

Senate Budget and Fiscal Review – Mark Leno, Chair
SUBCOMMITTEE #3 on
Health & Human Services

Chair, Senator Holly J. Mitchell

Senator William W. Monning
Senator Jeff Stone, Pharm. D.



March 5, 2015

9:30 a.m. or Upon Adjournment of Session

Room 4203, State Capitol

Agenda

(Michelle Baass)

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PLEASE NOTE:

Only those items contained in this agenda will be discussed at this hearing. *Please* see the Senate Daily File for dates and times of subsequent hearings.

Issues will be discussed in the order as noted in the Agenda unless otherwise directed by the Chair.

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4120 Emergency Medical Services Authority**1. Overview**

The Emergency Medical Services Authority (EMSA) develops and implements emergency medical services systems (EMS) throughout California and sets standards for the training and scope of practice of various levels of EMS personnel. The EMSA also has responsibility for promoting disaster medical preparedness throughout the state and, when required, managing the state's medical response to major disasters.

Budget Overview. The budget proposes expenditures of about \$32.2 million (\$8.4 General Fund and \$2.7 million federal funds) and 71 positions for EMSA. See table below for more information.

Table: EMSA Budget Overview

| Fund Source | 2013-14 Actual | 2014-15 Projected | 2015-16 Proposed | BY to CY Change |
|---------------------------|---------------------------|------------------------------|-----------------------------|----------------------------|
| General Fund | \$6,509,000 | \$7,684,000 | \$8,419,000 | 9.57% |
| Federal Trust Fund | \$1,698,000 | \$3,500,000 | \$2,653,000 | -24.20% |
| Reimbursements | \$11,524,000 | \$16,392,000 | \$16,826,000 | 2.65% |
| Special Funds | \$3,637,000 | \$4,030,000 | \$4,294,000 | 6.55% |
| Total Expenditures | \$23,368,000 | \$31,606,000 | \$32,192,000 | 1.85% |
| | | | | |
| Positions | 66.7 | 70.2 | 71.2 | 1.42% |

Outstanding Supplemental Report. As part of the 2014 budget, supplemental report language was adopted requiring EMSA to provide to the Legislature by January 10, 2015. The report, which has not yet been provided to the Legislature, is to include information on:

1. A detailed description of existing state and local resources, including resources managed by other state and local entities, that would be available in the event of a major medical disaster.
2. The projected time from when a disaster occurs to when resources would be fully deployed.
3. The number of individuals existing resources could serve in a major medical disaster.
4. A summary of existing funding for emergency preparedness in California and any anticipated reductions in funding over the next two fiscal years.
5. A comparison of California's emergency medical response infrastructure and capacity for a major medical disaster compared to the infrastructure and capacity available in other states of similar size, such as New York and Texas.

6. A description of how California's emergency medical response infrastructure and capacity could be improved and the resources necessary to implement such improvements.

Subcommittee Staff Comment. This is an informational item.

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

1. Please provide a brief overview of EMSA's programs and budget.
2. What is the status of the report due to the Legislature?

2. Disaster Preparedness and Emergency Response Resources for California

Budget Issue. EMSA requests \$500,000 General Fund and two permanent Senior Emergency Services Coordinators. The additional funding and new positions would be utilized to reestablish the southern California component of the California Medical Assistance Team, stabilize existing disaster medical preparedness programs, and coordinate joint activities with the Department of Public Health's (DPH) Emergency Preparedness Office including catastrophic event planning, and emergency operations center planning and development. Specifically, this proposal would fund:

- **California Medical Assistance Team (CAL-MAT) Program Stabilization (\$205,000):** EMSA would contract with a southern California Local Emergency Medical Services Agency to manage the southern California administrative functions associated with the reestablishment of a southern California Medical Assistance Team. (EMSA currently has one California Medical Assistance Team located in Northern California.)
- **California Medical Assistance Team Senior Emergency Services Coordinator (\$147,500):** A Senior Emergency Services Coordinator would coordinate the Northern California Medical Assistance Team to include administrative functions, training and assist with the maintenance of the three California Medical Assistance Team caches. This position would provide guidance to the southern California Local Emergency Medical Services office overseeing California Medical Assistance Team to include monitoring deliverables contained within the contract. This Senior Emergency Services Coordinator would also coordinate with DPH the activities related to Catastrophic Event Planning.
- **Ambulance Strike Team Senior Emergency Services Coordinator (\$147,500):** A Senior Emergency Services Coordinator would support the Ambulance Strike Team Program, the Training and Exercise Program, and Emergency Operations Center planning and development. This would also include auditing of the Disaster Medical Support Units placed with local providers and Disaster Medical Support Unit communications training that is not currently being provided.

Background. EMSA's Mobile Medical Assets Program is multi-tiered. The multi-tiered program is comprised of:

- **Tier One** - Ambulance Strike Teams represent the first tier of the Mobile Medical Assets Program and are organized groups of five ambulances, one support vehicle, and one Ambulance Strike Team leader to provide rapid response in meeting emergency medical transport needs in large-scale emergencies or disasters. There are 41 pre-designated teams throughout California with Disaster Medical Support Units provided by EMSA. The Disaster Medical Support Unit provides enhanced communications ability to support field deployment, including medical supplies and provisions for Ambulance Strike Team personnel. Ambulance Strike Teams respond within 2 hours of request.
- **Tier Two** - California Medical Assistance Teams represent the second tier of the Mobile Medical Assets Program and are teams activated by EMSA to provide medical care during

disasters. The three teams are rapidly deployable and ready to treat patients within hours at field treatment sites, shelters, existing medical facilities, alternate care sites, and mobile field hospitals. Teams are self-sufficient for 72 hours and include physicians, nurses, pharmacists, and logistical and support staff.

- **Tier Three** – Mobile Field Hospitals (MFH) represent the third tier of the Mobile Medical Assets Program. One MFH is currently being stored in EMSA’s Response Station Warehouse in Sacramento with on-going bio-medical equipment maintenance being performed. Deployment for this MFH is now estimated to be between 72-96 hours. The other two MFHs are in donated storage in delayed deployment status in the Sacramento area. These two MFHs are not being maintained. EMSA identified federal Hospital Preparedness Program funding to maintain the one MFH through the current year ending June 30, 2015. As of July 1, 2015, all MFHs will be considered non-deployable without extensive rehabilitation to equipment and supplies.

Emergency Operations Center Coordination is a role EMSA fulfills in cooperation with the Governor’s Office of Emergency Services (OES) and in partnership with DPH and in accordance with the State Emergency Plan.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open for further review and pending receipt of the supplemental report by EMSA, mentioned in the previous issue, regarding the state’s emergency medical services capacity.

Given past reductions in federal and General Fund support for EMSA, Subcommittee staff inquired about the EMSA’s prioritization of the activities proposed in this request over other EMSA-related programs such as Mobile Field Hospitals (MFHs). According to EMSA, with the decline of state and federal funds, the state has had to rethink surge capacity and prioritize needs. The first and second tiers are paramount for the state to mount a credible initial response to a disaster. Stabilizing the ability of the state to provide the second tier of the Mobile Medical Assets Program is a higher priority of the state, and provides CAL-MAT capability in Southern California. The CAL-MAT teams are multi-functional and are able to provide medical treatment for a variety of missions such as medical shelter operations, augmenting or replacing hospital staff and operating independently in a field medical station. The MFHs would require significant funding to maintain the program along with funding to restore the hospitals to a deployable condition. The two staff positions requested in the proposal stabilize the ability of the state to coordinate medical and health operations in the Emergency Operations Center environment as well as participate in critical medical and health disaster planning activities integrating those of both EMSA and DPH. In addition, one of these positions will develop and support a Southern California CAL-MAT.

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

1. Please provide a brief overview of this proposal.
2. Please explain EMSA’s rationale in prioritizing the resources in this proposal over other emergency preparedness resources, such a mobile field hospitals.

3. Document Imaging Workload and Efficiencies

Budget Proposal. EMSA requests one permanent Office Technician, three Seasonal Clerks and \$366,000 (Emergency Medical Services Personnel (EMSP) Fund) in 2015-16 to address increased workload associated with the document imaging of paramedic licensure and enforcement files. See table below for summary of this request.

Table: Proposal Funding Summary

| | Fiscal Year | | |
|-----------------------------|------------------|------------------|------------------|
| | 2015-16 | 2016-17 | 2017-18 |
| Temporary Help | \$167,000 | \$0 | \$0 |
| Office Technician | \$199,000 | \$193,000 | \$193,000 |
| EMSP Fund Authority Request | \$366,000 | \$193,000 | \$193,000 |

Background. The Emergency Medical Technician (EMT) 2010 Registry was designed to create operational efficiencies by streamlining both the paramedic application process and investigatory process through an online licensing and document imaging system.

According to EMSA, the workload associated with the document imaging of existing paper files was underestimated and current staffing levels are insufficient to meet the workload associated with integrating the very large amount of paper documents with the EMT 2010 Registry. Currently, the document imaging system is only being used to scan and convert new and renewal paramedic applications that were received during the 2013-14 and 2014-15 periods. Existing resources have been unable to maintain the level of scanning necessary to keep up with the incoming applications and Paramedic Licensure Unit is backlogged with two months of applications. Approximately 44,094 paramedic licensure and enforcement files still require document scanning and uploading. Due to the underestimation of staff hours required for document imaging, the Paramedic Licensure Unit at this time is unable to allocate sufficient resources to address the current backlog of files requiring document imaging. Until the backlog of existing files are scanned and uploaded to the document imaging system, staff will continue to spend excessive time tracking down and re-filing paper copies.

EMSA charges fees for the licensure and licensure renewal of paramedics in an amount sufficient to support the paramedic licensure and enforcement program at a level that ensures qualifications of the individuals licensed to provide quality care. Fees collected are deposited in the EMSP Fund, which was established in 1989 by the Legislature in the State Treasury. Monies in the EMSP Fund are held in trust for the benefit of the EMS Authority’s paramedic licensure and enforcement program. A fee increase is not necessary to support this proposal.

Subcommittee Staff Comment and Recommendation—Hold Open. No issues have been raised with this proposal; however, it is recommended to hold this item open pending receipt of the report due to the Legislature discussed in Issue 1.

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

1. Please provide an overview of this proposal.

4140 Office of Statewide Health Planning and Development

1. Overview

The Office of Statewide Health Planning and Development (OSHPD) collects and disseminates information about California's healthcare infrastructure, promotes an equitably distributed healthcare workforce, and publishes information about healthcare outcomes. OSHPD also monitors the construction, renovation, and seismic safety of hospitals and skilled nursing facilities and provides loan insurance to facilitate the capital needs of California's not-for-profit healthcare facilities.

Budget Overview. The budget proposes expenditures of \$147.5 million (\$1,000 General Fund) and 483.6 positions for OSHPD.

Table: OSHPD Budget Overview

| Fund Source | 2013-14 Actual | 2014-15 Projected | 2015-16 Proposed | BY to CY Change |
|-----------------------------|---------------------------|------------------------------|-----------------------------|--------------------------------|
| General Fund | \$0 | \$75,000 | \$1,000 | -98.67% |
| Federal Trust Fund | \$1,288,000 | \$1,449,000 | \$1,440,000 | -0.62% |
| Reimbursements | \$7,468,000 | \$7,860,000 | \$7,861,000 | 0.01% |
| Mental Health Services Fund | \$23,457,000 | \$55,921,000 | \$25,954,000 | -53.59% |
| Other Special Funds | \$103,215,000 | \$117,336,000 | \$112,264,000 | -4.32% |
| Total Expenditures | \$135,428,000 | \$182,641,000 | \$147,520,000 | -19.23% |
| Positions | 445.1 | 476.6 | 479.6 | 0.63% |

Subcommittee Staff Comment. This is an informational item.

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

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

2. Elective Percutaneous Coronary Intervention Program Outcomes Reporting

Budget Issue. OSHPD requests two permanent positions, one Research Scientist III and one Research Program Specialist I, and increased expenditure authority of \$372,000 in 2015-16 and \$319,000 ongoing from the California Health Data and Planning Fund for the implementation of SB 906 (Correa), Chapter 368, Statutes 2014. This bill establishes the Elective Percutaneous Coronary Intervention (PCI) Program and requires OSHPD to produce annual risk-adjusted public performance reports on participating hospital's PCI-related mortality, stroke, and emergency Coronary Artery Bypass Graft outcomes.

Background. SB 891 (Correa), Chapter 295, Statutes 2008, established the Elective PCI Pilot Program in the California Department of Public Health (DPH) which authorized up to six eligible acute care California hospitals with licensed cardiac catheterization laboratory services but without onsite surgical backup to perform scheduled, elective PCIs. SB 357 (Correa), Chapter 202, Statutes 2013, extended the Elective PCI Pilot Program until January 1, 2015, and required the oversight committee to conduct its final report by November 30, 2013. The bill required DPH, within 90 days of receiving the final report from the oversight committee, to prepare and submit its report to the Legislature on the initial results of the Elective PCI Pilot Program.

The Elective PCI Pilot Program established an advisory oversight committee to oversee, monitor, and make recommendations to the DPH concerning the results of the pilot program and whether elective PCI without onsite cardiac surgery should be continued in California. Six hospitals – Los Alamitos Medical Center, Sutter Roseville Medical Center, Kaiser Walnut Creek Medical Center, Doctors Medical Center-San Pablo, Clovis Community Medical Center and St. Rose Hospital-Hayward – participated in the pilot program.

The *Advisory Oversight Committee Report to the California Department of Public Health* and the subsequent report, *The Elective Percutaneous Coronary Intervention (PCI) Pilot Program: Report to the Legislature*, showed that the morbidity and mortality results of procedures from the pilot hospitals during the program's duration were consistent with the morbidity and mortality results from hospitals not enrolled in the pilot program. Thus, there was no increased risk to patients in allowing elective PCIs to be performed at hospitals without onsite cardiac surgery.

SB 906 makes permanent the Elective Percutaneous Coronary Intervention Program as of January 1, 2015. This bill requires DPH and OSHPD to obtain and use data collected by the American College of Cardiology's National Cardiovascular Data Registry, a national cardiovascular registry, to adopt and validate risk-adjustment models and annually report each certified hospital's PCI performance outcomes with regards to patient mortality, stroke, and emergency coronary artery bypass graft surgery.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as staff continues to evaluate the need for two permanent positions.

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

1. Please provide an overview of this proposal.
2. How will OSHPD work with stakeholders to ensure these reports are consumer-friendly?

3. Oversight of Peer Personnel Support-Investment in Mental Health Wellness Act of 2013

Oversight Issue. A 2013 budget trailer bill, SB 82 (Committee on Budget and Fiscal Review), Chapter 34, Statutes of 2013, established the Investment in Mental Health Wellness Act of 2013 which invests a total of \$206.2 million in mental health wellness. Of this total amount, \$2 million (Mental Health Services Act Fund - State Administration) was to provide training in the areas of crisis management, suicide prevention, recovery planning, and targeted case management and to facilitate employment of peer support classifications.

In April 2014, OSHPD awarded contracts to four organizations to support peer personnel by providing training in one or more of the following: crisis management; suicide prevention; recovery planning; targeted case management; and other related peer training and support functions to facilitate the deployment of peer personnel as an effective and necessary service to clients and family members and as triage and targeted case management personnel. The organizations awarded include:

Table: Contracts Awarded Regarding Peer Personnel Preparation, April 2014

| Organization Contracted | Contract Amount | Contract Term |
|---|------------------------|----------------------|
| Contra Costa Behavioral Health | \$436,386.00 | 4/9/2014 – 6/30/2016 |
| Mental Health Association of San Francisco | \$500,000.00 | 4/9/2014 – 6/30/2016 |
| National Alliance on Mental Illness San Diego | \$456,755.00 | 4/9/2014 – 6/30/2016 |
| Recovery Opportunity Center | \$500,000.00 | 4/9/2014 – 6/30/2016 |

Contractors are required to meet the following objectives:

- Develop and document career pathways for positions employing peer personnel that provide entrance to the public mental health system with defined opportunities to advance across healthcare systems (a defined career pathway). The identified positions must be able to be filled by Peer Personnel.
- Recruit Peer Personnel from the following populations and/or communities for participation in the defined career pathway: individuals and their families who currently are or who have received mental health, behavioral health, and/or substance use services, and individuals with health or mental health education and/or experience who can address cultural, diversity and language proficiency needs.
- Establish/expand an educational or training program that provides training that meets public mental health system needs, aligns with MHSA, provides field work, and includes career counseling and placement.
- Increase the total number of peer personnel employed in the public mental health system by recruiting and retaining peer personnel in identified entry-level positions.

To meet the aforementioned objectives, there are various tasks in which contractors are required to engage. Each contractor submitted a proposal including a work plan and timeline for how their

organization will complete the tasks. Each contractor has identified specific methods and partners to achieve its contractual obligations, based on their respective target community. This may include:

- Counties behavioral health departments partnering with training organizations to develop and implement a peer training program to place peers within their county.
- Community based organizations partnering with various counties in a region to provide training, job placement, mentoring and career pathway development for peer personnel.
- Training organizations collaborating with various public mental health system employers to train peers within their organization.

OSHPD requires contractors to submit quarterly progress reports that document and monitor progress towards meeting the objectives. These progress reports measure the contract's effectiveness by:

- Providing detailed information on progress made towards every contract deliverable.
- Requiring data collection via surveys to program participants such as peer personnel in field placements and employers.
- Identifying successes, challenges, and lessons learned from engaging in program activities.

In addition to progress reports, the contract specifically includes an evaluation deliverable with earmarked funds for contractors to evaluate their program and submit an annual evaluation report to OSHPD. Finally, contractors are required to present on their progress, lessons learned and evaluation to the Workforce, Education, and Training Advisory Committee.

Subcommittee Staff Comment. This is an informational item.

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

1. Please provide an overview of this issue.
2. Please provide an overview of the outcomes from the existing contracts and how these contractors are meeting the goals outlined in the Investment in Mental Health Wellness Act of 2013.

4. Oversight of 2014 Song-Brown Residency Program Funding

Oversight Issue. The 2014 budget included the following augmentations related to the Song-Brown Program:

- Song-Brown Program – New Residency Slots. Augmented OSHPD’s budget by \$4 million (California Health Data and Planning Fund) to fund new residency slots in the Song-Brown Health Care Workforce Training Program over the next three years. Adopted trailer bill language to specify criteria for this funding, including that priority shall be given to support new primary care physician slots and to physicians who have graduated from a California-based medical school.

The Request for Assistance for this program was released on January 22, 2015 and the deadline to apply for this funding is March 30, 2015. OSHPD anticipates 13 programs will apply and 26 residents would be funded. The decisions on funding are projected to be made at the April 28-29, 2015 California Healthcare Workforce Policy Commission.

- Song-Brown Program Residency Program. Approved \$2.84 million (California Health Data Planning Fund) per year for three years to expand the Song-Brown program. Adopted trailer bill language to expand the eligibility for Song-Brown residency program funding to teaching health centers and increased the number of primary care residents specializing in internal medicine, pediatrics, and obstetrics and gynecology. Approved one three-year limited-term position to develop and implement the program expansion.

The Request for Assistance for this program was released on January 22, 2015 and the deadline to apply for this funding is March 30, 2015. OSHPD anticipates 25 programs will apply and 53 residents would be funded. The decisions on funding are projected to be made at the April 28-29, 2015 California Healthcare Workforce Policy Commission.

Background. Song-Brown provides grants to support health professions training institutions that provide clinical training for family practice residents, family nurse practitioner, primary care physician assistant, and registered nurse students. Residents and trainees are required to complete training in medically underserved (Health Professional Shortage Areas, Medically Underserved Areas, Medically Underserved Populations, Primary Care Shortage Areas, and Registered Nurse Shortage Areas), underserved communities, lower socio-economic neighborhoods, and/or rural communities. According to OSHPD, Song-Brown funded programs have led practitioners to be at the forefront of curricula development and clinical care for many contemporary challenges facing California’s healthcare system such as homeless, refugee, and immigrant health. Various studies indicate that residents exposed to underserved areas during clinical training are more likely to remain in those areas after completing their training.

Subcommittee Staff Comment. This is an informational item.

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

1. Please provide an overview of this item.

0530 California Health and Human Services Agency

1. Office of Systems Integration – CalHEERS Oversight

Oversight Issue. Concerns have been raised regarding the processes by which stakeholder input is provided to the California Healthcare Eligibility, Enrollment, and Retention System (CalHEERS) project to aid decision-making, coordination, and rollout of system changes. Recently a 24-month roadmap for CalHEERS changes was released and it appears that changes to implement requirements of the Affordable Care Act (ACA) and state law regarding Medi-Cal continue to be delayed without any insight or justification for the delays provided to external stakeholders.

For example, under the ACA, former foster youth qualify for Medi-Cal coverage until age 26, regardless of their income. This law, which has been in effect since January 1, 2014, is still not programmed accurately into CalHEERS resulting in enrollment delays, enrollment in the wrong affordability program, or denial of Medi-Cal for these former foster youth. Changes necessary to correctly implement former foster youth coverage in Medi-Cal are not scheduled until February 2016. Similarly the changes to incorporate the Medi-Cal Access Program (formerly Access for Infants and Mothers-AIM) into CalHEERS are still not scheduled to be programmed into CalHEERS.

Background. The ACA requires a single, accessible, standardized paper, electronic, and telephone application process for insurance affordability programs, which require a joint application for Medi-Cal and Covered California. The joint application is required to be used by all entities authorized to make an eligibility determination for any of the insurance affordability programs. (Medi-Cal and Covered California with a premium or cost-sharing subsidy are “insurance affordability programs.”)

CalHEERS is the information technology system that is used to support this application process. The primary business objective of CalHEERS is to provide a ‘one-stop shop’ to determine eligibility for California’s health coverage programs offered by the Exchange and the Department of Health Care Services.

The CalHEERS Project is jointly sponsored by the Exchange and the Department of Health Care Services (DHCS). The CalHEERS Project has acquired Accenture, LLP as a prime vendor to develop the CalHEERS solution that will support the implementation of a statewide healthcare exchange.

The Office of Systems Integration (OSI) has been chosen by the Exchange to provide project management services during the design, development and implementation and system stabilization of the CalHEERS solution to help meet the federally mandated timelines and requirements.

CalHEERS Quality Assurance Team. OSI’s CalHEERS Quality Assurance (QA) team coordinates improvement efforts to enhance the project’s processes and protocols, including, but not limited to release management, change management, and meeting structures, in order to improve the collaboration and communication between the CalHEERS project and the project sponsors and stakeholders. To date this team has focused internally on the project stakeholders (e.g., Covered California, DHCS, county eligibility systems, County Welfare Directors Association, Department of Social Services, and the California Health and Human Services Agency).

This QA team has worked with the CalHEERS leadership team, project sponsors, and partners to identify the range of governance challenges and establish a common understanding of needs. After reviewing a variety of organization models, decision-making hierarchies, and project best practices, the OSI QA team drafted several recommendations to help improve the timeliness, collaboration, and transparency of project decision-making. The team is currently reviewing the recommendations with project stakeholders to gather feedback and establish a foundation for implementing the changes.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions on this topic. Subcommittee staff requested the list of OSI recommendations to help improve the timeliness, collaboration, and transparency of CalHEERS project decision-making and these recommendations have not yet been provided to the Subcommittee.

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

1. Please describe the governance structure of CalHEERS and OSI's role in regard to CalHEERS.
2. Please provide a high-level of OSI's recommendations in regard to CalHEERS governance and transparency of decision-making.
3. What is your understanding of the criteria that CalHEERS project sponsors use in establishing the release schedule?
4. Given that OSI's vision is to be the "trusted leader in the management and delivery of large, complex technology projects, enabling improved service delivery to the people of California," what do you think OSI's role is or should be in regard to ensuring that CalHEERS project sponsors consider and evaluate **external** stakeholder input regarding CalHEERS changes and releases?

2. Office of the Patient Advocate

Budget Issue. The Office of Patient Advocate (OPA) requests \$206,000 in 2015-16 and \$182,000 ongoing to convert one limited-term position, expiring June 30, 2015, to a permanent position, a data warehouse, and other services to implement the Complaint Data Reporting Project. The source of funding for this proposal is the Managed Care Fund (90 percent) and the Insurance Fund (10 percent).

Background. SB 857 (Committee on Budget and Fiscal Review), Chapter 31, Statutes 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, on 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.

**Table: Health Consumer Complaint Data from Consumer Assistance Call Centers
Status as of: February 20, 2015**

| Mandated Reporting Agency/ Department | Met with OPA on SB 857 Framework, Requirements, Timeline | Provide Information and Materials Associated with the Baseline Report | Provided Feedback to OPA on Standardized Data Collection Tool, Coding, and Tracking | Provided One Month of Pilot Test Data (# Complaint Records) in Prescribed Standardized Format |
|--|---|--|--|---|
| DMHC | Yes | In Process | Yes | 1,265 |
| CDI | Yes | In Process | Yes | 256 |
| DHCS | Yes | In Process | Yes | Total: 4,497 <ul style="list-style-type: none"> • Managed Care-4,001 • Fee-For-Service-319 • Dental-132 • Mental Health-27 • HIPAA-13 • Fiscal Intermediary-5 |
| Covered CA | Yes | In Process | No | 225 |

Table: Complaint Data Reporting Milestones and Timeline

| | Completed Milestones |
|---|---|
| July 2014 - February 2015 | <ol style="list-style-type: none"> 1. OPA issued the “Recommendation Report for Complaint Data Reporting.” 2. OPA held planning and development meetings with the state reporting entities. 3. OPA conducted an analysis of reporting elements. 4. OPA, in conjunction with stakeholders, used complaint codes and categories to standardize the data submissions. 5. OPA developed and issued Complaint Data Workbook. 6. Reporting entities submitted test complaint data in December and January. 7. OPA reviewed and analyzed the pilot test data and provided feedback to reporting entities. 8. OPA reached agreement with reporting entities on workbook reporting, data glossary, and data definitions. 9. OPA modified and finalized the Complaint Data Workbook. 10. OPA issued the Final Complaint Data Workbook. (2014 data) to reporting entities. |
| 2015 | Work in Progress |
| March | <ul style="list-style-type: none"> • Submission (2/20/15 – 3/6/15) by reporting entities of complaint data from calendar year 2014. • Data validation and quality assurance. • Data analysis begins. • Issuance of a supplemental survey to reporting entities to collect additional materials and information. |
| April | <ul style="list-style-type: none"> • Data analysis continues. • Submission of responses and materials (e.g., protocols, methodologies) to supplemental survey by reporting entities. • Analysis of survey submissions and preliminary findings. • Initiate report development. • Development of OPA website pages for complaint data report and data findings. |
| May | <ul style="list-style-type: none"> • Consultation with reporting entities on preliminary findings and draft report. • Quarterly Stakeholder Meetings – Status updates and input. |
| June | <ul style="list-style-type: none"> • Report review and approval. • OPA website deployment activities. |
| July | <ul style="list-style-type: none"> • Posting by 7/1/15 of Baseline Report to the OPA website. • Submission by 7/1/15 of the Complaint Data Analysis to the Legislature. |

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

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

1. Please provide an overview of this proposal and an update on Complaint Data Reporting project.

3. High Cost Drug Proposal

Budget Issue. The Governor’s budget includes funding of \$100 million General Fund in 2014-15 and \$200 million General Fund in 2015-16 to pay for new breakthrough drugs, such as those used to treat Hepatitis C. The budget does not allocate this funding to specific departments. The Governor’s budget includes these additional funds, given the uncertainty around the cost and utilization of these drugs. The individuals who may potentially be treated with the new Hepatitis C drugs include inmates in state prisons, patients in state hospitals, individuals enrolled in Medi-Cal, and individuals enrolled in the AIDS Drug Assistance Program (ADAP).

The Department of Health Care Services (DHCS), Department of Public Health (DPH), Department of State Hospitals (DSH), and the California Department of Corrections and Rehabilitation (CDCR) are already providing Hepatitis C drugs under their 2014-15 and 2015-16 budget authority. See table below for estimates of department/program funding included in the Governor’s budget.

Table: Summary of Hepatitis C Treatment Funding in Governor’s Budget

| Department/ Program | Estimated Number of Persons Receiving Treatment | | Estimated Total Cost | | Estimated General Fund | |
|------------------------|--|---------|----------------------|-----------------|------------------------|----------------|
| | 2014-15 | 2015-16 | 2014-15 | 2015-16 | 2014-15 | 2015-16 |
| DPH/ADAP | 69 | 135 | \$3.5 million | \$5.8 million | 0 | 0 |
| DHCS | 1,000 | 1,000 | \$105.7 million | \$105.7 million | \$51.1 million | \$51.1 million |
| DSH | 75 | Unknown | \$7.1 million | Unknown | \$7.1 million | Unknown |
| CDCR | NA | NA | \$10 million | \$10 million | \$10 million | \$10 million |

Note: DSH and CDCR pharmacy budgets are not specifically categorized by disease or drug. The numbers reflected above are estimates.

Budget Bill Provisional Language. The budget proposes provisional budget bill language to notify the Legislature of the expenditure of these funds as follows:

“Notwithstanding any other provision of law, items of appropriation in this act may be adjusted, as determined by the Director of Finance, to reflect changes to General Fund and Federal Trust Fund expenditures resulting from high cost medications. Adjustments authorized pursuant to this section shall be implemented upon notification to the chairpersons of the committees in each house of the Legislature that consider appropriations and the chairperson of the Joint Legislative Budget Committee.”

Workgroup. As part of this proposal, the Administration plans to convene a workgroup that will address the state's approach regarding high-cost drug utilization policies and payment structures. The workgroup will inform the state's guidelines for which individuals enrolled in state programs are eligible for treatment with the new Hepatitis C drugs, and to the extent possible, the state will try to generate a consistent set of treatment guidelines that can be implemented across state programs.

According to the Administration, the workgroup and proposal are focused on Hepatitis C treatments, but it expects that the workgroup will discuss additional medications in the future. The workgroup members are currently state departments and county representatives: the California Health and Human Services Agency, the California Public Employees Retirement System, the California State Association of Counties, the California State Sheriffs' Association, Covered California, the Department of Corrections and Rehabilitation/California Correctional Health Care Services, the Department of Finance, the Department of General Services, the Department of Health Care Services, the Department of Industrial Relations, the Department of Managed Health Care, the Department of Public Health, the Department of State Hospitals, the Department of Veterans Affairs, and the University of California.

The first workgroup meeting will be held in early March. The Administration is first coordinating with state departments and county entities and is working on a stakeholder engagement strategy. The workgroup plans to focus on key policy questions.

Marketplace Changes. Federal regulations prohibit the U.S. government from setting the price of pharmaceuticals. However, private insurance companies and government agencies are able to negotiate prices. In December 2013, the U.S. Food and Drug Administration (FDA) approved Sovaldi for the treatment of Hepatitis C. While this drug has been found to be very effective in curing Hepatitis C, a 12-week treatment costs \$84,000. In December 2014, FDA approved another Hepatitis C treatment regime called the Viekira Pack, made by AbbVie. Insurance companies now had another Hepatitis C treatment option comparable to Sovaldi, and this competition has led to deals between drug companies and insurance companies.

State Discounts for these High-Cost Drugs. DHCS had existing rebate agreements for Hepatitis C drugs Victrelis and Riba; and has recently reached agreement for supplemental rebates with the maker of Sovaldi and Harvoni.

California ADAP is a member of the ADAP Crisis Task Force (ACTF), which is a national-level negotiating body that represents all ADAPs in the country. The ACTF enters into negotiated, voluntary, confidential supplemental rebate agreements with drug manufacturers. In January 2015, the ACTF reached a new negotiated pricing agreement between pharmaceutical company AbbVie and the ADAPs for ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets (Viekira Pak™). AbbVie is the first company to offer ADAPs a negotiated discount on the price of a Hepatitis C virus medication. ADAP receives the negotiated discount in the form of supplemental drug rebate. This supplemental rebate is in addition to the federally mandated 340B rebate.

DSH does not negotiate directly with pharmaceutical companies. DSH purchases pharmaceuticals through contracts negotiated by the Department of General Services (DGS).

The Department of Corrections and Rehabilitation/California Correctional Health Care Services receives contracted pricing discounts on Hepatitis C pharmaceuticals.

LAO Findings and Recommendation. The LAO agrees with the Administration’s general approach to setting aside resources for this purpose and finds that there is considerable uncertainty associated with the actual future costs for the state. The LAO withholds recommendation on the amount of funds to be set aside to pay for the new high-cost drugs pending further information regarding the cost and projected utilization of the drugs. The LAO recommends the Legislature add additional requirements to the provisional budget language proposed by the administration in order to ensure legislative oversight of these funds.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as more details are provided. Subcommittee staff requested the list of key policy questions that this workgroup plans to consider and the Subcommittee has not yet received this information from the Administration.

Additionally, the Administration has not provided any details as to the basis for the \$300 million General Fund reserve. The Governor’s budget includes \$51.1million General Fund (with additional matching federal funds) for the Medi-Cal program’s Hepatitis C treatment costs. It is not clear why four times that amount is requested to be placed in a reserve for uncertainty.

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

1. Please provide an overview of this proposal.
2. Why does the Administration find that a special reserve of General Fund is necessary for the state program costs for Hepatitis C treatment?
3. What is the basis for the \$300 million General Fund placeholder?
4. What is the Administration’s estimate for current year expenditures related to Hepatitis C that exceed budget act authority?
5. What will be the process for the Legislature and external stakeholders to participate in this workgroup?
6. Please provide a brief review of the changing marketplace (new drugs, discounts, rebates) in regard to Hepatitis C drugs. Does the Administration’s placeholder funding include the consideration of the higher discounts that certain companies are offering in response to more drugs entering the market?
7. Why doesn’t this proposal include any investments in the prevention Hepatitis C infection, such as providing more access to testing and resources for syringe exchange programs? Please explain.

4265 Department of Public Health

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 \$3.1 billion (\$124.4 million General Fund) for the DPH as noted in the Table below and 3838 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 drinking water, 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.

The budget includes \$800.9 million for state operations and \$2.3 billion for local assistance. See tables below for more information on the proposed budget.

Table: DPH Budget Overview

| Fund Source | 2014-15 | 2014-15 | 2015-16 | BY to CY |
|--------------------------------|------------------------|------------------------|------------------------|--------------|
| | Enacted Budget | Revised | Proposed | Change |
| General Fund | \$118,121,000 | \$119,639,000 | \$124,393,000 | 5.31% |
| Federal Trust Fund | \$1,722,538,000 | \$1,742,541,000 | \$1,750,166,000 | 1.60% |
| Special Funds & Reimbursements | \$1,178,230,000 | \$1,106,174,000 | \$1,239,329,000 | 5.19% |
| Total Expenditures | \$3,018,889,000 | \$2,968,354,000 | \$3,113,888,000 | 3.15% |
| | | | | |
| Positions | 3795.7 | 3795.7 | 3838.1 | 1.12% |

Table: DPH Program Funding Summary

| Program | 2013-14 Actual | 2014-15 Projected | 2015-16 Proposed |
|---|---------------------------|------------------------------|-----------------------------|
| Public Health Emergency Preparedness | \$85,207,000 | \$98,188,000 | \$98,335,000 |
| Chronic Disease Prevention and Health Promotion | 265,305,000 | 303,433,000 | 344,851,000 |
| Infectious Diseases | 578,237,000 | 572,688,000 | 603,412,000 |
| Family Health | 1,549,830,000 | 1,640,859,000 | 1,674,457,000 |
| Health Statistics and Informatics | 25,879,000 | 27,434,000 | 27,666,000 |
| County Health Services | 14,627,000 | 15,638,000 | 15,112,000 |
| Environmental Health | 312,548,000 | 87,421,000 | 90,822,000 |
| Licensing and Certification | 174,856,000 | 209,322,000 | 241,449,000 |
| Laboratory Field Services | 10,499,000 | 13,372,000 | 13,452,000 |
| Administration | 32,678,000 | 34,742,000 | 35,979,000 |
| Distributed Administration | -32,679,000 | -34,743,000 | -35,980,000 |
| Total Expenditures (All Programs) | \$3,016,987,000 | \$2,968,354,000 | \$3,109,555,000 |

State Auditor – DPH High-Risk Agency. On March 3, 2015, the State Auditor notified the Legislature that DPH remains a high-risk agency due to weakness in program administration and because it has been slow to implement recommendations, especially those that have a direct impact on public health and safety. DPH noted that most of the department’s outstanding recommendations involve either licensing or laboratory field services, which represent only two of the over 200 programs at DPH, and that the challenges found within these areas are not indicative of the department as a whole.

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.
2. What is DPH’s response to the State Auditor’s notification that DPH remains a high-risk agency? What is DPH doing to address these recommendations?

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| 2. Office of AIDS (OA): AIDS Drug Assistance Program (ADAP) Update |
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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.

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

| Fund Source | 2014-15 Budget Act | 2014-15 Revised | 2015-16 Proposed |
|--|-------------------------------|----------------------------|-----------------------------|
| General Fund | \$0 | \$0 | \$0 |
| AIDS Drug Rebate Fund | \$278.6 | \$247.5 | \$288.6 |
| Federal Funds – Ryan White | \$107.8 | \$131.2 | \$108.1 |
| Reimbursements from Medicaid Waiver (Safety Net Care Pool Funds) | \$53.6 | \$6.2 | \$18.2 |
| Total | \$440.0 | \$384.9 | \$415.0 |

Table: Estimated ADAP Clients by Coverage Group for Medication Expenditures

| Coverage Group | 2014-15 | | 2015-16 | |
|-----------------------|----------------|----------------|----------------|----------------|
| | Clients | Percent | Clients | Percent |
| ADAP-only | 15,275 | 45.2% | 15,500 | 44.5% |
| Medi-Cal | 606 | 1.8% | 581 | 1.7% |
| Private Insurance | 8,878 | 26.0% | 9,591 | 27.6% |
| Medicare | 9,123 | 27.0% | 9,123 | 26.2% |
| Total | 33,791 | 100% | 34,795 | 100% |

Table: Estimated ADAP Clients by Coverage Group for Insurance Assistance Programs

| Coverage Group | 2014-15 | | 2015-16 | |
|-----------------------------|--------------|-------------|--------------|-------------|
| | Clients | Percent | Clients | Percent |
| OA - HIPP | 1,288 | 32.9% | 1,097 | 21.8% |
| OA- HIPP Covered California | 1,826 | 46.7% | 3,104 | 61.8% |
| OA – Medicare Part D | 797 | 20.4% | 821 | 15.6% |
| Total | 3,911 | 100% | 5,021 | 100% |

Current Year Changes. Compared to the 2014 Budget Act, estimated expenditures for current year have declined by 12.5 percent. This decline is due to the following factors:

- Covered California – A larger number of clients enrolled in Covered California during 2013-14 (913 clients) than was initially predicted.
- Medi-Cal Expansion – A larger number of clients are transitioning to Medi-Cal than was initially estimated.
- Hepatitis C – Fewer clients are predicted to access hepatitis C virus treatment than was initially estimated.

Budget Year Changes. Compared to the 2014 Budget Act, OA estimates that expenditures during 2015-16 will decline by 5.7 percent, but increase compared to the revised current year projection. This increase is due to new clients enrolling in ADAP. Covered California and Medi-Cal expansion had and will continue to have substantial impacts on the number and type of clients receiving ADAP services in 2014-15 as clients transition out of ADAP or to a different client group within ADAP. However, as these programs will be fully implemented at the end of 2014-15, OA expects that the number of clients leaving or changing client groups will stabilize and that client caseloads will again increase due to persons being newly diagnosed with HIV. Additionally, ADAP assumes the loss of Safety Net Care Pool Funds with the expiration of the current 1115 Medicaid Waiver. (These funds carried less restrictions than the use of Ryan White federal funds.)

ADAP Eligibility and Current Cost-Sharing. Individuals are eligible for ADAP if they:

- Reside in California;
- Are HIV-infected;
- Are 18 years of age or older;
- Have an adjusted federal income that *does not exceed* \$50,000;
- Have a valid prescription from a licensed Californian physician; and,
- Lack private insurance that covers the medications or do not qualify for no-cost Medi-Cal.

The ADAP is the *payer of last resort*. Individuals who have private health insurance, are eligible for Medi-Cal, or are eligible for Medicare, must access these services *first*, before the ADAP will provide services.

ADAP clients with incomes between \$45,961 (over 400 percent of poverty) and \$50,000 are charged monthly co-pays for their drug coverage which is established annually at the time of enrollment or recertification.

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). Generally, for every dollar of ADAP drug expenditure, the program obtains 70 cents in rebates. This 70 percent level is based on an average of rebate collections (both “mandatory” and “supplemental” rebates).

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 2014 federal Ryan White Part B grant year (04/01/2014-03/31/2015) is \$65,162,316. California’s match requirement will be met using DPH OA General Fund Support expenditures (\$3.62 million) and local assistance expenditures for OA’s HIV Surveillance (\$6.65 million) and Prevention (\$2.85 million) programs, as well as HIV-related expenditures from the California Department of Corrections and Rehabilitation (up to \$56.72 million) for a total of \$69.84 million.

Payment of Out-of-Pocket Medical Costs through OA-HIPP. As part of the 2014 budget, the Legislature adopted trailer bill language that allow OA-HIPP to pay for out-of-pocket medical expenses. OA anticipates this to begin January 2016. OA estimates that 711 additional clients will enroll in OA-HIPP Covered California due to this policy.

2014 Budget Act Augmentation – HIV Prevention Demonstration Projects. The 2014 Budget Act included an ongoing \$3 million General Fund augmentation for HIV Demonstration Projects.

ADAP Enrollment Workers. The budget includes \$2 million (rebate and federal funds) to local health jurisdictions for the costs associated with the administration of ADAP enrollment. These funds are allocated based on the proportion of ADAP clients the local health jurisdiction enrolled during the prior year. Local health jurisdictions may distribute the funds to ADAP enrollment sites, use the funds to support the local ADAP coordinator function, or spend the funds on equipment/supplies necessary for ADAP enrollment. These funds are fixed and do not change based on enrollment numbers.

These enrollment workers help ADAP clients navigate the various health affordability and coverage programs, such as Covered California and OA’s Insurance Assistance Programs (e.g., OA-HIPP).

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 \$3 million General Fund augmentation in the 2014 Budget Act (and ongoing) for HIV Demonstration Projects.

4. Please provide an update on the implementation of last year's trailer bill language to pay out-of-pocket medical costs through OA-HIPP.
5. Given the projected increases in ADAP enrollment and the increasing complexity of health affordability and coverage programs, how has OA considered the impact on ADAP enrollment workers and state support for these processes?

3. OA: ADAP Client Eligibility Verification Resources

Budget Issue. DPH requests \$536,000 in expenditure authority from the AIDS Drug Assistance Program Rebate Fund and five positions to manage the increase in client eligibility verification workload within the AIDS Drug Assistance Program (ADAP). These positions are needed to ensure program integrity and to comply with federal Health Resources and Services Administration (HRSA) client eligibility verification requirements.

Background. Statewide, local enrollment sites employ ADAP enrollment workers who are trained on proper client enrollment policies and procedures. Enrollment workers maintain secure paper-based client files at their respective local ADAP enrollment sites and enroll eligible clients electronically via ADAP's Pharmacy Benefits Manager, which provides centralized Pharmacy Benefits Manager services to ensure qualified ADAP clients receive direct prescription medication services from approximately 4,000 pharmacies in the California ADAP network.

ADAP state staff conduct periodic site visits to monitor ADAP's 175 local enrollment sites and review a small sample of client file documents to verify local enrollment workers are making proper client eligibility determinations. In addition, ADAP staff also provides technical assistance to local health jurisdictions and perform other tasks to administer the program and ensure eligible clients have access to their medications.

In November 2013, HRSA conducted a comprehensive site visit of DPH HRSA-funded Ryan White Part B Care Programs. HRSA reported the following findings:

1. "ADAP eligibility determination and ultimate approval rests solely on individual enrollment workers at local sites throughout the state. Documentation is not reviewed by another individual (local or state), leading to the potential for fraud and abuse of the system."
2. HRSA recommended that the Office of AIDS develop a centralized electronic system with uploading capability that will allow a secondary review of all ADAP client applications within CPH.

To address these issues, DPH amended the ADAP Pharmacy Benefits Manager contract to grant both DPH ADAP staff and ADAP local site enrollment workers the ability to add, store, view, and delete scanned ADAP client eligibility documents. This change meets the HRSA recommendation for a centralized electronic system, and once implemented, will reduce the amount of time it takes for DPH to ensure that client supporting documentation is consistent with eligibility criteria and will address the risk of potential program fraud or abuse.

By federal statute, HRSA funds may not be used for any item or service "for which payment has been made or can reasonably be expected to be made" by another payment source (Sections 2605(a)(6), 2617(b)(7)(F), 2664(f)(1) and 2671(i) of the federal Public Health Service Act). The statute requires grantees to verify client eligibility, and a HRSA policy notice released in 2013-14 clarified that client re-certifications must:

- At least once a year, verify that individual residency, income, and insurance status continues to meet the eligibility requirements, and verify that HRSA is the payer of last resort; and
- A second process at least once a year must include the collection of more in-depth supporting documentation similar to that collected at the initial eligibility determination.

According to DPH, the current staffing levels in ADAP are inadequate to review all projected 34,795 client files for 2015-16, resulting in ADAP continuing to be noncompliant with HRSA policies. Streamlining and making the verification process more efficient for review electronically at the state level does not solve the need for additional ADAP staff because ADAP staff are required to verify eligibility of all clients upon initial enrollment and upon annual recertification based on their month of birth. Under the new electronic system, in 2015-16 the Office of AIDS estimates it will take staff an average of 30 minutes per file to review ADAP client eligibility. For 2015-16, the Office of AIDS plans to reassign ADAP Branch staff (11 full-time equivalent) to perform this task; these staff are capable of reviewing 24,403 ADAP client files to verify eligibility. Additional staff could review another 10,392 client files; this would allow the Office of AIDS to become compliant with HRSA for 34,795 ADAP client files in FY 2015-16. Failure to comply with HRSA's site visit finding could result in future audit findings and potentially result in the loss of HRSA federal funds (\$167.2 million in FY 2014-15). A loss of HRSA federal funds would result in negative service impacts to clients.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions continue on this proposal.

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

1. Please provide an overview of this proposal.

4. OA: ADAP – Modernization

Issue. The Subcommittee is in receipt of proposals to expand eligibility for the AIDS Drug Assistance Program (ADAP) medication program and the ADAP insurance assistance programs--the OA-Health Insurance Premium Payment (HIPP) program. These proposals, which may result in program savings in out years because of the current drug rebate return, and include:

- a. Update Family Size - Financial eligibility for OA-HIPP and ADAP are the same. Currently the programs serve individuals with incomes up to \$50,000 annually based on federal adjusted gross income (FAGI) with no regard for family size. The result is that a single individual is treated the same as a person with dependents. Historically, ADAP served primarily single men with no dependents. Changes in the epidemic, changes in marriage and family rights for the LBGT community as well as new insurance coverage opportunities through the Affordable Care Act (ACA) make it important to consider the programs' eligibility standards regarding family size.
- b. Increase Income Limit - Another issue for consideration is increasing 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. Currently five other high income states operate programs with this income eligibility, including Maine, Maryland, Massachusetts, New Jersey and the District of Columbia.

This is not a proposal from the Administration.

Technical Assistance from DPH. Subcommittee staff requested technical assistance from DPH regarding the fiscal impact of this proposal. According to DPH, its preliminary estimate suggests that this proposal, if implemented, would cost roughly \$5-6 million in 2015-16, but would result in savings in subsequent years. The cost to ADAP would be higher in the first year of the program change than would be expected in subsequent years, assuming ADAP's current drug rebate return rates, because of the standard six month delay in receiving rebate after expenditures. This estimate includes costs/savings for both the ADAP medication program and the ADAP insurance assistance programs (OA-HIPP).

DPH OA estimates initial first year costs of \$5.5 million in 2015-16 as result of increasing the ADAP income eligibility limit to 500% FPL based on modified adjusted gross income (MAGI) and the six-month delay in rebate collections. See table on next page. ADAP would utilize available rebate funds and federal funds to cover these additional program expenditures. The federal Health Resources and Services Administration (HRSA) requires that any available 340B mandatory rebate funds be used before federal funds at the time each invoice is paid, so OA cannot predict exactly which portion will be covered by rebate versus federal funds.

Table: OA’s Estimated Impact for 2015-16

| 500% FPL INCOME ELIGIBILITY FOR ADAP*, 2015-16 | | | | | |
|---|-----------------------|---------------------|----------------------------|------------------------|--------------------|
| | Coverage Group | | | | |
| Line Item | ADAP Only | Medi-Cal SOC | Private Insurance** | Medicare Part D | Total |
| Premium Expenditures | \$0 | \$0 | \$1,959,935 | \$11,107 | \$1,971,042 |
| Medical OOP Expenditures | \$0 | \$0 | \$19,822 | \$0 | \$19,822 |
| Drug Expenditures | \$7,945,636 | \$193,813 | \$2,870,589 | \$521,073 | \$11,531,110 |
| Rebate received in 2015-16 | \$1,555,657 | \$0 | \$5,419,521 | \$1,007,624 | \$7,982,802 |
| Net Expenditures | \$6,389,979 | \$193,813 | -\$569,175 | -\$475,444 | \$5,539,173 |
| Clients | 363 | 26 | 1,066 | 172 | 1,626 |

*Includes both the ADAP medication program and the ADAP insurance assistance programs.

** Includes all ADAP Private Insurance clients who may or may not be co-enrolled in OA-HIPP.

After the initial first year costs, rebate would consist of a full year of rebate revenues, and the proposal would result in annual program savings of about \$2.4 million, assuming our current rebate return rates. See table below.

Table: OA’s Estimated Impact for Out Years.

| 500% FPL INCOME ELIGIBILITY FOR ADAP*, FUTURE YEARS | | | | | |
|--|-----------------------|---------------------|----------------------------|------------------------|---------------------|
| | Coverage Group | | | | |
| Line Item | ADAP Only | Medi-Cal SOC | Private Insurance** | Medicare Part D | Total |
| Premium Expenditures | \$0.00 | \$0.00 | \$1,959,935 | \$11,107 | \$1,971,042 |
| Medical OOP Expenditures | \$0.00 | \$0.00 | \$19,822 | \$0.00 | \$19,822 |
| Drug Expenditures | \$7,945,636 | \$193,813 | \$2,870,589 | \$521,073 | \$11,531,110 |
| Projected Full Year of Rebate | \$3,111,315 | \$0 | \$10,839,042 | \$2,015,248 | \$15,965,604 |
| Net Expenditures | \$4,834,321 | \$193,813 | -\$5,988,696 | -\$1,483,068 | -\$2,443,629 |
| Clients | 363 | 26 | 1,066 | 172 | 1,626 |

*Includes both the ADAP medication program and the ADAP insurance assistance programs.

** Includes all ADAP Private insurance clients who may or may not be co-enrolled in OA-HIPP.

DPH OA estimates 1,626 new clients will enroll in ADAP as result of increasing the ADAP income eligibility limit to 500% FPL based on MAGI. Of these new ADAP clients, OA estimates that 425 will also co-enroll in ADAP's insurance assistance programs.

At this time, OA is unable to determine the number of enrollees that would lose coverage based on the change in income eligibility because ADAP recently began collecting household income and OA does not have a full fiscal year of data to provide an estimate. The only clients who would lose coverage would be clients who are married or in a domestic partnership with a substantially higher income earning spouse/partner. This would include, for example, a client earning \$30,000 annually with a spouse who earns \$60,000 annually in which the couple has no children. Their annual household income is \$90,000, which is above 500% FPL for a household of two. OA assumes that the number of clients who would lose coverage would be small and have assumed it to be zero in the above estimate.

Currently, the ADAP enrollment application process asks for family size and household income but the Pharmacy Benefits Manager (PBM) electronic application system would need to be updated to capture MAGI. OA would work with the PBM to make the necessary changes and conduct training for enrollment workers on the new updates. One-time costs, which would be subject to negotiation with the PBM, may be needed to implement the system change.

According to DPH, to the extent that reserves are sufficient to cover the additional program expansion, this policy change would not impact the General Fund in 2015-16. ADAP would utilize available rebate funds and federal funds for additional program expenditures in 2015-16 if this policy change were implemented. The Fund Condition Statement reflects a sufficient Special Fund reserve of \$11.6 million in 2015-16. Beyond the budget year, OA estimates this proposal will result in savings since estimated rebate from the first full year of implementation, received in the second full year of implementation, will exceed estimated expenditures in the second full year of implementation. This assumes the rebate percentage return rate remains steady. Any change to the rebate return rate will impact our estimate.

If ADAP expands access to the new hepatitis C virus (HCV) medications to include all ADAP clients co-infected with HCV regardless of liver disease stage and ADAP realizes a significant increase in utilization of HCV medications, this could put pressure on rebate funds and federal funds.

Subcommittee Staff Comment and Recommendation—Hold Open. Modernizing ADAP could reduce ADAP expenditures while providing benefits to more people living with HIV/AIDS.

It is recommended to hold this item open as discussions continue on this proposal.

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

1. Please provide an overview of this issue and DPH's technical assistance.

5. Infant Botulism Treatment Program: Production Lot 6

Budget Issue. DPH requests a one-time increase in expenditure authority of \$2 million Infant Botulism Treatment and Prevention Fund in 2015-16 for the Infant Botulism Treatment and Prevention Program (IBTPP) to address the manufacturing costs for the current lot production of BabyBIG®.

Due to the collection of additional blood plasma from out of state donors to ensure an adequate supply of BabyBIG®, several manufacturing steps in the current lot 6 production cycle will be moved to 2015-16. These manufacturing processes are a key component to sustain the statutorily-mandated production, distribution, regulatory compliance, and other activities for DPH's public service orphan drug BabyBIG® (Human Botulism Immune Globulin).

Background. BabyBIG® is used for the treatment of infant botulism. The use of BabyBIG® shortens the average hospital stay from six weeks to two weeks and reduces hospital costs by \$103,000 per patient (2012 dollars). Since licensure of BabyBIG® in October 2003 by the federal Food and Drug Administration (FDA), more than 1,000 patients nationwide have been treated; thereby avoiding more than 70 years of patient hospital stays and more than \$100 million of hospital costs (2012 dollars). Use of BabyBIG® in California saves Medi-Cal approximately \$2.1 million per year, and results in cost avoidance savings to California hospitals of approximately \$4 million annually, and approximately \$11 million nationwide annually. Estimates of hospital cost savings were derived from the statewide clinical trial conducted from 1992 through 1997 and adjusted for current dollars (based on the federal Bureau of Labor Statistics, medical costs inflation). DPH is the only source of BabyBIG® in the world.

A \$45,300 fee is collected for BabyBIG® from hospitals and insurance companies and is deposited in the Infant Botulism Treatment and Prevention Fund, a special fund used for the mandated activities per Health and Safety Code Section 123704 which includes producing and distributing BabyBIG® to patients needing this treatment. The Infant Botulism Treatment and Prevention Fund is projected to have a fund balance reserve in excess of approximately \$7.4 million at the end of 2014-15.

A 2014-15 budget change request was approved that increased the appropriation authority by \$3 million in 2014-15 and \$951,000 in 2015-16 to address the increased costs due to new requirements from the FDA that increased costs for production. The prior budget request did not cover costs necessary to obtain the out of state blood plasma collection since the entirety of those costs was not known at the time.

Due to the higher usage level of BabyBIG® in the past 2-3 years, there is a need to increase the supply of BabyBIG® to treat more patients. Using more donors will ensure a sufficient supply is manufactured for the current lot 6 production to meet the public health need. The cost to obtain the blood plasma from out of state donors is anticipated to be \$2.25 million with \$1.77 million incurred in 2014-15 and \$480,000 in 2015-16. An inadequate supply from in-state donors has led to the necessity of the collection of blood plasma from donors in other states. This will shift several production steps originally anticipated to be completed in 2014-15 to now begin in 2015-16. These steps include the FDA regulatory assessment and evaluation, preparing and submitting chemistry, adhering to manufacturing and controls, vaccine stability testing, and qualification testing. Expansion of out of state blood plasma collection activities, including increased regulatory costs occurring in 2014-15, were not included in the

2014-15 BCP ID-01 since the entirety of those costs was not known at that time. These production activities require an additional \$2 million expenditure authority for 2015-16, the final Lot 6 production year.

Subcommittee Staff Comment and Recommendation—Approve. No issues have been raised regarding this proposal. It is recommended to approve this item to ensure that this program continues to provide life-saving medicine, support and diagnostic and other services for infants with botulism.

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

1. Please provide an overview of this issue.

6. Oversight of Licensing and Certification Program

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

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

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

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

Long-Standing Problems with L&C. There have been long-standing concerns about the L&C program. Multiple recent legislative oversight hearings, 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.

These issues include:

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

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

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

- **Insufficient Oversight of Los Angeles County Contract.** As discussed earlier, L&C contracts with Los Angeles County to license and certify health facilities in Los Angeles County. As revealed in March 2014, facing a backlog of hundreds of health and safety complaints about nursing homes, Los Angeles County public health officials told inspectors to close cases without fully investigating them. According to an April 21, 2014 letter from the federal CMS, the state was in jeopardy of losing federal funding if certain performance and management benchmarks regarding the L&C's investigation of complaints and L&C's oversight of the Los Angeles contract and are not met. (Ultimately, \$251,515 in federal funding was withheld.)
- **State Auditor Concerns with L&C.** In October 2014, the State Auditor released a report regarding the L&C program. The findings from this report include:
 - DPH's oversight of complaints processing is inadequate and has contributed to the large number of open complaints and entity reported incidents. For example, the Auditor found more than 11,000 complaints and entity-reported incidents open for an average of nearly a year.
 - DPH does not have accurate data about the status of investigations into complaints against individuals.
 - DPH has not established formal policies and procedures for ensuring prompt completion of investigations of complaints related to facilities or to the individuals it certifies.
 - DPH did not consistently meet certain time frames for initiating complaints and ERIs.
- **Unable to Understand Workload and Staffing Needs.** During the 2014-15 budget subcommittee process, the Administration admitted its current methodology to assess workload demands and needs was flawed and that it had no proposals to increase staffing related to its workload for health facilities. As an example of the unreliability of the methodology, it estimated that it would need 70 less staff, while the prior year's estimate indicated that L&C needed 122 more staff.

In the past, there has been a reluctance to add L&C positions because, in addition to the flawed methodology, it has been difficult to fill Health Facility Evaluator Nurses (HFEN) positions and; consequently, these classifications had a high vacancy rate. (HFENs are registered nurses who conduct health facility surveys and respond to complaints.)

- **Credit to Health Facilities Instead of Investing in Workforce.** For each of the last two years, L&C credited health facilities with over \$11 million from the special fund reserve instead of using these funds to address the problems with this program. Although L&C fees are to be used

to support the work associated with enforcing state laws and requirements, DPH was resistant to using this resource to hire more staff to improve its oversight of health facilities.

2014-15 Budget. During last year's budget subcommittee process, DPH indicated that it understood these concerns and was in the process of conducting a complete evaluation of its program. Prior to the completion of this evaluation, the Administration was not receptive to any additional resources to improve its health facility-licensing program.

Consequently, in an effort to provide transparency and accountability of the L&C program, the Legislature adopted trailer bill language¹ that required L&C to:

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

See the following website for the publication of this data:

<http://www.cdph.ca.gov/programs/Pages/CHCQPerformanceMetrics.aspx>

The 2014 budget also included (1) one-time funding of \$1.4 million from the Internal Departmental Quality Improvement Account to conduct business process improvement projects for its Central Applications Unit and Professional Certification Branch and contract for a project manager and consultant to facilitate and coordinate the multi-year implementation of the Hubbert System Assessment recommendations and (2) 18 two-year limited-term positions and \$1,951,000 (Licensing & Certification Special Fund) to support timely investigations of allegations/complaints filed against certified nurse assistants (CNAs), home health aides (HHAs), and certified hemodialysis technicians (CHTs).

In response to CMS' concerns, highlighted above, L&C contracted with Hubbert System Consulting for an organizational assessment of its effectiveness and performance. This assessment includes 21 recommendations for program improvement.

¹ SB 857 (Committee on Budget and Fiscal Review), Chapter 31, Statutes of 2014

Budget Proposal. The Governor’s budget includes the following requests related to the L&C program:

- **L&C Workload** - An increase of \$19.8 million in 2015-16 for 173 permanent positions and 64 two-year, limited-term positions, for a total of 237 positions (123 positions will become 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. This request attempts to address the L&C’s past failures to complete its survey workload and close/complete complaint investigations. The additional staffing would be used to:
 - Reduce the number of open complaints and entity-reported incidents;
 - Decrease the average number of days to close complaint and entity-reported incident investigations;
 - Increase the percent of immediate jeopardy complaint and entity-reported incident investigations that investigated within 24 hours (those constituting an immediate jeopardy to the health or safety of a patient).
- **L&C Quality Improvement Projects** – An increase of \$2 million in 2015-16 from the Internal Departmental Quality Improvement Account to implement quality improvement projects recommended by Hubbert Systems Consulting for the Licensing and Certification Program.
- **Los Angeles County Contract** - An increase in expenditure authority of \$9.5 million from the L&C Special Fund to augment the Los Angeles County contract to perform licensing and certification activities in Los Angeles County. This proposal includes \$2.6 million to fully fund the current contract positions at current Los Angeles County salary rates, and \$6.9 million to fund 32 additional Los Angeles County positions to enable the county to address long-term care facility complaints and entity-reported incidents, and investigate aging long-term care complaints and entity-reported incidents (Tier 1 and Tier 2 federal workload²).

For the past 30 years, DPH has contracted with Los Angeles County to provide federal certification and state licensing surveys and investigate complaints and entity reported incidents for approximately 2,500 health facilities in Los Angeles County. In July 2012, the contract was renewed for a three year period with an annual budget of \$26.9 million to fund 178 positions. However, due to a salary increase negotiated by Los Angeles County nurses, the current budget only funds 151 of the authorized positions. L&C used its state staffing model to assess Los

² Tier 1 workload includes federal recertification and life safety code surveys for skilled nursing facilities and intermediate care facilities for individuals with intellectual disabilities, recertification surveys for home health agencies, all complaints and entity-reported incident investigations prioritized as having a potential for immediate jeopardy, and sample validation and complaint validation surveys for general acute care hospitals, home health agencies, hospices, and ambulatory surgery centers. Tier 2 workload includes federal targeted recertification surveys for end stage renal dialysis clinics, hospices, rehabilitation clinics, ambulatory surgery centers, rural health clinics, transplant centers, and outpatient physical therapy providers and long-term care complaints and entity-reported incident investigations prioritized as non-immediate jeopardy, high and lower.

Angeles County's long-term care and non-long term care workload. L&C determined that to complete state licensing and federal certification activities, and investigate aging complaints and entity-reported incidents, Los Angeles County would require approximately \$41.3 million and 281 positions. This proposal focuses on a portion of the total assessed workload. Once Los Angeles County has hired and trained the additional positions requested in this proposal, L&C may request additional resources for Los Angeles County to complete additional workload. This incremental approach gives Los Angeles County time for recruitment and training. It takes 12-14 months for a newly hired nurse surveyor to complete all required training and become proficient.

L&C's review determined that 32 additional positions and \$6.9 million in additional funds are necessary to meet required responsibilities within reasonable timelines for completing Tier 1 and Tier 2 federal workload, including investigating long-term care complaints, and aging long-term care complaints and entity-reported incidents. In 2015-16 costs for the requested additional positions and to fully fund all current contracted positions salaries is \$9.5 million. The state has recently entered into contract negotiations with Los Angeles County regarding the renewal of this contract, which expires June 30, 2015.

- **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.

In addition, the Governor’s budget includes the following estimates in regard to L&C accounts:

| Account/Fund | Purpose | 2015-16 Budget (in thousands) | |
|---|---|-------------------------------|-----------------|
| State Health Facilities Citation Penalties Account | Used primarily to pay for temporary managers and/or receivers for SNFs. Funds (\$1.2 million) from this account are also used to support the Department of Aging’s Long Term Care Ombudsman programs. | | |
| | | Beginning Balance | \$11,272 |
| | | Revenues | \$2,661 |
| | | Expenditures | \$3,337 |
| | | Fund Balance | \$10,596 |
| Federal Health Facilities Citations Penalties Account | Used to fund innovative facility grants to improve the quality of care and quality of life for residents of SNFs or to fund innovative efforts to increase employee recruitment or retention subject to federal approval. | | |
| | | Beginning Balance | \$3,880 |
| | | Revenues | \$1,002 |
| | | Expenditures | \$937 |
| | | Fund Balance | \$3,909 |
| Internal Departmental Quality Improvement Account | Used to fund internal L&C program improvement efforts. Funded by administrative penalties on hospitals. | | |
| | | Beginning Balance | \$14,654 |
| | | Revenues | \$3,892 |
| | | Expenditures | \$2,292 |
| | | Fund Balance | \$16,254 |

Nurse Surveyor Vacancy Rates. According to a December 2014 report, the HFEN vacancy rate varies from 2.5 percent to 16.67 percent in the different field offices, with an average vacancy rate of about 7.2 percent.

LAO Findings and Recommendations. The LAO recommends approval of the proposals regarding Los Angeles County Contract Monitoring and L&C Quality Improvement Projects. The LAO withholds recommendation on the proposals regarding the Los Angeles County Contract and L&C Workload pending receipt of information on the ability of using professional position classifications other than Health Facility Evaluator Nurses (HFENs) to perform licensing and certification survey or complaint workload. Additionally, the LAO recommends the Legislature require the department to incorporate meaningful performance measures and benchmarks into the Los Angeles County contract and impose withholds of funding if the county fails to achieve these measures. The LAO further recommends that the contract, up for renewal in July 2015, be renewed for a one-year period in order to allow for annual adjustments to the performance measures and benchmarks. The LAO believes this approach to structuring the Los Angeles County contract will improve the county’s accountability to the state and incentivize improvements in quality, efficiency and effectiveness.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions continue on these proposals. While the Governor’s budget represents an acknowledgement by the Administration of the long-standing problems at L&C and makes an attempt to address the inconsistent and untimely enforcement of federal and state laws regarding health facilities licensure and certification, the following issues should be considered.

- **First Step, But Temporary Nature of Staffing Proposal Does Not Address Ongoing Workload.** As discussed above, the budget proposes an additional 237 positions, of which 64 would be limited-term, to address the outstanding and ongoing workload of the L&C program. Of these limited-term positions, 42 are HFENs (nurse surveyors) and seven are HFEN supervisors—the positions for which the L&C program has had the most difficult time hiring and retaining (both of these positions are registered nurses).

The state makes a significant investment in the training of HFENs and acknowledges that it takes 12 to 14 months for HFEN to complete the training necessary to become proficient and work independently. Consequently, these positions would only be available to actively complete workload for one year, since these positions are authorized for only two years. Given that L&C's problem is not just closing a backlog of complaints, but also timely investigation and completion of new complaints and surveys and monitoring for compliance with state health facility licensing requirements (which are generally more stringent than the federal requirements), it is not clear why these positions should be limited-term. Instead, once the backlog is addressed, these trained and skilled surveyors could be directed to address other workload activities that are not the focus of this Governor's proposal.

- **Continued Oversight on Overall Plan to Improve the Program.** As discussed above, a complete assessment of the L&C program was completed in August 2014. This assessment includes 21 recommendations to allow for meaningful and measurable improvements in the program. It will be important for the Legislature to continue its oversight of the L&C program and ensure that DPH is accountable for taking the steps necessary to accomplish this major program improvement effort.
- **Stronger State Oversight of Los Angeles County Contract.** The state's contract with Los Angeles County expires June 30, 2015. DPH anticipates that contract negotiations with Los Angeles County will begin in February. As noted above, the budget proposes three positions to provide on-site monitoring of the Los Angeles County contract and an increase of \$9.5 million to augment the Los Angeles County contract (\$2.6 million to fully fund the current contract positions at current Los Angeles County salary rates, and \$6.9 million to fund 32 additional Los Angeles County positions). It will be important for DPH to ensure that this new contract contains clear and specific performance metrics to ensure that Los Angeles County appropriately performs this workload on behalf of the state. Additionally, this new contract should include protections for the state if Los Angeles County does not meet these performance metrics.
- **Los Angeles County Contract Being Negotiated.** As discussed above, the state has recently entered into contract negotiation discussions with Los Angeles County regarding the renewal of this contract. Los Angeles County has raised concerns that the Governor's proposal does not sufficiently fund the workload as it does not take into consideration the county's salary rate, employee benefits, indirect costs, or county productive work hour formula, nor does it reflect the appropriate ratios of supervisor, support, or medical consultant positions. DPH indicates it is aware of these concerns and is taking Los Angeles County's concerns under advisement as it continues negotiations. Consequently, there is potential that the funding level reflected in the Governor's budget for this contract could change pursuant to the negotiation.

- **Significant Fund Balances Could Be Used for Long-Term Care Ombudsman Program.** Currently \$1.2 million from the State Health Facility Citation Penalties Account is used to support the Department of Aging’s Long-Term Care Ombudsman Program. The Long-Term Care Ombudsman Program investigates elder abuse complaints in long-term care facilities, including skilled nursing facilities (SNFs) which are regulated by L&C.

While no data exist to prove or quantify this, it is reasonable to assume that the ombudsman program’s presence and advocacy on behalf of SNF residents improves quality of life for these residents and improves a SNF’s compliance with state and federal laws. This is because the ombudsman is often able to intervene on behalf of a resident and investigate and resolve complaints before they result in more serious and costly cases of abuse and neglect.

Consequently, in an effort to address L&C problems from another perspective, the Legislature may want to consider using L&C special funds to augment the Long-Term Care Ombudsman Program in regard to its work on facilities regulated by L&C. As noted above, there is a \$10.6 million fund balance in the State Health Facilities Citation Penalties Account and a \$16.2 million fund balance in the Internal Departmental Quality Improvement Account. A modest investment (\$1 to \$2 million) from one or both of these funds could fund significant efforts to protect the residents of these facilities.

Statute requires any funds greater than \$10 million in the State Health Facilities Citation Penalties Account be reverted to the General Fund. In 2012-13, 2013-14, 2014-15 (projected), and 2015-16 (projected), the fund balance of this account was greater than \$10 million and; consequently, state penalties were deposited into the General Fund.

- **Outstanding Report Will Provide Valuable Information.** A 2014 trailer bill, SB 857 (Committee on Budget and Fiscal Review), Chapter 31, Statutes of 2014, requires DPH to assess the possibilities of using professional position classifications other than Health Facility Evaluator Nurses (HFENs) to perform licensing and certification survey or complaint workload by December 1, 2014. Given the difficulty in recruiting and retaining nurse surveyors it is important to understand if certain activities performed during surveys and inspections can be carried out by other personnel classifications; thereby, improving L&C’s ability to retain quality staff and complete its workload in a timely manner. The Legislature has not yet received this report, which is critical in the evaluation of the L&C budget.

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

1. Please provide a brief summary of the L&C budget estimate and the major changes to the L&C budgeting methodology. Why is the department more confident that this revised methodology will provide a more accurate estimate of workload?
2. Please provide an overview of the budget proposals. How do these proposals address the findings in the State Auditor’s report and the CMS letters? Specifically, how do they address the following concerns:
 - a. DPH’s oversight of complaints processing is inadequate and has contributed to the large number of open complaints and entity reported incidents.

- b.* DPH does not have accurate data about the status of investigations into complaints against individuals.
 - c.* DPH has not established formal policies and procedures for ensuring prompt completion of investigations of complaints related to facilities or to the individuals it certifies.
 - d.* DPH did not consistently meet certain time frames for initiating complaints and ERIs.
 - e.* DPH's inadequate oversight of district offices to ensure adequate staffing and that investigation of complaints are initiated and completed in a timely fashion.
3. Please describe the long-term efforts DPH is undertaking to address the concerns with the L&C program.
 4. Please provide an update on the contract negotiations with Los Angeles County.

7. Licensing and Certification 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 “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:

1. Increase fees by 20 percent on those facilities that would have received an increase as share of their percentage of the state’s total workload.
2. Keep fees at 2014-15 level for those facilities that would have had decreased fees 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/fiscallrep/Documents/licCertAnnualReport2015.pdf>

Table: Proposed Health Facility License Fees

| License Fees by Facility Type | | | |
|--|-------------------------|------------------------|---------------------------------|
| Facility Type | Fee Per Bed or Facility | FY 2014-15 Fee Amounts | FY 2015-16 Proposed Fee Amounts |
| Acute Psychiatric Hospitals | Bed | \$ 266.58 | \$ 319.90 |
| Adult Day Health Centers | Facility | \$ 4,164.92 | \$ 4,997.90 |
| Alternative Birthing Centers | Facility | \$ 2,380.19 | \$ 2,380.19 |
| Chemical Dependency Recovery Hospitals | Bed | \$ 191.27 | \$ 229.52 |
| Chronic Dialysis Clinics | Facility | \$ 2,862.63 | \$ 2,862.63 |
| Community Clinics | Facility | \$ 718.36 | \$ 862.03 |
| Congregate Living Health Facilities | Bed | \$ 312.00 | \$ 374.40 |
| Correctional Treatment Centers | Bed | \$ 573.70 | \$ 688.44 |
| District Hospitals Less Than 100 Beds | Bed | \$ 266.58 | \$ 319.90 |
| General Acute Care Hospitals | Bed | \$ 266.58 | \$ 319.90 |
| 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 | \$ 312.00 | \$ 374.40 |
| Intermediate Care Facilities (ICF) | Bed | \$ 312.00 | \$ 374.40 |
| ICF - Developmentally Disabled (DD) | Bed | \$ 580.40 | \$ 696.48 |
| ICF - DD Habilitative | Bed | \$ 580.40 | \$ 696.48 |
| ICF - DD Nursing | Bed | \$ 580.40 | \$ 696.48 |
| Pediatric Day Health/Respite Care | Bed | \$ 150.41 | \$ 180.49 |
| Psychology Clinics | Facility | \$ 1,476.66 | \$ 1,771.99 |
| Referral Agencies | Facility | \$ 2,795.53 | \$ 2,795.53 |
| Rehab Clinics | Facility | \$ 259.35 | \$ 311.22 |
| Skilled Nursing Facilities | Bed | \$ 312.00 | \$ 374.40 |
| Surgical Clinics | Facility | \$ 2,487.00 | \$ 2,984.40 |
| Special Hospitals | Bed | \$ 266.58 | \$ 319.90 |

Data Source: FY 15-16 Licensing Fees Chart

Subcommittee Staff Comment and Recommendation—Hold Open. 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.
2. Why are changes in the fees necessary this year?

| |
|---|
| 8. Genetic Disease Screening Program Update & AB 1559 (2014) |
|---|

Budget Issue. DPH proposes total expenditures of \$119.4 million (Genetic Disease Testing Fund) for the Genetic Disease Screening Program (GDSP). This reflects a net increase of \$2.5 million (Genetic Disease Testing Fund) as compared to the current-year. This program is fully fee-supported. See table below for funding summary.

Table: Genetic Disease Screening Program Funding Summary

| | 2014-15 | 2015-16 | BY to CY |
|-------------------------|---------------|---------------|-------------|
| | Revised | Proposed | Change |
| State Operations | \$28,792,000 | \$28,922,000 | \$691,000 |
| Local Assistance | \$87,947,828 | \$90,488,306 | \$1,834,306 |
| Total | \$116,739,828 | \$119,410,306 | \$2,525,306 |

Included in the GDSP budget estimate are the following proposals:

- **Expanding California’s Newborn Screening Program** – DPH requests one permanent position and \$1.975 million from the Genetic Disease Testing Fund in 2015-16 of which \$1.825 is one-time funding and \$150,000 is requested to be appropriated annually thereafter to implement with AB 1559 (Pan), Chapter 565, Statute of 2014, which expands the statewide Newborn Screening Program to include screening for adrenoleukodystrophy (ALD) as soon as ALD is added to the federal Recommended Uniform Screening Panel (RUSP).

ALD is an X-chromosome linked genetic disorder that is passed down from mother to son. The worst form affects young boys. Once symptoms present themselves, it progresses quickly and it is usually too late to do anything meaningful to mitigate the effects of the condition. Correct diagnosis based on symptoms is difficult due to the rarity of the disease and the nature of the early symptoms – which are behavioral and are often misdiagnosed as Attention Deficit Disorder, mental retardation, depression and even Multiple Sclerosis in the adult form.

Although there is no cure for ALD, early detection allows for early interventions which significantly enhance the health outcomes of children diagnosed with ALD. In addition, early detection of ALD by newborn screening can significantly minimize the financial burden to the family and the health care system and improve the outcome of treatment.

In the absence of early detection, an annual treatment cost for a child with ALD who has a late diagnosis (after symptoms appear) is estimated to be \$7.0 - \$8.2 million over 25 years. Whereas a child diagnosed through newborn screening is estimated to be \$3.1 - \$3.2 million, over the same time period.

Based on an assessment of laboratory and processing costs, an increase of \$11.00 to the current NBS Program fee of \$111.70 is required. The NBS program is fully fee-supported, as required by state statute, and the \$11.00 fee increase will provide the revenue to ensure the expansion is

fully implemented and sufficient resources are available on an ongoing basis. This funding will support expenditures associated with the ongoing workload of processing blood specimens at the DPH Genetic Disease Laboratory, staff needed to perform the actual blood screen, testing chemicals, equipment and supplies used to assay results. Funding will also be utilized to support follow-up costs for screen positive cases, such as case management, some of the diagnostic work-up, confirmatory processing, provider and family education, informative result mailers as well as incorporation and maintenance on an on-going basis of ALD into the Screening Information System (SIS).

Cost savings is thought to be as much as \$5.1 million for each newborn diagnosed with ALD. The GDSP expects to diagnose approximately 10 cases of ALD per year with potential savings to the health care system relating to those identified cases of approximately \$50 million dollars. Approximately 46 percent of California's population under the age of 18 has health coverage through a government run insurance company such as Medi-Cal. Savings to Medi-Cal could be nearly \$23 million.

Of the \$1.975 million being requested, \$1.825 million will fund one-time costs to upgrade the Screening information system to incorporate ALD and \$150,000 will fund 1.0 Research Scientist II which will support testing activities.

Background—Genetic Disease Testing Program. The Genetic Disease Testing Program consists of two programs—the Prenatal Screening Program and the Newborn Screening Program. Both screening programs provide public education, and laboratory and diagnostic clinical services through contracts with private vendors meeting state standards. Authorized follow-up services are also provided as part of the fee payment. The programs are self-supporting by fees collected from screening participants through the hospital of birth, third party payers, or private parties using a special fund—Genetic Disease Testing Fund.

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 questions.

1. Please provide an overview of the Genetic Disease Screening Program and budget.
2. Please provide an overview of the proposal related to AB 1559. Please describe the timing of ALD being added to the federal Recommended Uniform Screening Panel and the resources proposed in this budget request. What if ALD is not added to this screening panel, how would the department use these resources?

9. Food Safety Inspection

Budget Issue. DPH requests six permanent positions and \$804,000 (Food Safety Fund) in the Food and Drug Branch (FDB) to carry out statutorily mandated responsibilities to inspect food processors and distributors. DPH will utilize registration fee revenues collected specifically for this purpose to fund the activities.

Background. California Health and Safety Code (H&S) Section 110045 mandates that FDB enforce the provisions of the Sherman Food, Drug and Cosmetic Law (Sherman Law). H&S 110466(b) mandates FDB register food processors and distributors and conduct routine inspections of these facilities to verify they are operating under sanitary conditions. These activities are critical to ensure the safety of the food supply and reduce the incidence of food contamination and food-borne illness outbreaks.

FDB is required to inspect each new applicant's place of business prior to initiation of operations and before issuing an applicant's registration to ensure operation in conformance with the law. FDB is also required to conduct annual inspections at each food processor and distributor unless a lesser frequency, established by a risk assessment, is determined to be appropriate. FDB has established a three-tier risk-based inspection program that requires inspection of high risk firms annually, moderate risk firms every two years, and lower risk firms every three years. The risk assessment takes a variety of factors into consideration, including but not limited to, the commodity produced, the vulnerability of the population served by the company, compliance history, and process controls that have been implemented to control hazards associated with the foods produced or held. Based on the firm's compliance history, consumer complaints or reports of product contamination, FDB may inspect food processors on a more frequent basis than the indicated risk categorization.

FDB currently has 17 field staff positions, located in district offices throughout the state, which are funded by food processor registration fees. These fees are deposited in the Food Safety Fund, a special fund for use in conducting food inspection and enforcement activities. Fund revenues have steadily increased as a result of the increase in registrants. FDB is able to inspect approximately 3,300 firms annually, inclusive of pre-registration inspections, re-inspections and complaints.

FDB has seen an increase in the number of registration applications for food processors and distributors over the last five years. The inventory of registered firms has steadily grown from 5,300 in 2008 to 6,700 in April of 2014; a 26% increase in firms. However, staffing levels have not increased to keep pace with the new workload generated by this growing inventory. The current workload in the program requires 23 positions; however, FDB only has 17 positions budgeted. FDB requests an additional six full-time permanent Environmental Scientists to ensure that resources are available to complete this mandated workload.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending further review of this proposal.

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

1. Please provide an overview of this issue.

10. Food Safety Stipulated Judgment Appropriation

Budget Issue. DPH requests four five-year limited-term positions and \$716,000 (Food Safety Fund) to implement the food safety transportation enforcement activities as a result of the Sysco Corporation stipulated judgment. DPH also requests budget trailer bill language (TBL) to amend Health and Safety Code Section 110050 to authorize the deposit into the Food Safety Fund of awards to the department pursuant to court orders or settlements for food safety-related activities.

Background. DPH is mandated pursuant to Health and Safety Code Section 110045 to enforce the provisions of the Sherman Food, Drug and Cosmetic Law, ensuring that food is not adulterated, misbranded or falsely advertised. The Food and Drug Branch (FDB) conducts inspections and investigations of food processors and distributors to ensure they are operating in compliance with the law and that foods produced are safe, unadulterated and properly labeled. FDB is also responsible for ensuring that perishable foods are stored, transported and distributed under sanitary conditions and proper temperature controls to prevent microbial growth. These activities are critical to reduce the incidence of food contamination and food-borne illness outbreak events.

In July 2013 an investigation of Sysco Corporation was initiated by FDB as a result of a referral from an NBC news affiliate that had been investigating claims that Sysco was transporting and dropping off highly perishable foods at unrefrigerated public storage units for later pick-up and delivery to food facilities in the personal vehicles of Sysco Marketing Associates. The resulting investigation by FDB verified a significant gap in Sysco's food safety program. This investigation found gross violations including storing potentially hazardous foods in unregistered facilities, transporting and storing potentially hazardous perishable food in unrefrigerated conditions, and not protecting products from potential contamination. A review by FDB of distribution records associated with the Sysco Corporation over the last four years identified 23,827 violations related to storing foods in unregistered facilities; 405,859 violations related to holding and distributing misbranded food products; 156,740 violations related to failing to store and distribute potentially hazardous foods at temperatures below 45 degrees Fahrenheit, and a variety of other violations to bring the total violation count to 1,149,025. This investigation has led to other complaints and additional findings of inappropriate transportation and distribution practices. At the same time, these activities were occurring away from Sysco's registered distribution centers, in which the distribution centers were being operated in substantial conformance with the law, and routine inspections conducted by FDB did not uncover these illegal activities until an informant alerted the media.

Settlement of a Civil Complaint filed by the Santa Clara County District Attorney's Office as a result of FDB's investigation of Sysco Corporation includes \$3.3 million specifically earmarked for DPH to conduct food safety transportation enforcement activities within the state and identify other operations that are illegally storing and distributing perishable and non-perishable food in a manner that does not protect them from contamination.

The Sysco Corporation stipulated judgment is providing funding to support four positions for five years to focus on investigating food transportation safety and taking the necessary enforcement actions to ensure conformance with the law and protection of the food supply. The settlement funds provide DPH

with the opportunity to address a significant food safety issue without increasing fees on the food industry.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending further review of this proposal.

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

1. Please provide an overview of this issue.
2. Once these limited-term positions and funding expire, how will DPH conduct food safety transportation enforcement activities?

11. USFDA Tobacco Retail Inspection Contract

Budget Issue. DPH requests nine limited-term positions and \$1,078,000 additional Reimbursement authority coinciding with the remainder of DPH’s contract with the federal Food and Drug Administration (FDA) for its Stop Tobacco Access to Kids Enforcement (STAKE) Unit to inspect 20 percent of tobacco retailers annually in California.

Background. At the state level, since 1995 the Food and Drug Branch (FDB) has enforced the provisions of the Stop Tobacco Access to Kids Enforcement (STAKE) Act, which requires retailer compliance checks using teenage operatives, assessing and collecting penalties, serving legal notices on violators, administering penalty appeal hearings and managing a toll-free telephone number to report illegal tobacco sales to minors.

In 2009, the U.S. Family Smoking Prevention and Tobacco Control Act (FSPTCA) was signed into federal law. The FSPTCA provides the FDA authority to regulate tobacco products and ban the sale of tobacco to minors. The FSPTCA requires FDA to contract with states and territories in the U.S. to conduct youth tobacco enforcement (illegal tobacco sales to youth and advertising/labeling inspections). FDA initiated a three year contract with DPH starting on October 1, 2014 to continue FSPTCA-required tobacco enforcement activities. These activities are performed by the STAKE Unit.

According to DPH, by reducing the availability of tobacco to underage youth, young people will be more likely to not use tobacco, or to reduce their use of tobacco. This leads to positive health outcomes, such as increased quality and years of healthy life, as identified in the US Department of Health and Human Services’ strategic plan as one of the overarching goals of the federal Healthy People 2020 initiative.

DPH implemented the FDA requirements over the last three years and now needs to reach the 20% inspection mandate. The contract with the FDA effective October 1, 2014 mandates that DPH must perform inspections of 20 percent of all 37,000 licensed tobacco retailers in the state; this would equate to approximately 7,400 retailers for California. DPH will administratively establish positions to begin inspections in the current year. The positions requested would then give DPH the ability to conduct the 7,400 annual inspections required for the contract from July 1, 2015 until the contract’s end on September 30, 2017. The current contract stipulates that of the 7,400 annual inspections, 75 percent of these inspections must be undercover buys (UB) and 25 percent must be advertising and labeling inspections, equating to 5,550 UB’s and 1,850 advertising and labeling inspections. If DPH does not meet this requirement, FDA can contract with another state agency or local enforcement agency to complete the work.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending further review of this proposal.

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

1. Please provide an overview of this issue.

12. Medical Waste Resources (AB 333, 2014)

Budget Issue. DPH requests \$333,000 (Medical Waste Management Fund) in 2015-16 and 2016-17, and three two-year limited-term positions to implement the mandated activities specified in AB 333 (Wieckowski), Chapter 564, Statutes of 2014. This bill provides updates to the Medical Waste Management Act, and ensures public health protection for the proper transportation, temporary storage, and disposal of medical waste.

Background. The Medical Waste Management Program provides oversight of the healthcare and medical waste treatment industries through the use of annual facility compliance inspections that review and evaluate the medical waste management activities of these entities including, but not limited to, the generation, handling, storage, transport, treatment, and disposal of medical waste. These compliance inspections ensure that waste management activities conducted at these facilities are protective of public health and do not inadvertently expose facility personnel or the public to disease causing etiologic agents.

Federal law, through the United States Department of Transportation (USDOT), also governs the transportation of hazardous materials, including medical waste, on public roads and highways. AB 333 is a response to potential conflicts between federal rules and requirements and California law. A major component of AB 333 requires DPH to convene stakeholder meetings to examine the differences between federal and state law, and submit a report to the Legislature by January 1, 2016.

DPH is requesting one two-year, limited-term senior environmental scientist to conduct meetings and develop the report. In addition to the legislative report, AB 333 authorizes DPH to update standards related to the transportation of medical waste through the issuance of guidance documents. AB 333 also authorizes DPH to temporarily waive the transportation requirements of this bill while a federal preemption determination is pending. During this temporary waiver period, or if a federal preemption is found, the federal requirements would be deemed to be the law in California and enforceable by DPH. The requested senior environmental scientist will perform the following duties related to these provisions of the bill:

- Develop guidance documents based on the outcome of the stakeholder meetings and findings of the legislative report.
- Conduct training sessions for local enforcement agencies.
- Develop a process and review temporary waiver requests submitted in accordance with the provisions of AB 333.
- Prepare preemption petition documents as needed and respond to petitions initiated by entities other than DPH.
- Revise guidance documents and training sessions as necessary as a result of temporary waivers and the result of the USDOT petition process.

DPH is also requesting two two-year, limited-term environmental scientist positions. The two environmental scientists will assist the senior environmental scientist in all of the aforementioned duties.

In addition, the environmental scientists will conduct inspections as needed in order to meet the Medical Waste Management Program's statutorily mandated inspection rate.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions continue on the need for these positions.

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

1. Please provide an overview of this issue.

13. Inspection of Public Beaches Resources (SB 1395, 2014)

Budget Issue. DPH requests one three-year limited term position and \$384,000 (General Fund) in 2015-16 and \$182,000 (General Fund) in 2016-17 and ongoing to implement the mandated provisions of SB 1395 (Block), Chapter 928, Statutes of 2014. This bill authorizes the department to develop regulations for alternative beach water quality test that would shorten the amount of time required to produce results.

Background. Beach water quality monitoring and strong pollution prevention measures are critical for protecting beachgoers from water-borne diseases. Under the state’s Beach and Bay Water Quality Monitoring Program, county public health departments perform beach water sampling and close beaches or post warning signs if testing indicates water quality is below state standards. Current permissible tests are culture-based, involving a multiple sample standard for three indicators – total coliform, fecal coliform, and enterococcus. Lab results can take up to two days to determine if the beaches are safe.

In 2012, the United States Environmental Protection Agency (EPA) released a new rapid quantitative polymerase chain reaction (qPCR)-based method for detecting enterococcus in recreational water, Method 1611. In 2014, EPA released a second improved qPCR-based method for enterococcus detection in recreational water, Method 1609. These new methods can return results in approximately four hours, rather than the current culture-based methods which take up to two days for test results. When the EPA released these methods, they left it to states to develop guidelines and validation criteria for implementation of these methods.

SB 1395 authorized DPH to allow local environmental health officers to use a DPH approved qPCR Methods 1611 and 1609, as the single test for contamination under specified conditions to determine the level of enterococci bacteria and overall microbiological contamination conditions in all or part of that health officer’s jurisdiction. While qPCR-based testing methods would result in a more rapid result, the testing is site-specific and environmental inhibitors could impact the result of the test. These qPCR-based test methods must be validated at each specific location prior to implementation. The state will need to validate test methods and draft guidelines for performance and acceptance of the site-specific testing.

This proposal would provide the resources for the development of alternative beach water quality tests. DPH’s Drinking Water and Radiation Laboratory Branch (DWRLB) will hire one three-year limited term Research Scientist II (RS II) Microbiological Sciences, and purchase laboratory instruments/equipment, and laboratory supplies. Once the guidance documents have been developed, the department will need to evaluate the future changes required to develop new regulations and training for the testing methodologies.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open as discussions continue on the need for these positions.

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

1. Please provide an overview of this issue.

14. California Gambling Education and Treatment Services (CalGETS)

Budget Issue. DPH's Office of Problem Gambling (OPG) requests two permanent positions and \$5 million (Indian Gaming Special Distribution Fund) in 2015-16 to make permanent the regional pilot California Gambling Education and Treatment Services (CalGETS) program. Of this request, \$4 million will be allocated to local governments, public universities, and/or community organizations for treatment programs serving problem and pathological gamblers and their families. This proposal includes trailer bill language to delete outdated verbiage related to the program.

Background. As a result of legalized gambling expansion in California, the OPG was created in 2003. OPG's mission is to provide quality, research-driven leadership in prevention, intervention, and treatment for problem and pathological gamblers, their families and communities. Initially, OPG's first priority was its prevention program. In 2008-09, the OPG within the Department of Alcohol and Drug Programs (DADP) initiated a pilot treatment program in four regions (Sacramento, San Francisco, Los Angeles and San Diego) with limited-term funding and two positions. In 2011-12, funding was approved for an additional two years, increasing the term of the pilot to five years. Again in 2013-14, funding was approved for another two years, increasing the term of the pilot to seven years. The 2013 Budget Act transitioned OPG from DADP to DPH effective July 1, 2013. CalGETS expenditure and position authority will end on June 30, 2015.

CalGETS is the only specialized treatment program available to problem gamblers and affected individuals in California. According to DPH, in 2012-13, CalGETS clients reported improvement in their overall health condition, reduction in Diagnostic and Statistical Manual of Mental Disorders IV criteria for pathological gambling and also experienced a decrease in time and money spent gambling after treatment. Data on CalGETS clients indicate a relatively significant percentage are of low socioeconomic status and possess other risky health behaviors.

Over the past five years, an average of 13 individuals called the 1-800-GAMBLER helpline each day seeking assistance with gambling addiction. Currently there are, on average, 150 clients per month entering into CalGETS. To date, CalGETS has helped more than 6,300 clients.

According to DPH, by making the CalGETS program permanent, California will benefit via reduction of social costs. Problem gambling treatment saves money; every \$1 spent on treatment saved more than \$2 in social costs (National Council on Problem Gambling, March 2010). If CalGETS is not funded, other social programs, such as those that serve people with mental health and substance use disorders, could see an increase in utilization.

The current CalGETS awardees are:

| Contractor | Amount | Purpose of Contract |
|-------------------------------|---------------|----------------------------|
| UCLA Gambling Studies Program | \$400,000 | Training & Research |
| UCLA Gambling Studies Program | \$3,740,000 | Treatment Services |
| Auersoft | \$257,582 | Data Management System |
| Evalcorp | \$93,827 | CalGETS Evaluation |
| Total | \$4,491,409 | |

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending further review of this proposal.

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

1. Please provide an overview of this issue.

15. Biomonitoring Resources

Budget Issue. DPH requests six, two-year limited-term positions and \$900,000 annually for fiscal years 2015-16 and 2016-17 to support the 16 to support the California Environmental Contaminant Biomonitoring Program (CECBP) including investigating the feasibility of detecting and measuring emerging chemical threats to California. Funding for this request is split between the Toxic Substances Control Account (\$775,000) and the Birth Defects Monitoring Fund (\$125,000).

DPH is the designated lead for Biomonitoring California, coordinating with two CalEPA departments: the Office of Environmental Health Hazard Assessment (OEHHA) and the Department of Toxic Substances Control (DTSC).

Background. SB 1379 (Perata and Ortiz), Chapter 599, Statutes of 2006, established the tri-departmental CECBP. CECBP is a collaborative effort among DPH, OEHHA, and DTSC. CECBP's principal mandates are to measure and report levels of specific environmental chemicals in blood and urine samples from a representative sample of Californians, conduct community-based biomonitoring studies, and help assess the effectiveness of public health and environmental programs in reducing chemical exposures. CECBP provides unique information on the extent to which Californians are exposed to a variety of environmental chemicals and how such exposures may be influenced by factors such as age, gender, ethnicity, diet, occupation, residential location, and use of specific consumer products.

Overall, Biomonitoring California is supported across the three departments by five funds: the Toxic Substances Control Account (TSCA), Air Pollution Control Account, Pesticide Registration Fund, Childhood Lead Poisoning Prevention Fund, and Birth Defects Monitoring Fund (BDMF). Baseline program funding since 2008-09 has been approximately \$2.1 million (\$1.1 million is allocated to DPH) and supports 13 core staff (eight in DPH, three in OEHHA, and two in DTSC). In addition to the baseline state funding, the 2014-15 State budget includes \$700,000 annually for two years, from the TSCA and BDMF allocated equally between DPH and DTSC.

Biomonitoring California's funds have also been augmented by two competitive federal CDC grants. The initial five-year Cooperative Agreement (FFY 2009-14), which ended on August 31, 2014, provided \$2.65 million annually to California and supported up to 17 grant staff. CDC support played a critical role in allowing the program to establish much of its sophisticated laboratory instruments, develop needed methods, initiate multiple community studies, obtain blood and urine samples, and create report-return protocols. A new cooperative agreement with the CDC (FFY 2014-19) was awarded and began on September 1, 2014. Because of CDC's policy to lower the maximum award amount granted to individual states, the amount to California was reduced to \$1 million annually for five years and this amount only supports five grant staff. While this funding enables Biomonitoring California to retain some of its core functions, the overall impact on Biomonitoring California is a 62 percent reduction in supplemental funding. The current CDC cooperative agreement does not support research or development of new analytical methods. These important functions are therefore dependent on state funding.

This proposal requests six new two year limited-term, full-time state positions and \$900,000 annually from the TSCA and BDMF to offset the reduction in supplemental federal funds in 2015-16 and partially offset the reduced federal funds in 2016-17.

This proposal includes a request for \$50,000 in contract funding to recruit targeted Californians to participate in biomonitoring studies and to collect blood and urine specimens. Currently, there are no dedicated funds available from state sources for this purpose. Biomonitoring California is looking into obtaining blood and urine specimens from racially diverse populations around the state to investigate potentially vulnerable populations, like those identified using Cal/EPA's CalEnviroScreen. In addition, to maintain Biomonitoring California's highly specialized analytical instruments, this request includes \$37,500 annually for necessary maintenance service contracts and \$37,500 annually for other laboratory-related costs such as specialized non-reusable supplies.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this item open pending further review of this proposal.

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

1. Please provide an overview of this issue.
2. Please describe the changes in federal funding for this program over the last couple years.