AGENDA

ASSEMBLY BUDGET SUBCOMMITTEE NO. 1

HEALTH AND HUMAN SERVICES

ASSEMBLYMEMBER TONY THURMOND, CHAIR

MONDAY, MARCH 2, 2015

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

ITEMS TO BE HEARD

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4265 DEPARTMENT OF PUBLIC HEALTH

ISSUE 1: DEPARTMENT OVERVIEW

PANELISTS

- **Daniel Kim**, Chief Deputy Director, Operations, Department of Public Health
- **Jamey Matalka**, Principal Program Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office

The Department of Public Health (DPH) is dedicated to optimizing the health and well-being of the people in California, primarily through population-based programs, strategies, and initiatives. The DPH's goals are to 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; and promote and maintain an efficient and effective organization.

DPH Budget

As summarized in the table below, the Governor's proposed 2015-16 budget provides approximately $3.1 billion overall, representing a $92.5 million (3.1 percent) total funds, increase over the 2014 Budget Act.

- This increase primarily reflects a significant (61 percent) increase in the Licensing and Certification Program (L&C) Fund. The L&C Program's full budget estimate will be discussed in detail at the Subcommittee's hearing on Monday, March 9, 2015.

- General Fund dollars make up just 3.9 percent of the department's total budget while federal funds make up approximately 56 percent of the total budget.

- Of the total funds, $800.9 million is for State Operations, while the remaining $2.3 billion is for local assistance.

DEPARTMENT OF PUBLIC HEALTH *(Dollars In Thousands)*					
Fund Source	**2013-14 Actual**	**2014-15 Projected**	**2015-16 Proposed**	**Budget Act to BY Change**	**% Change**
General Fund	**$115,383**	**$119,639**	**$120,060**	**$4,677**	**4.1%**
Federal Funds	$1,705,912	$1,742,541	$1,750,166	$44,254	2.6%
Special Funds & Reimbursements	$1,117,731	$1,011,119	$1,113,996	$(3,735)	(0.3)%
Licensing & Certification	$77,961	$95,055	$125,333	$47,372	**61%**
Total Expenditures	**$3,016,987**	**$2,968,354**	**$3,109,555**	**$92,568**	**3.1%**
Positions	3,795.7	3556.1	3,838.1	42.4	1.1%

The following table shows the proposed expenditures by program area:

DPH Program Expenditures *(In Thousands)*			
Program	**2013-14 Actual**	**2014-15 Estimate**	**2015-16 Proposed**
Emergency Preparedness	$85,207	$98,188	$98,335
Chronic Disease Prevention & Health Promotion	$265,305	$303,433	$344,851
Infectious Disease	$578,237	$572,688	$603,412
Family Health	$1,549,830	$1,640,859	$1,674,457
Health Statistics & Informatics	$25,879	$27,434	$27,666
County Health Services	$14,627	$15,638	$15,112
Environmental Health	$312,548	$87,421	$90,822
Health Facilities	$174,856	$209,322	$241,449
Laboratory Field Services	$10,499	$13,372	$13,452
Total Expenditures	**$3,016,987**	**$2,968,354**	**$3,109,555**

Major Changes Proposed

- *Licensing & Certification (L&C).* The Governor's Budget includes $21.8 million from the State Department of Public Health Licensing and Certification Program Fund and 237 positions to meet state and federal licensing and certification workload and to implement quality improvement projects within the L&C Program. In addition, the Budget includes $9.5 million to augment the Los Angeles County Contract to allow the County to complete high-priority federal and state workload; and, $378,000 and 3 state positions to provide onsite oversight, training, and quality improvement activities in Los Angeles County. This proposal will be discussed in detail at the Subcommittee's hearing on Monday, March 9, 2015.

- *Food Safety*. The Governor's Budget includes two proposals to improve the oversight of food safety: (1) $716,000 from the Food Safety Fund and 4 positions to implement food safety transportation enforcement activities as a result of a court

judgment (The People of the State of California v. Sysco Corporation); and (2) $804,000 from the Food Safety Fund and 6 positions to review new applications and conduct statutorily-mandated inspections of food processors and distributors. These proposals will be heard at the Subcommittee's hearing on Monday, April 13, 2015.

- *Problem Gambling*. The Governor's Budget includes $5 million from the Indian Gaming Special Distribution Fund and 2 positions to make the California Gambling Education and Treatment Services regional pilot program permanent to continue to address problem gambling. This proposal will be heard at the Subcommittee's hearing on Monday, April 13, 2015.

BACKGROUND

The overall structure of DPH is as follows:

Department Director / State Public Health Officer
- Civil Rights
- California Conference of Local Health Officers
- Office of Health Equity
- Office of Quality Performance and Accreditation
- Administration and Public Affairs
- Center for Health Statistics and Informatics
- Emergency Preparedness Office
- Office of the State Public Health Laboratory Directors

Policy and Programs
- Emergency Preparedness Office
- Center for Health Statistics and Informatics
- Legislative and Governmental Affairs
- Office of State Laboratory Director
- Laboratory Field Services

Center for Chronic Disease Prevention and Health Promotion
- Chronic Disease and Injury Control
- Environmental and Occupational Disease Control
- Office of Problem Gambling

Center for Environmental Health
- Environmental Management
- Food, Drug, and Radiation Safety

Center for Family Health
- Family Planning
- Genetic Disease Screening Program
- Maternal, Child, and Adolescent Health
- Women, Infants, and Children

Center for Health Care Quality

- Healthcare Association Infections Program
- Licensing and Certification

Center for Infectious Diseases

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

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."

STAFF COMMENTS/QUESTIONS

The Subcommittee requests the DPH to provide an overview of the department and its proposed budget, and to respond to the following:

1. Please explain how the department sets public health priorities for the state.

2. What are or should be the state's public health priorities in 2015?

3. Please describe the department's "Public Health Accreditation." What is the value of this accreditation?

Staff Recommendation: This is an informational item and no action is necessary.

ISSUE 2: AIDS DRUG ASSISTANCE PROGRAM (ADAP) ESTIMATE & BUDGET CHANGE PROPOSAL

PANELISTS

- **Karen Mark**, Chief, Office of AIDS, Center for Infectious Diseases, DPH
- **Niki Dhillon,** Chief, AIDS Drug Assistance Program Branch, Center for Infectious Diseases, DPH
- **Kimberly Harbison**, Finance Budget Analyst, Department of Finance
- **Jamey Matalka**, Principal Program Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

The proposed 2015-16 ADAP budget includes total funding of $415 million, a $25 million decrease from the 2014 Budget Act, but a $30.1 million increase over the revised current year estimate of $384.9 million. This decrease primarily reflects savings resulting from the implementation of the Affordable Care Act (ACA), which has led to caseload shifting to comprehensive coverage through either Covered California or Medi-Cal, as well as lower Hepatitis C treatment costs than expected.

BACKGROUND

ADAP pays for HIV/AIDS drugs for individuals who could not otherwise afford them (up to $50,000 annual income). Drugs on the ADAP formulary slow the progression of HIV disease, prevent and treat opportunistic infections, and treat the side effects of antiretroviral therapy. Specifically, ADAP is made up of the following two services:

1) Medication Program. This pays the prescription costs for drugs on the ADAP formulary (either the full cost of medications or co-pays and deductibles) for the following groups:
   a) ADAP-only clients, for whom ADAP pays 100 percent of the prescription drug costs as these clients do not have a third-party payer;
   b) Medi-Cal share of cost clients, for whom ADAP pays 100 percent of the prescription drug costs up to the client's share of cost amount;
   c) Private insurance clients, for whom ADAP pays prescription drug co-pays and deductibles; and
   d) Medicare Part D clients, for whom ADAP pays the Medicare Part D drug co-pays and deductibles.

2) Insurance Assistance Program. This pays for private health insurance premiums or Medicare Part D premiums, for eligible clients with the following three types of health insurance:
   a) Non-Covered California private insurance;
   b) Private insurance purchased through Covered California; and
   c) Medicare Part D.

ADAP LOCAL ASSISTANCE BUDGET *(In Millions)*					
Funding Source	**2014-15 Budget**	**2014-15 Estimate**	**2015-16 Proposed**	**BA to BY Change**	**% Change**
General Fund	$0	$0	$0	$0	0%
Federal Fund	$107.8	$131.2	$108.1	$0.3	0.3%
Rebate Fund	$278.6	$247.5	$288.6	$10	3.6%
Reimbursements	$53.6	$6.2	$18.2	$(35.4)	(66.1)%
Total Expenditures	**$440.0**	**$384.9**	**$415.0**	**$(25)**	**(5.7)%**

The following are the significant influences on the ADAP budget since adoption of the 2014 Budget Act:

2014-15 Changes

- Covered California: a larger number of clients enrolled in Covered California than was initially predicted and is expected to continue through 2014-15. This reduces ADAP costs because the program covers only co-pays and deductibles for this population rather than the full cost of the drugs.
- Medi-Cal Expansion: a larger number of clients transitioned to Medi-Cal than was initially estimated.
- Hepatitis C Treatment: fewer clients are predicted to access hepatitis C treatment than was initially estimated.

2015-16 Changes

- The ADAP estimate includes a modest increase in expenditures in 2015-16 due to the fact that by the end of the 2014-15 fiscal year, the major caseload shifts to Covered California and Medi-Cal will be complete and therefore the caseload in ADAP will stabilize. Additionally, due to the life-saving ability of the HIV/AIDS drugs, an increasing number of people are living with HIV or AIDS while the infection rate is stable at approximately 5,000 new infections per year; therefore, an increasing number of people need assistance with the cost of these drugs.

The chart below compares the two major types of ADAP expenditures (medication and insurance assistance) for the current year and budget year:

ADAP Caseload & Expenditures								
	2014-15				2015-16			
	CASELOAD		EXPENDITURES		CASELOAD		EXPENDITURES	
	Number	%	Number	%	Number	%	Number	%
Medication	33,791	90	$366,148,333	96	34,795	87	$392,143,944	95
Insurance Assistance	3,911	10	$14,090,513	4	5,021	13	$18,534,825	5
TOTAL	**37,702**	**100**	**$380,238,846**	**100**	**39,816**	**100**	**$410,678,769**	**100**

ADAP Cost Assumptions

The following are additional assumptions or variables that affect the ADAP budget:

- *New Budget Projection Model.* DPH has changed its budgeting methodology for many of its large case-load driven budget estimates, including for ADAP. ADAP is no longer using a linear regression model because, according to the Office of AIDS (OA), the model was unable to accurately account for changing trends in caseload resulting from impacts of the ACA. The new model has two input variables – monthly clients served and expenditures per-client per-month.

- *Hepatitis C Treatment Costs.* As discussed in the Subcommittee's February 23, 2015 agenda under the Department of Health Care Services (DHCS), the proposed budget includes a $300 million set-aside to cover the costs of hepatitis C treatment across various state programs, including ADAP. The ADAP formulary already covers two hepatitis C drugs and expects to add more as they become FDA-approved. ADAP has access to discounted pricing on drugs generally, and ADAP programs nationally were able to negotiate a rebate on one of these drugs, though the specific amount of the rebate is still unknown. Several variables affect this situation making it difficult to estimate costs going forward, including: new drugs, evolving treatment guidelines, and the involvement of multiple state agencies. The OA points out that for people with both HIV and hepatitis C, the hepatitis progresses much faster.

- *Coverage for Out-Of-Pocket Costs.* In January of 2016, ADAP will begin covering out-of-pocket costs for ADAP clients who obtain private insurance coverage. Currently, these high out-of-pocket costs create a disincentive for people to obtain private insurance coverage and therefore some choose to stay in ADAP only. This assistance will remove this disincentive and result in savings estimated to be $3.1 million in 2015-16. This new assistance was approved through 2014 budget trailer bill.

- *Safety Net Care Pool Funds.* As discussed in the Subcommittees February 23, 2015 agenda, DHCS anticipates the loss of Safety Net Care Pool (SNCP) Funds with the expiration of the current 1115 Medicaid Waiver on October 31, 2015. Several state programs, including ADAP, have benefited from SNCP funds through the use of certified public expenditures. Therefore, the 2015-16 ADAP budget assumes the loss of these funds, which is addressed through a combination of decreasing program costs and an increase in the use of ADAP Rebate Fund. HIV/AIDS advocates point out that SNCP funds replaced General Fund in ADAP, and therefore make the case that in the absence of this funding, General Fund should be restored to the OA to address new and on-going HIV/AIDS prevention needs.

ADAP Eligibility Verification Budget Change Proposal

The OA is requesting $536,000 in ADAP Rebate Fund expenditure authority and 5.0 positions to support the client eligibility verification workload for ADAP, as required by the federal Health Resources and Services Administration (HRSA).

BACKGROUND

Currently, and historically, eligibility determinations for ADAP have been done through local ADAP offices. Local enrollment sites throughout the state employ ADAP enrollment workers who are trained on client enrollment procedures, and maintain secure paper-based client files. These local workers enroll clients electronically using ADAP's Pharmacy Benefits Manager, which provides centralized services to provide ADAP clients with direct prescription medication services from approximately 4,000 pharmacies in the ADAP network.

ADAP state staff conducts periodic site visits to monitor 175 local enrollment sites and review a small sample of client file documents to verify the accuracy of local program workers who are performing client eligibility determinations. Currently, verifying eligibility is a paper-based, and labor-intensive, process; staff are required to verify proof of: California residency, picture identification, income, other health insurance, HIV diagnosis from a physician, and laboratory test results.

In 2013, HRSA conducted an audit of California's ADAP and recommended changes to the program's system for eligibility verification. HRSA stated that the fact that ADAP eligibility documentation is not reviewed by anyone other than the local worker leads to the potential for fraud and abuse. Therefore, HRSA strongly recommended that the OA develop a centralized electronic system with uploading capability to allow DPH to conduct a secondary review of all ADAP client applications. Specifically, the HRSA audit states: "Public Health needs to strengthen its internal controls over the eligibility process and enhance training for local enrollment workers to ensure payments are only made to eligible recipients and that all required documentation to verify eligibility is maintained in the recipient's file."

In order to comply with the HRSA recommendation to develop and use a centralized electronic system, DPH has amended the ADAP Pharmacy Benefits Manager contract to grant both ADAP state staff and local enrollment workers the ability to add, store, view and delete scanned client eligibility documents. DPH states that this new system will be fully implemented and operational in July 2015.

DPH also explains that current staffing levels are not sufficient to review all projected 34, 795 client files, in order to achieve HRSA compliance, ultimately putting the state at risk of losing HRSA funding for ADAP ($167.2 million in 2014-15).

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present the ADAP estimate and the budget change proposal, and respond to the following:

1. Please describe significant changes to the ADAP budget.

2. Please describe the impact on the program of the expected loss of Safety Net Care Pool funding?

3. Please provide an update on the $3 million augmentation in the 2014 Budget Act for HIV Demonstration Projects.

4. Please clarify the classifications the requested positions would fall under.

5. Please provide some specific examples of the type of work to be done by these new positions.

Staff Recommendation: Staff recommends holding open the ADAP estimate until after the release of the May Revision, in order to consider updates and changes. Staff also recommends approval of the requested ADAP rebate fund expenditure authority of $536,000 and 5.0 positions to centralize ADAP eligibility verification.

ISSUE 3: WOMEN INFANTS & CHILDREN (WIC) PROGRAM ESTIMATE

PANELISTS

- **Connie Mitchell**, Deputy Director, Center for Family Health, DPH
- **Christine Nelson**, Chief, Women Infants & Children Division, Center for Family Health, DPH
- **Kimberly Harbison**, Finance Budget Analyst, Department of Finance
- **Jamey Matalka**, Principal Program Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

WIC provides supplemental food and nutrition for low-income families (185 percent of poverty or below) with pregnant women, breastfeeding and early postpartum mothers, infants, and children up to age five. WIC services include nutrition education, breastfeeding support, help finding health care and other community services, and checks for specific nutritious foods that are redeemable at retail food outlets throughout the state. WIC is not an entitlement program and must operate within the annual grant awarded by the USDA.

As shown in the table below, the WIC estimate proposes total expenditures of $1,188,528,224 in 2015-16, a $28.5 million (2.5%) increase over the revised estimate for 2014-15, and a $1.6 million (0.14%) decrease from the 2014 Budget Act.

WIC Expenditures					
	2014-15 Budget Act	**2014-15 Estimate**	**2015-16 Proposed**	**BA to BY Change**	**% Change**
Local Assistance	$1,136,320,825	$1,106,113,677	$1,134,668,224	$(1,652,601)	(0.15)%
State Operations	$53,860,000	$53,860,000	$53,680,000	$0	0%
Total Expenditures	**$1,190,180,825**	**$1,159,973,677**	**$1,188,528,224**	**$(1,652,601)**	**(0.14)%**

The WIC program is funded entirely with federal funds, including a Food Grant from the United States Department of Agriculture (USDA) as well as Nutrition Services and Administration (NSA) grant.

WIC Revenue					
	2014-15 Budget Act	**2014-15 Estimate**	**2015-16 Proposed**	**BA to BY Change**	**% Change**
Food Grant	$879,335,000	$858,507,870	$871,681,904	$(7,653,096)	(0.87)%
NSA Grant	$366,992,000	$389,180,635	$393,519,513	$26,527,513	7.23%
Total Revenue	**$1,246,327,000**	**$1,247,688,505**	**$1,265,201,417**	**$18,874,417**	**1.51%**

BACKGROUND

DPH administers contracts with 84 local agencies (half local government and half private, non-profit community organizations) that provide 650 locations statewide. Approximately 3,000 local WIC staff assesses and document program eligibility based on residency, income, and health or nutrition risk, and issue 4.8 million food checks each month. Local WIC agencies issue WIC participants paper vouchers to purchase approved foods at authorized stores. Examples of WIC foods are milk, cheese, iron-fortified cereals, juice, eggs, beans/peanut butter, and iron-fortified infant formula.

The goal of WIC is to decrease the risk of poor birth outcomes and improve the health of participants during critical times of growth and development. The amounts and types of food WIC provides are designed to meet the participant's enhanced dietary needs for specific nutrients during short but critical periods of physiological development.

WIC participants receive services for an average of two years, during which they receive individual nutrition counseling, breastfeeding support, and referrals to needed health and other social services. From a public health perspective, WIC is widely acknowledged as being cost-effective in decreasing the risk of poor birth outcomes and improving the health of participants during critical times of growth and development.

WIC Funding

DPH states that California's share of the national federal grant appropriation has remained at about 17 percent over the last 5 years. Federal funds are granted to each state using a formula specified in federal regulation to distribute the following:

- **Food**. Funds reimburses WIC authorized grocers for foods purchased by WIC participants. The USDA requires that 75 percent of the grant must be spent on food. WIC food funds include local Farmer's Market products.

- **Nutrition Services and Administration.** Nutrition Services and Administration (NSA) Funds that reimburse local WIC agencies for direct services provided to WIC families, including intake, eligibility determination, benefit prescription, nutrition education, breastfeeding support, and referrals to health and social services, as well as support costs. States manage the grant, provide client services and nutrition education, and promote and support breastfeeding with NSA Funds. Performance targets are to be met or the federal USDA can reduce funds.

- **WIC Manufacturer Rebate Fund.** Federal law requires states to have manufacturer rebate contracts with infant formula providers. These rebates are deposited in this special fund and must be expended prior to drawing down Federal WIC food funds.

Maximum Reimbursement Rate Methodology

The maximum amount that vendors are reimbursed for WIC food is based on the mean price per redeemed food instrument type by peer group with a tolerance for price variances (referred to as MADR). Effective May 25, 2012, USDA directed CA WIC to remove 1-2 and 3-4 cash register WIC vendors from the MADR-determination process and instead set MADR for these vendors at a certain percentage higher than the average redemption value charged by vendors with five or more registers in the same geographic region. The USDA was concerned that California was paying 1-2 and 3-4 cash register stores up to 50 percent higher than prices paid to other vendors. The WIC program submitted a plan to USDA to address price competitiveness, MADR methodology and cost containment, which was approved and implemented. The program has experienced lower overall food costs as a result.

WIC Store Moratorium

The state implemented a moratorium on new WIC stores several years ago which was lifted in phases over the past year. As of February 1, 2015, the moratorium was lifted fully for all types of new stores. Although new stores have come into the program, the overall number of WIC stores has declined, in part due to stores closing in response to the new reimbursement system put into place.

STAFF COMMENTS/QUESTIONS

The Subcommittee requests DPH to present the WIC estimate and describe significant changes to, and challenges and trends in, the program.

Staff Recommendation: Staff recommends holding this item open pending changes and updates included in the May Revision.

ISSUE 4: GENETIC DISEASE SCREENING PROGRAM ESTIMATE

PANELISTS

- **Connie Mitchell**, Deputy Director, Center for Family Health, DPH
- **Leslie Gaffney**, Assistant Division Chief, Genetic Disease Screening Program, Center for Family Health, DPH
- **John Bacigalupi**, Finance Budget Analyst, Department of Finance
- **Jamey Matalka**, Principal Program Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

The Genetic Disease Screening Program (GDSP) 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 to patients. The programs are self-supporting on fees collected from screening participants through the hospital of birth, third party payers, or private parties using a special fund—Genetic Disease Testing Fund.

The total GDSP proposed 2015-16 budget is $119.4 million, a $2.6 million increase (2.2%) over the 2014 Budget Act current year (2014-15) budget of $116.9 million. Of the proposed $119.4 million, $28.9 million is for state operations while $90.5 million is proposed for local assistance. As described in more detail below, under the description of the budget change proposal related to the Newborn Screening Program, the only significant change proposed to this program (to state operations*) is an increase of $1.975 million in Genetic Disease Screening Fund to implement AB 1559 (Pan, Chapter 565, Statutes of 2014).

GDSP Budget			
	2014-15 Budget Act	**2014-15 Estimate**	**2015-16 Proposed**
PNS Local Assistance	$42,879,713	$40,045,448	$39,962,334
NBS Local Assistance	$35,010,462	$36,838,380	$37,146,972
*State Operations	$10,763,825	$11,064,000	$13,379,000
TOTAL	**$88,654,000**	**$87,947,828**	**$90,488,306**

BACKGROUND

Prenatal Screening Program (PNS). This program screens pregnant women who consent to screening for serious birth defects. The fee paid for this screening is about $207. Most prepaid health plans and insurance companies pay the fee. Medi-Cal also pays it for its enrollees. There are three types of screening tests for pregnant women in order to identify individuals who are at increased risk for carrying a fetus with a specific birth defect. All three of these tests use blood specimens, and generally, the type of test used is contingent upon the trimester. Women who are at high risk based on the screening test results are referred for follow-up services at state-approved "Prenatal Diagnosis Centers." Services offered at these Centers include genetic counseling, ultrasound, and amniocentesis. Participation is voluntary.

Newborn Screening Program (NBS). This program provides screening for all newborns in California for genetic and congenital disorders that are preventable or remediable by early intervention. The fee paid for this screening is $111.70. Where applicable, this fee is paid by prepaid health plans and insurance companies. Medi-Cal also covers the fee for its enrollees. The NBS screens for over 75 conditions, including certain metabolic disorders, PKU, sickle cell, congenital hypothyroidism, non-sickling hemoglobin disorders, Cystic Fibrosis and many others. Early detection of these conditions can provide for early treatment that mitigates more severe health problems. Informational materials are provided to parents, hospitals and other health care entities regarding the program and the relevant conditions, and referral information is provided where applicable.

Medi-Cal Reimbursement Rate

According to DPH, DHCS applied the 10 percent Medi-Cal provider rate reduction contained in AB 97 (Committee on Budget, Statutes of 2011), to the GDSP consistent with applying AB 97 to lab rates in general. As a result, the GDSP has received a 10 percent rate reduction for GDSP participants enrolled in Medi-Cal. However, DPH has negotiated a change to this policy with DHCS, which will end this reduction and provide the GDSP with a refund. The following describes recent Medi-Cal rate reductions in recent years that have had an impact on this program:

TIME PERIOD	REDUCTION
July 2008 – February 2009	10% reduction (AB X3 5)
March 2009 – December 2011	Prior 10% reduced to 1% reduction
January 2012 – November 2013	10% reduction to lab services (AB 97)
December 2013 -	No reduction and GDSP expects a refund for June 2011 to November 2013

AB 1559 Newborn Screening Budget Change Proposal

DPH requests 1.0 permanent position and $1.975 million Genetic Disease Testing Fund in 2015-16. Of this request, $1.825 would be one-time funding and $150,000 would be ongoing. DPH is requesting these resources to comply with AB 1559 (Pan, Chapter 565, Statutes of 2014) which expands the NBS Program to include screening for adrenoleukodystrophy (ALD) as soon as ALD is added to the federal Recommended Uniform Screening Panel (RUSP).

BACKGROUND

AB 1559 requires DPH to add ALD to the list of conditions for which screening is done by the NBS, as soon as ALD is added to the federal RUSP. ALD has not yet been added to the RUSP, however DPH indicates that they are very confident that it will be, and possibly as soon as September 2015. DPH also explains that their interpretation of AB 1559 requires the program to begin screening for ALD as soon as it has been added to RUSP, despite the fact that the program will need approximately nine months to "ramp up" their readiness in terms of technological changes and upgrades. For this reason, they believe that it is imperative to secure the necessary resources and begin this ramp up as soon as possible.

ALD is an X-chromosome linked genetic disorder that is passed from mothers to sons. Once symptoms present themselves, the disease progresses quickly and successful treatment is unavailable. ALD can cause injury to the brain, nerves, and adrenal glands. The first signs of ALD are behavioral and rapidly lead to a vegetative state and ultimately death. The childhood form is the most severe and affects boys between the ages of four and eight years old. The slightly milder adult version affects men in their 20s and 30s. Unless treated before symptoms show, children affected with ALD will die within a few months to a few years. Early detection and treatment provides dramatically better quality of life for the affected individuals and their families. Cord blood and bone marrow transplants performed at a very early stage in the disease have proven to treat and heal the patient, enabling a healthy and long life. An August 26, 2000, article, "Long-term effect of bone-marrow transplantation for childhood-onset cerebral X-linked adrenoleukodystrophy," in the *Lancet* medical journal found the long-term beneficial effect of bone marrow transplantation when the procedure is done at an early stage of the disease.

DPH states that in the absence of early detection, annual treatment costs for a child with ALD, who has a late diagnosis (after symptoms appear), are estimated to be $7 to $8.2 million over 25 years; the costs for treatment of a child diagnosed through newborn screening are estimated to be approximately $3.2 million over the same time period. Overall, DPH expects health care cost savings of approximately $5.1 million for each newborn diagnosed with ALD, approximately 10 cases per year, and therefore total cost savings of approximately $50 million per year. The cost savings specifically for the Medi-Cal program is estimated to be $23 million.

The NBS is fully supported by fees, paid by insurance or individual patients, and therefore DPH proposes to raise the fee in order to cover the costs of this proposal. DPH proposes to raise the fee by $11.00 for a total fee of $122.70 beginning July 2016. DPH states that the new funding will cover the costs of: upgrading the Screening Information System, processing blood specimens, performing blood screens, testing chemicals, equipment and supplies used to assay results, and follow-up costs for screen positive cases, including case management, diagnostic work-up, confirmatory processing, provider and family education, and informative result mailers.

STAFF COMMENTS/QUESTIONS

Subcommittee staff queried DPH about whether or not it's justified to approve of these resources prior to ALD being added to the RUSP, given that the statute requires this be added to the state's screening program only if and when it has been added to the RUSP. DPH explained that they believe this is justified for two reasons: 1) they are very confident that it will be added to the RUSP, and believe that the legislation requires that the screening begin immediately; and 2) in the unlikely event that ALD is not added to the RUSP, the primary need for these resources is for technological upgrades which they state will be necessary for the eventual addition of other diseases and disorders to the NBS.

The Subcommittee requests DPH to present the GDSP estimate and the budget change proposal, and respond to the following:

Please explain what would happen to these resources in the unlikely event that the RUSP never adds ADL.

Staff Recommendation: Staff recommends holding open the GDSP estimate and the BCP to allow for May Revision updates. Staff also recommends that the Subcommittee request the administration provide provisional language as part of the May Revise, if ADL has not yet been added to the RUSP by then, that limits the department's authority to use these funds only for the purposes of AB 1559 and within the limits set forth in that statute.

ISSUE 5: RICHMOND LABORATORY CAPITAL OUTLAY PROPOSAL

PANELISTS

- **Timothy Bow**, Chief, Program Support Branch, DPH
- **Drew Johnson**, Assistant Deputy Director, Center for Infectious Diseases, DPH
- **Carlos Ochoa**, Finance Budget Analyst, Department of Finance
- **Koreen Hansen**, Principal Program Budget Analyst, Department of Finance
- **Shawn Martin**, Managing Principal Analyst, Legislative Analyst's Office
- **Public Comment**

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

BACKGROUND

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

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

- Unidirectional shower with in/out capabilities
- Pass-through autoclave sterilizer
- Equipment decontamination area
- Upgraded High-Efficiency Particulate Absorption filtration of the exhaust side of the Heating Ventilation and Air Conditioner (HVAC) system
- Positive sealing dampers on the HVAC system and through-wall ports for the safe gaseous decontamination for the laboratory
- Electronic monitoring systems within the HVAC system
- Mechanical/Valve Room changes to support the laboratory

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

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

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

3. Deconstruction of some existing walls; and

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

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

STAFF COMMENTS/QUESTIONS

As the administration describes, the VRLD is limited in its ability to quickly respond to the kinds of viruses and infectious diseases that experts reasonably expect to present in California in the future.

The Subcommittee requests DPH to present this proposal.

Staff Recommendation: Staff recommends approval of this request for $4.3 million General Fund for a one-time capital outlay appropriation to upgrade the Richmond Lab.