AGENDA

ASSEMBLY BUDGET SUBCOMMITTEE NO. 1

HEALTH AND HUMAN SERVICES

ASSEMBLYMEMBER TONY THURMOND, CHAIR

MONDAY, APRIL 13, 2015

1:30 P.M. - STATE CAPITOL ROOM 127

ITEMS TO BE HEARD

ITEMS TO BE HEARD

4120 EMERGENCY MEDICAL SERVICES AUTHORITY

ISSUE 1: DEPARTMENT OVERVIEW & PROPOSALS

PANELISTS

- **Howard Backer,** MD, MPH, FACEP (Director), Director, Emergency Medical Services Authority (EMSA)
- **Dan Smiley,** Chief Deputy Director, EMSA
- **Jamey Matalka**, Principal Program Budget Analyst, Department of Finance
- **John Bacigalupi,** Finance Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

The Emergency Medical Services Authority's (EMSA) mission is to coordinate emergency medical services (EMS) statewide; develop guidelines for local EMS systems; regulate the education, training, and certification of EMS personnel; and coordinate the state's medical response to any disaster.

The EMSA is comprised of the following three divisions:

- ***Disaster Medical Services Division*.** The Disaster Medical Services Division coordinates California's medical response to disasters. It is the responsibility of this division to carry out the EMS Authority's mandate to provide medical resources to local governments in support of their disaster response, and coordinate with the Governor's Office of Emergency Services, Office of Homeland Security, California National Guard, California Department of Public Health, other local, state, and federal agencies, private sector hospitals, ambulance companies and medical supply vendors to improve disaster preparedness and response.

- ***EMS Personnel Division*.** The EMS Personnel Division oversees licensure and enforcement functions for California's paramedics, personnel standards for pre-hospital emergency medical care personnel, trial studies involving pre-hospital emergency medical care personnel, first aid and CPR training programs for child day care providers and school bus drivers.

- ***EMS Systems Division*.** The EMS Systems Division oversees EMS system development and implementation by the local EMS agencies, trauma care and other specialty care system planning and development, EMS for Children program, California's Poison Control System, emergency medical dispatcher standards, EMS Data and Quality Improvement Programs, and EMS communication systems.

PROPOSED BUDGET

The department's proposed 2015-16 budget is summarized in the table below. Overall expenditures are proposed to increase by $586,000 (1.9%). The primary source of funding for this department is federal funds, which is included in the line below labeled "reimbursements," as those are federal funds that come through other departments first, namely the Departments of Health Care Services and Public Health.

EMERGENCY MEDICAL SERVICES AUTHORITY
(Dollars In thousands)

Fund Source	2013-14 Actual	2014-15 Projected	2015-16 Proposed	BY to CY Change	% Change
General Fund	**$6,509**	**$7,684**	**$8,419**	**$735**	**9.6%**
Federal Trust Fund	$1,698	$3,500	$2,653	$(84)	(24.2)%
Reimbursements	$11,521	$16,392	$16,826	$434	2.6%
Special Funds	$3,640	$4,030	$4,294	$264	6.6%
Total Expenditures	**$23,368**	**$31,606**	**$32,192**	**$586**	**1.9%**
Positions	66.7	70.2	71.2	1	1.4%

State Emergency Response Supplemental Report. As part of the 2014 budget, supplemental report language was adopted requiring EMSA to provide to the Legislature a report on the state's emergency medical response capacity, including 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.

EMSA provided this report to legislative staff on April 4, 2015. The report describes a very uneven distribution of resources and capacity based on geography. In other words, the response capacity of any given local area of the state is comprised of a combination of local, state and federal response resources, and local resources vary widely across counties. Los Angeles County (LA) exceeds the rest of the state by maintaining a trailer mobile hospital that has two surgical suites and ten patient exam beds. It also has an optional canopy system that can hold 100 cots. LA also has a 100 bed Blu-Med Tent mobile hospital. Therefore, both response time and level of care are dependent on the location of the emergency.

The report describes EMSA's 3-tier response system, including: 1) Ambulance Strike Teams (AST) that can respond within 2 hours; 2) California Medical Assistance Teams, designed to respond within 12 hours; and 3) three 200-bed Mobile Field Hospitals, of which only one is currently deployable within 72-96 hours. The report stops short of answering question #3 above, "The number of individuals existing resources could serve in a major medical disaster." Instead, the report describes the many variables that would affect this question, such as whether or not transportation infrastructure is intact and usable in a given disaster. EMSA states that California has 41 ASTs, and that ambulances can transport two patients at a time; however, again, calculating a total number would require knowing the distance to still-operating hospitals that can accept patients.

With regard to EMSA resources for emergency preparedness, the majority of funding is federal funds which have declined steadily since 2003-04. Specifically, these funds have decreased 40 percent from a high of $110 million to $65.7 million in 2014-15. Reductions in state resources also occurred during the recession which are discussed below.

The report states that the data necessary to compare California's capacity to other large states does not exist, and therefore such a comparison is not possible. Nevertheless, the report does provide some information about the response assets maintained by New York, Florida, and Texas. EMSA states that the department has identified gaps in California's emergency medical response infrastructure and that they are prioritized and addressed by the department's Budget Change Proposal (BCP), described in more detail later in this agenda. The report states that the minimum recommended level of preparedness is the ability to successfully respond to moderate level events and to provide some initial response to a catastrophic event. EMSA states that the resources requested through their BCP will bring the state to that level of preparedness.

Funding History

Due to the state's severe recession and fiscal crisis, substantial reductions were made over the past several years to the state's emergency preparedness infrastructure, most of which falls under the authority of the EMSA. The following describes the recent history of a few of the key components of the state's emergency medical response infrastructure:

- ***Mobile Field Hospitals (MHFs).*** Since 2006, the EMSA has maintained three MFHs, each of which consists of approximately 30,000 square feet of tents, hundreds of beds, and sufficient medical supplies to respond to a major disaster in the state, such as a major earthquake in a densely populated area. The 2006 Budget Act allocated $18 million in one-time funds for the purchase of the MFHs and $1.7 million in on-going General Fund funding for the staffing, maintenance, storage, and purchase of pharmaceutical drugs, annual training exercises, and required medical equipment for the MFHs.

  The original amount budgeted for the pharmaceutical drug cache was $23,000, which was later determined to be woefully inaccurate and insufficient. Recognizing that the value of the MFHs is quite limited in the absence of sufficient pharmaceutical supplies, the Governor put forth requests in 2009 and 2010 to augment the MFH budget by $448,000 General Fund, however the Legislature denied both requests. In 2011, the Governor instead proposed, and the Legislature approved, to eliminate the $1.7 million in on-going support for the MFHs. Nevertheless, there remain on-going storage and maintenance costs for the MFHs.

  The EMSA explored various potential shared responsibility arrangements with various non-state entities, such as the Red Cross, in order to find an affordable way for the state to continue to have access to the MFHs in a major disaster. Initially, the EMSA did the following: 1) consolidated the MFHs into two storage facilities in order to reduce warehouse space costs; and 2) entered into a 1-year, no-cost contract with Blu-Med (a subsidiary of Alaska Structures) to continue providing minimal maintenance for the MFHs, at no cost to the state, with the stipulation that Blu-Med could rent out one or two MFHs to any state or country dealing with a major disaster. The contract with Blu-Med has since ended and EMSA has cobbled together sufficient resources to cover maintenance costs over the past few years, including through a separate DPH re-appropriation of Hospital Preparedness Program (federal funds) funds which are currently covering the maintenance costs.

  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.

- ***Medical Stockpiles (Department of Public Health).*** In 2006-07, the state purchased a large supply of respirators, ventilators, and antivirals to be used in case of a natural disaster, act of terror or other public health emergency. In 2007-08, $8.5 million was re-appropriated to the DPH specifically to store and maintain that stockpile. That re-appropriation expired in FY 2010-11. In 2011, the Governor proposed, and the Legislature approved, of not providing the DPH with new General Fund of $4.1 million that they would need to continue storing and maintaining the stockpile.

- ***Federal Funds***. EMSA and DPH both anticipate further reductions in resources as a result of expected reductions to federal funds, such as the Hospital Preparedness Program (HPP) grant to the state. At EMSA, HPP funds support MFHs, the Disaster Health Care Volunteer System, emergency planning and training, and storage of emergency equipment.

BUDGET CHANGE PROPOSALS

Disaster Preparedness & Emergency Response Resources for California BCP

Budget Request. 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 to 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. This position also would 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. The functions of this coordinator also would 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 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.

Document Imaging Workload & Efficiencies BCP

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.

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.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests EMSA to provide an overview of the department and its proposed budget, present its Budget Change Proposals and provide an overview of the report requested by the Legislature last year on the state's medical emergency preparedness.

Staff Recommendation: Subcommittee staff recommends approving of both Budget Change Proposals as proposed by the Governor.

4265 DEPARTMENT OF PUBLIC HEALTH

ISSUE 1: NEW DEPARTMENT DIRECTOR & OFFICE OF HEALTH EQUITY UPDATE

PANELISTS

- **Karen Smith,** MD, MPH, Director, DPH, State Public Health Officer
- **Jahmal Miller,** Deputy Director, Office of Health Equity, DPH
- **Jamey Matalka**, Principal Program Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

BACKGROUND

New Department Director

On February 20, 2015, the administration announced the appointment of Karen Smith, MD, MPH, as the new Director of the Department of Public Health (State Public Health Officer) with the following information:

> "Dr. Smith is currently the Public Health Officer and Deputy Director for Public Health for Napa County. Prior to Napa, she was Deputy Health Officer and TB Control Officer for Santa Clara County. Dr. Smith completed her medical training and infectious diseases fellowship at Stanford University after having obtained a Master of Public Health degree in International Health at Johns Hopkins University. Prior to her medical training she worked in communicable disease control in Morocco, Thailand, and Nepal. She has served as a subject matter expert on Public Health Emergency Preparedness for working groups convened by the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and serves on the Board of Scientific Counselors of the CDC Office of Public Health Preparedness and Response. Dr. Smith is currently President-Elect of the California Conference of Local Health Officers."

Office of Health Equity Overview & Update

The Office of Health Equity (OHE) was established in 2012 to provide a key leadership role to reduce health and mental health disparities to vulnerable communities. A priority of this office is building cross-sector partnerships. The work of OHE is informed in part, by their advisory committee and stakeholder meetings. The OHE is comprised of the following three units: Community Development and Engagement; Policy; and Health Research and Statistics.

The OHE is charged with the following:

- Achieve the highest level of health and mental health for all people, with special attention focused on those who have experienced socioeconomic disadvantage and historical injustice, including, but not limited to, vulnerable communities and culturally, linguistically, and geographically isolated communities.
- Work collaboratively with the Health in All Policies Task Force to promote work to prevent injury and illness through improved social and environmental factors that promote health and mental health.
- Advise and assist other state departments in their mission to increase access to, and the quality of, culturally and linguistically competent health and mental health care and services.
- Improve the health status of all populations and places, with a priority on eliminating health and mental health disparities and inequities.

The duties of the OHE include, but are not limited to, the following:

- Establish a comprehensive, cross-sector strategic plan to eliminate health and mental health disparities (updated every two years).
- By October 1, 2013, establish an advisory committee.
- Establish an interagency agreement between the State Department of Public Health and the Department of Health Care Services to outline the process by which the departments will jointly work to advance the mission of the OHE.
- Conduct demographic analyses on health and mental health disparities and equities (updated periodically, but not less than every two years).
- Build upon and inform the work of the Health in All Policies Task Force.
- Assist and consult with state and local governments, health and mental health providers, community-based organizations and advocates, and various stakeholder communities.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests Director Smith to introduce herself and respond to the following:

1. What changes does she hope to bring to the department?

2. Where in the department does she see need for improvement?

3. What is the department doing to be able to respond to the changing world of public health, i.e., new significant health threats, such as climate change, drought, potential infectious disease outbreaks (such as Ebola), and the diabetes epidemic?

The Subcommittee requests DPH to provide an overview of the OHE, its progress and accomplishments.

Staff Recommendation: No action is recommended at this time.

ISSUE 2: CENTER FOR ENVIRONMENTAL HEALTH ISSUES

PANELISTS

- **Mark Starr**, DVM, Deputy Director, Center for Environmental Health, DPH
- **Miren Klein,** Assistant Deputy Director, Center for Environmental Health, DPH
- **John Bacigalupi**, Finance Budget Analyst, Department of Finance
- **Kimberly Harbison**, Finance Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

BUDGET CHANGE PROPOSALS

Food Safety Inspection BCP

Budget Proposal. 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.

Food Safety Stipulated Judgment Appropriation BCP & Related Trailer Bill

Budget Proposal. 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.

Trailer Bill. The related proposed trailer bill is technical in nature. The proposed statutory change is necessary to authorize depositing of the settlement funds into the Food Safety Fund.

Tobacco Retail Inspection Contract BCP

Budget Proposal. 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 percent 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.

Medical Waste (AB 333) BCP

Budget Proposal. 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.

Public Beaches: Inspection for Contaminants (SB 1395) BCP

Budget Proposal. 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 an 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 affect test results. 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.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present all five Center for Environmental Health Budget Change Proposals and respond to questions of the Subcommittee.

Staff Recommendation: Staff recommends approval of all five Budget Change Proposals, as proposed, and also recommends approval of the proposed food safety technical "placeholder" trailer bill.

ISSUE 3: CENTER FOR FAMILY HEALTH ISSUES

PANELISTS

- **Connie Mitchell**, MD, Deputy Director, Center for Family Health, DPH
- **Laurel Cima,** Branch Chief, Policy and Programs, Center for Family Health, DPH
- **Kristen Rogers**, Chief, California Home Visiting Program, Center for Family Health, DPH
- **Kimberly Harbison**, Finance Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

ISSUES

Home Visiting Program BCP

Budget Proposal. DPH is requesting authority to extend funding and 3–year limited-term position authority for 27.0 positions as follows: 11.0 positions ($697,000 federal funds) in 2015-16 and 16.0 additional positions ($3,490,000 federal funds) in 2016-17 for the California Home Visiting Program (CHVP). This funding is from the Health Resources and Services Administration (HRSA) Maternal, Infant, and early Childhood Home Visiting Program grant. Of these existing limited-term positions, 11.0 expire January 31, 2016 and the other 16.0 expire June 30, 2016. This proposal also includes $24 million in Local Assistance federal fund authority for 2016-17 through 2018-19 to support local CHVP sites.

Background. The CHVP was created as a component of the Affordable Care Act, and subsequently established in California through state legislation. The focus of the program is to provide comprehensive, coordinated, in-home services to support positive parenting and to improve outcomes for families residing in identified at-risk communities. The program is voluntary, offered to pregnant women and their children from birth to age 3. Currently, the program operates in 22 Local Health Jurisdictions. To date (as of the drafting of the January budget), the 22 program sites have performed 30,296 home visits and 2,577 clients have been enrolled in the program statewide.

The program is required to target six federally-mandated Benchmark Areas:

1. Improved maternal and newborn health;
2. Prevention of child injuries, child abuse, neglect or maltreatment and reduction of Emergency Department visits;
3. Improvements in school readiness and achievements;
4. Reduction in domestic violence;
5. Improvements in family economic self-sufficiency; and
6. Improvements in the coordination and referrals for other community resources and supports.

The program submits Benchmark data into a federal reporting system on an ongoing basis, and is required to show improvements in the Benchmarks in years 3 and 5 of the program in order to continue to receive federal funds, which are currently available through 2017. The future of the program beyond 2017 depends on Congressional action expected early this month. The department reports that the program is being evaluated vigorously and that evaluation results will be available in November 2015.

Black Infant Health Program Update

The 2014 Budget Act includes a $4 million General Fund augmentation to the Black Infant Health Program, an increase that the Legislature initiated. According to an update provided by the department, the funding has been used to bring San Bernardino and Riverside Counties back into the program and to revamp the program model based on the most recent research on effective public health strategies in this area. The program in its prior form focused on prenatal care outreach and tracking, and case management. Now, with recent changes, the program requires a commitment from participating women to attend 20 weekly group sessions (10 before giving birth, and 10 postpartum). The program also has updated client materials and provides assistance with child care and transportation, the most common barriers to participation. This new program model is being evaluated, however the department states that it will not have evaluation results for another two years. The department reports that the program operates in 17 Local Health Jurisdictions, which together serve 90 percent of the African American community in California. Currently, the program has approximately 800 participants, as compared to a one-time high of over 6,000.

STAFF COMMENTS/QUESTIONS

Subcommittee staff requests DPH to present the Home Visiting Budget Change Proposal and to provide an update on the Black Infant Health Program.

Please provide an update on the most recent Congressional action related to the future of the Home Visiting Program.

Staff Recommendation: Staff recommends approval of the Home Visiting Budget Change Proposal, as proposed.

ISSUE 4: CENTER FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION ISSUES

PANELISTS

- **Kevin Sherin**, MD, Deputy Director, Center for Chronic Disease Prevention & Health Promotion, Department of Public Health
- **Greg Oliva**, Assistant Deputy Director, Center for Chronic Disease Prevention & Health Promotion, Department of Public Health
- **John Bacigalupi**, Finance Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

BUDGET CHANGE PROPOSALS

Office of Problem Gambling BCP & Trailer Bill

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 former 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. DPH cites research that found that problem gambling treatment saves money; every $1 spent on treatment saved more than $2 in social costs (National Council on Problem Gambling, March 2010).

Biomonitoring Program BCP

Budget Issue. DPH requests six, two-year limited-term positions and $550,000 (Toxic Substances Control Account) annually for fiscal years 2015-16 and 2016-17 to support the California Environmental Contaminant Biomonitoring Program (CECBP) including investigating the feasibility of detecting and measuring emerging chemical threats to California.

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 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 $550,000 annually (TSCA fund) to offset the reduction in supplemental federal funds in 2015-16 and partially offset the reduced federal funds in 2016-17.

This proposal also 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, such as 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.

STAKEHOLDER PROPOSALS

Dental Disease Prevention Program (DDPP). Many stakeholder and advocates have proposed to the Subcommittee to restore $2.9 million General Fund to the DDPP. From 1980 to 2009, the DDPP provided school-based oral health prevention services to approximately 300,000 low-income school children in 32 counties in California. Approximately $3.2 million (General Fund) was eliminated from this program. Participating sites provided:

- Fluoride supplementation
- Dental sealants
- Plaque control
- Oral health education
- Dental screenings

Supporters of restoring funding for the DDPP cite research that supports all of the following:

- Poor dental health can disrupt normal childhood development and seriously damage overall health
- Dental disease can have a negative impact on a child's ability to learn and succeed in school.
- In 2007, more than half a million school-aged children in California missed at least one school day due to a dental problem – a total of 874,000 missed school days and a statewide average loss of nearly $30 million in attendance-based school district funding.
- For every dollar spent on oral health prevention, between $8 and $50 are saved in subsequent treatment costs.
- In 2007, there were over 83,000 emergency room visits for preventable dental problems at a cost of $55 million.

Supporters also cite the following program achievements:

- The DDPP was the only comprehensive school-based dental prevention program.
- In its last year of operation, local programs leveraged $2.1 million in additional funding.
- Nearly 7,000 children in the program in 2008-09 were alerted to the need for urgent care and were referred for dental services.
- More than 14,000 children received dental sealants in 2008-09.
- Over 200,000 children per year received fluoride treatments.

Parkinson's Disease Registry. Advocates and individuals with Parkinson's propose $3.7 million for three years to fund the California Parkinson's Disease Registry at DPH to support competitive grants/contracts to research institutes, universities and nonprofit organizations to implement and maintain a comprehensive Parkinson's disease registry. There is much unknown about Parkinson's such as: how many people have the disease; if young onset is increasing; and whether one is more susceptible living in an urban versus rural environment. Advocates report that the economic burden of the disease is at least $14.4 billion a year, nationwide. Supporters state that investment in medical research that leads to better treatments for Parkinson's disease could save millions of dollars each year and that if new therapies could be found that could produce even a modest ten percent delay in the progression of Parkinson's disease, hundreds of millions of dollars could be saved every year.

In 2004, California passed Assembly Bill 2245, creating a Parkinson's disease registry to count the number of cases and determine demographic and other characteristics of the disease. Two institutions, the UCLA School of Public Health and The Parkinson's Institute, cooperated and raised over a million dollars for a registry pilot project from 2007 to 2012. The pilot project contributed to getting considerable federal funding for several large NIH funded studies that helped identify specific pesticides that, together with head trauma and genetic factors, contribute to the cause of Parkinson's disease. The Parkinson's disease registry did not receive any funding from the state. California has experienced implementing and operating statewide disease registries, notably the California Cancer Registry.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present the two Center for Chronic Disease Prevention Budget Change Proposals and respond to any Subcommittee questions.

The Subcommittee requests the Legislative Analyst's Office to briefly describe the proposals from stakeholders and advocates that are described in this section of the agenda.

Staff Recommendation: Subcommittee staff recommends approval of the Office of Problem Gambling Budget Change Proposal, as proposed, and the proposed "placeholder" trailer bill related to this BCP. Staff also recommends approval of the Biomonitoring Budget Change Proposal and April 1 adjustment.

ISSUE 5: CENTER FOR INFECTIOUS DISEASES ISSUES

PANELISTS

- **Gil Chavez**, MD, Deputy Director, Center for Infectious Diseases, DPH
- **Karen Mark**, MD, Chief, Office of AIDS, Center for Infectious Diseases, DPH
- **Paul Kimsey,** Deputy Director, Office of State Public Health Laboratory Director, DPH
- **John Bacigalupi**, Finance Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

The mission of the DPH Center for Infectious Diseases (CID) is to protect the people in California from the threat of preventable infectious diseases and to assist those living with an infectious disease in securing prompt and appropriate access to healthcare, medications and associated support services. The CID helps investigate and diagnose infectious diseases of public health significance. In order to fulfill this mission, the CID engages in all of the following:

- Identifies, prevents, and interrupts the transmission of vaccine-preventable diseases, sexually transmitted diseases (STDs), HIV/AIDS, tuberculosis, viral hepatitis, emerging infectious diseases, vector-borne diseases, zoonotic diseases, healthcare-associated infections, and other contagious infectious diseases.
- Conducts and coordinates public health surveillance and epidemiologic studies to assist in defining, preventing, and controlling infectious diseases.
- Plans for and responds to natural or human-made emergencies due to infectious diseases.
- Helps local health departments and community-based organizations plan, develop, implement, and improve prevention, control, care, treatment, and social support programs for infectious diseases.
- Provides reference and diagnostic laboratory services essential for the detection, epidemiologic investigation, control, and prevention of diseases caused by microbial and viral agents.
- Provides technical assistance for developing and maintaining high quality local microbial and viral laboratory services, including consultation and training in state-of-the-art standardized laboratory procedures for local public health laboratory personnel.

The CID houses the following:

- Division of Communicable Disease Control
- Office of AIDS
- Office of Binational Health
- Office of Refugee Health

The DPH Emergency Preparedness Office also plays a key role in infectious disease control. This Office 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 needs during emergencies. The program also administers federal and state funds that support the Department's emergency preparedness activities.

The Emergency Preparedness Office is funded primarily by federal Public Health Emergency Preparedness and Hospital Preparedness Program funds. These funds provide operational support to the Department, which is responsible for the public health response to emergencies, including coordination between public health and medical care responsibilities. The surveillance of infectious diseases, detection and investigation of outbreaks, identification of etiologic agents and their modes of transmission, development of prevention and control strategies, and providing the public with accurate and timely information on the public health implications of emergencies are the responsibility of Public Health and local health departments.

The Emergency Preparedness Office also receives $400,000 in state funds to support public health and medical surge and $4.9 million in local assistance funds for pandemic planning. These state funds are utilized to meet the federal match requirement.

DPH has the following two budget proposals this year that are directly relevant to infectious disease control:

1. Ebola Emergency Preparedness Federal Grant. This proposal is described in detail in this agenda below; and

2. Richmond Laboratory Capital Outlay Proposal. The Subcommittee heard and approved this proposal on March 2, 2015.

Recent Infectious Disease Issues

Ebola. As of April 7, 2015, the CDC reports the following morbidity and mortality statistics associated with the 2014 Ebola outbreak in West Africa: 14,795 confirmed cases and 10,573 deaths. The United States has had 4 confirmed cases and 1 death. Since October 2014, the State of California has implemented a program of preparedness and response for Ebola both at the state, local, and healthcare provider levels. The California Ebola program plan, protocols, and procedures have been coordinated with the operational and emergency response plans for the state, including activation of state and local emergency operations centers in keeping with established communicable disease outbreak response plans. Public Health, in collaboration with the 61 local health departments, has implemented a traveler monitoring system to ensure active monitoring, direct active monitoring, investigation of, and locating any individual who is "lost" or not identified by the federal Centers for Disease Control and Prevention (CDC) but arrives in the jurisdiction, and a process to address noncompliant individuals.

The Department, working closely with the California Emergency Medical Services Authority, local health departments, and healthcare systems, has identified eight Ebola Treatment Hospitals and is in the process of identifying regional Ebola Assessment Hospitals for the care of suspected/confirmed Ebola cases. The Department established and continues to maintain a 24/7 contact number for local health departments and clinicians to report traveler symptoms and consult with a Public Health clinician on suspected/ confirmed cases, and maintains an Ebola hotline (telephone and email system) for questions from the general public. Local health departments have conducted drills focused on the safe and efficient transportation of suspected/confirmed Ebola cases to appropriate facilities. Public Health and local health departments have worked with hospitals to ensure preparedness to evaluate, isolate, obtain, and ship laboratory specimens to Laboratory Response Network-certified laboratories able to test for Ebola, after consultation with the CDC.

There are currently four laboratories in California that are able to test for Ebola, including the Department's State Public Health Laboratory in Richmond, the Los Angeles County Public Health Laboratory, the Sacramento Public Health Laboratory and the Orange County Public Health Laboratory. California quickly responded to the possible public health threat of Ebola, collaborating with partners across the disciplines and agencies, preparing for the monitoring and management of travelers, and preparing for the care of any suspect or confirmed Ebola case.

Measles. California is currently experiencing a significant measles outbreak. The outbreak started in December 2014 when at least 40 people who visited or worked at Disneyland theme park in Orange County in mid-December contracted measles. The outbreak has since spread to at least half a dozen other states.

As reported in the *Morbidity & Mortality Weekly Report* (MMWR, February 20, 2015): As of February 11, a total of 125 measles cases with rash occurring during December 28, 2014–February 8, 2015, had been confirmed in U.S. residents connected with this outbreak. Of these, 110 patients were California residents. Thirty-nine (35%) of the California patients visited one or both of the two Disney theme parks during December 17–20, where they are thought to have been exposed to measles, 37 have an unknown exposure source (34%), and 34 (31%) are secondary cases. Among the 34 secondary cases, 26 were household or close contacts, and eight were exposed in a community setting. Five (5%) of the California patients reported being in one or both of the two Disney theme parks during their exposure period outside of December 17–20, but their source of infection is unknown. In addition, 15 cases linked to the two Disney theme parks have been reported in seven other states: Arizona (seven), Colorado (one), Nebraska (one), Oregon (one), Utah (three), and Washington (two), as well as linked cases reported in two neighboring countries, Mexico (one) and Canada (10).

Among the 110 California patients, 49 (45%) were unvaccinated; five (5%) had 1 dose of measles-containing vaccine, seven (6%) had 2 doses, one (1%) had 3 doses, 47 (43%) had unknown or undocumented vaccination status, and one (1%) had immunoglobulin G seropositivity documented, which indicates prior vaccination or measles infection at an undetermined time. Twelve of the unvaccinated patients were infants too young to be vaccinated. Among the 37 remaining vaccine-eligible patients,

28 (67%) were intentionally unvaccinated because of personal beliefs, and one was on an alternative plan for vaccination. Among the 28 intentionally unvaccinated patients, 18 were children (aged <18 years), and 10 were adults. Patients range in age from 6 weeks to 70 years; the median age is 22 years. Among the 84 patients with known hospitalization status, 17 (20%) were hospitalized.

Measles is a highly contagious viral disease. It is widespread in many parts of the world, including Europe, Africa, and Asia. Measles begins with a fever that lasts for a couple of days, followed by a cough, runny nose, conjunctivitis (pink eye), and a rash. Infected people are usually contagious from about 4 days before their rash starts to 4 days afterwards. According to the CDC, Measles can cause serious health complications, such as pneumonia or encephalitis, and even death. Children younger than 5 years of age and adults older than 20 years of age are at high risk of getting a serious case of measles. About 1 in 4 unvaccinated people in the U.S. who get measles will be hospitalized; 1 out of every 1,000 people with measles will develop brain swelling (encephalitis); 1 or 2 out of 1,000 people with measles will die, even with the best care.

BUDGET CHANGE PROPOSALS

Infant Botulism BCP

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. According to DPH, 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.

Ebola Emergency Preparedness BCP

Budget Proposal. DPH requests $15.45 million (federal fund expenditure authority) to support accelerated state and local public health and healthcare facility preparedness and operational readiness for responding to the Ebola virus. This proposal implements a federal grant awarded to California.

Background. The threat of Ebola is a top national public health priority. To ensure that state and local health departments continue to actively monitor travelers and conduct surveillance of Ebola, and to ensure that the healthcare system can assess and treat suspect and confirmed Ebola patients, the federal government is providing $145 million from the CDC for *Public Health Emergency Preparedness* and $162 million in Part A *Hospital Preparedness Program* Ebola Supplemental funding to existing awardees.

Public Health Emergency Preparedness (PHEP) supplemental Ebola funding supports state and local public health preparedness planning and operational readiness for responding to Ebola. The funding is intended to:

- Support accelerated public health preparedness planning for Ebola within state, local, territorial, and tribal public health systems;
- Improve and assure operational readiness for Ebola;
- Support state, local, territorial, and tribal Ebola public health response efforts; and
- Assure collaboration, coordination, and partnership with the jurisdiction's healthcare system to assist in the development of a tiered system for Ebola patient care.

The PHEP Ebola supplemental funding budget period and project period are 18 months: April 1, 2015 through September 30, 2016. The precise award date is unknown at this time. The Department will receive $7.6 million to support activities in all California counties except Los Angeles, which will receive $3.2 million directly from the CDC. Funding can be used by the state and local health departments to build preparedness capabilities in the following areas: Community Preparedness, Public Health Surveillance and Epidemiological Investigation, Public Health Laboratory Testing, Non-Pharmaceutical Interventions, Public Health Responder Safety and Health, Emergency Public Information and Warning/Information Sharing, and Medical Surge.

Hospital Preparedness Program funds support hospitals, clinics and other health care facilities and emergency medical services systems to respond to any suspected Ebola case. The United States Department of Health and Human Services is awarding a total of $194.5 million in funding for Ebola healthcare system preparedness and response and the development of a regional Ebola treatment strategy across the 50 states and multiple territories. This funding is available over a five-year period with the expectation that most of the funds will be expended in the first year to build capacity. The application is due to the federal government on April 22, 2015 with an anticipated award date after May 18, 2015. The funding is divided into two parts: Part A funds are provided to support infrastructure costs, staff training, personal protective equipment, and annual exercises for California's identified Ebola Treatment and Assessment Hospitals, outside of Los Angeles, to ensure readiness to respond to Ebola virus disease over the five-year project period. The Department will receive $5.6 million in Part A funding and Los Angeles will receive $2.2 million directly to address Ebola Treatment and Assessment Centers located in Los Angeles. Part B funds are provided on a competitive basis to states at high risk, such as California, to build a Regional Treatment Center in each of the ten Health and Human Services regions creating a nationwide, regional treatment network for Ebola and other infectious diseases ($2.25 million in year one followed by $250,000 each year for four additional years). California will receive a total of $7.85 million in Part A and B funding in year one.

The *Hospital Preparedness Program* grant provisions include regional healthcare planning and preparedness – a critical element in California's ability to respond to, manage, and recover from public health emergencies like Ebola. Both *Public Health*

Emergency Preparedness and *Hospital Preparedness Program* capabilities require up-to-date operational response plans, staff training, and drills and exercises.

The CDC encourages awardees to collaborate closely with their jurisdictional infection control subject matter experts and the state's healthcare-acquired infection multidisciplinary advisory group (or other state infection control groups) to support the development of stronger hospital infection control programs. The CDC also strongly encourages state health departments to work closely with local and tribal entities in their jurisdictions to ensure they have the information and resources needed to properly prepare for and respond to infectious disease outbreaks such as Ebola, and to collaborate with the healthcare sector through recipient and sub-recipient participation in regional healthcare coalitions.

Planning for Ebola events is particularly important because the Department must apply limited response resources at hand while attempting to support accelerated public health preparedness within state, local, territorial, and tribal public health systems. Decisions to prioritize how and where to apply all types of limited resources for the most effective and efficient response are a challenging reality in an event like Ebola. Under these conditions, the goal is still to improve and assure operational readiness.

STAKEHOLDER PROPOSALS

Lab Aspire. The Health Officers Association of California (HOAC) requests $1 million to reinstate the Lab Aspire Program, and $102,000 to support a state public health microbiologist. The 2012 Budget Act eliminated $2.2 million (General Fund) for the Public Health Laboratory Training Program ("Lab Aspire"). This program provided local assistance grants to subsidize training, support, outreach and education, and provided funding for doctoral candidate stipends and post-doctoral fellowships for individuals training for public health laboratory directorships. There are 36 local public health labs in California. Public health lab directors must meet state and federal requirements to run a lab, that tests human specimens, and must have the leadership and public health training needed to oversee the functions of a laboratory that protect the health of the public. Federal law (the Clinical Laboratory Improvement Amendments of 1991) requires that public health lab directors have a doctoral degree, national board certification, and four years of supervisory experience post-doctorate. HOAC states that during the six years that this program received state funds, the program supported 13 students who graduated and became: 5 public health lab directors, 1 assistant lab director, 2 hospital directors, 1 UCLA faculty member, and several public health microbiologists.

HOAC supports restoring funding for this program, citing an ongoing insufficient supply of qualified lab directors in the state. Public health lab directors are required to hold a doctorate degree, board certification, California Public Health Microbiologist certification, and have at least four years of experience in a public health lab. Specifically, HOAC proposes to restore funding, but with modifications to the program such that assistance be limited to assistant lab directors employed in local public health labs. These individuals would be eligible for a four-year commitment to funds, thereby allowing them

to accrue the four years of lab experience necessary to become a public health lab director.

HOAC states that the proposed state microbiologist would provide expert support to local health departments, which need this expertise on an ongoing basis. It would be cost effective to have one microbiologist to serve the entire state, rather than each local health jurisdiction hiring its own. Moreover, this falls well within the purpose and function of the state public health laboratory, and is a key part of the state's overall response to communicable disease outbreak, including Ebola, measles, and others.

Hepatitis C Virus (HCV) Prevention

HCV advocates have brought three proposals (described below) to the Subcommittee in response to this epidemic. It is reported that an estimated 750,000 Californians have HCV, which can lead to many other conditions, including cirrhosis of the liver, hepatic coma, end-stage liver disease, liver cancer, and death. HCV is the leading indication for liver transplant in the U.S. and a substantial cause for hospitalizations; advocates report that between 2002 and 2011, there were over 400,000 hepatitis B and C-related hospitalizations in California, costing $26 billion. Syringe sharing, among people who inject drugs, is the leading cause of HCV transmission and the second leading cause of HIV transmissions.

1. ***$600,000 for HCV Rapid Tests***. This proposal is to provide $600,000 to the Office of AIDS to purchase rapid hepatitis C antibody test kits. The kits cost approximately $18 per kit and therefore this funding could purchase approximately 33,333 to be provided to community-based programs that serve low-income communities, especially the remaining uninsured. Advocates state that testing is a key component to preventing the spread of this, or any, disease.

2. ***$3 million for State Syringe Exchange Clearinghouse***. Advocates propose $3 million for syringe exchange and disposal programs by creating a state clearinghouse in order to purchase sharps disposal containers, sterile syringes, and other materials vital to the operation of these programs. The proposal is based on the notion that the state, as a single large buyer, could obtain these materials at lower cost than is available to each individual program, thereby reducing costs and providing much-needed support to the programs at the same time. Syringe exchange programs are the longest standing evidence-based intervention to prevent HIV and hepatitis C among injection drug users. Syringe programs have proven to dramatically reduce infection rates among active injection drug users. Advocates argue that, due to the long-standing ban on federal funding, coupled with the elimination of state funding, the effectiveness of this proven intervention has been diminished in California.

3. ***HCV Linkage & Retention in Care Demonstration Projects***. Advocates request $5 million for the Office of AIDS to support at least three 3-year demonstration projects to include innovative outreach, screening, and linkage to and retention in care efforts for people with HCV. The proposal estimates that these projects would serve approximately 55,555 people and would be modeled after successful programs on HIV patient navigation and linkages/retention in

care. Supporters of this proposal state that projects such as these would serve to reduce new HCV infections, improve health outcomes, reduce disparities in vulnerable populations, and reduce transmission of the virus to others.

AIDS Drug Assistance Program (ADAP)/Office of AIDS Health Insurance Premium Payment (OA-HIPP) Eligibility Modernization. Advocates propose to expand eligibility for the ADAP and OA-HIPP programs. These proposals, which may result in program savings in out-years because of the current drug rebate return, include:

1. 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.

2. Increase Income Limit – Advocates also propose 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.

   ***Technical Assistance from DPH*.** 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 ADAP 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. 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.

   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 this estimate.

AIDS Drug Assistance Program (ADAP)/Office of AIDS Health Insurance Premium Payment (OA-HIPP) Stability Funding. Advocates propose $2 million to increase staff, particularly enrollment workers, and propose an additional $1 million to implement program improvements identified in a study by the California HIV/AIDS Policy Research Centers. Advocates explain that as the healthcare world has changed substantially, primarily as a result of Affordable Care Act implementation, enrollment in these programs has increased substantially. Moreover, in 2016, OA-HIPP will begin to cover medical out-of-pocket costs, and therefore advocates estimate a doubling of enrollment in the program. In addition to helping individuals enroll in these programs, enrollment workers also often serve as the only point of contact for a client in resolving access problems with the programs. The study referenced above found that: 1) eligibility and enrollment procedures need to be clarified and streamlined; 2) communications problems need to be addressed; 3) programmatic challenges burden consumers; and 4) programmatic challenges and rapid growth have had a substantial impact on program staff. Supporters of this proposal hope to double the number of enrollment workers; add a manager to work with enrollment workers on solutions to problems; support enrollment workers with program changes; implement a hotline for enrollment workers to seek assistance with problems; and establish quality measures in both programs.

Pre-Exposure Prophylaxis (PrEP) Access & Affordability Program. Advocates propose $3 million for a PrEP Access and Affordability Pilot Program that would include: outreach and education, patient navigation, clinical and non-clinical provider training, and cost-sharing assistance for uninsured and underinsured individuals. PrEP is a promising new FDA-approved drug that prevents HIV infection in at-risk individuals. It is critically important for people who are in communities experiencing significant spikes in new HIV infections. If used correctly, PrEP is over 90 percent effective in preventing new infections. However, knowledge and use of this preventive drug therapy is quite limited due to several barriers, including the high cost of the drug. The actual cost of the drug is reported to be $1,300 per 30-day supply, and although the drug is covered by most (if not all) public and private insurance plans, often this coverage involves costly co-pays or deductibles. For example, advocates cite the Covered California Bronze plan would require a $6,600 deductible and a 30 percent "coinsurance," amounting to approximately $400 per month. Advocates also cite examples of health care providers failing to prescribe the drug to qualified patients due to concerns about side effects, drug resistance and sexual risk compensation. Supporters of this proposal describe this intervention as a key component to an overall effective strategy to reach 0 HIV infections. Both Washington State and New York have programs to promote the use of PrEP.

HIV Demo Projects in Small Counties. Advocates propose $3 million to support "high-impact" HIV services in small and mid-size counties. During the recent recession, at least $82 million was cut from the Office of AIDS for HIV prevention and testing, which advocates state affected small and mid-size counties the most, resulting in a substantial reduction in services in these counties. Although large counties represent the lion-share of HIV cases, some small counties have experienced recent surges in HIV rates that are going unaddressed, according to supporters of this proposal.

Sexually Transmitted Diseases (*STD) Prevention and Services*. Advocates are requesting $10 million to augment the current funding of $1.6 million for the STD Control Branch at DPH for their support of local health jurisdictions (LHJs) with high STD rates for STD prevention efforts. Advocates state that the current $1.6 million is distributed to 41 LHJs, some receiving as little as $4,500. They also project that funding will be eliminated for 13 LHJs in 2015-16, though these figures have yet to be confirmed by the administration. Supporters of this proposal cite Centers for Disease Control and Prevention estimates of approximately 19 million new STD infections each year, almost half of which are among people ages 15 to 24. The CDC also estimates U.S. health care costs resulting from STDs to be approximately $15.9 billion annually. The California Family Health Council reports California's annual health care costs of STDs to be $1 billion. STDs disproportionately affect young people, men who have sex with men, and communities of color. STD rates among African Americans in California are up to 26 times higher than rates experienced by Caucasians, according to the California Family Health Council. The AIDS Healthcare Foundation cites data from DPH that indicates a dramatic increase in STD rates in recent years. Specifically, from 2009 to 2013, chlamydia rates rose by 17 percent, gonorrhea rates by 63 percent, and syphilis rates by 76 percent.

STAFF COMMENTS/QUESTIONS

The Governor included substantial resources in the budget to cover the high costs of treating HCV, including $300 million above program-specific resources, such as within the Medi-Cal and ADAP budgets. Much discussion has ensued, including in this Subcommittee, regarding onerous HCV treatment costs, in light of the significant amount of treatment resources needed and their high cost. Therefore, it is incumbent upon the state to also consider public health strategies that have the potential to reduce the size of the population in need of high-cost treatment for HCV, as well as for many other infectious diseases.

The Subcommittee requests DPH to provide an overview of infectious disease control in California, present the Infant Botulism and Ebola Preparedness BCPs, and respond to the following:

1. Please provide funding history of infectious disease control, particularly with regard to reductions made during the recent recession.

2. What does DPH see as the most significant challenges in infectious disease control at this time?

The Subcommittee requests the Legislative Analyst's Office to provide a brief description of the proposals from stakeholders and advocates that are described in this section of the agenda.

Staff Recommendation: Subcommittee staff recommends approval of the Infant Botulism Budget Change Proposal, as proposed, and recommends holding open the Ebola Preparedness Proposal to allow for additional time for review.