Senate Budget and Fiscal Review—Holly J. Mitchell, Chair SUBCOMMITTEE NO. 3

Agenda

Senator Richard Pan, M.D., Chair Senator William W. Monning Senator Jeff Stone



Thursday, March 22, 2018 9:30 a.m. or upon adjournment of session State Capitol - Room 4203

Consultant: Scott Ogus

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PUBLIC COMMENT

Pursuant to the Americans with Disabilities Act, individuals who, because of a disability, need special assistance to attend or participate in a Senate Committee hearing, or in connection with other Senate services, may request assistance at the Senate Rules Committee, 1020 N Street, Suite 255 or by calling (916) 651-1505. Requests should be made one week in advance whenever possible.

4120 Emergency Medical Services Authority

Issue 1: Overview



Emergency Medical Services Authority – Department Funding Changes Since Budget Act			
Fund Source	2017-18 (Budget Act)	2017-18 (Revised)	2018-19 (Proposed)
General Fund (0001)	\$8,813,000	\$8,866,000	\$9,223,000
Federal Funds (0890)	\$6,224,000	\$6,313,000	\$6,290,000
Other Funds (detail below)	\$21,792,000	\$22,035,000	\$21,899,000
Total Department Funding:	\$36,829,000	\$37,214,000	\$37,412,000
Total Authorized Positions:	68.9	68.9	69.9
Other Funds Detail:			
EMS Training Prog. Approval Fund (0194)	\$208,000	\$217,000	\$217,000
EMS Personnel Fund (0312)	\$2,655,000	\$2,747,000	\$2,608,000
Reimbursements (0995)	\$17,421,000	\$17,518,000	\$17,520,000
EMT Certification Fund (3137)	\$1,508,000	\$1,553,000	\$1,554,000

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Background. The Emergency Medical Services Authority (EMSA), authorized by the Emergency Medical Services System and Prehospital Emergency Care Act, administers a statewide system of coordinated emergency medical care, injury preventions, and disaster medical response that integrates public health, public safety and health care services. Prior to the establishment of EMSA in 1980, California did not have a central state agency responsible for ensuring the development and coordination of emergency medical services (EMS) and programs statewide. For example, many jurisdictions maintained their own certification requirements for paramedics, emergency medical technicians (EMTs), and other emergency personnel, requiring individuals certified to provide emergency services in one county to re-test and re-certify to new standards to provide emergency services in a different county. EMSA is organized into three program divisions: the Disaster Medical Services Division, the Emergency Medical Services Personnel Division, and the Emergency Medical Services Systems Division.

Disaster Medical Services Division. The Disaster Medical Services Division coordinates California's medical response to major disasters by carrying out EMSA's mandate to provide medical resources to local governments in support of their disaster response efforts. The division coordinates with the Governor's Office of Emergency Services, the Office of Homeland Security, the California National Guard, the Department of Public Health, and other local, state, and federal agencies, private sector hospitals, ambulance companies, and medical supply vendors, to promote and improve disaster preparedness and emergency medical response in California.

EMS Personnel Division. The EMS Personnel Division is responsible for the certification, licensing, and discipline of all active paramedics throughout the state. The division develops and implements regulations that set training standards and the scope of practice for various levels of personnel; sets standards for and approves training programs in pediatric first aid, CPR, and preventive health practices for child day care providers and school bus drivers; and develops standards for emergency medical dispatcher training, pre-arrival emergency care instructions, and epinephrine auto-injector training.

EMS Systems Division. The EMS Systems Division is in charge of developing and implementing EMS systems throughout California, including supporting local Health Information Exchange projects that will allow the state to collect more meaningful data so emergency medical services providers can deliver better patient care. The division oversees system development and implementation by the local EMS agencies, the statewide trauma system, and emergency medical dispatcher and communication standards. It establishes regulations and guidelines for local agencies, reviews and approves local plans to ensure they meet minimum state standards, coordinates injury and illness prevention activities with the Department of Public Health and the Office of Traffic Safety, manages the state's EMS data and quality improvement processes, conducts Ambulance Exclusive Operating Area evaluations, and oversees the operation of California's Poison Control System and EMS for Children programs.

Subcommittee Staff Comment. This is an informational item.

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

1. Please provide a brief overview of EMSA's mission and programs.

Issue 2: Increased Information Technology Security Resources

Budget Issue. EMSA requests one permanent position and \$356,000 General Fund in 2018-19 and \$189,000 General Fund in 2019-20 and annually thereafter. If approved, these resources would allow EMSA to provide adequate staffing levels to strengthen the department's information technology (IT) infrastructure and compliance with state IT policy and regulatory requirements.

Program Funding Request Summary				
Fund Source 2018-19 2019-20*				
0001 – General Fund	\$356,000	\$189,000		
Total Funding Request:	\$356,000	\$189,000		
Total Requested Positions:	1.0	1.0		
	1.0	1.0		

* Positions and Resources are ongoing after 2019-20.

Background. AB 670 (Irwin), Chapter 518, Statutes of 2015, authorizes the California Department of Technology (CDT) to conduct independent security assessments of state departments and agencies, requiring no fewer than 35 assessments be conducted annually. AB 670 requires CDT to prioritize for assessment state departments or agencies that are at higher risk due to handling of personally identifiable information or health information protected by law, handling of confidential financial data, or levels of compliance with certain information security and management practices. Independent security assessments are conducted by the Cyber Network Defense (CND) Team at the California Military Department.

EMSA is responsible for administering a statewide system of coordinated emergency medical care, injury preventions, and disaster medical response that integrates public health, public safety and health care services. EMSA coordinates communications between state entities and local EMS agencies during disasters and other emergencies, assists local EMS agencies with planning, and oversees professional licensure of the state's paramedics and EMTs. In support of this mission, EMSA utilizes several software applications and information technology (IT) systems, including those utilized for licensing activities and the Disaster Medical Services Response Resources Unit's communication response assets. These applications and systems are currently maintained by an IT Unit comprised of a Chief Information Officer and five staff.

Independent Security Assessment. Pursuant to AB 670, EMSA underwent an independent security assessment conducted by CND in December 2016. According to EMSA, the assessment identified several deficiencies in EMSA's performance of its IT infrastructure and security responsibilities. The assessment also identified strategies and resources needed for remediation including one-time hardware and/or software upgrades and additional staff time dedicated to IT infrastructure responsibilities. In addition, EMSA currently designates one existing IT employee as the Information Security Officer (ISO), which is handled part-time as an ancillary duty. However, state information management policy prohibits ISOs from being "assigned multiple roles which present a conflict of interest, such as having direct responsibility for application development, information processing, technology operations, internal auditing functions, or for state entity programs". As a result, the assessment recommended EMSA designate a dedicated, full-time position to perform the functions of the ISO.

Information Security Officer and Recommended IT Upgrades. EMSA is requesting \$356,000 General Fund in 2018-19 and one Senior Information Systems Analyst to serve as ISO and oversee planning for remediation of the deficiencies identified in the CND assessment. The 2018-19 request includes \$196,000 for the one-time hardware and/or software upgrades recommended by the CND assessment to mitigate identified deficiencies. The ISO would oversee the procurement of these upgrades, as well as managing EMSA's information security and privacy planning and compliance with state IT management and security policies. In 2019-20 and annually thereafter, EMSA requests \$189,000 for ongoing support of the ISO position and maintenance of the purchased hardware and/or software.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

1. Please provide a brief overview of this proposal.

4140 OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT

Issue 1: Overview





General	Fund

Office of Statewide Health Planning and Development - Department Funding Summary			
Fund Source	2017-18 Budget Act	2017-18 Revised	2018-19 Proposed
General Fund (0001)	\$33,334,000	\$33,334,000	\$33,333,000
Federal Funds (0890)	\$1,447,000	\$1,572,000	\$1,464,000
Other Funds (detail below)	\$130,259,000	\$133,062,000	\$110,189,000
Total Department Funding:	\$165,040,000	\$167,968,000	\$144,986,000
Total Authorized Positions:	447.0	433.5	430.5
Other Funds Detail:			
Hospital Building Fund (0121)	\$61,820,000	\$63,485,000	\$63,521,000
CA Health Data and Planning Fund (0143)	\$30,557,000	\$31,388,000	\$31,752,000
Registered Nurse Education Fund (0181)	\$2,172,000	\$2,179,000	\$2,180,000
Health Fac. Const. Loan Ins. Fund (0518)	\$4,823,000	\$4,939,000	\$4,943,000

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Health Professions Education Fund (0829)	\$1,078,000	\$1,099,000	\$1,099,000
Medically Underserved Account/Phys (8034)	\$2,302,000	\$2,399,000	\$2,399,000
Reimbursements (0995)	\$863,000	\$868,000	\$868,000
Mental Health Practitioner Ed. Fund (3064)	\$394,000	\$395,000	\$395,000
Vocational Nurse Education Fund (3068)	\$224,000	\$224,000	\$224,000
Mental Health Services Fund (3085)	\$26,026,000	\$26,086,000	\$2,808,000

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

Health Care Workforce Development Division. OSHPD administers programs designed to increase access to healthcare to underserved populations and provide a culturally competent healthcare workforce. Specifically, OSHPD encourages demographically underrepresented groups to pursue healthcare careers, incentivizes primary care and mental health professionals to work in underserved communities, evaluates new and expanded roles for health professionals and new health delivery alternatives, designates health professional shortage areas, and serves as the state's central repository of health education and workforce data.

OSHPD awards scholarships and loan repayments to aspiring health professionals and graduate students who agree to provide direct patient care in medically underserved areas for one to four years. OSHPD serves as California's Primary Care Office supporting the state's healthcare workforce through pipeline development, training and placement, financial incentives, systems redesign, and research and policy with a focus on underserved and diverse communities.

Song-Brown Program. The Song-Brown Health Care Workforce Training Act (Song-Brown Program) was established in 1973 to increase the number of family physicians to provide needed medical services to the people of California. The program encourages universities and primary care health professionals to provide healthcare in medically underserved areas and provides financial support to family medicine, internal medicine, OB/GYN, and pediatric residency programs, family nurse practitioner, physician assistant, and registered nurse education programs throughout California. The Song-Brown program is aided by the California Healthcare Workforce Policy Commission (CHWPC), a 15-member citizen advisory board that provides expert guidance and statewide perspectives on health professional education issues, reviews applications, and recommends contract awards.

The Song-Brown program was funded exclusively with state General Fund until the 2004-05 fiscal year. Between 2004-05 and 2008-09, the program received a combination of General Fund and funding from the California Health Data and Planning Fund (Data Fund), which receives fee revenue from licensed health facilities in California. Beginning in 2008-09, the program received no General Fund resources until 2017-18. During that period, the program relied on resources from the Data Fund and a \$21 million grant from the California Endowment for family medicine and family nurse practitioner/physician assistance training.

The 2017 Budget Act authorized \$100 million over three years for augmentation of health care workforce initiatives at OSHPD previously approved in the 2016 Budget Act. The Legislature rejected the Administration's proposal to revert these funds to the General Fund and eliminate the health care workforce initiative augmentations permanently. The \$33.3 million annual allocation provides \$18.7 million for existing primary care residency slots, \$3.3 million for new primary care residency slots at existing residency programs, \$5.7 million for primary care residency slots at teaching health centers, \$3.3 million for newly accredited primary care residency programs, \$333,000 for the State Loan Repayment Program, and \$2 million for OSHPD state operations costs.

According to OSHPD, the Song-Brown program awarded the following in 2017-18:

- 1) Existing Primary Care Residency Slots \$16.8 million to support 134 slots in 55 programs
- 2) New Primary Care Residency Slots at Existing Programs \$2 million to support 13 slots in seven programs
- 3) Teaching Health Centers \$5.1 million to support 30 slots in six programs
- Newly Accredited Primary Care Residency Programs \$6.8 million (\$3.3 million General Fund, \$3.1 million Data Fund, and \$273,000 California Endowment Funds) to support 59 slots in ten new programs.

OSHPD reports these resources resulted in funding for a total of 72 new residency slots supported by the Song-Brown program for 2017-18.

Workforce Education and Training (WET) Program. In 2004, voters approved Proposition 63, the Mental Health Services Act (MHSA), to change the way California treats mental illness by expanding the availability of innovative and preventative programs, reduce stigma and long-term adverse impacts for those suffering from untreated mental illness, and hold funded programs accountable for achieving those outcomes. The act directed the majority of revenues to county mental health programs for community services and supports, prevention and early intervention, innovative programs, workforce education and training (WET), and capital facilities and technological needs. For WET programs, Proposition 63 allocated \$210 million to counties and \$234.5 million to the state over a ten year period beginning in 2008. The state's WET programs were originally administered by the Department of Mental Health (DMH), which developed the first five year plan for the program. After dissolution of DMH in 2012 program responsibility was transferred to OSHPD, which developed the second five year plan for 2014-2019 in coordination with the California Mental Health Planning Council.

OSHPD's WET program provides funding for stipends and loan assumption, education capacity, consumer and family member employment, regional partnerships, recruitment and retention, and evaluation of the program. According to OSHPD, in 2016-17 the WET program awarded the following:

- 1) *Stipends* \$16.2 million in stipends for psychiatric mental health nurse practitioners, clinical psychologists, marriage and family therapists, and social workers in public mental health systems (PMHS).
- 2) *Education Capacity* \$5.6 million to increase training capacity and provide clinical rotations in PMHS for psychiatric mental health nurse practitioners and clinical psychologists.
- 3) *Recruitment and Retention* \$2 million for exposure and scholarship rotations in PMHS.

In addition, OSHPD awarded multi-year grants of up to \$1.8 million to five Regional Partnerships between 2014-15 and 2016-17 to address regional needs in a variety of mental health disciplines. \$1.1 million was provided for evaluation of various program components.

WET Program "Fifth Year" Funding Proposal. Although the second five-year plan concludes in 2019, WET funding will expire on July 1, 2018, funding only four of the five years in the plan. OSHPD reports the WET program will begin to close out its existing funding awards as the expiration of funding approaches. Although no funding is allocated beyond 2018, OSHPD is still required by law to develop a five-year plan for the 2019-2024 period. OSHPD indicates it will develop strategic goals in this report without identifying funding sources. The California Council of Community Behavioral Health Agencies (CBHA) requests \$25.4 million General Fund to provide funding for 2018-19 to completely fund the fifth year of the five-year plan. According to CBHA, this funding will allow existing WET programs to continue while OSHPD and stakeholders work together on options for funding and implementing a new five-year plan.

State Loan Repayment Program. The State Loan Repayment Program (SLRP) is a federally funded, state-run program that provides student loan repayment funding to healthcare professionals who commit to practicing in Health Professional Shortage Areas (HPSAs) in California. Professionals eligible for awards under SLRP include physicians (M.D. and D.O.), psychiatric nurse specialists, dentists, mental health counselors, registered dental hygienists, health service psychologists, nurse practitioners (primary care), licensed clinical social workers, physician assistants (primary care), licensed professional counselors, certified nurse midwives, marriage and family therapists, and pharmacists. Recipients must also, among other requirements, commit to a two-year (four-year, if half-time) initial service obligation at a SLRP Certified Eligible Site (CES) in one of the areas designated as an HPSA. According to OSHPD, the SLRP made 70 awards totaling \$2 million in 2016-17.

Health Professions Education Foundation. OSHPD administers the Health Professions Education Foundation (HPEF), a 501(c)(3) non-profit public benefit corporation established in 1987 through legislation. The HPEF offers scholarships and loan repayments for students and graduates willing to practice in underserved areas. The HPEF manages the following six scholarship and seven loan repayment programs:

Program(s)	Eligible Professions
	Community Health Worker, Medical
	Assistant, Medical Imaging,
Allied Healthcare Scholarship (AHSP)	Occupational Therapy Assistant,
Allied Healthcare Loan Repayment (AHLRP)	Pharmacy Technician, Physical Therapy
	Assistant, Radiation Therapy
	Technician, Radiologic Technician
Vocational Nurse Scholarship (VNSP)	Vocational Nurses
Licensed Vocational Nurse Loan Repayment (LVNLRP)	
LVN to Associate Degree Nursing Scholarship (LVN to	Licensed Vocational Nurses
ADN)	
Associate Degree Nursing Scholarship (ADNSP)	Nursing (Associate Degree students)
Bachelor of Science in Nursing Scholarship (BSNSP)	Nursing (Bachelor's Degree students)
Bachelor of Science in Nursing Loan Repayment (BSNLRP)	

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Advanced Practice Healthcare Scholarship (APHSP) Advanced Practice Healthcare Loan Repayment (APHLRP)	Certified Nurse Midwives, Clinical Nurse Specialists, Dentists, Nurse Practitioners, Occupational Therapists, Pharmacists, Physical Therapists,
	Physician Assistants, Speech Language Pathologists
	Psychologists, Postdoctoral Psych.
Licensed Mental Health Services Provider Education	Assistants, Postdoctoral Psych.
(LMHSPEP)	Trainees, Marriage and Family
	Therapists, Clinical Social Workers,
	Professional Clinical Counselors
Mental Health Loan Assumption (MHLAP)	Determined by counties
Steven M. Thompson Physician Corp Loan Repayment	Primary care physicians (65 percent),
(STLRP)	geriatric physicians (15 percent),
	specialty physicians (up to 20 percent)

In 2016-17, the HPEF awarded 1,839 scholarships and loan repayments in its 13 programs for a total award amount of \$22.9 million. These programs are funded by a combination of foundation grant funding and licensing fees collected by professional licensing boards for the professions benefitting from HPEF training programs. Foundations providing funding include the California Endowment, the California Medical Services Project, the California Wellness Foundation, and Kaiser Permanente California Community Benefit Foundation.

Facilities Development Division – Hospital Seismic Safety. In 1971, the Sylmar earthquake struck the northeast San Fernando Valley, killing 64 people and causing significant damage to structures. In particular, the San Fernando Veterans Administration Hospital in Sylmar, constructed in 1926 with unreinforced concrete, collapsed, resulting in the deaths of 44 individuals trapped inside the building. In addition, a more recently constructed psychiatric ward at Sylmar's Olive View Community Hospital collapsed during the quake, resulting in three deaths and the evacuation of more than 1,000 patients. In response to these tragic events, the Legislature approved the Alfred E. Alquist Hospital Facilities Seismic Safety Act (Alquist Act), which required hospitals to meet stringent construction standards to ensure they are reasonably capable of providing services to the public after a disaster. In 1983, the act was amended to transfer all hospital construction plan review responsibility from local governments to OSHPD, creating the state's largest building department, the Facilities Development Division.

In 1994, the Northridge earthquake struck the San Fernando Valley again, resulting in major structural damage to many hospitals constructed prior to the Alquist Act, many of which were evacuated. In contrast, hospitals constructed in compliance with Alquist Act standards resisted the Northridge earthquake, suffering very little structural damage. In response, the Legislature approved SB 1953 (Alquist), Chapter 740, Statutes of 1994, which amended the Alquist Act to require hospitals to evaluate and rate all general acute care hospital buildings for seismic resistance according to standards developed by OSHPD to measure a building's ability to withstand a major earthquake. SB 1953 and subsequent OSHPD regulations also require hospitals to submit plans to either retrofit or relocate acute care and acute psychiatric hospitals comprised of 3,066 hospital buildings and 88,126 licensed beds covered by the seismic safety provisions of SB 1953. In addition to oversight of seismic safety compliance for

acute care hospitals, OSHPD is responsible for ensuring seismic and building safety compliance for skilled nursing facilities and intermediate care facilities. The Facilities Development Division receives funding from fees paid by hospitals and skilled nursing facilities for plan review and building permits of construction projects, as follows:

- 1) 1.95 percent of construction costs for collaborative phased plan review
- 2) 1.64 percent of construction costs for hospitals
- 3) 1.5 percent of construction costs for skilled nursing facilities

Cal-Mortgage Loan Insurance Division. OSHPD's Cal-Mortgage Loan Insurance Division administers the California Health Facility Construction Loan Insurance Program. Cal-Mortgage provides credit enhancement for eligible health care facilities when they borrow money for capital needs. Cal-Mortgage insured loans are guaranteed by the "full faith and credit" of California, which permits borrowers to obtain lower interest rates. Eligible health facilities must be owned and operated by private, nonprofit public benefit corporations or political subdivisions such as cities, counties, healthcare districts or joint powers authorities. Health facilities eligible for Cal-Mortgage include hospitals, skilled nursing facilities, intermediate care facilities, public health centers, clinics, outpatient facilities, multi-level facilities, laboratories, community mental health centers, facilities for the treatment of chemical dependency, child day care facilities (in conjunction with a health facility), adult day health centers, group homes, facilities for individuals with developmental disabilities, and office or central service facilities (in conjunction with a health facility). As of November 30, 2017, Cal-Mortgage insures 82 loans with a total value of approximately \$1.5 billion.

Information Services Division. The Information Services Division (ISD) collects and disseminates timely and accurate healthcare quality, outcome, financial, and utilization data, and produces data analyses and other products.

Information Technology Services and Support. The division supports operations, data collection, and reporting functions through maintenance of technical infrastructure and enterprise systems, including IT customer support, project portfolio management, and enterprise architecture.

Data Collection and Management. The division collects and publicly discloses facility level data from more than 6,000 licensed healthcare facilities including hospitals, long-term care facilities, clinics, home health agencies, and hospices. These data include financial, utilization, patient characteristics, and services information. In addition, approximately 450 hospitals report demographic and utilization data on approximately 16 million inpatient, emergency department, ambulatory surgery patients, and by physician, about heart surgery patients.

Healthcare Data Analytics. The division produces more than 100 data products, including maps and graphs, summarizing rates, trends, and the geographic distribution of services. Risk-adjusted hospital and physician quality and outcome ratings for heart surgery and other procedures are also published. The division conducts a wide range of special studies on such topics as preventable hospital admissions and readmission, trends in care, and racial or ethnic disparities. The division also provides information to the public on non-profit hospital and community benefits, and hospital prices and discount policies.

Engagement and Technical Assistance. The division provides assistance to the members of the public seeking to use OSHPD data and, upon request, can produce customized data sets or analyses for policymakers, news media, other state departments and stakeholders.

Subcommittee Staff Comment. This is an informational item.

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

- 1. Please provide a brief overview of OSHPD's mission and programs.
- 2. Please provide a brief update on the status of implementation and awards of funding provided for primary care workforce programs in the 2017 Budget Act.

Issue 2: Prescription Drug Cost Transparency Implementation Plan (SB 17)

Budget Issue. OSHPD requests three positions and expenditure authority from the California Health Data and Planning Fund of \$500,000 in 2018-19, \$850,000 in 2019-20, and \$800,000 in 2020-21 and annually thereafter. Beginning in 2019-20, OSHPD also requests an additional 2.5 positions for a total of 5.5 permanent positions. If approved, these positions and resources would allow OSHPD to implement prescription drug price transparency initiatives required by SB 17 (Hernandez), Chapter 603, Statutes of 2017. Pursuant to SB 17, the resources requested from the California Health Data and Planning Fund are funded by revenue transfers from the Managed Care Fund, administered by the Department of Managed Health Care, and the Insurance Fund, administered by the California Department of Insurance.

Program Funding Request Summary		
2018-19	2019-20	2020-21*
\$500,000	\$850,000	800,000
\$500,000	\$850,000	\$800,000
3.0	5.5	5.5
	2018-19 \$500,000 \$500,000	2018-19 2019-20 \$500,000 \$850,000 \$500,000 \$850,000

* Positions and Resources ongoing after 2020-21.

Revenue Transfers to CA Health Data and Planning Fund (0143)			
Fund Source	2018-19	2019-20	2020-21*
0217 – Insurance Fund	\$35,000	\$60,000	\$56,000
0933 – Managed Care Fund	\$465,000	\$790,000	\$744,000
Total Funding Request:	\$500,000	\$850,000	\$800,000

* Revenue Transfers ongoing after 2020-21.

Background. Approved by the Legislature in 2017, SB 17 was intended to provide drug cost transparency in response to the significant growth in expenditures for prescription drugs by public health care programs, commercial health plans, and the general public. These increased expenditures have been attributable to both blockbuster drugs newly brought to market, such as new treatments for hepatitis C, and existing drugs, often no longer under patent protection, for which a single manufacturer controls the drug's supply and substantially increases its price. SB 17 requires drug manufacturers to provide notice to health care purchasers and publicly report to OSHPD certain information regarding price increases for existing drugs exceeding 16 percent and for new drugs priced above certain federally established thresholds.

Implementation of OSHPD's SB 17 Responsibilities. OSHPD's primary responsibilities for implementation of SB 17 include the following:

Significant Price Increases for Existing Drugs – Notice to Purchasers of Health Care Services. SB 17 requires a drug manufacturer to report to certain public and private sector purchasers of health care services if the price of one of its manufactured drugs increases by more than 16 percent. The required notice must be provided at least 60 days prior to the price increase and must include cumulative price increases over the prior two years, the date of the expected increase, the current price, the dollar amount of the expected increase, and information about whether a change or improvement in the drug

necessitates the price increase. Prior to receiving price increase reports from drug manufacturers, a public or private sector purchaser must first register with OSHPD. OSHPD provides the list of registered purchasers to manufacturers to enable distribution of required notices of drug price increases exceeding the 16 percent threshold. These requirements took effect on January 1, 2018. OSHPD currently has an online submission form on its website for purchasers to register as well as a link to the list of registered purchasers for download by drug manufacturers.

Significant Price Increases for Existing Drugs – Quarterly Reporting. SB 17 also requires, effective no earlier than January 1, 2019, drug manufacturers subject to notice requirements due to price increases over the 16 percent threshold to report quarterly to OSHPD the following information:

- 1. A description of the factors used to make the decision to increase the price of the drug, the amount of the increase, and an explanation of how these factors explain the price increase.
- 2. A schedule of price increases for the drug for the previous five years if the drug was manufactured by the company.
- 3. If the drug was acquired by the manufacturer within the previous five years, all of the following information:
 - a. The price of the drug at the time of acquisition and the calendar year prior to acquisition.
 - b. The name of the company from which the drug was acquired, the date acquired, and the purchase price.
 - c. The year the drug was introduced to market and the price of the drug at the time of introduction.
 - d. The patent expiration date of the drug if it is under patent.
 - e. If the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug, as defined in federal regulations.
 - f. A description of the change or improvement in the drug, if any, that necessitates the price increase.
 - g. Volume of sales of the manufacturer's drug in the United States for the previous year.

OSHPD is required to post the information received from drug manufacturers quarterly and within 60 days of receipt on its website. OSHPD is also responsible for directing drug manufacturers on the format and timing of quarterly reporting requirements under these provisions of SB 17.

New High-Cost Drugs. Beginning January 1, 2019, for newly introduced drugs, SB 17 requires manufacturers to notify OSHPD within three days after release if the price exceeds the threshold set for a specialty drug for the Medicare Part D program. No later than 30 days after submitting the notification, manufacturers must provide the following information to OSHPD:

- 1. A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.
- 2. The estimated volume of patients that may be prescribed the drug.
- 3. If the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval.
- 4. The date and price of acquisition if the drug was not developed by the manufacturer.

OSHPD is required to post this information quarterly on its website on a per-drug basis that allows identification of the drug. OSHPD is also responsible for enforcement of the reporting requirements

contained within SB 17 including authority to impose civil penalties of \$1,000 per day required information is not reported after the end of the required reporting period.

OSHPD's current SB 17 implementation plan timelines are as follows:

Projected Time Period	OSHPD Activities
November – December 2017*	Compile a registry of state purchasers, healthcare service plans, health insurers, and pharmacy benefit managers that wish to receive 60-day notices of future increases, above the threshold specified, of the wholesale acquisition cost of prescription drugs.
December 1, 2017*	Open portal on OSHPD website for purchasers to register to receive 60-day notice.
January 1, 2018*	Registry to be available to drug manufacturers on OSHPD website.
January – March 2018	Begin outreach to stakeholders.
March 15, 2018	Conduct public workshop with data users.
April 11, 2018	Conduct public workshop with data submitters.
July 2018	Open rulemaking period and conduct public forum for comment.
September - December 2018	Release preliminary information reporting requirements and information collection format to drug manufacturers and share with stakeholders.
April – June 2018	Draft regulations that will take effect January 2019.
September – December 2018	Release information reporting requirements and information collection format to drug manufacturers.
January 1, 2019	Formally adopt regulations.
January 2019	Begin collecting information related to new prescription drugs from drug manufacturers. OSHPD to publish this information quarterly on its website beginning Spring 2019.
April 2019	Begin collecting first quarter 2019 prescription drug cost increase information for existing drugs from drug manufacturers.
By June 2019	Publish first quarter 2019 drug cost increase information for existing drugs on OSHPD website.

* Activity Completed

OSHPD is requesting positions and funding as follows:

For 2018-19: Three positions and \$500,000 from the California Health Data and Planning Fund.

• *One Staff Services Manager I (SSM I)* would establish a new unit in OSHPD's Accounting and Reporting Systems Section to coordinate collection and reporting of drug price information from manufacturers.

- *One Staff Information Systems Analyst* would be added to OSHPD's Information Technology (IT) Planning Group to oversee the implementation of IT systems necessary to collect and manage drug pricing and penalty collection data.
- *One Attorney III* would draft regulations to support implementation of the SB 17 program, establish support policies, procedures and appeals processes, as well as manage program enforcement.

For 2019-20: 2.5 additional positions and \$350,000 from the California Health Data and Planning Fund.

- *Two Associate Governmental Program Analysts* would support the SSM I proposed for 2018-19 to coordinate collection and reporting of drug price information from manufacturers.
- 0.5 Staff Programmer Analyst in OSHPD's IT Operations Branch to perform complex analysis, design, programming, and integration tasks for the development and ongoing maintenance of IT systems required for collection and reporting of drug price information.

Funding Provided by Managed Care Fund and Insurance Fund. SB 17 provides funding to support OSHPD's activities from the Managed Care Fund and the Insurance Fund. The Managed Care Fund, administered by the Department of Managed Health Care, collects fees from health care service plans regulated under the Knox-Keene Health Care Service Plan Act of 1975. The Insurance Fund, administered by the California Department of Insurance, collects fees from insurers regulated by the department. SB 17 governs the transfers from these two funds into the California Health Data and Planning Fund, which are based on the relative shares of covered lives in health care service plans (for the Managed Care Fund share) or health insurance products (for the Insurance Fund share). Based on this formula, seven percent of the funding for this request is provided by the Insurance Fund and 93 percent by the Managed Care Fund.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

1. Please provide a brief overview of this proposal.

4150 DEPARTMENT OF MANAGED HEALTH CARE

Issue 1: Overview





Department of Managed Health Care - Department Funding Summary				
Fund Source	2017-18 Budget Act	2017-18 Revised	2018-19 Proposed	
General Fund (0001)	\$0	\$0	\$0	
Federal Funds (0890)	\$0	\$0	\$0	
Other Funds (detail below)	\$77,221,000	\$80,167,000	\$79,207,000	
Total Department Funding:	\$77,221,000	\$80,167,000	\$79,207,000	
Total Authorized Positions:	416.6	416.6	417.6	
Other Funds Detail:				
Managed Care Fund (0933)	\$77,050,000	\$79,996,000	\$79,036,000	
Reimbursements (0995)	\$171,000	\$171,000	\$171,000	

Background. The Department of Managed Health Care (DMHC) is the primary regulator of the state's 137 health care service plans, which provide health, mental health, dental, vision, and pharmacy services to more than 26 million Californians. Established in 2000, DMHC enforces the Knox-Keene Health Care Service Plan Act of 1975, which implemented California's robust oversight regime of the managed care system. In fulfilling its regulatory responsibilities under the Act, DMHC conducts medical surveys and financial examinations to ensure health plan compliance and financial stability, provides a 24-hour call center to help consumers resolve health plan complaints, and administers Independent Medical Reviews of services denied by health plans.

Knox-Keene Health Care Service Plan Act of 1975. The Knox-Keene Health Care Service Plan Act of 1975, and subsequent amendments, is one of the most robust regulatory regimes for managed care organizations in any state in the nation. In addition to regulatory requirements related to consumer protections and plans' financial stability, the Knox-Keene Act imposes various network adequacy requirements on health care service plans designed to provide timely access to necessary medical care for those plans' beneficiaries. These requirements generally include the following standards for appointment availability: 1) Urgent care without prior authorization: within 48 hours; 2) Urgent care with prior authorization: within 96 hours; 3) Non-urgent primary care appointments: within 10 business days; 4) Non-urgent specialist appointments: within 15 business days; 5) Non-urgent appointment for ancillary services for the diagnosis or treatment of injury, illness or other health condition: within 15 business days. The Knox-Keene Act also requires plans to ensure primary care physicians are located within 15 miles or 30 minutes of a beneficiary and there is at least one primary care provider for every 2,000 beneficiaries in a plan's network.

Implementation of Timely Access Standards (SB 964). SB 964 (Hernandez), Chapter 573, Statutes of 2014, required DMHC to implement stricter oversight of health plans' compliance with standards meant to ensure timely access to care. SB 964 was introduced in response to significant expansions of managed care enrollment in both Medi-Cal and Covered California, as well as reports that certain plan products offered "narrow" provider networks that were inadequate to provide timely access to medical care for beneficiaries. SB 964 requires annual review of plans' compliance with Knox-Keene standards for providing timely access to care. DMHC previously reviewed plans' compliance every three years. SB 964 also requires plans to report the following information regarding provider networks:

- 1. Provider office location
- 2. Area of specialty
- 3. Hospitals where providers have admitting privileges, if any
- 4. Providers with open practices
- 5. Number of patients assigned to a primary care provider or a provider's capacity to be accessible and available to enrollees
- 6. Network adequacy and timely access grievances received by the plan

Plans are also required to provide these data separately for Medi-Cal and small group lines of business. DMHC is required to create a standardized methodology for plan reporting on timely access to care by January 2020.

In 2015-16, DMHC received 25 positions and expenditure authority from the Managed Care Fund of \$3.8 million to implement the provisions of SB 964. Legal staff and health program analysts in the

Office of Plan Licensing were approved to annually review provider networks and ensure compliance with timely access standards. Positions were also approved in the department's Help Center to review enrollee complaints regarding timely access and network adequacy.

In February 2017, DMHC published its timely access report for calendar year 2015. According to DMHC, 90 percent of the timely access compliance reports submitted by plans contained one or more significant inaccuracies including: 1) submission of data for providers not in the plan's network, 2) errors in calculating compliance rates, and 3) omission of compliance data for one or more required provider types. The use of an external vendor by 24 health plans to gather data and prepare compliance reports contributed to the submission of erroneous reports. The widespread inaccuracy of the data submissions made it impossible for DMHC to analyze whether plans were in compliance with timely access standards for 2015. In response, DMHC required the use of a department-approved vendor to monitor data accuracy for the 2016 calendar year submissions.

In February 2018, DMHC published its timely access report for calendar year 2016. According to DMHC, although it required health plans to use an approved external vendor to perform validation and quality assurance review of data collection, much of the data for the 2016 report had already been collected under prior methodological standards. Although the submitted data contained fewer errors than the 2015 report, there were still analytical challenges due to non-standardized data collection methods and insufficient sample sizes. The data the department was able to report included the results of surveys regarding how often providers in health plan networks had appointment availability within the required timeframes. According to DMHC, it is working with statisticians to quantify how that percentage translates into a reliable estimate of an enrollee's ability to obtain timely appointments.

Prohibition of Surprise Balance Billing (AB 72). AB 72 (Bonta), Chapter 492, Statutes of 2016, establishes a provider reimbursement, reconciliation, and complaint resolution infrastructure to eliminate "surprise balance billing", the practice of billing consumers for health care services delivered by out-ofnetwork (non-contracting) providers at an in-network (contracting) health facility. Specifically, AB 72 establishes a reimbursement rate formula for non-contracting providers, an independent dispute resolution process (IDRP) to resolve claim disputes between non-contracting providers and health plans, and regulatory and reporting requirements for DMHC and the California Department of Insurance. For consumers, AB 72 ensures that consumers are only billed for the in-network cost sharing amounts pursuant to their health care service plan contract when selecting an in-network facility for their care.

AB 72 requires DMHC to:

- 1. Establish an IDRP for claim disputes between health care service plans and non-contracting providers by September 1, 2017.
- 2. Establish uniform written procedures for the submission, receipt, processing and resolution of claim payment disputes.
- 3. Provide a report to the Governor and the Legislature containing data related to the IDRP, a summary of payments related to AB 72, and findings regarding the impact of the bill on network adequacy by January 1, 2019.
- 4. Develop a standardized methodology for plans and delegated entities to determine the average contracted rates for services subject to AB 72 by January 1, 2019.

- 5. Engage stakeholders throughout the development process with a stakeholder meeting no later than July 1, 2017.
- 6. Review average contracted rates and the policies and procedures for calculating these rates as part of the Office of Financial Review's examination of plans' fiscal and administrative affairs. Plans provide DMHC with the data, methodology and policies and procedures used to determine their average contracted rates for the 2015 calendar year, which is the base year for rate development in 2017 and beyond.

According to DMHC, no claim disputes have been received since the IDRP was established.

Consumer Outreach and Assistance Program. Section 1368.05 of the Health and Safety Code requires DMHC to contract with community-based organizations to assist consumers in navigating private and public health care coverage. Since 2012, DMHC has contracted with the Health Consumer Alliance (HCA) through the Consumer Outreach and Assistance Program (COAP) to advocate for health care consumers confronting barriers to eligibility, coverage, or obtaining services by providing free legal assistance. HCA is a statewide collaborative of consumer assistance programs operated by community-based legal services organizations, including: Bay Area Legal Aid, California Rural Legal Assistance, Central California Legal Services, Greater Bakersfield Legal Assistance, Legal Aid Society of Orange County, Legal Aid Society of San Diego, Legal Aid Society of San Mateo, Legal Services of Northern California, Neighborhood Legal Services of Los Angeles County, the National Health Law Program, and the Western Center on Law and Poverty.

According to HCA, COAP has been funded by \$2.5 million from the Managed Care Fund since 2014. The program receives an explicit allocation through provisional budget language of \$660,000, but HCA reports DMHC provides additional funding through redirection of other allocations within its overall appropriation from the Managed Care Fund. HCA requests an explicit allocation of \$2.6 million from the Managed Care Fund, which includes continued funding of the program at its current level and a cost-of-living adjustment of \$100,000.

Subcommittee Staff Comment. This is an informational item.

Questions. The subcommittee has requested DMHC to respond to the following:

- 1. Please provide a brief overview of DMHC's mission and programs.
- 2. Please summarize the findings of the 2016 Timely Access Report. Was the department able to determine whether health plans were complying with timely access standards?
- 3. What steps is DMHC taking to ensure the 2017 Timely Access Report and future reports provide useful information about compliance with required timely access standards?
- 4. How frequently do non-contracting providers offer services in contract hospitals? Has there been any change in contracting practices for these providers since implementation of AB 72?
- 5. How does the use of non-contracting providers in contract hospitals factor into the evaluation of a plan network's ability to provide timely access to care?

Issue 2: Federal Mental Health Parity Compliance Review Resources Extension

Budget Issue. DMHC requests permanent extension of expiring, limited-term expenditure authority from the Managed Care Fund of \$529,000 in 2018-19 and annually thereafter. If approved, these resources will allow DMHC to continue to review health care service plan filings for compliance with the mental health parity requirements of the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

Program Funding Request Summary					
Fund Source 2018-19 2019-20*					
0933 – Managed Care Fund	\$529,000	\$529,000			
Total Funding Request:	\$529,000	\$529,000			
Total Requested Positions:	0.0	0.0			

* Resources ongoing after 2019-20.

Background. The federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) prevents group health plans and health insurance issuers that provide mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical or surgical benefits. The federal Affordable Care Act (ACA) and the state legislation governing ACA implementation extended the parity requirements of MHPAEA to individual and small group products, as well. In November 2013, the federal Department of Health and Human Services released its final rule on MHPAEA compliance, including specific requirements on health plans to conduct parity analyses. DMHC is responsible for ensuring health plan compliance with MHPAEA.

MHPAEA Compliance Review Process. DMHC's MHPAEA compliance reviews consist of two components:

- 1) Front-end: reviews of documentation submitted by plans to determine MHPAEA compliance.
- 2) Back-end: onsite reviews to verify plans are operating in accordance with compliance filings.

The MHPAEA final rules require review of the health plans' processes and justifications for classifying benefits within the following six permissible classifications:

- 1. Inpatient, In-Network
- 2. Inpatient, Out-of-Network
- 3. Outpatient, In-Network, including:
 - a. Outpatient Office Visits
 - b. Outpatient Other Items and Services
- 4. Outpatient, Out-of-Network, including:
 - a. Outpatient Office Visits
 - b. Outpatient Other Items and Services
- 5. Emergency Care
- 6. Prescription Drugs

After classifying all benefits into one of these categories, health plans must determine parity for:

- 1) Financial requirements, such as deductibles, copays, or coinsurance.
- 2) Quantitative treatment limitations (QTLs), such as number of visits or days of treatment.
- 3) Non-quantitative treatment limitations (NQTLs), including subjective limitations on treatment, such as utilization management.

DMHC conducts complex reviews for all new commercial product filings, including an analysis of classification of benefits, financial requirements, QTLs, and NQTLs. In addition to complex reviews, DMHC expects to conduct focused reviews on plans that have already undergone complex reviews, but have changed any aspect of previously approved compliance methods or factors. Focused reviews are more narrow in scope and require less time than complex reviews.

Resource History for MHPAEA Compliance Activities. The 2014 Budget Act included a one-time augmentation of \$369,000 (Managed Care Fund) for clinical consulting services to conduct initial frontend compliance reviews to ensure oversight of California's implementation of the MHPAEA and five positions to enforce these requirements. The 2015 Budget Act authorized additional resources to further support onsite medical surveys of the plans subject to MHPAEA. The 2016 Budget Act authorized limited-term expenditure authority from the Managed Care Fund of \$529,000 for two years to fund clinical consultants to perform the clinical aspect of MHPAEA compliance reviews.

DMHC requests permanent extension of the previously approved expenditure authority scheduled to expire on June 30, 2018. According to DMHC, the MHPAEA clinical consultant workload is permanent in nature as certain clinical assessments, such as classification of benefits and NQTLs in a plan's coverage disclosure documentation, cannot be performed by existing civil service classifications.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

Questions. The subcommittee has requested DMHC to respond to the following:

1. Please provide a brief overview of this proposal.

Issue 3: Prescription Drug Cost Transparency (SB 17)

Budget Issue. DMHC requests one position and expenditure authority from the Managed Care Fund of \$307,000 in 2018-19 and \$281,000 in 2019-20 and annually thereafter. If approved, these resources would allow DMHC to compile health plan information on prescription drug costs pursuant to SB 17 (Hernandez), Chapter 603, Statutes of 2017.

Program Funding Request Summary				
Fund Source2018-19				
\$307,000	\$281,000			
\$307,000	\$281,000			
1.0	1.0			
	2018-19 \$307,000			

* Position and Resources ongoing after 2019-20.

Background. Approved by the Legislature in 2017, SB 17 was intended to provide drug cost transparency in response to the significant growth in expenditures for prescription drugs by public health care programs, commercial health plans, and the general public. These increased expenditures have been attributable to both blockbuster drugs newly brought to market, such as new treatments for hepatitis C, and existing drugs, often no longer under patent protection, for which a single manufacturer controls the drug's supply and substantially increases its price. SB 17 requires health care service plans to publicly report to DMHC certain information regarding expenditures on prescription drugs on behalf of beneficiaries.

Implementation of DMHC's SB 17 Responsibilities. DMHC's primary responsibilities for implementation of SB 17 include the following:

Health Plan Expenditures on High Cost and High Utilization Drugs – SB 17 requires health plans that file certain rate information to report by October 1 of each year the following information for all covered prescription drugs:

- The 25 most frequently prescribed drugs.
- The 25 mostly costly drugs by total annual plan spending.
- The 25 drugs with the highest year-over-year increase in total annual plan spending.

SB 17 also requires DMHC by January 1 of each year to compile and publish this information by plan in a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The report data is required to be aggregated so that information specific to individual health plans remains confidential. SB 17 requires DMHC to include the report as part of its annual public meeting on aggregate trends in the large group market.

Large Group Expenditures on Prescription Drugs – SB 17 requires health plans that file annual large group rate information to include the following information:

- The percent of premium attributable to drug costs for each category of prescription drugs (e.g. generic, brand name, and brand name/generic specialty).
- The year-over-year increase, as a percentage, in per member, per month costs for each category.

- The year-over-year increase in per member, per month costs for drug prices compared to other components of the health care premium,
- The specialty tier formulary list.
- The percentage of the premium attributable to prescription drugs administered in a doctor's office that are covered under the medical benefit as separate from the pharmacy benefit, if available.
- Information on use of a pharmacy benefits manager (PBM), if any, including which components of prescription drug coverage are managed by the PBM.

DMHC requests one Associate Life Actuary in its Division of Premium Rate Review to modify reporting formats and instructions, review health plan and large group rate information filing, and compile the annual report on high cost and high utilization drugs. In addition, DMHC requests consultant funding of \$50,000 annually to assist with preparation of the report and public meetings, \$25,000 annually for public meeting venue costs and \$18,000 one-time for development of online forms for health plan data submission. The total requested expenditure authority from the Managed Care Fund is \$307,000 in 2018-19 and \$281,000 in 2019-20 and annually thereafter.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

Questions. The subcommittee has requested DMHC to respond to the following:

1. Please provide a brief overview of this proposal.

4150 DEPARTMENT OF MANAGED HEALTH CARE 4260 DEPARTMENT OF HEALTH CARE SERVICES

Issue 1: Oversight Item: Managed Care Timely Access to Care Enforcement

Background. Health care service plans that operate in the state of California are regulated by the Department of Managed Health Care for compliance with the Knox-Keene Health Care Service Plan Act of 1975 and other state and federal requirements. In addition, health care service plans that provide coverage in the Medi-Cal managed care delivery system must adhere to state and federal Medicaid requirements contained in statute, regulations, and the terms of managed care contracts. These regulatory programs, among other protections, require a health care service plan to ensure timely access to necessary medical care for its beneficiaries.

Knox-Keene Act and Network Adequacy. The Knox-Keene Health Care Service Plan Act of 1975, and subsequent amendments, is one of the most robust regulatory regimes for managed care organizations in any state in the nation. In addition to requirements related to financial stability, the Knox-Keene Act imposes various network adequacy requirements on health care service plans, including Medi-Cal managed care plans except county organized health systems (COHS), designed to provide timely access to necessary medical care for those plans' beneficiaries. These requirements, under the enforcement and oversight of DMHC, generally include the following standards for appointment availability:

- 1) <u>Urgent care without prior authorization</u>: within 48 hours.
- 2) <u>Urgent care with prior authorization</u>: within 96 hours.
- 3) *Non-urgent primary care appointments*: within 10 business days.
- 4) <u>Non-urgent specialist appointments</u>: within 15 business days.
- 5) <u>Non-urgent appointment for ancillary services for the diagnosis or treatment of injury, illness or</u> <u>other health condition</u>: within 15 business days.

Plans are also generally required to ensure that:

- 1) Primary care physicians are **located within 15 miles or 30 minutes** of a beneficiary's place of residence.
- 2) Plan networks include one primary care provider for every 2,000 beneficiaries.

Non-COHS Medi-Cal managed care plans are required to have a Knox-Keene license and are, therefore, required to be in compliance with these provisions. DHCS contracts with COHS plans to provide health care services to Medi-Cal beneficiaries in those counties. Although they are not required to have a Knox-Keene license, the department's sample contract with COHS plans includes the same or greater network adequacy and timely access requirements as the Knox-Keene Act.

Recent Medicaid Managed Care Regulations Expand Network Adequacy Requirements. In May, 2016, the federal Centers for Medicare and Medicaid Services (CMS) released a final rulemaking for state Medicaid programs with beneficiaries served by managed care organizations. One of the most significant changes imposed by the regulations is the requirement that capitation rates be set at a single

rate, rather than in a range, which will change the way DHCS and its contracted actuary calculate capitation rates for Medi-Cal managed care plans. In addition, the rules require:

- California's network adequacy standards expand from one provider type (primary care) to an additional six provider types.
- Collection of quality data to be used to improve the managed care program.
- Enhanced beneficiary supports.
- Monthly, rather than semi-annual, updates of provider directories
- Implementation of an 85 percent medical loss ratio (MLR) for Medi-Cal managed care plans.

2017 Legislation Specifies Network Adequacy Requirements for Medi-Cal Managed Care. AB 205 (Wood) and SB 171 (Hernandez), Chapters 738 and 768, Statutes of 2017, codified in state law specific requirements for Medi-Cal managed care related to implementation of the federal managed care regulations. In particular, these bills manage the implementation of the 85 percent MLR for Medi-Cal managed care plans, including the remittance process, and establish time and distance and appointment availability standards for the various classes of providers covered by the new federal rules.

Commencing January 1, 2018, the time and distance standards are as follows:

- <u>Primary care providers</u>: 10 miles or 30 minutes from the beneficiary's place of residence.
- *<u>Hospitals</u>*: **15 miles or 30 minutes** from the beneficiary's place of residence.
- <u>Dental managed care</u>: **10 miles or 30 minutes** from the beneficiary's place of residence.
- <u>Obstetrics and gynecology</u>: 10 miles or 30 minutes from the beneficiary's place of residence.

Commencing July 1, 2018, the time and distance standards are as follows:

- <u>Specialists</u>, including cardiology/interventional cardiology, nephrology, dermatology, neurology, endocrinology, ophthalmology, ear, nose, and throat/otolaryngology, OB-GYN specialty care, orthopedic surgery, gastroenterology, physical medicine and rehabilitation, general surgery, psychiatry, hematology, oncology, and pulmonology, HIV/AIDS specialists/infectious diseases, and outpatient mental health services, the following time and distance standards by county:
 - <u>15 miles or 30 minutes from the beneficiary's place of residence</u>: Alameda, Contra Costa, Los Angeles, Orange, Sacramento, San Diego, San Francisco, San Mateo, and Santa Clara;
 - 2) <u>30 miles or 60 minutes from the beneficiary's place of residence</u>: Marin, Placer, Riverside, San Joaquin, Santa Cruz, Solano, Sonoma, Stanislaus, and Ventura;
 - 45 miles or 75 minutes from the beneficiary's place of residence: Amador, Butte, El Dorado, Fresno, Kern, Kings, Lake, Madera, Merced, Monterey, Napa, Nevada, San Bernardino, San Luis Obispo, Santa Barbara, Sutter, Tulare, Yolo, and Yuba; and,
 - 4) <u>60 miles or 90 minutes from the beneficiary's place of residence</u>: Alpine, Calaveras, Colusa, Del Norte, Glenn, Humboldt, Imperial, Inyo, Lassen, Mariposa, Mendocino,

Modoc, Mono, Plumas, San Benito, Shasta, Sierra, Siskiyou, Tehama, Trinity, and Tuolumne.

- <u>*Pharmacy services*</u>: 10 miles or 30 minutes from the beneficiary's place of residence (all counties).
- <u>Outpatient substance use disorder services</u> other than opioid treatment programs, the following time and distance standards by county:
 - <u>15 miles or 30 minutes</u> from the beneficiary's place of residence: Alameda, Contra Costa, Los Angeles, Orange, Sacramento, San Diego, San Francisco, San Mateo, and Santa Clara;
 - 2) <u>30 miles or 60 minutes from the beneficiary's place of residence</u>: Marin, Placer, Riverside, San Joaquin, Santa Cruz, Solano, Sonoma, Stanislaus, and Ventura; and,
 - 3) <u>60 miles or 90 minutes from the beneficiary's place of residence</u>: Alpine, Amador, Butte, Calaveras, Colusa, Del Norte, El Dorado, Fresno, Glenn, Humboldt, Imperial, Inyo, Kern, Kings, Lake, Lassen, Madera, Mariposa, Mendocino, Merced, Modoc, Monterey, Mono, Napa, Nevada, Plumas, San Benito, San Bernardino, San Luis Obispo, Santa Barbara, Shasta, Sierra, Siskiyou, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo, and Yuba.
 - *<u>Opioid treatment programs</u>*, as follows:
 - <u>15 miles or 30 minutes from the beneficiary's place of residence</u>: Alameda, Contra Costa, Los Angeles, Orange, Sacramento, San Diego, San Francisco, San Mateo, and Santa Clara;
 - 2) <u>30 miles or 60 minutes from the beneficiary's place of residence</u>: Marin, Placer, Riverside, San Joaquin, Santa Cruz, Solano, Sonoma, Stanislaus, and Ventura;
 - 45 miles or 75 minutes from the beneficiary's place of residence: Amador, Butte, El Dorado, Fresno, Kern, Kings, Lake, Madera, Merced, Monterey, Napa, Nevada, San Bernardino, San Luis Obispo, Santa Barbara, Sutter, Tulare, Yolo, and Yuba;
 - <u>60 miles or 90 minutes from the beneficiary's place of residence</u>: Alpine, Calaveras, Colusa, Del Norte, Glenn, Humboldt, Imperial, Inyo, Lassen, Mariposa, Mendocino, Modoc, Mono, Plumas, San Benito, Shasta, Sierra, Siskiyou, Tehama, Trinity, and Tuolumne.
- <u>Skilled nursing facility and intermediate care facility services</u>, the following time and distance standards by county:
 - 1) <u>Within five business days of the request</u>: Alameda, Contra Costa, Los Angeles, Orange, Sacramento, San Diego, San Francisco, San Mateo, and Santa Clara.
 - 2) <u>Within seven business days of the request</u>: Marin, Placer, Riverside, San Joaquin, Santa Cruz, Solano, Sonoma, Stanislaus, and Ventura;
 - Within fourteen calendar days of the request: Amador, Butte, El Dorado, Fresno, Kern, Kings, Lake, Madera, Merced, Monterey, Napa, Nevada, San Bernardino, San Luis Obispo, Santa Barbara, Sutter, Tulare, Yolo, and Yuba; and,

- 4) <u>Within **fourteen calendar days** of the request</u>: Alpine, Calaveras, Colusa, Del Norte, Glenn, Humboldt, Imperial, Inyo, Lassen, Mariposa, Mendocino, Modoc, Mono, Plumas, San Benito, Shasta, Sierra, Siskiyou, Tehama, Trinity, and Tuolumne.
- <u>County Drug Medi-Cal-Organized Delivery System (DMC-ODS)</u>: appointment within **three business days** to an opioid treatment program (all counties).
- <u>Dental managed care plan services</u>: <u>Routine pediatric services</u>: appointment within **four weeks** of a request. <u>Specialist pediatric services</u>: appointment within **thirty calendar days** of a request.

Alternative Access Standards. AB 205 allows DHCS to permit Medi-Cal managed care plans to adhere to alternative access standards that deviate from any of the required time and distance requirements if either of the following occur:

- 1. The plan has exhausted all other reasonable options to obtain providers to meet the applicable standard.
- 2. The department determines the plan has demonstrated that its delivery structure is capable of delivering the appropriate level of care and access.

In February 2018, DHCS released an All Plan Letter (18-005) that outlines the process for plans to request an alternative access standard. Plans must submit requests no later than 105 days prior to the beginning of the contract year and requests must be submitted for specific zip codes and provider types. The application requires plans to include a variety of information related to provider availability in the affected regions, including the impacted provider types, geographic information about the nearest innetwork and out-of-network providers to affected beneficiaries, number of beneficiaries impacted, and the proposed alternative standards for time and/or distance.

The Knox-Keene Act also allows DMHC to permit health care service plans to adhere to an alternative access standard. According to DMHC, the Knox-Keene Act allows a health plan to request an alternate geographic access standard when it is unable to provide enrollee access to a primary care physician or a hospital within 15 miles or 30 minutes from where enrollees live or work. This occurs most frequently in rural areas of the state. DMHC considers alternate geographic access requests in accordance with the numerous factors set forth in timely access regulations, including but not limited to analyses of established patterns of practice in the marketplace, as well as the existence of geographically closer providers.

Subcommittee Staff Comment. This is an informational item.

Questions. The subcommittee has requested DMHC and DHCS to respond to the following:

<u>DMHC</u>

1. Please detail the department's enforcement activities and processes for determining health plan compliance with timely access standards under the Knox-Keene Act and other state and federal regulatory requirements. Specifically:

- a. What documentation is required from plans regarding compliance with appointment availability and time and distance requirements?
- b. How does DMHC evaluate a plan's compliance documentation? (e.g. desk reviews, auditing, provider surveys, etc.)
- c. How does DMHC respond if, after review, plan documentation indicates insufficient compliance with required standards?
- d. What enforcement actions does DMHC undertake to sanction or correct non-compliance?
- e. Does DMHC undertake independent analysis of verification of network adequacy and provider availability, such as geo-mapping, secret shopper or availability verification phone calls?
- 2. How does DMHC evaluate plan requests for alternative access standards under the Knox-Keene Act?
- 3. How many alternative access standards are currently in place?
- 4. How long does it take to approve or deny an alternative access request and what is the process?
- 5. What factors must exist preventing a plan from meeting the Knox-Keene timely access standards that would qualify the plan for approval of alternative access standards?
- 6. How does/will DMHC evaluate whether a plan will be allowed to operate under an alternative access standard?
- 7. Will DMHC make any adjustments in its process or standards as a result of the new Medi-Cal managed care rules?
- 8. How will DMHC handle complaints from Medi-Cal plans?

DHCS

- 1. Please detail the department's enforcement activities and processes for determining Medi-Cal managed care plan compliance with timely access standards contained in the new federal managed care regulations, the terms of managed care plan contracts, and codified in AB 205. Specifically:
 - a. What documentation is currently, or will be, required from plans regarding compliance with appointment availability and time and distance requirements?
 - b. How does/will DHCS evaluate a plan's compliance documentation? (e.g. desk reviews, auditing, provider surveys, etc.)
 - c. How does/will DHCS respond if, after review, plan documentation indicates insufficient compliance with required standards?
 - d. What enforcement actions does/will DHCS undertake to sanction or correct non-compliance?
 - e. Are there plans for additional monitoring and verification, such as secret shopper or random calls to verify provider availability for Medi-Cal enrollees?
- 2. County Organized Health Systems (COHS) are not required to obtain Knox-Keene licensure. How do timely access requirements contained in DHCS' contracts with COHS compare to similar requirements under the Knox-Keene Act? How are they enforced?
- 3. How does/will DHCS evaluate plan requests for alternative access standards under the new requirements?
- 4. How many alternative access requests has DHCS received to date?
- 5. What factors must exist preventing a plan from meeting the statutory and regulatory standards that would qualify the plan for approval of alternative access standards?

- 6. Does/will DHCS coordinate with DMHC to compare alternative access requests and the data that is submitted?
- 7. How does/will DHCS evaluate whether a plan will be allowed to operate under an alternative access standard?

DMHC and DHCS

- 1. Non-COHS Medi-Cal managed care plans are generally required to obtain Knox-Keene licensure. These plans are subject to requirements and responsibilities under both the Knox-Keene Act and Medi-Cal requirements pursuant to state and federal Medicaid laws, regulations, and contract terms. Please describe how DHCS and DMHC coordinate on enforcement of timely access requirements under both regulatory structures. Specifically:
 - a. How does/will oversight and enforcement activities for DHCS differ from similar activities by DMHC?
 - b. How does/will the two departments coordinate to avoid duplication of oversight and enforcement efforts?
- 2. How do the two departments coordinate on corrective action plans? Specifically, when a plan is found out of compliance with one or both departments' regulatory structures, what are the areas of overlap of sanctions or corrective action requirements and what areas are different?

4260 DEPARTMENT OF HEALTH CARE SERVICES

Issue 1: Overview



Department of Public Health - Department Funding Summary				
Fund Source	2017-18 Budget Act	2017-18 Revised	2018-19 Proposed	
General Fund	\$19,922,319,000	\$20,514,661,000	\$21,862,524,000	
Federal Funds	\$69,664,489,000	\$64,466,719,000	\$67,921,295,000	
Other Funds	\$20,344,119,000	\$18,298,528,000	\$14,759,646,000	
Total Department Funding:	\$109,930,927,000	\$103,279,908,000	\$104,543,465,000	
Total Authorized Positions:	3430.0	3364.1	3395.6	
Other Funds Detail:				
Breast Cancer Control Account (0009)	\$11,519,000	\$11,613,000	\$11,692,000	
Childhood Lead Poisoning Prev Fund (0080)	\$867,000	\$867,000	\$867,000	
DUI Program Licensing Trust Fund (0139)	\$1,806,000	\$1,861,000	\$1,212,000	
Hospital Svc. Account, Prop 99 (0232)	\$111,400,000	\$103,682,000	\$75,580,000	
Physician Svcs. Account, Prop 99 (0233)	\$40,220,000	\$33,320,000	\$21,732,000	
Unallocated Account, Prop 99 (0236)	\$72,071,000	\$61,153,000	\$45,117,000	

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Nana Treatment Prog Lie Trust Fund (0242)	\$1,724,000	\$1.778.000	\$1,757,000
Narc Treatment Prog Lic Trust Fund (0243)	\$1,734,000	\$1,778,000	\$1,757,000
Perinatal Insurance Fund (0309)	\$11,363,000	\$14,511,000	\$19,924,000
Major Risk Medical Ins Fund (0313)	\$0	\$0	\$0
Audit Repayment Trust Fund (0816)	\$67,000	\$67,000	\$67,000
Medi-Cal Inpt Payment Adj Fund (0834)	\$177,556,000	\$220,792,000	\$150,533,000
Special Deposit Fund (0942)	\$56,317,000	\$73,139,000	\$68,031,000
Reimbursements (0995)	\$5,035,931,000	\$3,700,586,000	\$1,672,183,000
County Health Init Matching Fund (3055)	\$176,000	\$176,000	\$176,000
Childrens Med Services Rebate Fund (3079)	\$16,000,000	\$18,000,000	\$14,088,000
Mental Health Services Fund (3085)	\$1,353,598,000	\$1,840,710,000	\$1,836,412,000
Priv Hospital Supplemental Fund (3097)	\$9,150,000	\$9,150,000	\$19,500,000
Mental Heath Facility Lic Fund (3099)	\$375,000	\$375,000	\$375,000
Residential/Outpatient Prog Lic Fund (3113)	\$6,771,000	\$6,967,000	\$6,903,000
Childrens Health/Human Svcs Fund (3156)	\$428,017,000	\$428,731,000	\$0
Hosp Qual Assurance Revenue Fund (3158)	\$6,384,246,000	\$5,035,239,000	\$4,381,598,000
SNF Quality & Accountability Fund (3167)	(\$1,899,000)	(\$1,900,000)	(\$1,900,000)
Emerg Air Trans/Children's Fund (3168)	\$7,890,000	\$7,890,000	\$8,525,000
Public Hosp Invest, Improve, Inc Fund (3172)	\$800,000,000	\$885,500,000	\$760,000,000
LIHP/MCE Out-of-Network Fund (3201)	\$116,250,000	\$0	\$0
LongTerm Care Qual Assurance Fund (3213)	\$482,975,000	\$539,842,000	\$504,609,000
Health and Human Svcs Spec Fund (3293)	\$2,392,507,000	\$2,367,559,000	\$2,519,214,000
Healthcare Treatment Fund, Prop 56 (3305)	\$1,257,166,000	\$1,070,558,000	\$850,925,000
Health Plan Fines/Penalties Fund (3311)	\$57,479,000	\$58,874,000	\$5,794,000
Medi-Cal Emerg Med Transport Fund (3323)	\$0	\$0	\$1,003,000
Whole Person Care Pilot Spec Fund (8107)	\$360,000,000	\$290,910,000	\$323,365,000
Global Payment Program Spec Fund (8108)	\$1,152,567,000	\$1,044,787,000	\$1,066,905,000
Desig Public Hosp GME Spec Fund (8113)	\$0	\$471,791,000	\$393,459,000

Fiscal Year:	2016-17	2017-18	2018-19	BY to CY
·	STA	TE OPERATIONS		·
Fund Source	Actual	Revised	Proposed	Change
General Fund	\$190,756,000	\$220,828,000	\$219,075,000	(\$1,753,000)
Federal Funds ¹	\$309,486,000	\$399,920,000	\$414,138,000	\$14,218,000
Special Funds/Reimb	\$39,801,000	\$58,649,000	\$52,061,000	(\$6,588,000)
Total Expenditures	\$540,043,000	\$679,397,000	\$685,274,000	(\$5,877,000)
Total Auth. Positions	3458.1	3364.1	3395.6	31.5

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LOCAL ASSISTANCE (MEDI-CAL AND OTHER PROGRAMS)				
Fund Source	Actual	Revised	Proposed	Change
General Fund	\$19,242,332,000	\$20,293,833,000	\$21,643,449,000	\$1,349,616,000
Federal Funds ¹	\$59,281,854,000	\$64,066,799,000	\$67,507,157,000	\$3,440,358,000
Special Funds/Reimb	\$13,369,053,000	\$18,239,879,000	\$14,707,585,000	(\$3,532,294,000)
Total Expenditures	\$91,893,239,000	\$102,600,511,000	\$103,858,191,000	\$1,257,680,000
¹ Federal Funds include Funds 0890, 7502, and 7503				

Background. The Department of Health Care Services' (DHCS) mission is to protect and improve the health of all Californians by operating and financing programs delivering health care services to eligible individuals. DHCS programs provide services to ensure low-income Californians have access to health care services and that those services are delivered in a cost-effective manner. DHCS programs include:

- *Medi-Cal.* DHCS serves as the single state agency for Medi-Cal, California's Medicaid program. Medi-Cal is a health care program for low-income and low-resource individuals and families who meet defined eligibility requirements. Medi-Cal coordinates and directs the delivery of health care services to approximately 13.5 million qualified individuals, including low-income families, seniors and persons with disabilities, children in families with low-incomes or in foster care, pregnant women, and low-income people with specific diseases. As of January 1, 2014, due to the Affordable Care Act, childless adults up to 138 percent of the federal poverty level are also eligible for services in Medi-Cal.
- *Children's Medical Services.* Children's Medical Services coordinates and directs the delivery of health care services to low-income and seriously ill children and adults. Its programs include the Genetically Handicapped Persons Program, California Children's Services Program, and Child Health and Disability Prevention Program.
- **Primary and Rural Health**. Primary and Rural Health coordinates and directs the delivery of health care to Californians in rural areas and to underserved populations. Its programs include: Indian Health Program, Rural Health Services Development Program, Seasonal Agricultural and Migratory Workers Program, State Office of Rural Health, Medicare Rural Hospital Flexibility Program/Critical Access Hospital Program, Small Rural Hospital Improvement Program, and the J-1 Visa Waiver Program.
- *Mental Health & Substance Use Disorder Services*. As adopted in the 2011 through 2013 Budget Acts, DHCS oversees the delivery of community mental health and substance use disorder services, reflecting the elimination of the Departments of Alcohol and Drug Programs and Mental Health.
- *Other Programs*. DHCS oversees family planning services, cancer screening services to lowincome under-insured or uninsured women, and prostate cancer treatment services to lowincome, uninsured men, through the Every Woman Counts Program, the Family Planning Access Care and Treatment Program, and the Prostate Cancer Treatment Program.

Subcommittee Staff Comment and Recommendation. This is an informational item.

Questions. The subcommittee has requested DHCS to respond to the following:

1. Please provide a brief overview of DHCS programs and budget.

Issue 2: November 2017 Medi-Cal Estimate - Overview

Budget Issue. The November 2017 Medi-Cal Local Assistance Estimate includes \$100 billion (\$20.1 billion General Fund, \$63.7 billion federal funds, and \$16.3 billion special funds and reimbursements) for expenditures in 2017-18, and \$101.5 billion (\$21.6 billion General Fund, \$67.1 billion federal funds, and \$12.8 billion special funds and reimbursements) for expenditures in 2018-19.

Medi-Cal Local Assistance Funding Summary					
Fiscal Year:	2017-18	2018-19	BY to CY		
	Benefits				
Fund Source	Revised	Proposed	Change		
General Fund	\$18,866,694,000	\$20,388,693,000	\$1,521,999,000		
Federal Funds	\$60,011,965,000	\$63,651,192,000	\$3,639,227,000		
Special Funds/Reimbursements	\$16,284,778,000	\$12,767,374,000	(\$3,517,404,000)		
Total Expenditures	\$95,163,437,000	\$96,807,259,000	\$1,643,822,000		
	ty Administration	I	I		
Fund Source	Revised	Proposed	Change		
General Fund	\$1,030,976,000	\$1,083,553,000	\$52,577,000		
Federal Funds	\$3,384,520,000	\$3,280,762,000	(\$103,758,000)		
Special Funds and Reimbursements	\$11,994,000	\$4,960,000	(\$7,037,000)		
Total Expenditures	\$4,427,490,000	\$4,369,275,000	(\$58,215,000)		
	<u>cal Intermediary</u>				
Fund Source	Revised	Proposed	Change		
General Fund	\$160,741,000	\$116,846,000	(\$43,895,000)		
Federal Funds	\$288,451,000	\$211,277,000	(\$77,174,000)		
Special Funds and Reimbursements	\$-	\$-	\$-		
Total Expenditures	\$449,192,000	\$328,123,000	(\$121,069,000)		
TOTAL MEDI-CAL LOCAL ASSISTANCE EXPENDITURES					
Fund Source	Revised	Proposed	Change		
General Fund	\$20,058,411,000	\$21,589,092,000	\$1,530,681,000		
Federal Funds	\$63,684,936,000	\$67,143,231,000	\$3,458,295,000		
Special Funds and Reimbursements	\$16,296,772,000	\$12,772,334,000	(\$3,524,438,000)		
Total Expenditures	\$100,040,119,000	\$101,504,657,000	\$1,464,538,000		

Caseload. In 2017-18, the budget assumes annual Medi-Cal caseload of 13.5 million, a decrease of 1.6 percent compared to assumptions for the 2017 Budget Act. The department estimates 81 percent of
Medi-Cal beneficiaries, or 10.9 million, will receive services through the managed care delivery system while 19 percent, or 2.6 million, will receive services through the fee-for-service delivery system.

In 2018-19, the budget assumes annual Medi-Cal caseload of 13.5 million, a 0.05 percent increase compared to the revised caseload estimate for 2017-18. The department estimates 81.3 percent of Medi-Cal beneficiaries, or 11 million, will receive services through the managed care delivery system while 18.7 percent, or 2.5 million, will receive services through the fee-for-service delivery system.

Significant General Fund Adjustments. The November 2017 Medi-Cal Local Assistance Estimate includes the following significant adjustments to General Fund expenditures:

2017-18 General Fund Deficiency - The budget includes increased expenditures in the Medi-Cal program of \$543.7 million General Fund compared to the 2017 Budget Act. The current year increase is primarily attributable to cost-shifts and adjustments related to pharmacy rebates, caseload-related adjustments to managed care expenditures, retroactive managed care and dental payments, and reduced General Fund savings from the Hospital Quality Assurance Fee. (For more information, see *Issue 3: Medi-Cal Unanticipated Costs – 2017-18 Deficiency*)

Medi-Cal Optional Expansion – The budget includes \$17.7 billion (\$1.4 billion General Fund, \$14.8 billion federal funds, and \$1.5 billion other funds and reimbursements) in 2017-18 and \$22.9 billion (\$1.6 billion General Fund, \$20.5 billion federal funds, and \$756 million other funds and reimbursements) in 2018-19 for the optional expansion of Medi-Cal eligibility to childless adults up to 138 percent of the federal poverty level pursuant to the federal Affordable Care Act. The state assumed a six percent share of cost for the optional expansion population in calendar year 2018, will assume a seven percent share in calendar year 2019, and a ten percent share in calendar year 2020 and beyond.

Proposition 56 Supplemental Provider Payments - The budget includes \$169.4 million to support new growth in Medi-Cal expenditures compared to the 2016 Budget Act. The budget allocates \$1.1 billion (\$360.1 million Proposition 56 funds and \$788.2 million federal funds) in 2017-18 and \$2 billion (\$649.9 million Proposition 56 funds and \$1.4 billion federal funds) in 2018-19 for supplemental provider payments for services provided by physicians, dentists, women's health providers, intermediate care facilities for individuals with developmental disabilities, and AIDS Waiver providers. The 2018-19 allocation represents an increase of \$289.8 million over the Administration's revised 2017-18 estimate, but is only \$103.9 million over the revised 2017-18 estimate, the Administration proposes to allocate approximately \$163 million for physician payments and \$70 million for dental payments.

Home Health Rate Increase - The budget includes \$64.5 million (\$31.6 million Proposition 56 funds and \$32.9 million federal funds) for a 50 percent rate increase and associated increases in utilization for home health providers that provide medically necessary in-home services to children and adults in the fee-for-service system or through home and community-based services waivers.

Full Restoration of Adult Dental Benefits - The budget includes \$84.7 million (\$31.7 million General Fund and \$53.1 million federal funds) in 2017-18 and \$212.2 million (\$79.5 million General Fund and \$132.7 million federal funds) in 2018-19 to restore full dental services for adult beneficiaries in the Medi-Cal program, effective January 1, 2018. While approval from the federal Centers for Medicare

and Medicaid Services for the restoration is still pending, the department has notified providers they may begin claiming for restored services.

Children's Health Insurance Program (CHIP) Reauthorization - Effective October 1, 2015 through September 30, 2019, the federal Affordable Care Act (ACA) increased the program's federal share of cost from the historical rate of 65 percent to 88 percent. The budget includes additional General Fund costs of \$300.6 million in 2017-18 and \$599.8 million in 2018-19 reflecting an 88 percent federal share through December 31, 2017, and 65 percent beginning January 1, 2018. The budget assumes the program would be reauthorized at a 65 percent federal share effective January 1, 2018. In January 2018, Congress approved the Healthy Kids Act, which extended authorization and federal funding for the CHIP program for six years. The Healthy Kids Act also extends the enhanced federal match for CHIP of 88 percent until September 30, 2019, reduces the match to 76.5 percent until September 30, 2020, and reduces the match to its traditional 65 percent thereafter. Because the Healthy Kids Act was approved after release of the budget, the May Revision will reflect reduced General Fund expenditures in Medi-Cal to account for the additional federal matching funds.

Medi-Cal County Administration Cost-of-Doing-Business Adjustment – SB 28 (Hernandez), Chapter 244, Statutes of 2013, requires DHCS to develop and implement a new budgeting methodology for Medi-Cal county administration base costs no sooner than 2015-16. DHCS reports it was unable to secure a vendor to develop the new budgeting methodology. In the interim, the budget proposes a cost-of-doing-business adjustment for county eligibility workload of \$54.8 million (\$18.5 million General Fund and \$36.3 million federal funds) in 2018-19. The adjustment was calculated based on adjusting the existing level of funding by the California Price Index, which is currently 2.8 percent. A similar increase will be applied in 2019-20 and 2020-21 as the county eligibility systems move to a single Statewide Automated Welfare System. (For more information, see *Issue 4: County Administration Estimate and Budget Proposals*)

Hospital Quality Assurance Fee Extension - On November 8, 2016, voters passed Proposition 52, which amends the state Constitution to permanently extend the existing Hospital Quality Assurance Fee. The budget assumes General Fund savings of \$852 million in 2017-18 and \$885 million in 2018-19 from the hospital fee. This reflects a decrease of approximately \$168.7 million General Fund compared to the 2017 Budget Act due to federal changes to upper payment limit requirements.

School-Based Medi-Cal Administrative Activities and Local Education Agency Billing Option Program -The budget includes General Fund costs of \$58.4 million in 2017-18 and \$163.4 million in 2018-19 for repayments to the federal government resulting from overpayments to local education agencies for administrative activities related to Medi-Cal. To the extent a local education agency has an outstanding balance owed to the federal government, the budget withholds one-time discretionary funding from the agency's Proposition 98 appropriation in the 2018-19 fiscal year to repay the General Fund for the outstanding balance owed to the federal government.

Drug Medi-Cal Organized Delivery System Pilot - The budget includes \$372.9 million (\$76.2 million General Fund and \$296.7 million federal funds) in 2017-18 and \$1 billion (\$209.8 million General Fund and \$829.8 million federal funds) for the five-year pilot program for participating counties using an organized delivery system to provide expanded substance use disorder services to eligible Medi-Cal

beneficiaries. Five counties implemented the waiver in 2016-17, 15 counties are expected to implement the waiver in 2017-18, and 20 counties are expected to implement the waiver in 2018-19.

Managed Care Mental Health Parity - The budget includes \$21.3 million (\$3 million General Fund and \$18.2 million federal funds) for counties to comply with the 2016 federal Mental Health and Substance Use Disorder Parity Final Rule for Medicaid and Children's Health Insurance Program, which requires restrictions or limits on mental health and substance use disorder services not be applied more stringently than those applied for medical and surgical services.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold this issue open as updated estimates of caseload and expenditures will be provided at the May Revision.

Questions. The subcommittee has requested DHCS to respond to the following:

1. Please provide a brief overview of the significant General Fund changes in the Medi-Cal program in the 2018-19 fiscal year.

Issue 3: Medi-Cal Unanticipated Costs – 2017-18 Deficiency

Budget Issue. The Administration estimates unanticipated increases in Medi-Cal program expenditures in 2017-18 will exceed its 2017 Budget Act appropriation, resulting in a current year General Fund deficiency of approximately \$543.7 million.

Background. The 2017 Budget Act appropriated \$19.5 billion of General Fund for the Medi-Cal program in 2017-18. According to DHCS, updated estimates of Medi-Cal expenditures for 2017-18 will be \$20.1 billion, an increase of \$543.7 million over the 2017 Budget Act appropriation. DHCS reports this substantial increase in General Fund expenditures is primarily due to the following factors:

- 1) Shifting of retroactive drug rebate adjustments from prior years.
- 2) Offsetting increased drug rebates based upon recent actual data.
- 3) Corrections to the proportions of dual-eligibles and non-dual-eligibles in managed care.
- 4) Increases in retroactive managed care and dental payments.
- 5) Reduced General Fund savings from Hospital Quality Assurance Fee (QAF).

Retroactive Federal Recoupment of Drug Rebates and Additional Drug Rebates. Federal Medicaid law and regulations allow the Medi-Cal program to receive rebates from drug manufacturers for prescriptions provided to beneficiaries. In addition to required federal rebates, Medi-Cal negotiates supplemental state rebates that increase the total amount of rebate received. DHCS collects rebate revenue from manufacturers and reimburses the federal government for the federal matching funds provided for the original claim. Traditional Medi-Cal beneficiaries' claims receive a 50 percent match, Children's Health Insurance Program (former Healthy Families Program) beneficiaries currently receive an 88 percent match, and optional expansion (ACA) beneficiaries currently receive a 94 percent match.

Until April 2016, the department's Rebate Accounting and Information System was unable to identify ACA pharmacy claims. As a result, federal reimbursement was never remitted for drug rebates on claims between April 2015 and June 2016. According to DHCS, these revenues were reported as General Fund savings in the 2015-16 fiscal year and supported additional Medi-Cal expenditures in subsequent fiscal years. The retroactive recoupment owed to the federal government for these claims, funded with state General Fund, is approximately \$487.3 million. DHCS reports this payment was made in September 2016 and the adjustment was reflected in the 2017 Budget Act.

The budget includes General Fund expenditures of \$303.1 million for federal repayment of additional ACA and CHIP rebate claims received during the April 2015 through June 2016 period and for ACA and CHIP rebate claims for the period between January and March 2017. These federal repayments were made in 2017-18.

The budget also includes offsetting General Fund savings of \$280.7 million for additional drug rebates based on reconciliation with actual claims data. These savings are reflected in the November 2017 Estimate and include rebates for the Breast and Cervical Cancer Treatment Program (BCCTP), Family Planning, Access, Care, and Treatment (Family PACT), Federal Drug Rebates, State Supplemental Rebates, and Managed Care Drug Rebates.

Correction of Proportion of Dual-Eligibles and Non-Dual Eligibles in Managed Care. The budget assumes approximately 81 percent of Medi-Cal beneficiaries will receive benefits through the managed care delivery system. For each Medi-Cal managed care plan and each category of aid, DHCS and its contracted actuary, Mercer, develop capitation rates paid on a monthly basis to each plan for the care of each plan's enrolled beneficiaries. When DHCS budgets for capitation payments to Medi-Cal managed care, it calculates estimates of monthly caseload for each of the different categories of aid, including those dually eligible for Medi-Cal and Medicare (dual-eligible), and multiplies those caseload figures by the capitation rates for the relevant period to arrive at total expenditures.

According to DHCS, the 2017 Budget Act caseload assumptions for the 2017-18 fiscal year overestimated the proportion of beneficiaries enrolled in managed care that were dual-eligibles. The department corrected the proportion of beneficiaries that are dual-eligible compared to non-dual-eligibles in the November 2017 Estimate. As a result, the budget includes a General Fund adjustment of approximately \$200 million in the managed care base to reflect the increased costs of non-dual-eligibles consistent with this change in caseload assumptions.

Retroactive Managed Care and Dental Payments. The budget includes General Fund expenditures of \$335 million for retroactive managed care rate adjustments for Coordinated Care Initiative beneficiaries for prior contract years, a \$143.6 million increase from the amount included in the 2017 Budget Act. In addition, the budget includes General Fund expenditures of \$73.4 million for retroactive adjustments to dental managed care and dental fee-for-service rates for prior fiscal years, a \$64.3 million increase from the amount included in the 2017 Budget Act. These retroactive adjustments result in a combined increase of General Fund expenditures in 2017-18 of \$207.9 million.

Reduced General Fund Savings from Hospital QAF. The budget includes an increase in General Fund expenditures of \$168.7 million in 2017-18 due to reduced savings amounts received from the Hospital QAF. According to DHCS, these reduced savings are due to including a new Private Hospital Directed Payments methodology in managed care, conducting an Upper Payment Limit (UPL) review on prior years' expenditures, and removal of prior fee-for-service Hospital QAF payments.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended this issue be held open pending further updates to Administration estimates of the 2017-18 deficiency at the May Revision.

Questions. The subcommittee has requested DHCS to respond to the following:

- 1. Please provide a brief overview of the deficiency related to the retroactive federal repayments of drug rebates.
- 2. Please provide a brief overview of the deficiency related to recalculation of the proportion of dual-eligibles and non-dual-eligibles enrolled in managed care.
- 3. Please provide a brief overview of the deficiency related to reduced Hospital QAF savings.

Issue 4: County Administration Estimate and Budget Proposals

Budget Issue. The budget includes \$2 billion (\$979 million General Fund and \$979 million federal funds) in 2017-18 and \$2 billion (\$1 billion General Fund and \$1 billion federal funds) for the base allocation to counties for eligibility determinations for Medi-Cal beneficiaries. The base allocations include \$655.3 million (\$327.7 million General Fund and \$327.7 million federal funds) in 2017-18 and \$673.7 million (\$336.8 million General Fund and \$336.8 million federal funds) in 2018-19 allocated for costs related to eligibility determinations for newly eligible beneficiaries under the federal Affordable Care Act (ACA). Beginning in 2018-19 the budget combines the base allocation with the allocation for ACA, which had previously been reflected separately in the Medi-Cal estimate. The combined base allocation for county administration in 2017-18 is unchanged from the amount included in the 2017 Budget Act. Included in these allocations is \$54.8 million (\$18.5 General Fund and \$36.3 million federal funds) in 2018-19 for a cost-of-doing-business adjustment for county eligibility workload.

County Administration Funding Summary							
Fiscal Year:	2017-18	2018-19	BY to CY				
County Administration Base							
Fund Source	Revised	Proposed*	Change				
0001 – General Fund	\$651,341,500	\$669,579,000	\$18,237,500				
0890 – Federal Trust Fund**	\$651,341,500	\$669,579,000	\$18,237,500				
Total Expenditures	\$1,302,683,000	\$1,339,158,000	\$36,475,000				
		•	•				
Imple	mentation of ACA						
Fund Source	Revised	Proposed*	Change				
0001 – General Fund	\$327,655,000	\$336,829,500	\$9,174,500				
	. , ,						
0890 – Federal Trust Fund**	\$327,655,000	\$336,829,500	\$9,174,500				

*Beginning in 2018-19, the County Administration Base includes the ACA, and will no longer be reflected separately in the budget. In this display, the two figures are reflected separately for comparison purposes.

** Federal fund adjustments for ACA and CHIP beneficiaries are budgeted separately. In this display, funding reflects a 50 percent federal match.

Background. DHCS provides funding for county staff and support costs to perform administrative activities associated with the Medi-Cal eligibility, enrollment, retention, and redetermination process. Counties have traditionally served as the primary access point for low-income individuals to apply for Medi-Cal coverage and other public assistance programs. Using workload data, expenditure data, and other available information, DHCS determines a base allocation for each county based on estimates of staff costs, support costs, and staff development costs. Two years after development of the base allocation for a fiscal year, DHCS reconciles the budgeted base allocation with a county's actual expenditures, with additional funds provided to counties that spent more than their allocation and repayment to the state of unspent county funds. According to DHCS, the practice of reallocating unspent funds to other counties will be discontinued.

Implementation of the federal Affordable Care Act (ACA) significantly changed county Medi-Cal eligibility workload. Changes to the enrollment and redetermination processes designed to simplify beneficiaries' application for the program result in additional complexity. The new process included an interface with the California Healthcare Eligibility, Enrollment and Retention (CalHEERS) system, California's portal for health insurance affordability program applications. System implementation issues with CalHEERS' county interfaces led to significant increases in county eligibility workload and delay in eligibility determinations. In response to these issues, DHCS has provided counties additional funding over their base allocation to account for the increase in workload. Beginning in 2018-19, these additional amounts are included in the base allocation for county administration.

In anticipation of the workload changes required by ACA implementation, the Legislature approved SB 28, which requires DHCS to develop and implement a new budgeting methodology for county administration of the Medi-Cal program. The methodology, to be developed in consultation with county stakeholders, was meant to reflect changes in county operations as a result of implementation of the ACA. In 2014-15, the Legislature approved two limited-term positions and contract funding to begin working on the new methodology. According to DHCS, the approved staff were engaged in efforts to learn current county processes and spending patterns, research prior efforts to create a new budgeting methodology, and prepare documents required to engage the services of a contractor. DHCS also reports it worked with the County Welfare Directors Association and the Service Employees International Union to develop a scope of work for a contractor to perform time/motion studies and make other estimates of county costs to assist in the development of the new methodology.

The 2017 Budget Act authorized extension of the resources previously approved, as follows:

- Three-year expenditure authority of \$244,000 (\$122,000 General Fund and \$122,000 federal funds) equivalent to one Staff Services Manager I and one Associate Governmental Program Analyst to work with counties and a contractor to develop the new budgeting methodology.
- Two-year expenditure authority of \$1.2 million (\$608,000 General Fund and \$607,000 federal funds) to continue funding a contractor to develop the new budgeting methodology.

Cost-of-Doing-Business-Adjustment in 2018-19. DHCS reports it was unable to secure a vendor to develop the new budgeting methodology required by SB 28. The budget includes \$54.8 million (\$18.5 General Fund and \$36.3 million federal funds) in 2018-19 for a cost-of-doing-business adjustment for county eligibility workload. This cost-of-doing-business-adjustment is intended as an interim solution as the Administration and its county partners evaluate next steps for implementation of a budgeting methodology. The adjustment was calculated based on adjusting the existing level of funding by the California Price Index, which is currently 2.8 percent. A similar increase will be applied in 2019-20 and 2020-21 as the county eligibility systems move to a single Statewide Automated Welfare System.

Subcommittee Staff Comment and Recommendation—Hold Open. It is recommended to hold these issues open as updated estimates of caseload and expenditures will be provided at the May Revision.

Questions. The subcommittee has requested DHCS to respond to the following:

1. Please provide a brief overview of the local assistance estimate for County Administration.

- 2. Why was the department unable to secure a vendor for implementation of a county administration budgeting methodology? What is the department's plan going forward? If development of the methodology is not moving forward, how is the department utilizing the positions and resources approved for this purpose in the 2017 Budget Act?
- 3. Please explain the department's rationale for restricting the reallocation of unspent county administration funds between counties during the reconciliation process.

Issue 5: Stakeholder Proposals: Expansion of Medi-Cal Eligibility and Enrollment

Background. Medi-Cal covers 13.5 million Californians, including more than five million children, at a total estimated cost of \$100 billion in 2017-18 and \$101.5 billion in 2018-19. Of that amount, the federal government is expected to contribute \$63.7 billion in 2017-18 and \$67.1 billion in 2018-19 as a share of health care-related expenditures for Medi-Cal beneficiaries. The rate at which federal matching funds are provided to states is dependent on a state's per capita income. California has traditionally received a federal match of 50 percent, the minimum percentage allowable, due to the state's high per capita income relative to other states. Certain beneficiary populations and categories of Medi-Cal expenditures are eligible for higher federal matching rates, such as children eligible for the Children's Health Insurance Program (CHIP), adults eligible for the expansion of Medi-Cal under the Affordable Care Act (ACA), family planning expenditures, and improvements to information technology systems.

Affordable Care Act Expanded Medi-Cal Coverage to 3.9 million Newly Eligible Californians. The ACA authorizes states to expand their Medicaid programs to previously uninsured individuals. ABX1 1 (Pérez) and SBX1 1 (Hernandez), Chapters 3 and 4, Statutes of 2013, authorized California's optional expansion of the Medi-Cal program. The optional expansion, effective January 1, 2014, expanded eligibility for previously ineligible persons, primarily childless adults at or below 138 percent of the federal poverty level. Optional expansion beneficiaries are mandatorily enrolled in managed care for their Medi-Cal benefits.

For states that expanded Medicaid, the ACA authorized federal matching funds of 100 percent for services provided to this population until January 1, 2017. States received a federal match of 95 percent for calendar year 2017, and will receive a federal match of 94 percent for calendar year 2018, 93 percent for calendar year 2019, and 90 percent for calendar year 2020 and beyond. Medi-Cal assumed a five percent General Fund share for the optional expansion population beginning January 1, 2017, and a six percent General Fund share beginning January 1, 2018. In addition, the share of capitation payments for abortion-related services offered by Medi-Cal managed care has been borne by the state's General Fund since 2014, as federal funding is not available for this purpose.

The budget includes \$17.7 billion (\$1.4 billion General Fund, \$14.8 billion federal funds, and \$1.8 billion county and other funds) in 2017-18 and \$22.9 billion (\$1.6 billion General Fund, \$20.5 billion federal funds, and \$756 million county and other funds) in 2018-19 for coverage of the optional expansion population. The department estimates optional expansion enrollment of approximately 3.9 million beneficiaries in 2017-18 and 2018-19.

Medi-Cal Eligibility for Children Regardless of Immigration Status. SB 75 (Committee on Budget and Fiscal Review), Chapter 18, Statutes of 2015, expanded eligibility for full-scope Medi-Cal to all incomeeligible children under age 19, regardless of immigration status. Undocumented children were previously eligible for restricted-scope Medi-Cal coverage, which includes emergency and pregnancy related services only. Services provided under restricted-scope Medi-Cal receive a 50 percent federal match, while the additional non-emergency services provided under the full-scope expansion are funded entirely by state General Fund. DHCS estimated 250,000 undocumented children under age 19 would become eligible under the expansion. As of December 2017, a total of 218,571 undocumented children have enrolled in full-scope Medi-Cal, in two distinct populations:

- 1. <u>Restricted-Scope Medi-Cal Beneficiaries</u> As of December 2017, 120,614 undocumented children previously enrolled in restricted-scope Medi-Cal coverage have transitioned into full-scope Medi-Cal coverage.
- 2. <u>Not Previously Enrolled</u> DHCS estimated 130,924 undocumented children that were eligible for, but not enrolled in, restricted-scope Medi-Cal would be eligible for full-scope coverage under the expansion of eligibility. As of December 2017, 97,957 children in this category have enrolled in full-scope benefits, or 74.8 percent of the department's estimate of eligible children.

Proposals to Expand Medi-Cal Eligibility and Promote Medi-Cal Enrollment. Stakeholders have expressed interest in expanding Medi-Cal coverage to individuals not currently eligible due to immigration status or because income limits for those eligible due to age or disability differ from those of other populations. In addition, stakeholders have expressed interest in expanding outreach and assistance efforts to enroll individuals that are currently eligible, but not enrolled. These proposals are as follows:

Expand Full-Scope Medi-Cal to Otherwise Eligible Adults Regardless of Immigration Status. The California Immigrant Policy Center, Health Access California, and a coalition of 80 organizations request General Fund resources, likely in the low billions of dollars, to fund expansion of full-scope Medi-Cal services to otherwise eligible adults regardless of immigration status. According to the coalition, California's robust implementation of the Affordable Care Act (ACA) has brought the uninsured rate to a historic low of 6.8 percent. In 2015, California showed great leadership by investing in access to full-scope Medi-Cal for all income eligible children under the age of 19, regardless of immigration status, which has provided comprehensive care to over 200,000 undocumented children. Through these efforts, California now provides near-universal coverage for children. However, their parents and other undocumented adult Californians still face exclusions to health care access. Of the nearly three million uninsured Californians, 58 percent are undocumented adults who are locked out of health care access simply because of their immigration status. Any effort to achieve universal health coverage in California must include immigrati communities who shape our state and who call California home.

Aged and Disabled Program Eligibility. AB 2877 (Thomson), Chapter 93, Statutes of 2000, established the Aged and Disabled program, which extends full-scope Medi-Cal coverage to individuals with income under 100 percent of the federal poverty level (FPL) and who are over age 65 or are disabled. The statute also provided for an income disregard of \$230 for an individual or \$310 for a couple, raising the effective level of eligibility to those with income higher than 100 percent of the FPL, currently about 124 percent of the FPL. This income disregard has not been updated since the program was implemented. Prior to AB 2877, aged and disabled individuals could qualify for the Medically Needy program, which imposes a monthly share of cost, which must be paid prior to receiving Medi-Cal benefits. Today, aged and disabled individuals whose incomes exceed 100 percent of the FPL plus the income disregard are still eligible under the Medically Needy program and must pay a monthly share of cost, which is the difference between eligible income and the Maintenance Need Income Level, a fixed dollar amount in statute intended to provide for food, rent and utilities. This level is \$600 for an individual and \$934 for a couple.

The Western Center on Law and Poverty (WCLP), Disability Rights California, Justice in Aging, and a coalition of 50 organizations request approximately \$30 million General Fund annually to raise the

income eligibility for Medi-Cal's Aged and Disabled program to 138 percent of the federal poverty level. This proposal would bring the Aged and Disabled program into alignment with other incomebased Medi-Cal eligibility programs. While the Administration reports it does not possess sufficient data to provide a specific estimate of the costs of this proposal, its fiscal analyses of previous versions of this proposal estimate ongoing General Fund costs in the tens of millions of dollars, consistent with the budget request from the coalition.

According to the coalition, when the aged and disabled program was established, the income standard was equivalent to 133 percent FPL, the same level as most other adults enrolled in Medi-Cal. However, the disregards lose real value every year, because they are specific dollar amounts rather than percentages of FPL. Today, these unchanged dollar amounts place the resulting income standard at 123 percent FPL. When a senior has even a small increase in their income that puts them over 123 percent FPL, they are forced into the Medi-Cal Medically Needy program with a high share of cost.

Express Lane Eligibility for Women, Infants, and Children (WIC) Program Participants. SBX1 1 required the state to participate in a federal option to simplify the Medi-Cal enrollment process for those receiving benefits in the Supplemental Nutrition Assistance Program (SNAP), known in California as CalFresh. As of the 2015 Budget Act, DHCS estimated approximately 209,000 individuals would take up Medi-Cal coverage through Express Lane Eligibility related to CalFresh participation. In addition to CalFresh, federal guidance allows states to establish Express Lane programs within agencies capable of making a finding regarding one or more programmatic eligibility requirements, using information the Express Lane agencies already collect. One of the allowable programs under this federal guidance is the Women, Infants, and Children (WIC) program, which is administered in California by the Department of Public Health and provides nutrition services and food assistance for pregnant, breastfeeding, and non-breastfeeding women, infants, and children up to their fifth birthday at or below 185 percent of the federal poverty level.

A coalition of five children's advocacy organizations requests General Fund resources of \$9 million to establish an Express Lane program for children and a presumptive eligibility program for pregnant women participating in the WIC program. Approximately \$1 million would fund needed administrative expenses to establish the program, while \$8 million would fund health care services for the additional children and pregnant women enrolled in Medi-Cal as a result of the program. According to the coalition, the WIC eligibility system currently checks participants' Medi-Cal enrollment by linking to the Medi-Cal Eligibility Data System. About 90,000 WIC children and 13,000 WIC pregnant women do not have Medi-Cal, despite eligibility. Federal Express Lane Eligibility authority allows WIC income eligibility findings to be used to determine Medicaid enrollment for children. State statute authorizes a WIC automated enrollment gateway but requires a budget appropriation. Express enrollment for pregnant women would require a federal waiver. However, with a state plan amendment, WIC pregnant women could be determined presumptively eligible for Medi-Cal while a full application is completed.

Funding for Medi-Cal Enrollment Assistance and Outreach. Beginning in January 2014 DHCS received a \$12.5 million contribution from the California Endowment for purposes of implementing an enrollment and outreach program to supplement county efforts to enroll eligible but not enrolled individuals into the Medi-Cal program. Among other program requirements, grants were provided for efforts that place special emphasis on one or more of the following populations:

- 1) Persons with mental health disorder needs
- 2) Persons with substance use disorder needs
- 3) Persons who are homeless
- 4) Young men of color
- 5) Persons who are in county jail, state, prison, on state parole, on county probation, or under post release community supervision
- 6) Families of mixed-immigration status
- 7) Persons with limited English proficiency

According to DHCS, the cumulative progress of Enrollment and Outreach (O&E) is as follows:

	Totals
Amount Invoiced	\$22,388,499
Number of AB 82 individuals reached by O&E efforts	1,801,991
Number of AB 82 individuals assisted with enrollment into Medi-Cal	202,461
Number of approved Medi-Cal applications resulting from Medi-Cal O&E efforts	87,678
Number of AB 82 beneficiaries that retained Medi-Cal coverage as a result of the O&E efforts	30,683

Source: DHCS - O&E Quarterly Progress Report: Outreach, Enrollment, and Retention - Cumulative Totals

Maternal and Child Health Access and a coalition of ten organizations request \$53 million (\$26.5 million General Fund and \$26.5 million federal funds) to continue outreach, enrollment and troubleshooting for health coverage programs for low-income Californians. The funds would be allocated to counties on the basis of a funding formula and administered by counties, as occurred under AB 82 (Committee on Budget), Chapter 23, Statutes of 2013.

According to the coalition, between 2014 and 2018, statewide outreach and enrollment efforts were funded through a combination of legislative and foundation efforts and federal matching funds under Medi-Cal and CHIP. Most of the non-federal funding will come to an end, however, at the end of June 2018. For community agencies in Fresno County over \$1 million in outreach and enrollment resources are about to end. In Sacramento, local groups face a loss of nearly \$900,000, as do partners in Santa Clara County. The combined cut for four participating North Coast counties (Del Norte, Mendocino, Sonoma and Marin) would be over \$562,480, and \$697,000 on the Central Coast (Monterey, San Luis Obispo and Santa Cruz).

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding these items open to allow continued discussions in advance of the May Revision.

Questions. The subcommittee has requested advocates to present these proposals and respond to questions from subcommittee members.

Issue 6: Discontinuation of 340B Drug Reimbursement – Panel Discussion

Trailer Bill Language. DHCS requests trailer bill language to restrict the scope of the use of the 340B Program within the Medi-Cal program to comply with existing federal requirements. According to DHCS, these restrictions would help protect program integrity, prevent unnecessary overpayments, result in additional drug rebate savings, as well as serve to mitigate the amount of time and resources expended to resolve drug rebate disputes related to 340B claims.

Background. The federal Veterans Health Care Act of 1992 established the 340B Drug Pricing Program (340B Program), which requires drug manufacturers that participate in Medicaid to offer significantly reduced prices to certain safety net health care providers, known as covered entities. According to the federal Health Resources and Services Agency (HRSA), which oversees the 340B Program, these discounts enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Health care organizations eligible to be covered entities are defined in federal statute and include HRSA-supported health centers and look-alikes (e.g. federally qualified health centers), Ryan White clinics and state AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.

Prescription Drug Rebates in Medi-Cal. The federal Omnibus Budget Reconciliation Act of 1990 established the Medicaid Drug Rebate Program, which requires drug manufacturers to pay rebates to state Medicaid programs for drugs dispensed to Medicaid beneficiaries. These rebates are shared between states and the federal government according to the relevant federal matching rate for the beneficiaries to whom the drugs were dispensed. In addition to the federal rebate program, California law requires DHCS to enter into contracts with drug manufacturers to provide supplemental rebates for drugs dispensed to Medi-Cal beneficiaries in the fee-for-service delivery system or enrolled in county organized health systems (COHS). These rebates are in addition to those received through the federal rebate program. In 2010, the federal Affordable Care Act further extended eligibility for the federal rebate program to drugs dispensed to beneficiaries enrolled in non-COHS Medi-Cal managed care plans. The budget includes General Fund savings from drug rebates of approximately \$1.4 billion in 2017-18 and \$1.5 billion in 2018-19 through the federal rebate program, state supplemental rebate program, from managed care beneficiaries, and beneficiaries in the Family Planning Access, Care, and Treatment (Family PACT) program and Breast and Cervical Cancer Treatment Program (BCCTP).

In general, federal law prohibits states from receiving federal drug rebates for Medicaid beneficiaries if the drugs dispensed were already discounted as part of the 340B Program. Rebates inappropriately claimed under both programs are known as "duplicate discounts". HRSA provides guidance to 340B covered entities and states to prevent duplicate discounts, including the Medicaid Exclusion File (MEF), a provider level data source that compiles the National Provider Identification (NPI) Number or Medicaid Provider Number of covered entities which dispense 340B discounted drugs to Medicaid beneficiaries. The MEF is available for preventing duplicate discounts in fee-for-service. However, HRSA has encouraged covered entities to work with states to develop strategies to prevent duplicate discounts for drugs dispensed to managed care beneficiaries.

Contract Pharmacies. HRSA permits covered entities to dispense drugs purchased in the 340B Program through off-site contract pharmacies, often commercial retail pharmacies. These arrangements

are permitted only if the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts. The covered entity must report any such arrangement to HRSA. The HRSA guidance establishing this requirement did not apply to drugs dispensed to managed care beneficiaries. However, federal regulations on Medicaid managed care organizations released in May 2016 required states to include managed care contract provisions requiring plans to establish procedures for excluding 340B claims from utilization data provided to states for rebate collection.

Trailer Bill Language Proposal Discontinues 340B Reimbursement in Medi-Cal. According to DHCS, legislation is needed to provide DHCS the authority to restrict the scope of the use of the 340B Program within the Medi-Cal program in order to comply with existing federal statutory requirements. Such restrictions would help protect program integrity, prevent unnecessary overpayments, result in additional drug rebate savings, as well as serve to mitigate the amount of time and resources expended to resolve drug rebate disputes related to 340B claims.

The proposed trailer bill language would:

- 1. Repeal state law requiring 340B covered entities to dispense only 340B inventory to Medi-Cal beneficiaries and bill at average acquisition cost for those drugs.
- 2. Require DHCS to seek federal approval to prohibit covered entities from dispensing or administering a 340B drug to a Medi-Cal beneficiary.
- 3. Require DHCS, in the event federal approval is not obtained to prohibit dispensing or administering a 340B drug to a Medi-Cal beneficiary, to seek federal approval to limit the use of contract pharmacies by a covered entity; and/or, to prohibit or limit which covered entities, and which specified drugs, can be dispensed or administered to a Medi-Cal beneficiary.
- 4. Allow DHCS to apply those prohibitions and limitations to the entirety of the Medi-Cal program, or a segment thereof, including but not limited to the Medi-Cal fee-for-service and managed care delivery systems, and any other program eligible for federal drug rebates.
- 5. Require a covered entity subject to the limitations proposed to bill DHCS or a managed care plan their usual and customary charge.
- 6. Require that covered entities bill the Medi-Cal program at their acquisition cost, plus the appropriate dispensing fee for the applicable delivery system (fee-for-service or managed care) in which they operate.
- 7. Allow that, if a covered entity required to use 340B drugs is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary. The covered entity is required to maintain documentation of their inability to obtain the 340B drug, in the form and manner specified by DHCS.
- 8. Require a covered entity to identify a 340B drug on the claim submitted to the Medi-Cal program or to a managed care plan for reimbursement.
- 9. Require DHCS, upon federal approval, to implement these changes on a prospective basis at least 90 days from the date federal approval is obtained, but no sooner than January 1, 2019.
- 10. Allow DHCS to implement changes without taking regulatory action, but commits DHCS to adopting regulations within five years.

According to DHCS, the budget includes no additional General Fund savings as a result of this proposal. However, the Administration indicates it expects General Fund savings beginning in 2019-20 after federal approvals are received and the program is implemented.

Previous Administration 340B Proposal Not Approved. DHCS submitted a trailer bill language proposal accompanying the 2017 May Revision to correct problems regarding the use of contract pharmacies in the 340B Program. According to DHCS, some 340B covered entities do not directly dispense medications, but instead contract with a different, non-340B pharmacy that receives a higher, non-340B price billed to the department under fee-for-service or to a Medi-Cal managed care plan. The proposed trailer bill language prohibited the use of contract pharmacies in the 340B program in Medi-Cal, consistent with recent concerns raised by federal agencies and a federal audit. The proposal was intended to avoid inappropriate duplicate discounts by claiming federal drug rebates on already discounted drugs and prevent unnecessary overpayment in Medi-Cal. Due to the likelihood that the proposed language would have imposed significant changes on current operations for many 340B entities, as well as the lack of sufficient time for proper legislative consideration of the impacts of the proposal on essential Medi-Cal providers, the Legislature did not adopt this proposal.

The current trailer bill language proposal includes provisions that allow DHCS, should it not receive federal approval to prohibit dispensing of 340B drugs to Medi-Cal beneficiaries, to subsequently submit a proposal for federal approval to prohibit or limit the use of contract pharmacies to dispense 340B drugs to Medi-Cal beneficiaries. This subsequent proposal provided for by the current trailer bill language is substantially similar to the department's 2017 proposal that was not approved.

Panel Discussion. The subcommittee has requested the following panelists, in addition to the Department of Health Care Services and the Department of Finance, to comment on this proposal:

- **Denise Foreman**, Director of Pharmacy Services, Woodland Health Care
- Dr. Susan Ehrlich, Chief Executive Officer, Zuckerberg San Francisco General Hospital
- Britta Guerrero, Chief Executive Officer, Sacramento Native American Health Center
- Francis Pickford, Vice President of Finance, Planned Parenthood of the Pacific Southwest

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

Questions. The subcommittee has requested DHCS to respond to the following:

- 1. Please provide a brief overview of this proposal.
- 2. How does DHCS currently track 340B claims to prevent duplicate discounts in fee-forservice? How does it track 340B claims in managed care?
- 3. What factors prevent sufficient tracking of 340B claims to avoid duplicate discounts?

Issue 7: Federal Managed Care Regulations Implementation

Budget Issue. DHCS requests ongoing extension of nine expiring, limited-term positions and expenditure authority of \$3.1 million (\$1.5 million General Fund, \$1.5 million federal funds). If approved, these resources would allow DHCS to continue efforts to implement the federal Medicaid managed care regulations. Included in the resource request is \$1.3 million (\$650,000 General Fund and \$650,000 federal funds) for the department's contract with an External Quality Review Organization to perform quarterly access assessments.

Program Funding Request Summary					
Fund Source 2018-19 2019-2					
0001 – General Fund	\$1,547,000	\$1,547,000			
0890 – Federal Trust Fund	\$1,547,000	\$1,547,000			
Total Funding Request:	\$3,094,000	\$3,094,000			
Total Requested Positions:	9.0	9.0			

* Positions and Resources ongoing after 2019-20.

Background. Medi-Cal beneficiaries receive health care services through one of two separate delivery systems: fee-for-service and managed care. The managed care delivery system provides services to more than 80 percent of Medi-Cal beneficiaries through 22 Medi-Cal managed care plans. Each plan maintains its own network of providers and is paid a monthly capitation payment for each beneficiary based on rates calculated annually for each plan, county, and the beneficiary's category of aid. Rate development is based on actual encounter and claims data and is required to be certified as actuarially sound by the department's contracted actuary, Mercer.

Counties have adopted four primary models of managed care systems: two plan model, county organized health systems, geographic managed care, and the regional model. In recent years, several large populations of beneficiaries have transitioned into the managed care delivery system, making it the primary mode of service delivery in the Medi-Cal program. Certain services, however, have been exempted from delivery through managed care, particularly for sensitive populations and services.

In addition to Medi-Cal managed care plans, DHCS contracts with 56 county mental health plans, two primary care case management plans and six dental managed care plans. The county mental health plans provide realigned specialty mental health services to Medi-Cal beneficiaries under the terms of a waiver with the federal government. The two primary care case management plans are AIDS Healthcare Foundation and Family Mosaic, which provide services to specific populations in Los Angeles and San Francisco, respectively. The dental managed care plans provide dental services in two counties: Sacramento and Los Angeles. Enrollment in dental managed care is mandatory in Sacramento and voluntary in Los Angeles.

Medicaid Managed Care Regulations. In May 2016, the federal Centers for Medicare and Medicaid Services (CMS) released a final rulemaking for state Medicaid programs with beneficiaries served by managed care organizations. One of the most significant changes imposed by the regulations is the requirement that capitation rates be set at a single rate, rather than in a range. Another significant change is a restriction on directing payments by managed care plans to specified providers. Both of

these new rules could potentially undermine several safety net financing mechanisms, such as the hospital quality assurance fee and intergovernmental transfers, which DHCS uses to draw down additional federal funding for various health care services.

In addition to capitation rate development rules that complicate existing safety net financing programs, the rules require California's network adequacy standards be expanded from one provider type (primary care) to an additional six provider types; collection of quality data to be used to improve the managed care program; enhanced beneficiary supports; and monthly, rather than semi-annual, updates of provider directories.

The new managed care regulations apply to several different types of managed care providers in Medi-Cal. The regulations apply to the four primary models of managed care systems, mental health plans, primary care case management plans, and dental managed care plans. In addition to these plans, the regulations will apply to county programs participating in the Drug Medi-Cal Organized Delivery System Waiver.

Compliance-Related Resources Received in 2016-17 and 2017-18. The 2016 Budget Act approved 38 positions and expenditure authority of \$10.4 million (\$5 million General Fund and \$5.4 million federal funds) to complete the workload required to comply with the new regulations. The limited-term expenditure authority is equivalent to an additional 19 positions. These resources were approved primarily to begin work on compliance for the 22 Medi-Cal managed care plans. This workload included: monitoring network adequacy, more frequent updates of provider directories, quality measurement, plan technical assistance, new rate development requirements, auditing of plan operations, and legal and research activities.

The 2017 Budget Act approved 15 positions and expenditure authority of \$8.9 million (\$4.5 million General Fund and \$4.5 million federal funds) in 2017-18 through 2020-21 and \$2.6 million (\$1.3 million General Fund and \$1.3 million federal funds) in 2021-22. The four-year, limited-term expenditure authority is equivalent to an additional 40 positions. The approved resources also included contract funding for external quality review, language accessibility compliance, and technical infrastructure and assistance. The resources were received by the following DHCS divisions:

- 1. <u>Managed Care Quality and Monitoring Division</u> Limited-term resources equivalent to four positions to manage increased managed care compliance, including monitoring network adequacy and performance, and ensuring quality of data submitted by two new managed care plans.
- 2. <u>Managed Care Operations Division</u> Limited-term resources equivalent to seven positions to manage contract changes, ensure monthly updates to provider directories and consistent enrollee communications, and implement payment system control changes.
- 3. <u>Medi-Cal Dental Services Division</u> Limited-term resources equivalent to seven positions to collect and report data, monitor network adequacy, promulgate necessary regulations, ensure program integrity, and implement quality improvement strategies for dental managed care plans.
- 4. <u>Enterprise Innovation and Technology Services</u> Limited-term resources equivalent to five positions to manage required data reporting to the federal government.
- 5. <u>Information Management Division</u> Limited-term resources equivalent to two positions to collect, report, analyze, and manage data to be reported to the federal government.

- 6. <u>Office of HIPAA Compliance</u> Limited-term resources equivalent to five positions to ensure HIPAA compliance, quality and integrity of the data being reported to the federal government.
- 7. <u>Office of Legal Services</u> Limited-term resources equivalent to two positions to provide legal support to compliance activities for dental managed care plans and mental health plans.
- 8. <u>Mental Health Services Division</u> 11 permanent positions and limited-term resources equivalent to three positions to oversee provider network adequacy, monitor and certify compliance and manage other required quality and regulatory compliance for county mental health plans.
- 9. <u>Substance Use Disorder Program, Policy and Fiscal Division</u> Four permanent positions and limited-term resources equivalent to one position to manage reporting, quality assurance, monitoring, technical assistance, and network adequacy requirements related to the new Drug Medi-Cal Organized Delivery System waiver plans. These plans are categorized as prepaid inpatient hospital plans and are subject to requirements of the new federal managed care regulations.

Permanent Extension of Limited-Term Resources Approved in 2016-17. The limited-term expenditure authority approved in the 2016 Budget Act included resources equivalent to 19 positions, as well as funding for the EQRO, which expires on June 30, 2018. DHCS requests permanent extension of nine of these expiring positions, and limited-term extension of resources equivalent to four positions, including resources in the following divisions:

- 1. <u>Managed Care Quality and Monitoring Division</u> Five Associate Governmental Program Analysts (AGPA), one Health Program Specialist I and one Research Program Specialist II to continue required monitoring and reporting requirements on health care encounters and performance measures, reporting on access and network adequacy, development of guidance documents, development of enhanced policies related to program integrity, and strengthened efforts to improve the delivery systems that serve Medi-Cal beneficiaries. In addition, these resources allow the division to continue its contract with the EQRO to perform quarterly access assessments of each of the 22 Medi-Cal managed care plans and two specialty health plans.
- 2. <u>Managed Care Operations Division</u> One AGPA and one Associate Information Systems Analyst to review documentation and oversee standardization for provider directories, provider network review and certification, enhance beneficiary protection and beneficiary support systems
- 3. <u>Integrated Systems of Care Division</u> Limited-term resources equivalent to one AGPA to manage incorporation of managed long-term services and supports (MLTSS) delivery requirements including analyses of housing initiatives for applicability and compliance with MLTSS delivery, and review and respond to queries, concerns, or questions received both internally and externally in relation to MLTSS delivery and housing.
- 4. <u>Office of Legal Services</u> One Attorney III and limited-term resources equivalent to two Attorneys to support ongoing program monitoring, quality of care, and timely access for Medi-Cal managed care beneficiaries.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

Questions. The subcommittee has requested DHCS to respond to the following:

1. Please provide a brief overview of this proposal.

4265 DEPARTMENT OF PUBLIC HEALTH

Issue 1: Overview



<u>Department of Public Health – Three-Year Funding Summary</u> (dollars in millions)

Department of Public Health - Department Funding Summary					
Fund Source	2017-18 Budget Act	2017-18 Revised	2018-19 Proposed		
General Fund	\$135,537,000	\$148,300,000	\$142,789,000		
Federal Funds	\$1,594,078,000	\$1,566,944,000	\$1,589,349,000		
Other Funds (detail below)	\$1,491,465,000	\$1,476,642,000	\$1,462,221,000		
Total Department Funding:	\$3,221,080,000	\$3,191,886,000	\$3,194,359,000		
Total Authorized Positions:	3605.2	3563.7	3608.2		
Other Funds Detail:					
Breast Cancer Research Account (0007)	\$1,098,000	\$1,098,000	\$2,104,000		
Nuclear Planning Assessment Acct (0029)	\$979,000	\$984,000	\$984,000		
Motor Vehicle Acct, Trans. Fund (0044)	\$1,446,000	\$1,491,000	\$1,493,000		
Sale of Tobacco to Minors Ctrl Acct (0066)	\$1,105,000	\$702,000	\$1,104,000		

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Other Funds Detail (continued):			
Occup. Lead Poisoning Prev Acct (0070)	\$3,405,000	\$3,517,000	\$3,653,000
Medical Waste Management Fund (0074)	\$2,590,000	\$2,785,000	\$2,767,000
Radiation Control Fund (0075)	\$25,413,000	\$26,307,000	\$25,704,000
Tissue Bank License Fund (0076)	\$593,000	\$620,000	\$630,000
Childhood Lead Poisoning Prev Fund (0080)	\$31,447,000	\$31,946,000	\$31,588,000
Export Document Program Fund (0082)	\$699,000	\$722,000	\$758,000
Clinical Lab. Improvement Fund (0098)	\$11,758,000	\$12,195,000	\$12,096,000
Health Statistics Special Fund (0099)	\$25,911,000	\$26,921,000	\$27,380,000
Dept. of Pesticide Regulation Fund (0106)	\$298,000	\$321,000	\$321,000
Air Pollution Control Fund	\$285,000	\$297,000	\$297,000
CA Health Data and Planning Fund (0143)	\$240,000	\$240,000	\$240,000
Food Safety Fund (0177)	\$10,206,000	\$10,603,000	\$10,777,000
Genetic Disease Testing Fund (0203)	\$131,586,000	\$132,382,000	\$132,924,000
Health Education Account, Prop 99 (0231)	\$42,223,000	\$40,599,000	\$36,551,000
Research Account, Prop 99 (0234)	\$4,148,000	\$4,193,000	\$5,813,000
Unallocated Account, Prop 99 (0236)	\$2,825,000	\$2,862,000	\$3,245,000
Infant Botulism Treatment/Prev Fund (0272)	\$6,113,000	\$6,192,000	\$6,302,000
Child Health and Safety Fund (0279)	\$551,000	\$551,000	\$551,000
Registered Enviro. Health Spec Fund (0335)	\$403,000	\$427,000	\$427,000
Indian Gaming Spec Dist Fund (0367)	\$8,198,000	\$8,236,000	\$8,238,000
Vectorborne Disease Account (0478)	\$179,000	\$187,000	\$194,000
Toxic Substances Control Acct (0557)	\$754,000	\$786,000	\$439,000
Domestic Violence Training/Ed Fund (0642)	\$621,000	\$632,000	\$605,000
CA Alzheimers Research Fund (0823)	\$777,000	\$782,000	\$871,000
Special Deposit Fund (0942)	\$5,506,000	\$5,506,000	\$5,421,000
Reimbursements (0995)	\$193,475,000	\$205,290,000	\$208,291,000
Drug and Device Safety Fund (3018)	\$6,996,000	\$6,217,000	\$7,135,000
Tobacco Settlement Fund (3020)	\$600,000	\$1,200,000	\$0
WIC Manufacturer Rebate Fund (3023)	\$236,711,000	\$233,307,000	\$230,852,000
Medical Marijuana Program Fund (3074)	\$190,000	\$160,000	\$191,000
AIDS Drug Assistance Program Fund (3080)	\$286,888,000	\$293,824,000	\$307,651,000
Cannery Inspection Fund (3081)	\$2,604,000	\$2,707,000	\$2,748,000
Mental Health Services Fund (3085)	\$50,217,000	\$11,839,000	\$42,384,000
Licensing and Certification Fund (3098)	\$147,669,000	\$152,809,000	\$156,153,000
Gambling Addiction Program Fund (3110)	\$150,000	\$150,000	\$150,000
Birth Defects Monitoring Prog Fund (3114)	\$4,334,000	\$4,383,000	\$4,208,000
Lead-Related Construction Fund (3155)	\$632,000	\$690,000	\$659,000

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Other Funds Detail (continued):			
Cost/Impl Acct, Air Poll. Ctrl Fund (3237)	\$358,000	\$358,000	\$358,000
Cannabis Control Fund (3288)	\$13,161,000	\$13,501,000	\$16,022,000
State Dental Program Acct., Prop 56 (3307)	\$37,500,000	\$37,500,000	\$30,000,000
Tobacco Law Enforc Acct., Prop 56 (3308)	\$7,500,000	\$7,500,000	\$0
Tobacco Prev/Control Acct., Prop 56 (3309)	\$181,123,000	\$181,123,000	\$0
DPH Tobacco Law Enforc, Prop 56 (3318)	\$0	\$0	\$6,000,000
DPH, Tobacco Prev/Ctrl, Prop 56 (3322)	\$0	\$0	\$125,942,000

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

According to DPH, their goals include the following:

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

The department is composed of seven major program areas:

- (1) Center for Chronic Disease Prevention and Health Promotion This center works to prevent and control chronic diseases, such as cancer, cardiovascular diseases, asthma, adverse pregnancy outcomes, and diabetes; to reduce the prevalence of obesity; to provide training programs for the public health workforce; to prevent and control injuries, violence, deaths, and diseases related to behavioral, environmental, and occupational factors; to promote and support safe and healthy environments in all communities and workplaces; and to prevent and treat problem gambling.
- (2) Center for Environmental Health This center works to protect and improve the health of all California residents by ensuring the safety of drinking water, food, drugs, and medical devices; conducting environmental management programs; and overseeing the use of radiation through investigation, inspection, laboratory testing, and regulatory activities.
- (3) Center for Family Health This center works to improve health outcomes and reduce disparities in access to health care for low-income families, including women of reproductive age, pregnant and breastfeeding women, and infants, children, and adolescents and their families.
- (4) Center for Health Care Quality This center regulates the quality of care in approximately 8,000 public and private health facilities, clinics, and agencies throughout the state; licenses nursing home administrators, and certifies nurse assistants, home health aides, hemodialysis technicians, and other direct care staff.
- (5) Center for Infectious Disease This center works to prevent and control infectious diseases, such as HIV/AIDS, viral hepatitis, influenza and other vaccine preventable illnesses, tuberculosis, emerging infections, and foodborne illnesses.

- (6) Center for Health Statistics and Informatics This center works to improve public health by developing data systems and facilitating the collection, validation, analysis, and dissemination of health information.
- (7) **Public Health Emergency Preparedness** This program coordinates preparedness and response activities for all public health emergencies, including natural disasters, acts of terrorism, and pandemic diseases. The program plans and supports surge capacity in the medical care and public health systems to meet needs during emergencies. The program also administers federal and state funds the support DPH emergency preparedness activities.

Subcommittee Staff Comment and Recommendation. This is an informational item.

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

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

Issue 2: Alzheimer's Disease Program Grant Awards

Budget Issue. DPH requests expenditure authority of \$3.2 million (\$3.1 million General Fund and \$104,000 CA Alzheimer's Disease and Related Disorders Research Fund) in 2018-19 and \$3 million (\$3.1 million General Fund and a reduction of \$138,000 CA Alzheimer's Disease and Related Disorders Research Fund) in 2019-20 and annually thereafter. If approved, these resources would allow DPH to fund research related to the study of Alzheimer's disease and related disorders.

Program Funding Request Summary					
Fund Source	2018-19	2019-20*			
0001 – General Fund	\$3,115,000	\$3,115,000			
0823 – CA Alzheimer's Disease & Related Disorders Fund	\$104,000**	(\$138,000)			
Total Funding Request:	\$3,219,000	\$2,997,000			

* Resources ongoing after 2019-20.

** Consists of a reduction of \$138,000 State Operations offset by an increase in \$242,000 for Local Assistance grants

Background. The Alzheimer's Disease Program (ADP), established in 1984, seeks to reduce the human burden and economic costs associated with Alzheimer's Disease and related dementias. The program, currently funded by individual voluntary contributions by taxpayers on state tax returns, performs two primary functions:

- 1. *California Alzheimer's Disease Centers*. ADP established and administers a statewide network of ten California Alzheimer's Disease Centers (CADCs) at university medical centers. These Centers provide diagnostic and treatment services; professional training for medical residents, postdoctoral fellows, nurses, interns, and medical students; and community education such as caregiver training and support.
- 2. *Alzheimer's Disease and Related Disorders Research Fund Grants.* ADP established and administers the Alzheimer's Disease and Related Disorders Research Fund (ADRDF), which awards grants through a competitive process to scientists in California engaged in the study of Alzheimer's disease and related disorders.

California Alzheimer's Disease Centers. The ADP established ten CADCs across the state, which serve as Centers of Excellence for the diagnosis and treatment of Alzheimer's Disease and related disorders. Individuals with symptoms of memory loss, disorientation, or confusion are eligible to receive a comprehensive assessment at a CADC, which may include medical, neurological, psychological, and psychosocial evaluations, laboratory tests and imaging. Services are provided by a multidisciplinary clinical team which may include neurologists, psychiatrists, physician assistants, psychologists, nurse specialists, neuropsychologists and social workers. Most services are covered by Medicare, Medi-Cal or private insurance. The ten CADCs are:

- UC Davis (Sacramento)
- UC Davis (East Bay)
- UC San Francisco (San Francisco)
- UC San Francisco (Fresno)
- Stanford University
- UCLA

- Univ. of Southern California (Los Angeles)
- Univ. of Southern California (Rancho Los Amigos)
- UC Irvine
- UC San Diego

Alzheimer's Disease and Related Disorders Research Grants. Since its creation, ADP has provided more than \$22 million of funding for 134 research projects to contribute to the better understanding, care, and support of patients and families affected by Alzheimer's Disease and related disorders. Past research grants have contributed to significant breakthroughs including: identifying a novel specific plasma biomarker for Alzheimer's Disease, improving differential diagnosis and training, and providing definitive evidence of how amyloids contribute to the basic pathophysiological abnormalities typical of Alzheimer's and other neurodegenerative diseases.

ADP has funded between five and seven research grants in recent years. The most recent grant cycle funded seven grants in the broad areas of biomarkers and early detection, caregiving, epidemiology, and health disparities. The seven research grants currently funded are as follows:

BIOMARKERS AND EARLY DETECTION:

- University of California, Los Angeles "Plasma Neuronal Pentraxins as Markers of Synaptic Dysfunction in Alzheimer's Disease"
- University of California, Los Angeles "Diagnostic and Prognostic Test for Alzheimer's Disease"
- University of California, Davis "Lipopolysaccharide and Bacterial Molecules in Alzheimer's Disease Brains"

CAREGIVING:

- University of Southern California, in consortium with Family Caregiver Alliance "Pilot Test and Evaluation of Online Multi-Component Support Program for Caregivers of Adults with Alzheimer's Disease and Related Dementias"
- University of California, San Francisco "Elucidating the Effects of Alzheimer's Caregiving Using the Brain Health Registry"

EPIDEMIOLOGY:

• University of California, San Francisco - "Late Life-Span Use of Alcohol: Prospective Effects on Dementia Risk and Cognitive Functioning"

<u>HEALTH DISPARITIES</u>:

• University of California, San Diego - "Cognitive Decline in Hispanic versus non-Hispanic Alzheimer Caregivers"

Mistakenly Awarded Research Grants. DPH reports the Alzheimer's Disease Program mistakenly awarded research grants during the most recent grant cycle that exceeded the program's budget authority from the ADRDF by \$242,000. While DPH indicates the program is taking steps to avoid mistakes in the grant process in the future, including establishing additional layers of review and oversight, the program has committed to funding that exceeds its currently appropriated resources. DPH proposes to

increase the program's local assistance funding by \$242,000 to cover the cost of these commitments, while reducing state operations funding by \$138,000. The net increase in funding from the ADRDF would be \$104,000 in 2018-19. While the local assistance grant increase is only for 2018-19, the \$138,000 reduction in state operations would be ongoing.

Additional General Fund Allocation for Research Grants. DPH also proposes to increase funding for grants funded by the ADP with an additional, ongoing allocation of \$3.1 million from the state's General Fund. According to DPH, these resources will fund six additional research projects. The average value of each of these new grants will be higher than previously funded grants. After consultation with stakeholders, the program concluded larger grants would be more appropriate to assist grantees to build research infrastructure.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

1. Please provide a brief overview of this proposal.

Issue 3: Expanded Lead Testing for California Children (AB 1316)

Budget Issue. DPH requests two positions and expenditure authority from the Childhood Lead Poisoning Prevention Fund of \$276,000 in 2018-19 and annually thereafter. If approved, these resources would allow DPH to develop regulations and perform additional blood lead testing and analysis under an expanded standard of care required by AB 1316 (Quirk), Chapter 507, Statutes of 2017.

Program Funding Request Summary					
Fund Source	2018-19	2019-20*			
0080 – Childhood Lead Poisoning Prevention Fund	\$276,000	\$276,000			
Total Funding Request:	\$276,000	\$276,000			
Total Requested Positions:	2.0	2.0			

* Positions and Resources ongoing after 2019-20.

Background. The CLPP program was established in 1986 to take steps necessary to reduce the incidence of childhood lead exposure in California. The program focuses on young children considered at increased risk for lead exposure, particularly those receiving publicly-funded services such as Medi-Cal and WIC, or those living in older housing stock with lead-based paint or lead-contaminated dust and soil. Children at high risk of exposure are required to be blood tested for lead and children with high blood lead levels are eligible for CLPP services.

There are 43 local CLPP programs in 40 counties and three cities that provide services to eligible children in the remaining 18 counties. These services include outreach to populations at high risk of lead exposure, educational and other services for children with high blood lead levels, full public health nursing and environmental services to children with lead poisoning, and follow-up to ensure sources of lead exposure are removed. The state CLPP program also provides information on laboratory reported lead tests to local CLPP programs; and statewide surveillance, data analysis, oversight, outreach and technical assistance for all counties.

Expanded Standards for Determining Lead Poisoning Risk. AB 1316 requires DPH to adopt regulations by July 1, 2019, establishing a new expanded standard of care to determine whether a child is at risk for lead poisoning. including consideration of the following environmental risk factors:

- Time spent in a home, school, or building built before 1978.
- Proximity to a former lead or steel smelter or an industrial facility that historically emitted or currently emits lead.
- Proximity to a freeway or heavily traveled roadway.
- Other potential risk factors for lead exposure and known sources of lead contamination.

The regulations must also include questions to be asked by health care providers to assess the risk of lead exposure, including the new environmental risk factors and potential sources of exposure in the expanded standard of care. According to DPH, these questions would be incorporated into existing lead screening questionnaires after consultation with medical experts, environmental experts, professional organizations, and the public. DPH expects the regulatory process to take a minimum of two years.

AB 1316 also requires DPH to report certain data on its website. Specifically, DPH must report every March 1, beginning in 2019, information that evaluates the department's progress in meeting the goals of the Childhood Lead Poisoning Prevention Act. In addition, AB 1316 requires a list of census tracts in which children test positive at a rate higher than the national average for blood lead levels.

DPH requests one Health Program Specialist I and one Research Scientist II (Epidemiology/Biostatistics) to convene stakeholders to review and update regulations regarding blood lead screening, educate local health care providers and jurisdictions about the changed testing requirements, and report and analyze additional blood lead tests.

According to DPH, these changes to risk factors will likely increase the number of blood tests by 300,000 per year, or nearly 43 percent. DPH also estimates that, as a result, approximately 20 percent more children will be identified as cases of lead poisoning and receive necessary treatment services. DPH reports it cannot estimate the level of additional follow-up workload that will result from a higher level of identification of lead poisoning cases and indicates it will request additional resources, if needed, in future budget requests.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

1. Please provide a brief overview of this proposal.

Issue 4: Program Update: Oral Health Program

Background. The current Oral Health Program was established by the 2014 Budget Act, which included General Fund and reimbursement resources to establish a State Dental Director, hire an epidemiologist, and provide consulting services to re-establish a statewide oral health program. DPH proposed that this program would: 1) offer surveillance and evaluation capacity to determine the burden of dental disease; 2) evaluate dental health infrastructure capacity and assess the impact of interventions; 3) provide vision and leadership to engage partners in an advisory committee to guide program priorities; and 4) develop a state dental plan to identify strategies to reduce the burden of dental disease. While DPH initially proposed publication of an Oral Disease Burden Report and a State Oral Health Plan in 2015, difficulties in hiring a State Dental Director delayed development and publication of these reports. In August 2015, Dr. Jay Kumar was appointed as the State Dental Director.

The Oral Disease Burden Report was published in April 2017 and the California Oral Health Plan for 2018-2028 was published in January 2018. The Oral Disease Burden Report, among other findings, indicated: 1) nearly one-third of children have untreated tooth decay, 2) there are significant disparities in the prevalence of tooth decay and other dental disease by race and income levels, and 3) among the more than 5 million children receiving dental services through Medi-Cal, only 44 percent of beneficiaries enrolled for at least 90 continuous days received a least one dental service.

Based on the findings of the Oral Disease Burden Report, the Oral Health Plan identified five key goals for improving oral health and achieving oral health equity in California:

- 1. Goal 1: Improve the oral health of Californians by addressing determinants of health and promote healthy habits and population-based prevention interventions to attain healthier status in communities.
- 2. Goal 2: Align the dental health care delivery system, payment systems, and community programs to support and sustain community-clinical linkages for increasing utilization of dental services.
- 3. Goal 3: Collaborate with payers, public health programs, health care systems, foundations, professional organizations, and educational institutions to expand infrastructure, capacity, and payment systems for supporting prevention and early treatment services.
- 4. Goal 4: Develop and implement communication strategies to inform and educate the public, dental teams, and decision makers about oral health information, programs, and policies.
- 5. Goal 5: Develop and implement a surveillance system to measure key indicators of oral health and identify key performance measures for tracking progress.

In addition, the Oral Health Program is working on the following initiatives: 1) Community Water Fluoridation Implementation Project; 2) Oral Health Workforce Expansion Program; 3) Perinatal Infant Oral Health Quality Improvement Program; and 4) California Children's Dental Disease Prevention Program. These initiatives are currently funded by a combination of state and federal funds.

Proposition 56 allocates \$30 million annually to the Oral Health Program (\$37.5 million was allocated in 2017-18 to account for collection of the tax beginning in the final quarter of 2016-17). According to the text of the initiative, this allocation is "for the purpose and goal of educating about, preventing and treating dental disease, including dental disease caused by use of cigarettes and other tobacco products. This goal shall be achieved by the program providing this funding to activities that support the state dental plan based on demonstrated oral health needs, prioritizing serving underserved areas and

populations. Funded program activities shall include, but not be limited to, the following: education, disease prevention, disease treatment, surveillance, and case management."

The ongoing allocation of resources from Proposition 56 is intended to create a comprehensive public health infrastructure to support oral health education, prevention, surveillance, and treatment of dental disease. The funding helps expand the capacity of the Oral Health Program, local health jurisdictions, and Denti-Cal to implement the goals, objectives, strategies, and activities of the Oral Health Plan, Healthy People 2020 Oral Health Objectives, Denti-Cal and Maternal and Child and Health Services Block Grant performance measures, and the California Wellness Plan. The impact of the expanded program activities will be evaluated through analysis of: 1) oral health surveys of kindergarten and 3rd grade children; 2) Denti-Cal utilization reported in the annual Denti-Cal performance report; 3) the Maternal and Infant Health Assessment; 4) the Behavioral Risk Factor Surveillance System; 5) the Youth Risk Behavior Surveillance System; 6) the California Health Interview Survey; 7) the National Survey of Children's Health; 8) the California Cancer Registry; and 9) surveys of dental practitioners.

The 2017 Budget Act authorized 11 positions and expenditure authority from the State Dental Program Account of the Proposition 56 Fund (Fund 3307) of \$37.5 million in 2017-18 and \$30 million annually thereafter for the Oral Health Program, including funding for: 1) local health department allocations; 2) community-focused competitive contract awards to non-profit organizations to promote oral health and tobacco prevention programs; 3) statewide-focused competitive grants, contracts, and interagency agreements for training and technical assistance; 4) a statewide-focused competitive grant, contract, or interagency agreement for an oral health literacy and media campaign; and 5) evaluation and surveillance contracts and interagency agreements.

Local Health Jurisdiction Grant Funding. Proposition 56 funding for the Oral Health Program is intended, in part, to provide funding to local oral health programs in 61 local health jurisdictions in California. According to DPH, the goal of the program is to create and expand capacity at the local level to educate, prevent, and provide linkages to treatment programs, including dental disease caused by the use of cigarettes and other tobacco products. Local health jurisdictions are expected to establish or expand upon existing local oral health programs by providing education, disease prevention, linkage to treatment, case management and surveillance, with a priority on underserved areas and populations. The anticipated start date of the grants was January 2018.

Stakeholder Trailer Bill Language Proposal for Local Health Jurisdiction Funding Flexibility. The California Health Executives Association of California, the California Dental Association, and a coalition of eight organizations request trailer bill language to allow flexibility to local health jurisdictions to expend Proposition 56 funds received under the Oral Health Program. According to application documents for Oral Health Program funding, of the annual funding amounts for local health jurisdictions, "[u]nexpended funds cannot be rolled-over or carried forward from year-to-year". The coalition reports this restriction is inconsistent with other local health jurisdiction grant programs, such as the Tobacco Prevention Program. According to the coalition, "without the flexibility to distribute funds in a timely manner and access these dollars in subsequent fiscal years, we are concerned that the Oral Health Program, CDPH and potentially local health jurisdictions will be dictated by restrictive policies and timelines instead of strategic disbursements, creating delays and missed opportunities to fully realize the benefit of the funding voters intended to improve the oral health of all Californians."

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

- 1. Please provide a brief overview of the Oral Health Program, including regulatory responsibilities, organizational structure, and major programs.
- 2. Please summarize how the Oral Health Program is meeting the five goals identified in the California Oral Health Plan?
- 3. What is the status of grant awards to local health jurisdictions? How many grants were awarded? Please summarize the types of programs that were funded?

Issue 5: Public Beaches Inspection for Contaminants (SB 1395)

Budget Issue. DPH requests General Fund expenditure authority of \$354,000 in 2018-19, \$242,000 in 2019-20, \$370,000 in 2020-21, and \$125,000 in 2021-22 and 2022-23. If approved, these resources would allow DPH to finalize development of guidelines approving the use of new rapid test methods to replace current conventional culture methods for determining closures of public beaches, pursuant to the provisions of SB 1395 (Block), Chapter 928, Statutes of 2014. Staff funded by these resources would be redirected from other divisions within DPH.

Program Funding Request Summary					
Fund Source 2018-19 2019-20*					
0001 – General Fund	\$354,000	\$242,000			
Total Funding Request:	\$354,000	\$242,000			
Total Requested Positions:	0.0	0.0			

* Additional fiscal year resources requested: <u>2020-21</u>: \$370,000; <u>2021-22 and 2022-23</u>: \$125,000.

Background. To protect visitors to California beaches from water-borne diseases, the Beach and Bay Water Quality Monitoring Program requires county public health departments to perform beach water sampling and testing and close beaches or post warning signs if water quality falls below standards set by DPH. Currently approved water quality tests that detect total coliform, fecal coliform, and *Enterococcus* are culture-based, requiring time for bacterial cultures to grow. As a result, testing to determine the safety of California beaches can be delayed by up to two days, increasing the potential for exposure of beachgoers to water-borne diseases during the interim testing period.

SB 1395, approved in 2014, requires DPH to develop guidelines for approving the use of new rapid test methods at specific beaches as alternatives to slower, culture-based methods. Beginning in 2012, the United States Environmental Protection Agency (EPA) released a quantitative polymerase chain reaction (qPCR) method for detection of *Enterococcus* in recreational water, such as beaches. Since 2012, EPA has approved two additional qPCR-based tests and a new droplet digital PCR (ddPCR) test, which can return results in approximately four hours. Utilization of these rapid testing methods could allow beach closures and public notifications in response to unsafe water contamination to occur more quickly, reducing the potential for exposure.

Resource History and Implementation of SB 1395 Requirements. The 2015 Budget Act authorized one three-year, limited-term position to begin implementation of SB 1295, including: 1) developing guidance documents for application of qPCR methods, 2) developing validation criteria and quality control for site specific applications, 3) developing defined standards to compare effectiveness of qPCR methods to existing culture methods, 4) developing lab accreditation criteria for qPCR testing, and 5) consulting and engaging with county public health departments and various stakeholders.

Since approval of these resources, DPH has been working with local jurisdictions to validate rapid testing methods for specific beach sites. Each of California's beaches has different environmental and ecological conditions that require site-specific validation of testing methods to ensure proper controls for local variations in background contaminants. Keller Beach in the San Francisco Bay/Sacramento-San Joaquin Estuary was the first site of study and provided preliminary findings. According to DPH, the

next phase of site-specific testing validation will take place at 46 Southern California beaches over a year-long period.

DPH requests General Fund expenditure authority of \$354,000 in 2018-19, \$242,000 in 2019-20, \$370,000 in 2020-21, and \$125,000 in 2021-22 and 2022-23. If approved, these resources would fund staff, redirected from other divisions, to fulfill the requirements of SB 1395, including the following activities:

- 1. Develop the experimental plan for the study of 46 Southern California beaches.
- 2. Conduct the study in cooperation with the County of San Diego Environmental Health Department and the San Diego County Public Health Laboratory.
- 3. Complete reporting and data on the Keller Beach study, as well as future reporting and data on the Southern California beach study.
- 4. Develop training materials on PCR techniques in recreational water quality monitoring, requirements for quality assurance and quality control of PCR techniques, auditing checklists, and training for laboratories and laboratory auditors.
- 5. Develop PCR guidance documents in collaboration with stakeholders.

In addition to funding redirected staff resources, the request includes General Fund expenditure authority of \$197,000 in 2018-19 and \$87,000 in 2019-20 and 2020-21 for laboratory equipment, reagents, and supplies.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

- 1. Please provide a brief overview of this proposal.
- 2. Please summarize the status of utilization of new rapid testing methods by local health departments to measure beach contamination.
- 3. With utilization of rapid testing, have any local health departments made progress in reducing the time between collection of samples and test results that lead to beach closures or public notices?

Issue 6: Oversight: California Safe Cosmetics Program

Background. SB 484 (Migden), Chapter 729, Statutes of 2005, authorized the California Safe Cosmetics Program (CSCP) in DPH to provide information to consumers and other users of cosmetics regarding the presence of certain toxic ingredients. Under the program, cosmetics manufacturers are required to report to CSCP if they sell products in California and those products contain ingredients that have been identified by authoritative bodies as known or suspected of causing cancer or reproductive or developmental toxicity. The authoritative bodies upon which CSCP relies to determine which ingredients must be reported include:

- 1) Proposition 65 List of Chemicals Known to Cause Cancer or Reproductive Toxicity.
- 2) United States Environmental Protection Agency.
- 3) National Toxicology Program (NTP) Office of Health Assessment and Translation.
- 4) National Toxicology Program (NTP) Report on Carcinogens (RoC).
- 5) International Agency for Research on Cancer.

Ingredient reporting to the CSCP began in 2009 and, in 2014 the program launched an online searchable database, which provides the public with access to the ingredient information reported by cosmetics manufacturers. To date, 77 unique ingredients have been reported in over 57,000 products by nearly 500 companies. These products are in the following categories:

	Number of	
Product Categories	Products	Percentage ¹¹
Makeup Products (non-permanent)	38,896	63%
Nail Products	7,979	13%
Skin Care Products	5,012	8.1%
Sun-Related Products	3,715	6.0%
Bath Products	2,077	3.3%
Hair Coloring Products	1,391	2.2%
Hair Care Products (non-coloring)	1,038	1.7%
Tattoos and Permanent Makeup	691	1.1%
Personal Care Products	577	0.9%
Fragrances	397	0.6%
Oral Hygiene Products	217	0.3%
Shaving Products	161	0.3%
Baby Products	33	0.1%
Total ¹²	62,184	

Source: DPH, Cosmetics Containing Ingredients Linked to Cancer or Reproductive Harm. August 2016. Note: Some products are in more than one category

According to DPH, the program was implemented in response to limitations to existing regulatory authority, public concern about safety and the right to know about ingredients, potential health impacts on vulnerable populations, and the opportunity for safer chemical substitutions. The program reports to date that 151 companies have removed chemical ingredients known or suspected to cause cancer or reproductive or developmental toxicity from 1,765 products.

The program is currently funded with approximately \$370,000 annually from the state's General Fund. These resources fund one Research Scientist III, who serves as the program lead, and one Associate Governmental Program Analyst to support data collection and analysis. According to DPH, the program has no enforcement authority and responds to potential non-compliance by sending reminder letters to companies regarding their responsibility to report under the program. The authorizing statute does not include enforcement penalty authority.

Stakeholder Proposal: Fee and Penalty Authority for Enforcement and Program Improvements.

Breast Cancer Prevention Partners and a coalition of companies manufacturing safer cosmetics, public health and environmental health organizations request General Fund expenditure authority of up to \$1.5 million to increase staffing and for enforcement and program improvement activities. The coalition also requests implementation of a \$30 fee for each reportable product and penalty authority of \$10,000 per company or \$1,000 per product for failure to report covered products to the CSCP for inclusion in the database. The fee and penalty revenue would be used to reimburse the General Fund for the increased funding request.

According to the coalition, increased funding would provide the following:

- Increase staffing of the program to fulfill its statutory mandates and fully implement the law.
- Enable the program to address underreporting by manufacturers.
- Enable the program to address the industry abuse of "trade secret" designations which businesses have used to conceal hundreds of toxic chemicals from public view.
- Initiate investigations into the safety of ingredients and products.
- Refer investigations that find potential harm to Cal/OSHA to protect California's salon workers.
- Allow for increased awareness and use of the Safe Cosmetics Database and regular outreach to consumers and salon workers.
- Require companies to report to the state's database whether their products are intended for professional salon use or consumer use.
- Overhaul and modernize the SCP's outdated platform to address database malfunctioning.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

- 1. Please provide a brief summary of the data collection and reporting activities of the Safe Cosmetics Program.
- 2. How does the Safe Cosmetics Program verify that all cosmetics products containing chemicals known or suspected of causing cancer, birth defects, or reproductive toxicity are being reported to the program?
- 3. Please describe what remedies are available to the program if a product is discovered containing a reportable chemical and the product has not been reported to the program's database?

Issue 7: Women, Infants, and Children (WIC) Local Assistance Estimate

Budget Issue. The November 2017 Women, Infants, and Children (WIC) Program Estimate includes total expenditure authority of \$1.2 billion (\$1.1 billion federal funds and \$233.3 million WIC manufacturer rebate funds) in 2017-18 and \$1.2 billion (\$1.1 billion federal funds and \$230.9 million WIC manufacturer rebate funds) in 2018-19. The federal fund amounts include state operations costs of \$63.5 million in 2017-18 and \$63.7 million in 2018-19.

Women, Infants, and Children (WIC) Funding Summary						
	2018-19	BY to CY				
Fund Source	Revised	Proposed	Change			
0890 – Federal Trust Fund						
State Operations:	\$63,463,000	\$63,684,000	\$221,000			
Local Assistance:	\$899,152,000	\$889,131,000	(\$10,021,000)			
3023 – WIC Manufacturer Rebate Fund						
Local Assistance:	\$233,307,000	\$230,852,000	(\$2,455,000)			
Total WIC Expenditures	\$1,195,922,000	\$1,183,667,000	(\$12,255,000)			

Background. The WIC program provides nutrition services and food assistance for pregnant, breastfeeding, and non-breastfeeding women, infants, and children up to their fifth birthday at or below 185 percent of the federal poverty level. WIC program services include nutrition education, breastfeeding support, assistance with finding health care and other community services, and vouchers for specific nutritious foods that are redeemable at WIC-authorized retail food outlets throughout the state. The WIC program receives federal funds from the United States Department of Agriculture (USDA) under the federal Child Nutrition Act of 1966. Specific uses of WIC Program funds are governed by federal laws and regulations, and DPH must report funds and expenditures monthly.

The WIC program's food expenditures are funded by a combination of federal grants and rebates from manufacturers of infant formula. Federal WIC regulations require that state WIC programs have sole supplier rebate contracts in place with infant formula manufacturers for milk-based and soy-based infant formula. As infant formula is provided to WIC recipients, the program receives a rebate from the manufacturer which is used to fund additional food expenditures. In addition to food expenditures, the program receives federal funds from the Nutrition Services and Administration (NSA) grant, which are used to contract with local agencies for direct services provided to WIC families including intake, eligibility determination, benefit issuance, nutrition education, breastfeeding support, and referrals to health and social services. The NSA grant also funds state operations for administering the WIC program.

Food expenditures are divided into five participant categories, each with special nutrition needs that influence food costs:

• **Pregnant women** are eligible for the WIC program at any point in their pregnancy, and receive supplemental foods high in protein, calcium, iron, vitamin A, and vitamin C to support optimal fetal development.

- **Breastfeeding women** are eligible for benefits up to their infant's first birthday, and receive an enhanced supplemental food package with foods high in protein, calcium, iron, vitamin A, and vitamin C to support caloric needs during breastfeeding.
- **Non-breastfeeding women** are eligible for benefits up to six months after the birth of their infants, and receive a supplemental food package to help in rebuilding nutrient stores, especially iron and calcium, and achieving a healthy weight after delivery.
- **Infants** are eligible until one year of age. The WIC Program promotes breastfeeding as the optimal infant feeding choice due to its many health, nutritional, economical, and emotional benefits to mother and baby. Infants may also receive supplemental foods that are rich in protein, calcium, iron, vitamin A, and vitamin C during this critical period of development.
- **Children** are eligible from age one up to age five, and receive supplemental foods rich in protein, calcium, iron, vitamin A, and vitamin C. These nutrients have been shown to be lacking in the diets of children who qualify for WIC benefits and are needed to meet nutritional needs during critical periods of development. The food package also provides foods lower in saturated fat to reduce the risk of childhood obesity.

EXPENDITURE COMPARISON (all funds)							
					SFY 2018-19		
Expenditure Category	2017 Budget Act	November Estimate	Change f 2017 Budg		November Estimate	Change f 2017 Budge	
Pregnant	63,379,000	59,344,000	(4,035,000)	-6.37%	56,986,000	(6,393,000)	-10.09%
Breastfeeding	58,188,000	53,928,000	(4,260,000)	-7.32%	53,586,000	(4,602,000)	-7.91%
Non-Breastfeeding	29,309,000	28,202,000	(1,107,000)	-3.78%	27,618,000	(1,691,000)	-5.77%
Infants	321,211,000	319,084,000	(2,127,000)	-0.66%	314,878,000	(6,333,000)	-1.97%
Children	376,717,000	346,813,000	(29,904,000)	-7.94%	342,190,000	(34,527,000)	-9.17%
Reserve	25,464,000	24,221,000	(1,243,000)	-4.88%	23,858,000	(1,606,000)	-6.31%
Total Food Expenditures	874,268,000	831,592,000	(42,676,000)	-4.88%	819,116,000	(55,152,000)	-6.31%
Food Expenditures Paid from Rebate Funds	236,711,000	233,307,000	(3,404,000)	-1.44%	230,852,000	(5,859,000)	-2.48%
Food Expenditures Paid from Federal Funds	637,557,000	598,285,000	(39,272,000)	-6.16%	588,264,000	(49,293,000)	-7.73%
Other Local Assistance Expenditures (Federal NSA)	300,867,000	300,867,000	-	0.00%	300,867,000	-	0.00%
Total Federal Local Assistance Expenditures (Food + NSA)	938,424,000	899,152,000	(39,272,000)	-4.18%	889,131,000	(49,293,000)	-5.25%
State Operations (Federal NSA)	63,463,000	63,463,000	-	0.00%	63,684,000	221,000	0.35%

According to the WIC program Estimate, food expenditures by participant category are as follows:

The budget assumes 1,075,108 average monthly WIC participants in 2017-18, a decrease of 64,197 or 5.6 percent from the assumptions in the 2017 Budget Act. The budget assumes 1,024,382 average monthly WIC participants in 2018-19, a decrease of 50,726 or 4.7 percent from the revised 2017-18 caseload estimate.

Food Expenditures Estimate. The budget includes \$831.6 million in 2017-18 for WIC program food expenditures, a decrease of \$42.7 million or 4.9 percent, compared to the 2017 Budget Act. According

to DPH, this decrease is due to lower than projected participation levels. Of these expenditures, federally funded food expenditures are \$598.3 million, a decrease of \$39.3 million from the 2017 Budget Act, and WIC Manufacturer Rebate Fund food costs are \$233.3 million, a decrease of \$3.4 million from the 2017 Budget Act.

The budget includes \$819.1 million in 2018-19 for WIC program food expenditures, a decrease of \$55.2 million or 6.3 percent from the revised 2017-18 food expenditures estimate. According to DPH, this decrease is due to the continued downward trend of total participation in the program. Of these expenditures, federally funded food costs are \$588.3 million, a decrease of \$49.3 million from the revised 2017-18 food expenditure estimate, and WIC Manufacturer Rebate Fund food costs are projected to be \$230.9 million, a decrease of \$5.9 million from the revised 2017-18 food expenditure estimate.

Nutrition Services and Administration (NSA) Estimate. The budget includes \$300.9 million for other local assistance expenditures for the NSA budget in 2017-18 and 2018-19, which is unchanged from the level assumed in the 2017 Budget Act. The budget also includes \$63.5 million for state operations expenditures in 2017-18, also unchanged from the level assumed in the 2017 Budget Act. The budget includes \$63.7 million for state operations expenditures in 2018-19, an increase of \$221,000 or 0.4 percent compared to the revised 2017-18 estimate. According to DPH, the increase in 2018-19 is attributed to a \$2.9 million increase in expenditures for the eWIC Electronic Benefit Transfer (EBT) and Management Information System (MIS) Project, offset by a \$2.7 million decrease in expenditures due to miscellaneous technical adjustments.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

- 1. Please provide a brief overview of the caseload and expenditure changes for the WIC program.
- 2. Please provide an update on participation in the program as a percentage of eligible individuals in the state.
- 3. What is DPH doing to maximize participation in the WIC program to make full use of available federal WIC funding?

Issue 8: Infant and Early Childhood Home Visiting Program

Budget Issue. DPH requests permanent extension of 27 expiring, limited-term positions and federal fund expenditure authority of \$903,000 in 2018-19 and \$21.8 million in 2019-20. Of the 27 positions, 11 would be renewed in January 2019, and 16 would be renewed in July 2019. If approved, these resources would allow DPH to continue operation of the California Home Visiting Program (CHVP).

Program Funding Request Summary			
Fund Source	2018-19	2019-20*	
0890 – Federal Trust Fund			
State Operations	\$903,000	\$4,000,000	
Local Assistance	\$-	\$17,800,000	
Total Funding Request:	\$903,000	\$21,800,000	
Total Requested Positions:	11.0	27.0	

* Positions and Resources ongoing after 2019-20.

Background. The California Home Visiting Program (CHVP), established in 2010 by authority contained in the federal Affordable Care Act, provides voluntary, evidence-based home visiting services to pregnant and newly parenting families who have one or more of the following risk factors: domestic violence, inadequate income, unstable housing, education less than 12 years, substance abuse, and depression and/or mental illness. Services are provided by a public health nurse or paraprofessional in the family's home and may begin prenatally or right after the birth of a baby up to age three.

Two Evidence-Based Models for Service Delivery. CHVP home visiting services are provided to eligible families by 23 local health jurisdictions (LHJ). Each uses one of the following evidence-based models, based on the specific needs of the local area:

- 1) <u>Healthy Families America (HFA)</u>
 - a. Serves low-income families who must be enrolled within the first three months after an infant's birth.
 - b. A trained paraprofessional provides one-on-one home visits to parents and their babies primarily up to age three.
 - c. Uses a strength-based approach.
 - d. Uses motivational interviewing to build on the parents' own interests.
 - HFA Counties (8): Tehama, Butte, Nevada, Yolo, Merced, Madera, Imperial, Los Angeles*
- 2) Nurse Family Partnership (NFP)
 - a. Serves low-income, first-time mothers who must be enrolled by the 28th week of pregnancy.
 - b. A public health nurse provides one-on-one home visits to parents and their babies up to age two.
 - c. Uses a strength-based approach.
 - d. Uses motivational interviewing to build on the parents' own interests.

<u>NFP Counties (16)</u>: Del Norte, Humboldt, Shasta, Sonoma, Solano, Sacramento, San Francisco, Contra Costa, Alameda, San Mateo, Stanislaus, Fresno, Kern, Riverside, San Diego, Los Angeles*

*Los Angeles offers services under both the HFA and NFP models.

According to DPH, the CHVP is a high-yield investment that strengthens parent-child relationships, increases language and literacy skills, and reduces child abuse, neglect, poor health, academic failure and crime. According to a fact sheet developed by the Pacific Institute for Research and Evaluation¹, the Nurse-Family Partnership model resulted in the following outcomes in 2010:

Present Value of Benefits and Costs per Family Served by Nurse-Family	Per Case
Partnership, California, 2010 Benefits of NFP	
Reduced Smoking While Pregnant	\$3
Reduced Preeclampsia	\$670
Fewer Preterm First Births	\$1,664
Fewer Subsequent Births	\$435
Fewer Subsequent Preterm Births	\$1,309
Fewer Infant Deaths	\$24,324
Fewer Child Maltreatments:	
Substantiated Cases	\$3,756
Indicated & Unreported Cases	\$6,598
Fewer Nonfatal Child Injuries	\$889
Fewer Remedial School Services	\$90
Fewer Youth Crimes:	
Arrests	\$1,440
Crimes	\$9,892
Reduced Youth Substance Abuse	\$29
More Immunizations:	
Savings Net of Immunization Cost	\$105
Total Benefits	\$51,204
Resource Cost Savings	\$10,947
Intangible Savings (work, quality of life)	\$40,257
Cost of NFP	\$12,075
Net Cost Saving	\$39,129
Resource Cost Savings Net of Program Costs	-\$1,128
Benefit-Cost Ratio	4.2

According to DPH, as of October 2017, CHVP completed 141,091 home visits and served over 7,554 families at its 23 local sites.

Resource History and Status of Federal Funding. CHVP is fully supported by federal funds provided by the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program grant. MIECHV was initially funded for its first five years, from 2010 through 2014, at \$1.5 billion nationwide. The

¹ Miller, T.R. 2017. Societal Return on Investment in Nurse-Family Partnership Services in California. Fact Sheet. Pacific Institute for Research and Evaluation, Beltsville, MD.

Protecting Access to Medicare Act of 2014 funded the program at \$400 million nationwide in 2015, and separated the program from the balance of the Affordable Care Act. The Medicare and CHIP Reauthorization Act extended funding until September 30, 2017 at \$372 million nationwide. The Bipartisan Budget Act of 2018, approved in February 2018, funded the program at \$400 million nationwide for an additional five years, until September 30, 2022.

California's federal funding from MIECHV since 2010 has been as follows:

Federal Fiscal Year (OctSept.)	2010	2011	2012	2013	2014	2015	2016	2017
California Funding Level (millions)	\$8.2	\$20.9	\$20.9	\$20.2	\$20.6	\$22.6	\$22.2	\$22.0

After DPH was awarded funding from MIECHV Program grants in 2010-11 and 2011-12 to establish the CHVP, the 2010 and 2011 Budget Acts authorized a total of 36 five-year, limited-term positions to develop appropriate home visiting models, develop reporting and compliance procedures and manage the program. The 2015 Budget Act extended 27 of these positions for an additional three years. DPH requests to reauthorize the program's staff on a permanent basis. Based on the success of home visiting programs nationally and bipartisan federal support, DPH expects to continue to receive federal MIECHV Program grants for the CHVP. The current program staff positions proposed for permanent extensions consist of the following classifications:

Classification	2018-19	2019-20
Office Technician	1.0	1.0
Associate Accounting Analyst	1.0	1.0
Staff Services Manager II (Supvry)	1.0	1.0
Associate Governmental Program Analyst	1.0	3.0
Research Scientist I	0.0	3.0
Research Scientist II	1.0	4.0
Research Scientist III	1.0	2.0
Research Scientist IV	1.0	1.0
Research Scientist Supervisor I	1.0	1.0
Research Scientist Manager	1.0	1.0
Public Health Medical Officer III	1.0	1.0
Health Program Specialist I	0.0	3.0
Health Program Specialist II	1.0	5.0
TOTAL	11.0	27.0

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

1. Please provide a brief overview of this proposal.

Issue 9: Genetic Disease Screening Program (GDSP) Local Assistance Estimate

Budget Issue. The November 2017 Genetic Disease Screening Program Estimate includes expenditure authority from the Genetic Disease Testing Fund of \$132.3 million (\$27.7 million state operations and \$104.7 million local assistance) in 2017-18, and \$132.9 million (\$29.5 million state operations and \$103.5 million local assistance) in 2018-19.

Genetic Disease Screening Program (GDSP) Funding Summary				
	2017-18 2018-19		BY to CY	
Fund Source	Revised	Proposed	Change	
0203 – Genetic Disease Testing Fund				
State Operations:	\$27,650,000	\$29,451,000	\$1,801,000	
Local Assistance:	\$104,732,000	\$103,473,000	(\$1,259,000)	
Total GDSP Expenditures	\$132,382,000	\$132,924,000	\$542,000	

Background. According to DPH, the Genetic Disease Screening Program (GDSP) performs the following tasks to support its mission:

- Screens newborns and pregnant women for genetic and congenital disorders in a costeffective and clinically effective manner. The screening programs provide testing, follow-up and early diagnosis of disorders to prevent adverse outcomes or minimize clinical effects.
- Ensures quality of analytical test results and program services by developing standards and quality assurance procedures, and monitoring compliance.
- Fosters informed participation in its programs in an ethical manner through a combination of patient, professional, and public education, and accurate and up-to-date information and counseling.
- Provides ongoing critical review, testing, and evaluation of existing programs to ensure program objectives and goals are being met.
- Develops programs to adopt new methods and implement new services that further enhance the effectiveness and efficiency of current and future prevention programs.
- Promotes use of high-quality consumer education materials on genetic disorders, screening for birth defects and genetic services.

GDSP operates two primary screening programs: the Newborn Screening program and the Prenatal Screening program. Caseload and expenditures for these programs are reflected in the GDSP Estimate along with operational support costs for the programs.

Newborn Screening (NBS) Program. Newborn screening, recognized nationally as an essential preventive health measure, began in California in 1966 with the testing of infants for phenylketonuria (PKU). In 1980, the program was expanded to include galactosemia, primary congenital hypothyroidism, and included a more comprehensive follow-up system. In 1990, screening for sickle cell disease was added to the screening program, which allows for identification of related non-sickling hemoglobin disorders, including beta-thalassemia major, and Hb E/beta thalassemia. In 1999, the program implemented screening for hemoglobin H and hemoglobin H - Constant Spring disease. In 2005 the screening panel was expanded to include additional metabolic disorders and congenital adrenal

hyperplasia (CAH), and in 2007, the screening panel was expanded to include cystic fibrosis (CF) and biotinidase deficiency (BD). In 2010, Severe Combined Immunodeficiency (SCID) was added to the screening panel.

According to DPH, disorders screened for by the program have varying degrees of severity and, if identified early, many can be treated before they cause serious health problems. Between 1980 and 2009, 14,989,863 babies were screened resulting in early identification of the following disorders:

Disorder	Cases
Phenylketonuria (PKU)	1,026
Primary Congenital Hypothyroidism	5802
Galactosemia	191
Sickle Cell Disease and other clinically significant Hemoglobinopathies	2,500
Hemoglobin H Disease	529
Biotinidase Deficiency (BD)	16
Cystic Fibrosis (CF)	242
Congenital Adrenal Hyperplasia (CAH)	114
Metabolic/Fatty Acid Oxidation Disorders	559
TOTAL	10,979

The NBS program currently screens infants in California for 80 separate disorders. Pursuant to SB 1095 (Pan), Chapter 363, Statutes of 2016, two additional disorders, Mucopolysaccharidosis type I (MPS-I) and Pompe disease, will be added to the screening panel by August 30, 2018. In addition, as conditions are added to the federal Recommended Uniform Screening Panel (RUSP), they will be added to the NBS program screening panel within two years. The fee for screening in the NBS program is currently \$130.25. Beginning July 1, 2018, the NBS program fee will increase by \$12 to \$142.25 to support workload for addition of MPS-I and Pompe disease to the screening panel.

<u>Caseload Estimate:</u> The budget estimates NBS program caseload of 480,607 in 2017-18, a decrease of 1,744 or 0.4 percent, compared to the 2017 Budget Act. The budget estimates NBS program caseload of 478,321 in 2018-19, an increase of 2,287 or 0.5 percent, compared to the revised 2017-18 estimate. These estimates are based on state projections of an increase in the number of live births. DPH assumes 99.4 percent of births will participate in the NBS program annually.

Prenatal Screening (PNS) Program. The Prenatal Screening (PNS) program provides prenatal screening services and follow-up diagnostic services, where indicated, to all pregnant women in California to detect birth defects during pregnancy. The program offers three types of screening tests to pregnant women in order to identify individuals who are at increased risk for carrying a fetus with a specific birth defect:

- <u>Sequential Integrated Screening</u> This screen combines first and second blood test results with nuchal translucency (NT) ultrasound results, which measure the back of a fetus' neck. This measurement helps screen for Down syndrome (trisomy 21).
- <u>Serum Integrated Screening</u> This screen combines a first trimester blood test screening result with a second trimester blood test screening result.

• <u>Quad Marker Screening</u> - One blood specimen drawn at 15 weeks - 20 weeks of pregnancy (second trimester test).

The PNS program provides pregnant women with a risk assessment for open neural tube defects (NTD), Down syndrome (trisomy 21), trisomy 18 and Smith-Lemli-Opitz Syndrome (SLOS) through one or two blood tests. The screening test indicates risk, but does not diagnose fetal birth defects.

For women with screening results indicating a high risk for a birth defect, the program provides free follow-up diagnostic services at state-approved Prenatal Diagnosis Centers (PDCs). Services offered at these centers include genetic counseling, ultrasound, and amniocentesis. Participation in the screening testing and follow-up services is voluntary and the fee for testing through the PNS program is \$221.60.

<u>Caseload Estimate:</u> The budget estimates PNS program caseload of 343,933 in 2017-18, a decrease of 4,504 or 1.3 percent, compared to the 2017 Budget Act. The budget estimates PNS program caseload of 342,297 in 2018-19, a decrease of 1,636 or 0.5 percent, compared to the revised 2017-18 estimate. These estimates are based on state projections of an increase in the number of live births. DPH assumes 71.1 percent of births will participate in the PNS program annually.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

- 1. Please provide a brief overview of the caseload and expenditure changes for the Newborn Screening Program.
- 2. Please provide a brief overview of the caseload and expenditure changes for the Prenatal Screening Program.

Issue 10: New Genetic Disorders (SB 1095) and Second Tier Testing

Budget Issue. DPH requests 18 positions and expenditure authority from the Genetic Disease Testing Fund of \$2.7 million. If approved, these resources would allow DPH to comply with expanded testing requirements pursuant to SB 1095 (Pan), Chapter 363, Statutes of 2016, including new screening for Mucopolysaccharidosis type I (MPS-I), Pompe disease, and any future additions to the Recommended Uniform Screening Panel (RUSP).

Program Funding Request Summary			
Fund Source	2018-19	2019-20*	
0203 – Genetic Disease Testing Fund			
State Operations:	\$2,690,000	\$2,690,000	
Local Assistance**:	[(\$460,000)]	[(\$460,000)]	
Total Funding Request:	\$2,690,000	\$2,690,000	
Total Requested Positions:	18.0	18.0	

* Positions and Resources ongoing after 2019-20.

** Local Assistance reductions are non-add and are reflected in the GDSP Local Assistance Estimate.

Background. GDSP administers a statewide genetic disorder screening program for pregnant women and newborns that is fully supported by fees. When the Newborn Screening (NBS) program within GDSP began in 1980, each newborn was screened for only three disorders. Today, more than 500,000 newborns are screened for 80 disorders annually, resulting in more than 700 diagnoses. According to DPH, California leads the nation in the number of disorders screened and provides the most comprehensive program in terms of quality control, follow-up services, genetic counseling, confirmatory testing, and diagnostic services.

SB 1095 requires the NBS program to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal Recommended Uniform Screening Panel (RUSP). There are two disorders currently on the RUSP that are not on the NBS program panel. Mucopolysaccharidosis type I (MPS-I) and Pompe disease were added to the RUSP in 2016 and 2015, respectively, and will be added to the panel for newborn screening by August 30, 2018.

DPH also plans to couple its primary screening methods with a second-tier, linked test that can improve diagnostic specificity without reducing sensitivity and uses the same blood specimen that was sampled for the original test. The secondary screen measures additional metabolites that either strongly support the presumption of a true positive case or demonstrate the patient does not have the disorder. According to DPH, significant published research supports the public health and cost-saving benefits of adoption of a second-tier testing method to rule out false positive results.

Resources for Implementation of New Screening Protocols Results in Fee Increase. Based on an assessment of laboratory and processing costs, an increase of approximately \$10.00 to the current NBS program fee of \$130.25 will be required to implement the new testing protocols and provide ongoing funding. Funding from the fee increase will support expenditures associated with processing blood specimens; performing the actual blood screen; testing chemicals, equipment and supplies used to assay results; and arranging for follow-up services for positive cases. Follow-up services may include case

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management, diagnostic work-up, confirmatory processing, provider and family education, or informative result mailers.

DPH requests one position and expenditure authority from the fee-supported Genetic Disease Testing Fund of \$2.69 million. If approved, \$2.25 million would fund one-time costs to develop testing protocols to incorporate MPS-I and Pompe disease into the NBS program screening panel by August 30, 2018. \$139,000 would fund one Research Scientist II to support testing activities. In addition, DPH is requesting a one-time increase of \$300,000 in state operations expenditure authority and a transfer of \$330,000 in expenditure authority from local assistance to state operations for the purchase of mass spectrometry equipment and support for second-tier testing. The department plans to purchase the equipment in early 2017-18 to begin performing second-tier testing by early 2018.

According to DPH, implementation of second-tier testing would save the NBS program approximately \$380,000 per year in local assistance costs related to follow-up services provided in response to a false positive result, beginning in 2018-19.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding this item open to allow continued discussions in advance of the May Revision.

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

1. Please provide a brief overview of this proposal.

Issue 11: Additional Proposals for Investment

Stakeholder Proposal for Managing Hypertension. The American Heart Association (AHA) and American Stroke Association (ASA) request \$10 million General Fund to create a 3-5 county pilot program for hypertension awareness, education, prevention, and control. The pilot program would focus on the counties with the highest prevalence of hypertension and establishes best practices in participating health care systems (federally qualified health centers, rural health centers, and/or private providers). According to the AHA and ASA, the program would fund the following activities:

- Identify 5 counties with the highest prevalence of blood pressure.
- Increase utilization rates of blood pressure cuffs among participating Medi-Cal patients. Blood pressure equipment is a covered benefit, but the utilization rates are incredibly low. Participating providers are encouraged to consistently prescribe blood pressure cuffs for self-measured home blood pressure monitoring. Formalizing this best practice will empower patients to fully engage in their own self-care through home monitoring.
- Patients will record their own blood pressure readings daily and subsequently transfer their readings to a patient's electronic health record.
- The care team will require patients to return for a follow-up no later than three months after the initial diagnosis, ideally returning within one month.
- Harness the power of community health workers (CHW) to expand the care team to provide more comprehensive health care. CHWs will make home visits to high-risk patients to provide more education on blood pressure, ensure that patients are using the blood pressure cuffs properly, tracking their readings, and assist in lifestyle modification.
- The program's goal would be to increase the hypertension control rate to at least 70% of participating patients.

Stakeholder Proposal to Implement Systems of Care for Amyotrophic Lateral Sclerosis (ALS). The ALS Association requests \$3 million General Fund to help support the critical System of Care, both clinic- and community-based, for ALS patients and their caregivers. According to the ALS Association, ALS, often referred to as Lou Gehrig's disease, is a progressive and fatal neuro-degenerative disease. When motor neurons die, the ability of the brain to initiate and control muscle movement is lost. The result is that people with ALS lose the ability to move, speak, swallow and breathe. The life expectancy of a person diagnosed with ALS is 2 to 5 years, and there is no effective treatment or cure. There are only two drugs approved by the FDA for ALS, neither are proven to extend life by more than 2 to 4 months. The only way to meaningfully extend the length and quality of life for people diagnosed with ALS is to provide them with access to the ALS Association's evidence-based model of care. This model of care involves the seamless integration of community and clinic based multidisciplinary services. This "wraparound" model of care is proven to help people diagnosed with ALS to live significantly longer and better than the only FDA approved drugs.

Subcommittee Staff Comment and Recommendation—Hold Open. Subcommittee staff recommends holding these items open to allow continued discussions in advance of the May Revision.

Questions. The subcommittee has requested advocates to present these proposals and respond to questions from subcommittee members.