and timeliness of services provided to facilities. Once complete, the redesign will enable the center to provide more accurate and timely information on facility ownership and compliance history. Further, the redesign will enable the Central Applications Unit to achieve greater staff efficiencies by fully centralizing all ownership tracking activities that currently take place in the Central Applications Unit, district offices, and Los Angeles County.

DPH also proposes to redesign the Health Facilities Consumer Information System. Established in 2008, the Health Facilities Consumer Information System provides consumers and patients access to information about the DPH's licensed long-term care facilities and hospitals throughout the state. The website provides profile information for each facility, as well as performance history including complaints, facility self-reported incidents, state enforcement actions, and deficiencies identified by Public Health staff; the system also allows consumers to submit complaints to Public Health electronically. According to DPH, the current system is outdated and not as user-friendly or accessible as many other public-facing consumer-centric websites.

Background. SB 541 (Alquist) Chapter 605, Statutes of 2008, established the Internal Departmental Quality Improvement Account. The account is funded by administrative penalties DPH imposes penalties against health facilities for violations that meet the definition of immediate jeopardy of death or serious harm to a patient. As of December, 2015, the Internal Departmental Quality Improvement Account fund balance is near $16 million.

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." In response to CMS' concerns, L&C contracted with Hubbert System Consulting for an organizational assessment of its effectiveness and performance.

DPH 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." DPH created a plan to implement the 21 recommendations, and is tracking the progress made toward fully implementing the recommendations.

In 2014-15, DPH 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.

In 2015-16, DPH received $2 million in expenditure authority from the Internal Departmental Quality improvement Account. DPH plans to spend $1.8 million of this appropriation to fund the following:

1. Contract with UC Davis to provide change and project management services to implement the Hubbert Systems Consulting recommendations. This contract provides two full-time consultants. This contract also provides for leadership development and change management training for CHCQ staff. CHCQ estimates spending approximately $500,000 in 2015-16 on this contract.

2. Purchase software to automate the processing of forms in the Centralized Applications Unit and the Professional Certification Branch. The cost of this purchase was $327,099.

3. CHCQ released a request of offer (RFO) in early December 2015 to evaluate and assist with CHCQ's retention and onboarding practices. The majority of responses to this solicitation were considered non-responsive. CHCQ re-released the RFO on February 4, 2016. CHCQ anticipates work starting on this contract by March 31, 2016. The estimated cost of this contract is $250,000, not all of which will be expended in 2015-16.

4. CHCQ released a RFO for recruitment services in December, 2015. CHCQ did not receive any bids for this project. The RFO was re-released on February 2, 2016. CHCQ anticipates work starting on this contract by March 31, 2016. The estimated cost of this contract is $250,000, not all of which will be expended in 2015-16.

5. CHCQ also completed work on a contract with UC Davis for work related to the Healthcare Associated Infections Program. The contract provided several infection prevention positions, and expired December 31, 2015. The total cost of this contract in 2015-16 is approximately $450,000.

6. CHCQ completed work on a contract with UC Davis to evaluate the adequacy of federal regulations in select facility types. The cost of this contract in 2015-16 is approximately $49,000.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

2. What have you learned from the current year contracts?

Issue 8: L&C: Timely Investigations of Caregivers

Budget Issue. DPH requests an additional $2.5 million in expenditure authority from the State Department of Public Health Licensing and Certification Program Fund to convert 18.0 existing two-year limited-term positions to permanent positions, and fund two 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.

Background. DPH's 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 daily living in skilled nursing facilities licensed by Public Health, and may also provide direct care in residences through licensed home health agencies.

Federal and state laws require investigation of complaints against caregivers. DPH 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 of 698 open complaints. According to DPH, 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, DPH has instituted a number of business process improvements. 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.

According to DPH, despite the reduction in pending cases, it will be unable to keep current with the approximately 1,200 new cases received annually unless the 18.0 limited-term positions are made permanent. Augmenting the existing analysts with position and spending authority by converting the 18.0 two-year limited-term positions will allow DPH to improve the timeliness of complaint investigations from greater than one year to less than three months by fiscal year 2018-19.

Additionally, according to DPH, adding the two attorney positions to serve as the Professional Certification Branch's house counsel and litigation support will better represent DPH at administrative appeal hearings. DPH finds that the Professional Certification Branch needs dedicated house counsel and litigation support to prepare for and testify at these hearings and address the Administrative Law Judges' concerns about DPH's representation at these hearings.

One of the requested attorneys will provide litigation support at administrative appeal hearings. This attorney will provide legal expertise to the Professional Certification Branch in preparing pre-and post-hearing briefs, statements of issues, accusations, responses to discovery requests, and analyst and witness testimony for administrative appeal hearings. At some hearings, this attorney will appear and represent Public Health. The attorney will also provide on-going training to analysts regarding hearing protocol, legal grounds for objections, and introducing evidence. The second requested attorney will serve as the Professional Certification Branch house counsel. The house counsel will become familiar with the branch's work and issues. The house counsel will provide legal advice, review, and assistance

on disciplinary actions, regulations, policies and procedures, bill analyses, contracts, subpoenas, Public Records Act requests, and media responses. The house counsel will also assist the Professional Certification Branch in interpreting complex federal regulations related to requirements for professional staff in long-term care facilities (e.g., the federal registry and the national data bank for suspended and excluded providers). The house counsel will work closely with the administrative litigation attorney to provide consistent guidance to help ensure appealed disciplinary actions are upheld by the Administrative Law Judges.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

Issue 9: L&C: Licensing Fees

L&C 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 pre-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.

The department proposes to:

- Increase fees by up to 40 percent on those facilities that would have received an increase as a share of their percentage of the state's total workload.
- Keep fees at the 2015-16 level for those facilities that would have received a decrease as a share of their percentage of the state's total workload.

The DPH Fee Report provides considerable detail regarding these calculations, as well as useful data on L&C workload associated with the various types of health care facilities, along with a clear description regarding the details of the methodology. This report can be found at:

http://www.cdph.ca.gov/pubsforms/fiscalrep/Pages/LicenseFeeReports.aspx

Table: Proposed Health Facility License Fees

License Fees by Facility Type			
Facility Type	Fee Per Bed or Facility	2015-16 Fee	2016-17 Proposed Fee
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	$ 2,380.19
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	$ 2,761.90
Hospices (2-Year License Total)	Facility	$ 2,970.86	$ 2,970.86
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: 2016-17 Licensing Fees Chart

* Fee includes the basic licensing fee plus an additional $3.35 in support of the Long Term Care Ombudsman Program.

The Center calculates state workload percentages for each workload activity by facility type. Workload activities include state licensing, federal certification, and initial state and federal certification, follow-up/revisits, complaints, and investigations. The following data are used to develop the workload percentages for each activity within each facility type:

- The number of open and active facility counts (licensure and federal certification workload survey activities only);
- The annualized workload frequency for each workload activity as mandated by either state or federal requirements;

- The standard average hours obtained from the Time Entry and Activity Management (TEAM) data. These data reflect the three-year average of hours required to complete each workload activity.
- The state funding percentage. This is the percentage charged to the L&C special fund based on the specific workload activity.

The specific workload for each facility can be found in the fee report cited above.

Subcommittee Staff Comment and Recommendation—Hold Open. No issues or concerns have been raised to subcommittee staff regarding these fee increases. It is recommended to hold this item open as discussions continue on the L&C program.

Questions. The Subcommittee has requested the L&C Program to respond to the following:

1. Please provide an overview of the changes in health facility fees.

Issue 10: Proposition 99 – California Tobacco Health Protection Act of 1988

Budget Issue. The Governor's budget projects $244.6 million in net revenue from Proposition 99 for 2016-17 and the following increases to various Proposition 99 accounts as a result of updated Proposition 99 revenue projections:

1. **Health Education**. An increase of $4,194,000 in the Proposition 99 Health Education Account. This includes a proposed increase of $200,000 for state operations, $1,916,000 for the media campaign, $250,000 for competitive grants, $410,000 for evaluation of, and an increase for local lead agencies of $1,418,000. The funds will be used for statewide and community education and media efforts aimed at preventing and reducing tobacco use, and to conduct surveillance and evaluation that assess the impact of the California Tobacco Control Program.

2. **Research Account.** An increase of $970,000 in Proposition 99 Research Account for state operations. This includes an $873,000 increase to Chronic Disease Surveillance and Research Branch and a $97,000 increase to the Environmental Health Investigations Branch. The funds will be used to continue improving cancer data production and quality assurance through automation, and conducting community-based research activities related to exposure and health effects from electronic cigarettes.

3. **Unallocated Account.** An increase of $822,000 in Proposition 99 Unallocated Account for state operations in the Environmental Health Investigations Branch. The funds will be used for advancing current plans for health equity and environmental justice projects and conducting asthma research and education.

Background. In November 1988, California voters approved the California Tobacco Health Protection Act of 1988, also known as Proposition 99. This initiative increased the state cigarette tax by 25 cents per pack and added an equivalent amount on other tobacco products. The new revenues were earmarked for programs to reduce smoking, to provide health care services to indigent persons, to support tobacco-related research, and to fund resource programs for the environment. The money is deposited by using the following formula: 20 percent is deposited in the Health Education Account (HEA); 35 percent in the Hospital Services Account; 10 percent in the Physician Services Account; five percent in the Research Account; five percent in the Public Resources Account; and 25 percent in the Unallocated Account (Revenue and Taxation Code 30124).

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending May Revision updates.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide a brief review of this proposal.

Issue 11: Active Transportation Safety Program

Budget Issue. DPH requests $733,000 in reimbursement expenditure authority and an increase of 4.5 positions to implement the Active Transportation Safety Program with funds provided through an Interagency Agreement with the California Department of Transportation (Caltrans).

Background. The Active Transportation Program was created within Caltrans and funded by SB 99 (Committee on Budget and Fiscal Review), Chapter 359, Statutes of 2013, and AB 101 (Committee on Budget), Chapter 354, Statutes of 2013. It consolidated existing federal and state transportation programs, including the Transportation Alternatives Program, Bicycle Transportation Account, and State Safe Routes to School, into a single program with a focus to make California a national leader in active transportation. Caltrans has executed an interagency agreement with DPH's Safe and Active Communities Branch to be a part of the new program.

Since 2007, Caltrans had contracted with the University of California, San Francisco to operate a Safe Routes to School Technical Assistance Resource Center at a cost of approximately $700,000 annually. This amount supported five positions to provide trainings, technical assistance, and resources to local communities to help them develop and implement Safe Routes to School non-infrastructure programs throughout California. The Technical Assistance Resource Center was housed with, and overseen by, staff from the Safe and Active Communities Branch, who provided in-kind support for nearly eight years, with no contract or funding from Caltrans. The prior contract between Caltrans and University of California, San Francisco was operating on a no-cost extension and originally expired on September 30, 2015. Caltrans has sought to partner with the Safe and Active Communities Branch to be a major component in their new Active Transportation Program. The University of California, San Francisco staff have been involved in discussions about the transition of the contract between Caltrans and University of California, San Francisco to DPH, and have expressed no objections. Most of University of California, San Francisco's staff that have been providing these services to Caltrans are on the exam lists and are eligible and encouraged to apply for the newly established DPH positions.

Specific goals of the Active Transportation Program include reducing pedestrian and bicycle injuries and fatalities, reducing greenhouse gas emissions, improving air quality, increasing safe, physical activity among youth, and improving equity for disadvantaged communities.

According to DPH, Caltrans is committed to continuing technical support services provided by DPH to increase public health expertise in the implementation of its Active Transportation Program to ensure public health-related goals are met. Caltrans will transfer funding to DPH through an interagency agreement in the amount of $733,000 for the period July 1, 2016 to June 30, 2017, with annual renewal contingent upon budget reauthorization for the Active Transportation Program.

According to DPH, many of the statutorily required goals of Caltrans' Active Transportation Program have a direct connection and benefit to public health, including: increasing safety for non-motorized users; increasing mobility for non-motorized users; advancing the efforts of regional agencies to achieve greenhouse gas reduction goals (through reduction in vehicle miles traveled); enhancing public health, including the reduction of childhood obesity by increasing walking and bicycling to school through Safe Routes to School Programs; ensuring that disadvantaged communities fully share in program benefits (25% of program), and providing a broad spectrum of projects to benefit many types of active transportation users.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

Issue 12: Protecting Children from the Effects of Lead Exposure

Budget Issue. DPH requests an increase of $8.2 million annually ($1.4 million in state operations and $6.8 million in local assistance) for four years from the Childhood Lead Poisoning Prevention Special Fund and to establish seven positions to extend services to children who have been exposed to lead as now defined by a lower blood lead level by the Centers for Disease Control and Prevention (CDC).

Background California established a Childhood Lead Poisoning Prevention (CLPP) Program to prevent childhood lead exposure, set standards for testing children for blood lead, monitor laboratory reported blood lead test results, educate and counsel families about lead, provide public health nursing and environmental home inspections and follow-up services to children identified with the highest blood lead levels, and identify sources of lead exposure and seeing that they are corrected. The CLPP Program has been successful in reducing the number of children exposed to high levels of lead; however, direct case services could be expanded to a larger child population with lower lead exposure levels.

Direct services to children are provided by 43 local CLPP programs in 40 counties and three cities which contract with the CLPPB for funding. The state is responsible for services in the remaining 18 counties. Funding is provided to these local programs by CLPPB contract criteria based on their: population of high-risk, young, low-income children; number of children with evidence of increased lead exposure on blood testing; and the proportion of children living in older housing (often associated with lead exposure).

All blood lead tests are required to be reported to the CLPPB. Approximately 700,000 tests are reported each year by over 300 laboratories and processed by CLPPB to assure receipt of accurate and complete information, including identification and location of children who have increased blood lead levels needing services. Test results are stored in the CLPPB web-based data system and are viewable by local health jurisdictions. In 2012, approximately 650,000 individual children up to age 21 were blood lead tested in California (some children are tested more than once); about 600,000 were under age six.

Children with the highest blood lead levels ($\geq$ 20 micrograms per deciliter (mcg/dL) or persistent values of $\geq$15 mcg/dL) are currently deemed "cases" of lead poisoning requiring follow-up case management. Approximately 200 new children are identified as cases of lead poisoning each year.

Alerts are sent by the CLPPB data system to initiate interventions by public health nurses and environmental professionals to reduce lead exposure in these children. The nurses and environmental professionals make home visits to educate the family about reducing lead exposure and to carry out inspections to detect sources of lead. The children receive special health care referrals as needed and ongoing collaboration occurs with their health care providers. They receive follow-up treatment for two to three years to ensure that blood lead levels decline and remain low.

The CLPP Program has been successful in reducing the number of children exposed to high levels of lead. The annual number of children identified as cases of lead poisoning has decreased fivefold since the program began in the early 1990s and the percent of tested children identified with increased blood lead levels ($\geq$ 10 mcg/dL) has decreased more than twofold since complete laboratory reports of these blood lead levels became available in 2007.

The CDC recommends that an even lower blood lead level (≥5 mcg/dL) be used to define need for services for, and follow-up of, lead-exposed children. Most lead-exposed children with blood lead levels not high enough to be "cases," do not currently receive extensive services. They may receive some educational or home inspection services to decrease lead exposure, as resources allow. Approximately 12,500 children in 2012 were identified with blood lead levels that would not currently qualify them as lead poisoning cases, but are levels that are now known to be harmful. Numbers vary by year but only 4,200 to 6,400 of such children receive any services each year.

CLPPB is proposing to lower the blood lead levels defining a "case" of poisoning from a single blood lead ≥ 20 mcg/dL to ≥ 15 mcg/dL and changing the persistent values of ≥ 15 mcg/dL to ≥ 10 mcg/dL. The current, higher blood lead criteria being used to define a child as case of lead poisoning is based on the blood lead level delineated for these interventions by CDC in the 1990s and early 2000s. In 2004, the CDC described the need for case management services for blood lead levels of ≥ 10 mcg/dL because lower lead levels are associated with developmental delays, permanent loss of IQ, and behavioral disorders in infants and young children.

CLPPB is proposing to also implement the new CDC recommendations for monitoring and providing outreach, education, and basic services to all children identified with blood lead values ≥ 5 mcg/dL. The CDC in 2012 recommended that a lower reference blood lead level of 5 mcg/dL be used to define the need for services to see that additional lead exposure is prevented and follow up is provided to ensure that blood lead levels decline. This recommendation for providing services at lower levels has also been promoted by the American Academy of Pediatrics since 2013. With this proposal, children with blood lead levels lesser than or equal to 5 mcg/dL would not receive full case management services, but would receive follow-up services to reduce lead exposure, including family contact and educational outreach, and collaboration with the health care provider.

Services Currently Provided and Those Proposed

Blood Lead Level, in mcg/dL	Effects of Lead Exposure	Current Services Provided	Proposed Services
Single value ≥ 20 or Persistent values ≥15 to <20, at least a month apart.	Neurotoxin, includes all the effects at lower levels. Can also cause anemia, abdominal pain, kidney disease, cardiovascular disease, and at very high levels can cause seizures, coma, and fatalities.	Meets current definition of state case of lead poisoning. Full services required. This includes public health nursing home visits and environmental inspections, family education on sources of lead exposure, identification of sources exposing child, removal of these sources, correction of environment, coordination with health care provider, health referrals as needed, and follow-up until blood lead level declines.	Will continue to meet definition of state case of lead poisoning. Full services required. Services provided will be the same as for currently defined cases.
Single value ≥ 15, or persistent values of ≥ 10 to < 15, at least a month apart.	Neurotoxin, life-long health affects including: reduced IQ, behavioral disorders, decreased academic achievements. May also affect cardiovascular, immunologic, and endocrine systems.	No services currently required. As available resources in each jurisdiction allow, these children may receive some services, ranging from educational materials for the family, to contact with the health care provider, to home visits and inspections. Some children in this category are receiving contact and have blood lead monitored; limited numbers receive visits and inspections.	Will meet new definition of state case of lead poisoning. Full services, as are currently provided to cases, will be required.
Single value ≥ 5 to < 10.	Neurotoxin, life-long health affects including: reduced IQ, behavioral disorders, and decreased academic achievement.	No services currently required. As available resources allow, these children may receive some services, ranging from educational materials for the family, to contact with the health care provider, to home visits and inspections. Most children in this category are not receiving any services.	Full services will not be required but all children will receive some contact and educational outreach, collaboration with their health care providers, and monitoring to be sure blood lead values decline and do not increase further. As resources allow and trends in the child's lead level dictates, home visits and inspections will be provided.
Value <5.	No known safe level according to Centers for Disease Control and Prevention.	No services currently required. All children receive anticipatory guidance on the adverse effects of lead at well child visits and through statewide outreach and education.	No services required. All children receive anticipatory guidance on the adverse effects of lead at well child visits and through statewide outreach and education.

With the large increase in the number of children to receive services and be monitored to assure reduction in blood lead levels, DPH is requesting $900,000 annually from the Childhood Lead Prevention Special Fund to support seven positions for four years. The positions include: 1.0 Nurse Consultant III (Specialist); 1.0 Nurse Consultant II; and 2.0 Environmental Scientist positions that are needed to carry out direct case management and lead inspections and for statewide technical assistance and oversight of the increased statewide workload; 1.0 Associate Governmental Program Analyst position to perform blood lead test verification and monitor subsequent blood lead levels; 1.0 Research Scientist I position for data analysis and identification of populations needing services for blood lead values ≥ 5 mcg/dL; and 1.0 Associate Governmental Program Analyst position for oversight of expanded local contracts that cover the new workload.

CLPPB is also requesting $500,000 annually for four years beginning in 2016-17 in Information Technology services to modify and update its blood lead reporting, surveillance and case management system through an external contract or augmented reimbursement to DPH Information Technology Services Division, as available expertise dictates. The web-based, data system receives blood lead test results from laboratories, is viewable by the state and local jurisdictions, and is used to track blood lead tests and manage lead-exposed children. The changes will accommodate: 1) case management alerting functions at the lower case definition; 2) tracking of activities conducted for lower blood lead levels; increased data analysis and reporting; and, 3) improved identification and mapping of areas and populations at risk for lead exposure. It will allow for documentation of the services provided. Archiving of older blood lead values and case information will also be performed to increase data system efficiency.

The additional workload in the local jurisdictions is projected to involve public health nurses, environmental staff, and their support staff. The $6,800,000 for local assistance is projected for the increased work, using current case management and professional personnel allocations.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions continue on the interaction with this proposal and the Medi-Cal program. According to the Administration, the Department of Health Care Services does not intend to submit a State Plan Amendment to reflect these changes for the Medi-Cal program. If the Medi-Cal program was updated to be consistent with this proposal, the state could draw down federal funds for these purposes.

Questions. The Subcommittee has requested DPH to respond to the following questions.

1. Please provide an overview of this proposal.

2. How many more children to you expect to serve under this proposal?

Issue 13: California Environmental Contaminant Biomonitoring Program

Budget Issue. DPH requests two permanent positions and $350,000 from the Toxic Substances Control Account for two years. The positions were established as limited-term positions and are set to expire on June 30, 2016.

Background. Biomonitoring California was established through SB 1379 (Perata) Chapter 599, Statutes of 2006. The program is a collaborative effort involving DPH as the designated lead, the Office of Environmental Health Hazard Assessment (OEHHA), and the Department of Toxic Substances Control (DTSC). It receives technical advice and peer review from a Scientific Guidance Panel and input from the public.

Biomonitoring California's principal mandates are to: (1) measure and report levels of specific environmental chemicals in blood and urine samples from a representative sample of Californians, (2) conduct community-based biomonitoring studies, and (3) help assess the effectiveness of public health and environmental programs in reducing chemical exposures. Biomonitoring provides unique information on the extent to which people are exposed to a variety of environmental chemicals and on how such exposures may be influenced by factors such as age, gender, ethnicity, diet, occupation, residential location, and use of specific consumer products. This information is essential to inform policy decisions in public health and environmental protection (e.g., the reformulation and enhanced safety of consumer products under the Safer Consumer Product Regulations implemented by DTSC).

Biomonitoring California is funded through five special funds including the Toxic Substances Control Account (TSCA), the Air Pollution Control Fund (APCF), the Department of Pesticide Registration Fund (DPRF), the Childhood Lead Poisoning Prevention Fund (CLPPF), and the Birth Defects Monitoring Fund (BDMF). DPH has eight permanent staff positions for Biomonitoring California and eight limited-term positions created in 2014-15 (two positions ending on June 30, 2016) and 2015-16 (six positions ending on June 30, 2017).

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

Issue 14: Medical Marijuana (AB 243, AB 266, and SB 643 of 2015)

Budget Issue. DPH requests 37 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 AB 266 (Bonta), Chapter 689, Statutes of 2015, AB 243 (Wood), Chapter 688, Statutes of 2015, and SB 643 (McGuire), Chapter 719, Statutes of 2015. DPH requests to phase-in these positions, as follows: six positions and $457,000 in reimbursement authority for 2015-16; eight additional positions and $3,438,000 in 2016-17; two additional positions and $2,520,000 in 2017-18; and the final 21.0 additional positions and $5,658,000 in 2018-19.

This request includes:

- A one-time appropriation to purchase laboratory equipment that will be needed during the development of testing methodologies and regulations. Total cost will be $1,180,000.
- On-going annual funding for reagents and consumables that will be utilized during the methodology development and on-going testing. Total cost will be $22,000 per year.
- A one-time appropriation of $270,000 for the purchase of vehicles for the Investigators/Environmental Scientists.
- On-going annual funds of $15,000 for vehicle maintenance and safety equipment.
- On-going annual funds of $30,000 annually for product sampling for enforcement purposes.
- On-going annual funds of $60,000 for equipment maintenance contracts.
- A one-time appropriation of $36,000 for Peace Officer Standards Training (POST) in 2018-19.
- On-going annual funds of $2,400 for on-going annual POST annual training.

This budget change proposal requests position authority and funding to develop regulations and standards for medical cannabis product manufacturers and testing laboratories. Once regulations have been developed, the department will move forward with the licensing of cannabis manufacturers, licensing and registration of testing laboratories and enforcement provisions. Implementation of these bills will be phased in over approximately three years.

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 (Vasconcellos), 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. 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 (DPH). 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 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 DPH. DPH 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, is required to 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, is required to 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, is required to 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, DPH estimates that the number of testing laboratories that will seek licensure and registration in California could be approximately 100 testing laboratories. According to DPH, the 100 testing laboratories is a conservative estimate based on the number of certified laboratories in Colorado. California is a much larger state and has approximately seven times the population of Colorado. As of 2014, Colorado began requiring testing for retail marijuana and retail marijuana products prior to their sale. There are currently 17 licensed testing laboratories in Colorado, with an additional 23 licensed testing facilities that have received certification for other residual solvents testing. At this time, licensed medical marijuana businesses in Colorado can voluntarily test their products at licensed and certified marijuana testing facilities but such testing is not mandatory. The demand for licensed testing laboratories is expected to be higher in California to meet the expected testing requirements outlined in the act.

DPH will establish the Office of Medical Cannabis Licensing in order to implement the mandates of the new Medical Marijuana Regulation and Safety Act. DPH will implement the provisions of the new act over three phases. The office will provide overall policy guidance and oversight to ensure that the act is implemented in accordance with the statutory requirements. The office will be responsible for the development of the statewide standards, regulations, licensing procedures, and policy issues to license medical cannabis manufacturers and register and license testing laboratories in order to regulate the testing and manufacturing of medical cannabis and medical cannabis products in California. Staff will meet with DCA, BOE, DPR, CDFA, the California Health and Human Services Agency, and the Governor's Office to ensure coordination of regulations, licensing, and enforcement activities. The expectation in the act is that licenses will be issued beginning January 1, 2018. The act places protection of the public as the highest priority in the licensing, regulatory and disciplinary functions of the act.

The legislation authorizes the bureau to establish an advisory committee to advise the licensing authorities on the development of standards and regulations pursuant to the act, including best practices and guidelines to ensure qualified patients have adequate access to medical cannabis and medical cannabis products. DPH expects to be part of the advisory committee and this participation will require staff time. DPH expects that on average that there will be meetings scheduled for all licensing authorities on a monthly basis. Staff from the office will attend these meetings and will be required to prepare, document and distribute information to staff upon their return from these meetings. Beginning March 1, 2023 and on or before March 1 of each following year, DPH shall prepare and submit to the Legislature an annual report on the department's activities and post the report on its internet web site.

Office of Medical Cannabis Licensing. In Phase I, starting in 2015-16 DPH will hire the Office of Medical Cannabis Licensing Chief and the Research Scientist Supervisor II to plan, manage and direct all staff within the Medical Cannabis Manufacturing and Testing programs. DPH will also hire an attorney to provide guidance to the programs in the interpretation of the Act, and the development of the regulations.

In 2016-17, the Office of Medical Cannabis Licensing will hire the Staff Services Manager II (SSM II) to oversee the development of licensing procedures, cost methodologies, and program expenditures.

In 2016-17 a Staff Programmer Analyst will support the DPH's interface with CDFA and BOE as they adopt a system for reporting the movement of commercial cannabis and cannabis products throughout the distribution chain. Additionally, CDFA will create an electronic database containing the electronic shipping manifests. The database will be designed to flag irregularities for all licensing authorities to investigate. All licensing authorities may access the database and share information related to licensees, including social security and individual taxpayer identifications.

In Phase II (2017-18) an Associate Governmental Program Analyst (AGPA) will be hired to provide support for the Office with the regulatory public comment process, and overall development of the administrative aspects. In Phase III (FY 2018-19), an Executive Secretary will be added to provide the Office Chief and SSM II with administrative support once licensing and full program activities commence.

Testing Laboratories. The Act identifies 12 different licensing classifications dependent upon the type of medical cannabis business. Those include cultivation, manufacturing, testing, dispensary, distribution and transportation. DPH is responsible for manufacturing and testing licenses.

DPH is required to issue a Type 8 "testing" license classification to a testing laboratory. To accomplish this, the department will promulgate regulations governing the registration and licensing of testing laboratories. The testing laboratories will be required to register with the department and to renew that registration on an annual basis requiring that the department develop a process for laboratory registration. In order to develop the regulations and standards, DPH will develop standard methods, sampling procedures and validate testing methodologies. The standard method development will include testing requirements for medical cannabis, which includes testing for identifications of potential contaminants.

Phase I (2016-17) and Phase II (2017-18). In order to implement a registration and licensing program for testing laboratories and all testing requirements, DPH will begin by developing regulations and standards to address contaminant levels for the following areas: residual solvent or processing chemicals; pesticide residues; foreign material, such as: hair, insects or related adulterant; microbiological impurity; fungal toxins; heavy metals; whether the batch is within specification for odor and appearance; and volatile organic compounds. The regulation development for testing laboratories in Phases I and II will require a total of 5.0 Research Scientists in both chemical and microbiological capacities, and 1.0 AGPA will support scientific staff to purchase equipment, assist with the development of regulations, and coordinate contracts and maintenance for equipment and to assist with hiring and other administrative duties. This AGPA position will also be critical in assisting in the development of the licensing fees. DPH will conduct the following activities:

- Develop medical cannabis testing standards and methodologies for both chemical and microbiological contaminants.

- Develop requirements for standards for testing laboratories, personnel requirements, quality assurance and maintenance of records.

- Conduct scientific research of complex studies related to the safety of marijuana products and survey of other state's regulations and requirements. DPH will be required to perform research regarding any current existing analytical methodologies and also consult with other states that already have developed these standards and come up with similar protocols.

- Validate testing methodologies.

- Develop lists for required testing for drug potency, chemical contaminants, and microbiological contaminants.

- Develop a process for laboratory licensing and registration that will specify what requirements need to be met by testing laboratories for licensure and registration. For testing laboratories there are several requirements in the act that have to be met, including that the laboratory is accredited through International Standards Organization (ISO) standards.

- Develop methodologies for setting licensing fees.

- Develop procedures and regulations to enforce its duties under the act, to take disciplinary actions and suspend or revoke licenses of testing laboratories after an investigation and hearing.

- Develop registration and licensing procedures.

- Purchase of laboratory equipment. Equipment purchase will take place in 2016-17 as it can take up to six months to obtain equipment, set up and install, and train staff on how to utilize the equipment.

Phase III (2018-19 and on-going). Upon development and adoption of the regulations and standards, DPH expects to begin registering and licensing testing laboratories and also begin its supporting role as a reference laboratory for the medical cannabis manufacturing enforcement capabilities. This will require 1.0 Office Technician and an additional 4.0 Research Scientists to assist with performance of analysis testing of samples submitted by the medical cannabis manufacturing program during performance of enforcement responsibilities. Support will be needed to provide for ongoing testing capabilities including chain of custody documentation, oversight of samples received, sample preparation, analysis, data interpretation, and report writing providing details of the outcomes of the analysis.

The annual licensing and registration of testing laboratories will begin in 2018 and require that the Research Scientists review applications for personnel qualifications, quality assurance, and maintenance of records in accordance with the regulations and standards. The Research Scientists will also conduct inspections of testing laboratories with a schedule to be established in regulations, and work on any potential hearings actions related to the suspension or revocation of licenses, investigations and preparation for any potential hearings.

The establishment of methodologies and research for medical marijuana are new and will continue to evolve. The Research Scientists from Phase I and II in chemical and microbiological capacities will continue to perform permanent ongoing research and updates for testing methodologies and for updates to the standards of procedures and testing. Staff will prepare laboratory analysis reports including scientific research reports needed for the validation of testing of different contaminants.

Licensing of Manufacturers. AB 266 requires the department to adopt regulations for the licensing structure for cannabis manufacturers in order to regulate the manufacturing of medical cannabis in California. This requires that the department establish regulations, standards, and procedures for licensing medical cannabis manufactures. Licenses will be required to obtain a license and renew it on an annual basis. DPH will also be required to consult with CDFA on the development of a data system that will be used to store and share relevant information on licensees and the tracking and tracing of regulated commodities.

Phase I (starting in 2015-16) and Phase II (2017-18). In order to implement a licensing program for manufacturing of medical cannabis products, DPH will develop regulations and standards. The regulation development in Phases I will require a Staff Toxicologist, a Food and Drug Program Specialist and an AGPA. In Phase II, an additional AGPA will be phased in to begin the development of licensing desk procedures, development of applications and/or forms, create tracking records, metric development for licensing and enforcement activities, maintaining documentation, and providing analytical support.

Regulations, standards, and procedures will be developed for:

- Licensing of level 1 manufacturers (Type 6 license) which includes licensing of cannabis manufacturers sites that utilize nonvolatile solvents.
- Licensing of level 2 manufacturers (Type 7 license) for sites that utilize volatile solvents.
- Standards for the production and labeling of all edible medical cannabis products.
- Extraction and infusion methods.
- Inventory procedures.
- Transportation process.
- Quality control procedures.
- Inspection, sanitation and health and safety standards.
- Enforcement, disciplinary action, and suspension or revocation of licenses.
- Advertising, labeling, inspection process and sampling.
- Determining adulteration and misbranding are also needed for a comprehensive program to ensure safety for the public regarding this new commodity.
- Warnings about allergens.
- Source of date of cultivation and manufacture.
- Unique identifier information issued by CDFA.

Phase III (2018-19 and on-going). After the regulations have been developed, DPH will begin licensing the medical cannabis manufacturers and commence enforcement activities. A third AGPA and an Office Technician will be phased in to assist in budgeting, and other administrative duties (purchasing, developing and monitoring contracts, human resources, accounting, budgeting) and all other analytical administrative support. The 2 AGPAs from Phase I and II will oversee the licensing desk which will include processing incoming requests for customer support regarding the licensure process, process license paperwork and payments, track licensees, verify and validate licensees, and conduct associated administrative work.

An Environmental Program Manager (EPM) I and 2.0 unit supervisors will be hired to oversee field staff. The EPM I will supervise and direct the investigation and inspection of enforcement staff, coordination of the collection, and submission of samples for testing. DPH will need 10.0 Investigators/Environmental Scientists that will conduct the investigations and inspections of manufacturers and persons engaged in the manufacturing, storage, distribution, sale and advertising of medical cannabis products throughout the state. The investigations will include detailed and comprehensive physical inspections of buildings, as well as the inspection and thorough review of manufacturing processes, operating procedures, and records. Inspections include gathering of facts and samples, assessing compliance, issuing notices of violations, discussing observations and corrective actions with firm management; preparing in-depth inspection or investigational reports; and making recommendations regarding corrective action and appropriate disposition of cases based on adequacy of evidence or procedures.

There are varying numbers of estimated medical marijuana dispensaries from different published websites ranging anywhere from 500 to 4,000. Based on information from the Sunrise Questionnaire and the Emerald Growers Association, there are an estimated 40,000 cultivation sites throughout California. According to www.weedmaps.com, there are over 4,000 medical marijuana dispensaries operating within California. The act allows for cultivators (small) and dispensaries to also hold a manufacturing license. It is unknown at this time how many cultivators and dispensaries will request a license as a manufacturer. However, the department estimates that approximately 1,000 manufacturers will need to be licensed. The estimate of 1,000 manufacturers is also based on the 194 licensed manufacturers that Colorado currently has for an industry that is presumably much smaller than California's will be.

LAO Findings. The LAO generally finds that DPH is funding initial startup activities as required. However it identifies the following as issues for legislative consideration:

- ***Implementation Will Require Substantial Amount of Cross-Agency Coordination.*** The administration appears to be prioritizing communication and alignment of various efforts, but numerous activities will need to be coordinated across multiple departments. For example, at least three departments—CDFA, DPH, and DCA—will have to coordinate to develop regulations, licensing fee structures, and an IT system to track medical marijuana production from cultivation through distribution and sale.

- ***Implementation Will Require Substantial Amount of Coordination With Locals.*** The administration plans to actively engage with local governments, but aligning state and local policies and efforts will require ongoing communication and coordination. For example, DFW wardens will need to coordinate with local law enforcement and prosecutors to ensure investigations of cultivation sites are conducted safely, legally, and effectively.

- ***Ongoing Regulatory Costs Still Unclear.*** Amount of workload departments ultimately will experience depends on many unknown factors, including the eventual size of the regulated medical marijuana industry, the number of authorized dispensaries, and the scale of environmental impacts. Follow-up proposals are expected in the coming years, including for what could be a significant new IT project.

- ***Timely Implementation May Be a Challenge.*** Given scope of new responsibilities, departments may have difficulty promulgating regulations, developing fee structures, and crafting new policies and guidelines.

- ***Other Factors Could Change Landscape.*** The potential exists for factors outside of the Legislature's control to alter current plans for implementing these laws. For example, potential voter expansion of legalized marijuana use could change the regulatory role of the state, perhaps requiring additional resources or modified regulations. Alternatively, a change in federal drug policy could complicate the state's approach to overseeing medical marijuana production and use.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending further review of this proposal. Additionally, the following should be considered:

- **Timely Regulation Development Likely Difficult.** DPH anticipates completing regulations by January 2018 (the statutory deadline), which is less than two years from now. DPH indicates that it has already begun its research, is consulting with other states that have implemented similar standards, and plans to hire an attorney who will be dedicated to working on the medical cannabis regulations. Despite these efforts, it is unclear how DPH will meet this deadline, not only because of DPH's past difficulties in promulgating regulations in a timely manner but also because this is a new industry for the department.

- **Opportunity to Create Public Health Surveillance System.** Given this crucial moment in the establishment of a regulatory framework to regulate the cultivation, sale, testing, manufacturing and transportation of medical cannabis in California, it is critical to consider what type of public health surveillance system is necessary to assure quality of the regulatory system. The Legislature may wish to consider working with DPH to establish a public health surveillance system (e.g., tracking of emergency room visits related to the use of medical marijuana) as part of implementation of this proposal.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

2. Please discuss what steps DPH is taking to ensure timely development of regulations.

3. Has DPH considered what type of public health surveillance system should be developed in conjunction with the implementation of these bills?

Issue 15: End of Life Option Act (AB 15 X2, 2015)

Budget Issue. DPH requests $323,000 from the Health Statistics Special Fund in 2016-17, $245,000 in 2017-18 and annually thereafter, and two permanent positions to meet the new mandate to establish the End of Life Option Act program as specified in AB 15 X2 (Eggman), Chapter 1, Statutes of 2015, Second Extraordinary Session. 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, the Director of DPH, the state 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. DPH 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 DPH, and allows terminally ill adults seeking to end their life to request aid-in-dying drug from their attending physician. DPH will be responsible for receiving forms specified in statute, tabulating reported data, and preparing an annual statistical report.

DPH requests two permanent positions to perform confidential program and reporting duties, including (1) collect forms and data, enter reports received, and track program utilization and associated deaths; (2) follow-up with providers regarding incomplete or missing forms; (3) perform data analysis, cross-check decedent deaths with the list of prescribed participants, and draft various statistical reports; (4) prepare the annual report mandated by the bill; (5) maintain program information on the public website and respond to inquiries regarding program policy; and (6) update the website as needed, and make reporting forms available for download from the site.

DPH also requests funding to develop a secure database for this new program. Although the number of aid-in-dying cases is projected to be small, special protections for the data will be required because of the sensitivity of this information. One-time development costs for this secure database are estimated to be approximately $88,000, and ongoing yearly maintenance costs are expected to be $10,000.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

Issue 16: Collection of Data: Multi-Race or Multi-Ethnic Origin (AB 532, 2015)

Budget Issue. DPH requests $236,000 for fiscal year 2016-17 and $234,000 for fiscal year 2017-18 from the Health Statistics Special Fund to meet the new mandate to tabulate the data for both single and multiple race or ethnic designations in reports provided to other state departments as specified by AB 532 (McCarty), Chapter 433, Statutes of 2015.

Background. The State Registrar, the Director of DPH, 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.

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 DPH 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 DPH to turn vital record data into actionable public health information.

AB 532 establishes a new requirement for DPH programs that collect demographic data, prior to and no later than January 1, 2022, to provide forms that offer the option of selecting one more ethnic or racial designations. The bill also requires DPH to ensure that the data reported to any other state agency, board, or commission is neither tabulated nor reported without the number or percentage of respondents who identify with each ethnic or racial designation alone, and not in combination with any other ethnic or racial designation; those who identify with each ethnic or racial designation, whether alone or in combination with other ethnic or racial designations; those who identify with multiple ethnic or racial designations; and to comply with the federal guidance developed for the allocation of multiple race responses for use in civil rights monitoring and enforcement.

The new workload associated with AB 532 includes the need for development of new statistical coding of data to produce the strata specified for the data files, and to ensure the integrity and quality of the data produced. DPH will redirect two positions among its vacant authorized positions to meet the workload.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

Issue 17: Lesbian, Gay, Bisexual, & Transgender Disparities Reduction Act (AB 959, 2015)

Budget Issue. DPH requests one-time expenditure authority of $125,000 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, AB 959 (Chiu), Chapter 565, Statutes of 2015.

Background. The State Registrar, the Director of DPH, 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 issuance of death and birth certificates is a key process in generating data required by both the Centers for Disease Control and DPH 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 DPH to turn vital record data into actionable public health information.

AB 959 establishes a new requirement for DPH programs that collect demographic data, as early as possible, but no later than July 1, 2018, to collect voluntary self-identification information pertaining to sexual orientation and gender identity. The statute requires DPH to use information voluntarily provided about sexual orientation and gender identity only for demographic analysis, coordination of care, quality improvement of its services, conducting approved research, fulfilling reporting requirements, and guiding policy or funding decisions. In addition, the bill requires that the data collection duties and reporting requirements are consistent with federal law, and that DPH protect the identity of individuals within small data sets by aggregating the data.

DPH requests a one-time special fund expenditure authority of $125,000 to comply with this new law and add new fields for voluntary self-identification information pertaining to sexual orientation and gender identity of parents. This funding is required to modify the existing electronic birth registration system, and would be accomplished by the system contractor, UC Santa Barbara, via an amendment to the current interagency agreement; and modify the existing fetal death registration system, via an amendment to the current contract with UC Davis.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.

Issue 18: Office of AIDS (OA): AIDS Drug Assistance Program (ADAP) Update

Background. The Office of AIDS has two programs within ADAP that provide access to life saving medications for eligible California residents living with HIV/AIDS. These are:

A. Medication Program – In this program, ADAP pays prescription drug costs for drugs on the ADAP formulary for the following coverage groups:

1. ADAP-only clients, for whom ADAP pays 100 percent of the prescription drug costs because these clients do not have a third-party payer.

2. Medi-Cal Share of Costs clients, for whom ADAP pays 100 percent of the prescription drug cost up to the client's share of cost amount.

3. Private Insurance clients, for whom ADAP pays prescription drug co-pays and deductibles.

4. Medicare Part D clients, for whom ADAP pays the Medicare Part D drug co-pays and deductibles.

B. Insurance Assistance Programs – These programs pay for private health insurance premiums or Medicare Part D premiums for clients co-enrolled in ADAP. These are for the following three types of health insurance:

1. Non-Covered California private insurance – OA – Health Insurance Premium Payment Program (OA-HIPP)

2. Covered California private insurance – OA HIPP Covered California

3. Medicare Part D – OA Medicare Part D

See tables below for ADAP budget summary and caseload estimates.

Governor's ADAP Expenditures for Current Year and Budget Year (dollars in millions)

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

Estimated ADAP Clients by Coverage Group

Coverage Group	2015-16	2016-17
	Clients	Clients
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**

Estimated ADAP Clients by Coverage Group for Insurance Assistance Programs

Coverage Group	2015-16	2016-17
	Clients	Clients
OA - HIPP	1,047	895
OA- 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.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending updated information at May Revision.

Questions. The Subcommittee has requested the Office of AIDS to respond to the following:

1. Please provide an overview of the ADAP budget.

2. Please provide an update on the transition of ADAP clients to Medi-Cal and Covered California.

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

Issues 19: Increase Access to HIV Pre-Exposure Prophylaxis (PrEP)

Budget Issue. DPH proposes to expend $2.6 million in federal funds ($1.4 million local assistance and $1.3 million state operations) in 2015-16 and $3.5 million ($1.8 million local assistance and $1.7 million state operations) in 2016-17, and requests the addition of five permanent positions, to implement a three-year Centers for Disease Control and Prevention (CDC) grant awarded to DPH on September 3, 2015.

A Section 28 Budget Letter, dated October 30, 2015, notified the Legislature of this grant and the related increase in current year federal fund authority.

Background. The 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.

DPH 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 (Committee on Budget), Chapter 18, Statutes of 2015, the $2 million 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.

At the end of 2013, there were an estimated 121,060 persons living and diagnosed with HIV in California and reported to OA; however, the CDC estimates 11.3 percent of all persons living with HIV in California are unaware of their infection. Eighty-seven percent of persons diagnosed with HIV in California are male. While California has made progress in identifying people who are unaware of their HIV status, the state has been only minimally successful in reducing the annual number of newly diagnosed HIV infections statewide, from 5,469 in 2009 to 4,712 in 2013. Over 70 percent of new infections are among men who have sex with men. Approximately 25 percent of Californians newly diagnosed with HIV (1,220 people) were living in the CDC-determined eligible jurisdictions for this funding: San Diego, Orange, Alameda and Riverside. Of those newly diagnosed, 75 percent were men who have sex with men and 1.2 percent were transgendered persons.

PrEP is a new prevention tool for people at high risk for HIV acquisition that has been shown to decrease HIV infection. Prior to its use as an HIV preventative for those who are HIV negative, PrEP medication has been used by those who are HIV positive as an HIV antiretroviral medication for the past 11 to 14 years. Taken daily, and as long as the patient is at substantial risk for HIV acquisition, PrEP medication can reduce HIV acquisition by over 90 percent.

Twenty-four state, local, and territorial health jurisdictions were eligible to apply for this funding, including direct funding to the Los Angeles County and the San Francisco County Metropolitan Statistical Areas. The department applied for the funding on behalf of eligible California Metropolitan Statistical Areas/Divisions as determined by the CDC in order of HIV prevalence: San Diego, Orange, Alameda, and Riverside. Nationally, 12 jurisdictions received PrEP funding, including Los Angeles and San Francisco.

To implement the PrEP activities, DPH is requesting $3.5 million in federal funds and five permanent positions to meet the requirements of this grant opportunity. Of the five positions requested, four positions will be located in OA's HIV Prevention Branch, and the fifth position will be located in the Prevention Research and Evaluation Section of OA's Surveillance, Research, and Evaluation Branch. PrEP activities will include administering the funding at the state level, and determining in consultation with the eligible local health jurisdictions the most effective levels of funding. The CDC requires the use of these demonstration project funds to develop and provide the training and technical assistance for navigation and outreach services, and to develop and distribute educational resources for clinical and non-clinical private providers, local health department staff and community-based staff, as well as resources for consumers/patients.

The development and coordination of these education, outreach, and patient navigation services needs to be centrally developed by DPH so efforts are not duplicated, program activities are standardized, evaluation of local program components are independently evaluated, and resources are centrally administered.

Per CDC Request for Applications funding opportunity announcement, funding cannot be used to purchase PrEP medications.

Subcommittee Staff Comment and Recommendation—Hold Open.

Questions. The Subcommittee has requested DPH to respond to the following:

1. Please provide an overview of this issue.