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**INFORMATIONAL HEARING:
PRESCRIPTION DRUG AFFORDABILITY AND
EXPANDING MEDI-CAL COVERAGE**

Thursday, February 14, 2019
John L. Burton Hearing Room (4203)
9:30 a.m.

PART A - Full-Scope Medi-Cal Coverage for Undocumented Young Adults

- I. PRESENTATION – “Towards Universal Health Coverage: Expanding Medi-Cal to Low-Income Undocumented Adults”

Laurel Lucia, Director, Health Care Program, UC Berkeley Labor Center

- II. PANEL – Governor’s Proposed Expansion of Full-Scope Medi-Cal Coverage

Mari Cantwell, Chief Deputy Director, Department of Health Care Services
Andrieu Ching, Chief, Adult Programs & Automation, Department of Social Services
Laura Ayala, Staff Finance Budget Analyst, Department of Finance
Sydney Tanimoto, Staff Finance Budget Analyst, Department of Finance

Ben Johnson, Senior Fiscal and Policy Analyst, Legislative Analyst’s Office

- III. STAKEHOLDER PANEL

PART B - Governor's Prescription Drug Proposals

I. PANEL – Governor's Executive Order on Bulk Purchasing Initiatives

Matt Bender, Legislative Affairs Manager, Department of General Services

Clint Kellum, Assistant Program Budget Manager, Department of Finance

Ben Johnson, Senior Fiscal and Policy Analyst, Legislative Analyst's Office

II. PANEL – Transition of Medi-Cal Pharmacy to Fee-For-Service Delivery System

Jennifer Kent, Director, Department of Health Care Services

Ryan Miller, Assistant Program Budget Manager, Department of Finance

Ben Johnson, Senior Fiscal and Policy Analyst, Legislative Analyst's Office

III. STAKEHOLDER PANEL

PUBLIC COMMENT

Medi-Cal for Undocumented Young Adults

BACKGROUND

Although California has reduced its uninsured population more than any other state, from 17.2 percent in 2013 to 7.2 percent in 2017, nearly 2.8 million California residents remain without adequate health coverage.¹ In particular, approximately 1.5 million undocumented residents are expected to be uninsured by 2020, 90 percent of whom would otherwise be eligible for coverage under the Medi-Cal program, but for their immigration status.² The Legislature has proposed state-funded coverage for all or portions of this population several times in recent years, including a successful effort in 2015 to provide full-scope Medi-Cal coverage to income-eligible children up to age 19, regardless of immigration status.

The Governor's January budget proposes to expand full-scope Medi-Cal coverage to approximately 138,000 income-eligible young adults up to age 26, regardless of immigration status. The cost of the Governor's proposal would be partially offset by redirecting county realignment funding for indigent health care to the state. In addition, two bills currently pending in the Legislature, SB 29 (Lara and Durazo) and AB 4 (Arambula, Bonta, and Chiu), would expand coverage to all income-eligible adults, regardless of immigration status.

Medi-Cal Covers One in Three Californians. Medi-Cal covers 13.2 million Californians, including more than five million children, at a total estimated cost of \$98.5 billion in 2018-19 and \$100.7 billion in 2019-20. Of that amount, the federal government is expected to contribute \$62.7 billion in 2018-19 and \$65.4 billion in 2019-20 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, family planning expenditures, and improvements to information technology systems.

Limitations on Health Care Options for Undocumented Californians. Federal Medicaid law prohibits federal matching fund payments to states for full-scope coverage of undocumented residents. However, federal law does allow payments for emergency and pregnancy (restricted-scope) services provided to undocumented residents. According to the Department of Health Care Services (DHCS), the total cost of providing restricted-scope services was \$1.6 billion in 2016-17. As of July 2018, DHCS estimates that 952,683 undocumented adults are enrolled in restricted-scope Medi-Cal. 268,811 undocumented children up to age 19 are also eligible and enrolled in state-funded full-scope Medi-Cal benefits. The state continues to be eligible for federal matching

¹ Edward R. Berchick et al., "Health Coverage in the United States: 2017". (United States Census Bureau, September 18, 2018)

² Miranda Dietz et al., "California's Health Coverage Gains to Erode Without Further State Action". (UC Berkeley Center for Labor Research and Education and UCLA Center for Health Policy Research, November 27, 2018)

funds for emergency and pregnancy services for this population. (For more information, see *Medical Eligibility for Children Regardless of Immigration Status*, below).

Federal law also prohibits undocumented residents from participating in the Covered California health benefit exchange established after passage of the federal Affordable Care Act. Covered California provides health care service plan coverage options in the individual market for eligible citizens and legal permanent residents. Covered California participants with incomes up to 400 percent of the federal poverty level (FPL) receive federally financed premium subsidies to make coverage more affordable. Covered California also serves as an active purchaser, utilizing its selective contracting authority to negotiate with health plans to lower premiums for California health care consumers. Undocumented residents may enroll in off-exchange coverage options similar to those negotiated by the exchange, but are ineligible for federally financed premium subsidies that make such coverage affordable.

County Indigent Health Programs Provide Coverage for the Uninsured. State law requires counties to serve as the health care provider of last resort for residents age 18 and over who cannot afford care, known as medically indigent adults.³ The services offered and requirements for eligibility vary significantly by county. County indigent programs generally fall into two categories:

1. *County Medical Services Program (CMSP)*⁴ – 35 mostly small and rural counties contract with Advanced Medical Management to administer a standardized benefit for limited-term health coverage for uninsured low-income, indigent adults not otherwise eligible for publicly funded health care programs. An eleven member CMSP Governing Board sets program eligibility requirements, determines the scope of covered health care benefits, and sets the payment rates paid to providers. CMSP counties include: Alpine, Amador, Butte, Calaveras, Colusa, Del Norte, El Dorado, Glenn, Humboldt, Imperial, Inyo, Kings, Lake, Lassen, Madera, Marin, Mariposa, Mendocino, Modoc, Mono, Napa, Nevada, Plumas, San Benito, Shasta, Sierra, Siskiyou, Solano, Sonoma, Sutter, Tehama, Trinity, Tuolumne, Yolo, and Yuba.
2. *Medically Indigent Service Program* – 23 counties manage their own medically indigent programs with different service delivery options and eligibility requirements. These counties include: Alameda, Contra Costa, Fresno, Kern, Los Angeles, Merced, Monterey, Orange, Placer, Riverside, Sacramento, San Bernardino, San Diego, San Francisco, San Joaquin, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, Santa Cruz, Stanislaus, Tulare, and Ventura.

1991 Realignment Funds County Indigent Programs. County indigent health programs are generally funded by revenues received under 1991 Realignment, which shifted significant fiscal and programmatic responsibility for certain health and human services programs from the state to the counties. 1991 Realignment revenues have historically allowed county indigent health programs to provide care for the uninsured and those ineligible for other coverage. Prior to 2014,

³ Welfare and Institutions Code Section 17000

⁴ County Medical Services Program. “Program Administration” & “Participating Counties” (http://www.cmspcounties.org/about/program_administration.html. Accessed February 9, 2019)

many programs covered undocumented individuals, as well as childless adults that were previously ineligible for Medi-Cal coverage.

The federal Affordable Care Act authorizes states to expand their Medicaid programs to previously uninsured individuals. AB1 X1 (Pérez) and SB1 X1 (Hernandez), Chapters 3 and 4, Statutes of 2013, First Extraordinary Session, 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 with incomes at or below 138 percent of the federal poverty level. Optional expansion beneficiaries are mandatorily enrolled in managed care for their Medi-Cal benefits.

As a result of the expansion of coverage to previously uninsured individuals through the state's Medi-Cal program, county indigent health programs were no longer responsible for providing care for this population. AB 85 (Committee on Budget), Chapter 24, Statutes of 2013, provides for the redirection of health-related 1991 Realignment revenues from counties to offset state General Fund costs to account for this shift in responsibility and health care expenditures for the Medi-Cal expansion population. The redirection of 1991 Realignment funds offsets expenditures in the California Work Opportunity and Responsibility to Kids (CalWORKs) program that were previously funded through the state's General Fund.

AB 85 requires CMSP counties to redirect 60 percent of the realignment funds they would have previously received. That legislation also gave another group of counties the option to redirect 60 percent of realignment funds or base the redirection amount on a formula that takes into account a county's cost and revenue experience. Counties with public hospitals, except Los Angeles, base redirection amounts on the cost and revenue formula. Los Angeles County adheres to a county-specific formula.

Certain County Indigent Health Programs Offer Non-Emergency Care for Undocumented.

After implementation of the Medi-Cal expansion, undocumented residents are the largest proportion of the remaining uninsured for whom county indigent health programs are responsible to provide care. While all programs offer emergency care covered by Medi-Cal to undocumented residents, some counties have recently expanded the scope of coverage to include certain non-emergency, limited-scope primary care benefits.

CMSP Counties: Eligibility Expansion and Primary Care Benefit. Beginning in 2016, the CMSP Governing Board approved an expansion of eligibility requirements for its 35-county indigent health program from 200 percent to 300 percent of the FPL. In addition, the board approved the Primary Care Benefit program, a two-year pilot to provide CMSP participants, including undocumented residents, with certain non-emergency benefits for a renewable, six-month enrollment period. These benefits include⁵:

1. Up to three office visits for primary care, specialty care, or physical therapy,
2. Preventative health screenings and lab tests,
3. Prescription drugs with a five dollar co-pay and up to \$1,500 in benefits, and

⁵ County Medical Services Governing Board. "CMSP All County Welfare Directors Letter 16-03: New CMSP Primary Care Benefit Program". (April 27, 2016).

4. Services provided by contracting community health centers, clinics, and other providers.

Beginning in September 2018, the CMSP Governing Board authorized the Primary Care Benefit program to be permanently incorporated into the CMSP standard benefit package in its indigent health program.

Los Angeles County: My Health LA. Los Angeles County implemented My Health LA in 2014 to provide primary and specialty care services to more than 144,319 uninsured county residents.⁶ The program provides primary preventive, specialty care, hospital inpatient, urgent and emergency care through county public hospitals, clinics and other providers. In addition, the program provides prescription drugs, mental health and substance use treatment services, lab tests, and other health care services.



Source: Health Access California. "Profiles of Progress: California Counties Taking Steps to a More Inclusive and Smarter Safety-Net". (2016)

⁶ My Health LA Program. "Key Demographics and Enrollment Summary" (LA Dept of Health Services, Jan 2019)

According to an analysis by Health Access California, the following counties also provide some non-emergency coverage for undocumented residents through their county indigent programs: Fresno, Sacramento, Contra Costa, Monterey, and Santa Clara.

Full-Scope 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 income-eligible children under age 19, regardless of immigration status. Undocumented children were previously only eligible for restricted-scope Medi-Cal coverage, which receives a federal match depending on the child’s eligibility category, while the additional non-emergency services provided under the full-scope expansion are funded entirely by state General Fund. DHCS estimated that 250,000 undocumented children under age 19 would become eligible under the expansion. As of January 2019, a total of 268,811 undocumented children have enrolled in full-scope Medi-Cal, in two distinct populations:

1. Previous Restricted-Scope Medi-Cal Beneficiaries: As of January 2019, 120,614 undocumented children previously enrolled in restricted-scope Medi-Cal coverage have transitioned into full-scope Medi-Cal coverage.
2. Not Previously Enrolled: As of January 2019, 148,197 undocumented children who were previously eligible, but not enrolled in, restricted scope Medi-Cal have enrolled in full-scope benefits.

Full-Scope Medi-Cal Coverage for Children Regardless of Immigration Status, by County (Jan. 2019)⁷							
County	Covered Children	County	Covered Children	County	Covered Children	County	Covered Children
Alameda	11,472	Kings	1,105	Placer	744	Sierra	*
Alpine	*	Lake	559	Plumas	*	Siskiyou	99
Amador	62	Lassen	*	Riverside	14,284	Solano	2,088
Butte	565	Los Angeles	97,628	Sacramento	7,838	Sonoma	2,194
Calaveras	69	Madera	1,320	San Benito	356	Stanislaus	4,447
Colusa	193	Marin	1,752	San Bernardino	11,572	Sutter	487
Contra Costa	6,416	Mariposa	*	San Diego	13,254	Tehama	404
Del Norte	*	Mendocino	730	San Francisco	4,904	Trinity	*
El Dorado	372	Merced	2,970	San Joaquin	5,038	Tulare	4,415
Fresno	6,387	Modoc	34	San Luis Obispo	1,040	Tuolumne	67
Glenn	234	Mono	101	San Mateo	6,479	Ventura	5,211
Humboldt	348	Monterey	4,886	Santa Barbara	4,250	Yolo	1,020
Imperial	732	Napa	703	Santa Clara	10,278	Yuba	370
Inyo	63	Nevada	208	Santa Cruz	1,441	Statewide	268,811
Kern	7,544	Orange	19,398	Shasta	462		

* = Value suppressed due to low enrollment totals.

⁷ Research and Analytic Studies Division. “SB 75 Transitions and New Enrollees by County” (Department of Health Care Services, January 9, 2019). https://www.dhcs.ca.gov/services/medi-cal/eligibility/Documents/SB75/SB75_Enrollees_County_010219.pdf

Proposals to Expand Medi-Cal Eligibility to Remaining Uninsured Populations. Legislators and stakeholders have expressed interest in expanding Medi-Cal coverage to undocumented families and individuals not currently eligible due to immigration status, including adults up to age 26, adults ages 26 to 64 and seniors age 65 and older. Prior to approval of the 2018 Budget Act, the Assembly adopted a proposed expansion of full-scope Medi-Cal to undocumented young adults up to age 26, while the Senate adopted a proposed expansion of full-scope Medi-Cal to undocumented seniors over age 65. The 2018 Budget Act ultimately included neither proposal.

In addition, SB 29 (Lara and Durazo) and AB 4 (Arambula, Bonta, and Chiu) were introduced in the current legislative session to provide full-scope Medi-Cal coverage to all adults regardless of immigration status. These bills are awaiting their first committee hearings.

GOVERNOR'S PROPOSAL

Expansion of Medi-Cal to Young Adults Regardless of Immigration Status. The Governor's January budget proposes to expand full-scope Medi-Cal coverage to young adults up to age 26, regardless of immigration status. According to the Administration, the cost of expanding Medi-Cal coverage would be \$257.1 million (\$194 million General Fund, \$63.1 million federal funds). The federal funds are the result of the federal match provided for emergency and pregnancy services provided to this population that would have previously been provided under restricted-scope coverage. In addition, the expansion would result in \$2.2 million General Fund costs for the Department of Social Services to provide In-Home Supportive Services for newly eligible young adults with disabilities.

DHCS estimates that 137,703 young adults would be newly eligible for full-scope Medi-Cal coverage. The department's estimate includes the following assumptions:

1. 85,939 undocumented young adults currently enrolled in restricted-scope Medi-Cal would be automatically transitioned to full-scope coverage during the first month of eligibility.
2. 14,323 undocumented children who would have previously aged out of full-scope coverage under the SB 75 expansion will be eligible to continue coverage under the Governor's proposed expansion.
3. 37,441 undocumented young adults who are eligible, but not enrolled, in restricted-scope Medi-Cal will enroll in full-scope coverage in the 2019-20 fiscal year. This estimate assumes that, of 66,562 eligible but not enrolled undocumented young adults, 49,921 or 75 percent, will eventually enroll in full-scope coverage, with 37,441 or 75 percent of those individuals enrolling in the first year.

Some Costs of Expanded Coverage Offset by Redirection of County Realignment Revenue. The Governor's January budget also proposes to offset the costs for expansion of full-scope Medi-Cal by increasing the redirection amount for CMSP counties and other counties that adopted a fixed redirection formula under AB 85. The budget proposes to change the fixed proportion of redirected realignment funds from 60 to 75 percent. The counties that adopted a cost- and revenue-based redirection formula are expected to increase the proportion of realignment funds redirected

to the state as those counties' indigent health costs decrease due to the expansion of Medi-Cal coverage. According to the Administration, accounting for additional redirected revenue results in a net General Fund cost for the expansion of \$133.5 million. The total expected interim redirection amounts in 2019-20 under the proposed formula are \$617.7 million. For reference, the 2018-19 interim redirection amounts under the previous formula were \$530.5 million.

ISSUES TO CONSIDER

Most of the Remaining Uninsured in California are Undocumented. The Governor's proposed expansion of full-scope Medi-Cal coverage to 138,000 undocumented young adults is a reasonable first step towards covering the remaining uninsured in California. However, because undocumented adults comprise such a significant share of California's remaining uninsured, particularly those who would otherwise be income-eligible for Medi-Cal, the state will not be able to achieve universal coverage without addressing this population's coverage needs. While county indigent health programs have begun to offer more primary care and other non-emergency services to undocumented adults, these programs are generally limited in the scope of services provided and likely insufficient to provide for the health needs of individuals in need of comprehensive health coverage.

Fiscal Estimates for Full-Scope Medi-Cal Expansion to All Adults. Since the release of the Governor's January budget, DHCS has provided fiscal estimates for providing full-scope Medi-Cal coverage to all undocumented adults and seniors.

Expansion to Undocumented Adults Ages 26-64. According to DHCS, expanding full-scope Medi-Cal benefits to undocumented adults ages 26 to 64 would result in costs of \$2 billion (\$1.5 billion General Fund and \$507.6 million federal funds). These figures do not account for additional General Fund costs for In-Home Supportive Services that would be provided to newly eligible individuals with disabilities. The department's estimate expects approximately one million additional undocumented adults ages 26 to 64 would enroll in full-scope Medi-Cal coverage. The estimate includes the following assumptions:

1. 879,100 undocumented adults ages 26 to 64 currently enrolled in restricted-scope Medi-Cal would be automatically transitioned to full-scope coverage during the first month of eligibility.
2. 164,513 undocumented adults ages 26 to 64 who are eligible, but not enrolled, in restricted-scope Medi-Cal will enroll in full-scope coverage in the 2019-20 fiscal year. This estimate assumes that, of 292,468 eligible but not enrolled undocumented young adults, 219,351 or 75 percent, will eventually enroll in full-scope coverage, with 164,513 or 75 percent of those individuals enrolling in the first year.

Expansion to Undocumented Seniors Age 65 and Over. According to DHCS, expanding full-scope Medi-Cal benefits to undocumented seniors age 65 and over would result in costs of \$115.3 million (\$94.5 million General Fund and \$20.9 million federal funds). These figures do not account for additional General Fund costs for In-Home Supportive Services that would be provided to newly eligible seniors. The department's estimate expects that 28,379 undocumented seniors would be

enrolled in full-scope Medi-Cal coverage. The estimate assumes that all of these seniors are currently enrolled in restricted-scope Medi-Cal and would be automatically transitioned to full-scope during the first month of eligibility. The department's estimate assumes no new enrollment in full-scope benefits from individuals currently eligible but not enrolled in restricted-scope coverage.

County Indigent Health Programs Fill Some of the Gaps. Many counties have acknowledged the value of providing non-emergency benefits to their undocumented residents, particularly primary and preventative care services. However, the limited nature of these benefits, combined with restricted-scope Medi-Cal is an inefficient and incomplete care delivery system that leaves out many of the services considered essential health benefits under the Affordable Care Act. These limits also likely result in more expensive modes of health care delivery, including higher emergency department and hospital inpatient utilization. Because most county services are provided in county safety net systems, the financial and operational challenges of caring for undocumented individuals generally fall on public hospitals and clinics. Expanding full-scope coverage would likely reduce some of these challenges for county health programs.

Redirection of 1991 Realignment Funds as a Source of Funding Coverage Expansions. The expansion of Medi-Cal under the Affordable Care Act resulted in state- and federally-funded coverage of nearly four million previously uninsured individuals whose care was the statutory responsibility of county indigent health programs. The state's mandated redirection of a significant proportion of county realignment revenues to account for this shift in health care responsibilities was reasonable given the large population. The Governor's proposed expansion of full-scope Medi-Cal for undocumented young adults increases the fixed proportion of realignment funds redirected as the state assumes responsibility for health care coverage for this population. However, the Legislature may wish to consider whether there are limits to the use of these revenues as a funding source for coverage expansions, given the ongoing need for county indigent health programs in the absence of universal coverage.

Prescription Drug Affordability

BACKGROUND

While recent health reform efforts have led to significant expansions of health insurance coverage in California and across the United States, a complementary goal of these health reform efforts has also been to reduce the growth of health care costs. One of the primary drivers of rising health care costs has been the growth in the price of prescription drugs, which in 2017 accounted for approximately one out of every ten dollars in national health care expenditures.⁸ Employer-based health plans experience even higher expenditures for prescription drugs, which make up 19 percent of employer-based health spending.⁹

California has implemented several federal and state programs designed to lower the cost of prescription drugs for state, local, and commercial health care purchasers. These programs include bulk purchasing arrangements, state and federal prescription drug rebate programs, and price transparency initiatives. In January 2019, the Governor issued an Executive Order to address the high cost of prescription drugs by directing state agencies to expand existing bulk purchasing efforts and transitioning Medi-Cal pharmacy expenditures from managed care into the fee-for-service delivery system to enhance the ability of the state to negotiate drug rebates.

Prescription Drug Coverage in California. According to the federal Centers for Medicare and Medicaid Services (CMS), California has experienced average annual growth in prescription drug expenditures of seven percent between 1991 and 2014, with total expenditures rising from \$7.7 billion in 1991 to \$36.9 billion in 2014.¹⁰

Medi-Cal, which covers 13.2 million low-income Californians, is also one of the largest purchasers of prescription drugs in the state. The Governor's January budget estimates that Medi-Cal will spend \$1.4 billion in 2018-19 and \$2 billion in 2019-20 on prescription drugs in the fee-for-service delivery system. These figures are net of rebates provided by manufacturers under state and federal drug rebate programs (see *Prescription Drug Rebates in Medi-Cal*) and do not include drugs purchased on behalf of Medi-Cal beneficiaries by managed care plans.

Many other California state entities are impacted by high prescription drug spending. Total prescription drug costs for state employees and retirees covered by the California Public Employee Retirement System (CalPERS) were \$1.25 billion for Basic Plans and \$880.1 million for Medicare

⁸ Centers for Medicare and Medicaid Services. "National Health Expenditures 2017 Highlights". <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>. Accessed February 9, 2019.

⁹ Peterson-Kaiser Health System Tracker. "Retail drugs as a share of national health spending and as a share of employer health benefits, 2017".

¹⁰ Centers for Medicare and Medicaid Services. "Health expenditures by state of residence: summary tables, 1991-2014. Table 8: Total All Payers State Estimates by State of Residence (1991 - 2014) - Drugs and Other Non-durable Products".

plans in 2017.¹¹ Other state entities prescription drug expenditures in the 2015-16 fiscal year were as follows:

Prescription Drug Expenditures by Various State Departments, 2015-16 ¹²	
Department	Expenditures
CA Dept. of Corrections Rehabilitation: California Correctional Health Care Services	\$239,454,095
Department of State Hospitals	\$34,895,455
Department of Developmental Services	\$8,539,096
California State Universities	\$3,569,905
CA Dept. of Corrections and Rehabilitation: Division of Juvenile Justice	\$275,695

High-Cost Specialty Drugs Dramatically Increase Costs for Public Health Care Programs.

One of the primary drivers in the growth of overall prescription drug expenditures is the high cost of specialty drugs. According to a Health Affairs Blog post from May 2016, specialty drugs account for a disproportionate share of overall drug spending and have a corresponding effect on spending growth. In fact, spending on specialty medicines was responsible for 73 percent of overall medicine spending growth over the past five years. Approval of these drugs by the federal Food and Drug Administration, along with the requirement of public health care programs to cover approved, medically necessary prescription drugs have placed enormous fiscal and programmatic pressures on these programs in recent years. In particular, the emergence of Sovaldi and Harvoni, specialty drugs developed by Gilead Sciences, which effectively cure individuals infected with hepatitis C, illustrate the potential for unexpected skyrocketing costs to public health programs. In response to these costs, the 2015-16 Governor’s January budget reserved \$300 million for the combined impact of hepatitis C treatment on California’s public health programs including Medi-Cal, the Department of State Hospitals, and the California Department of Corrections and Rehabilitations. Medi-Cal implemented a supplemental capitation payment for hepatitis C treatment for Medi-Cal managed care beneficiaries. The Governor’s January budget estimates Medi-Cal will spend a total of \$400.9 million in 2018-19 and \$359.3 million in 2019-20 for hepatitis C treatment for managed care beneficiaries.

While hepatitis C treatment is one of the more well-known instances of high-cost specialty drugs that impact public health care programs, the population with hepatitis C is relatively small. Several other specialty drugs have been approved, or are nearing approval that could target much larger populations. Specialty drugs treating high cholesterol or other common conditions could result in increased expenditures dramatically higher than those experienced for hepatitis C treatments. The prices of specialty drugs are also growing dramatically. For example, the Memorial Sloan Kettering Cancer Center reported that the median launch price of new cancer agents doubled in the last decade, from \$4,500 per month to more than \$10,000 per month. Similarly, the launch prices of new multiple sclerosis drugs increased from \$8,000 to \$12,000 per year in the 1990s to

¹¹ CalPERS Pension and Health Benefits Committee. “Board Agenda Item 5c: Prescription Drugs Utilization and Cost Trends”. September 25, 2018.

¹² Legislative Analyst’s Office. “Department of General Services’ Efforts to Control State Prescription Drug Spending”. (Handout - Assembly Health Committee. February 14, 2017).

\$50,000 to \$65,000 per year today. Specialty drugs also often experience substantial price growth every year they are on the market. For example, the AARP Public Policy Institute's December 2016 Rx Price Watch report found that the retail prices of specialty drugs widely used by older Americans increased by almost 11 percent in 2013.

Generic Drugs Also Subject to Sharp Price Increases. Significant price increases are not limited to specialty drugs. Prices for drugs that have been on the market for decades have also seen inexplicable increases. For example, over the past 20 years, the price of human insulin produced by two major manufacturers – Eli Lilly and Novo Nordisk – rose 450 percent after accounting for inflation, according to a 2016 Washington Post analysis of data from Truven Health Analytics. A single 10-milliliter vial of Eli Lilly's Humalog insulin, which is less than a month's supply for many adults, was listed at \$254.80 in 2016, compared with \$20.82 in 1996.

California has implemented and participated in various efforts to bring down the price of prescription drugs, particularly for state purchasers. These efforts have included bulk purchasing initiatives, prescription drug rebate programs, and price transparency initiatives.

Statewide Pharmaceutical Program and California Pharmaceutical Collaborative. The Department of General Services (DGS) administers the Statewide Pharmaceutical Program (SPP), which coordinates the efforts of various state and local governmental entities to identify and implement opportunities for cost savings and quality improvement regarding pharmaceuticals and medical supplies. As part of the SPP, DGS is also the facilitator of the California Pharmaceutical Collaborative, a working group of state entities established to coordinate and align the development of clinical guidelines, oversee and optimize California's bulk drug procurement program, monitor California's purchasing of high cost prescription drugs, and provide coordination between California's major prescription drug purchasers.

In 2001, DGS established the Common Drug Formulary to assist state departments with health care delivery systems to identify pharmaceutical products that are the most medically appropriate and cost-effective, while assuring the continuity and standardization of medication care. Participants in the formulary are the Department of State Hospitals, the Department of Developmental Services, the California Department of Corrections and Rehabilitation, and the California State University System. In addition to the formulary, the SPP achieves cost savings through coordinated purchasing, utilization controls, leveraged pricing agreements, and wholesaler agreements. The goal of the program is to achieve an average savings of 60 percent compared to pharmaceutical Suggested Wholesale Prices. The following chart illustrates the savings achieved by the SPP below Suggested Wholesale Price in 2017.



Source: Department of General Services. "Pharmaceutical Acquisitions Section Scorecard"

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. However, managed care drug utilization is not eligible for state supplemental rebates.

The Governor’s January budget includes General Fund savings from drug rebates of approximately \$1.6 billion in 2018-19 and \$1.4 billion in 2019-20 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).

Medi-Cal Drug Rebates, 2019-20 Governor’s January Budget		
Rebate Program	2018-19	2019-20*
Managed Care (Fed only)	\$(549,832,000)	\$(639,218,000)
Federal Rebate Program	\$(953,904,000)	\$(727,582,000)
State Supplemental	\$(65,385,000)	\$(67,262,000)
Family PACT	\$(3,067,000)	\$(3,213,000)
BCCTP	\$(3,166,000)	\$(3,251,000)
TOTAL	\$(1,575,354,000)	\$(1,440,526,000)

* 2019-20 rebates deposited in the Medi-Cal Rebate Fund, which will offset General Fund expenditures

Federal 340B Drug Pricing Program Supports Safety Net Providers. 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 (ADAP), Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.

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. 340B-covered entities are also required to provide drugs purchased under the 340B program to Medi-Cal beneficiaries in the fee-for-service delivery system at the 340B price. It is unclear the extent to which Medi-Cal managed care plans, in an effort to maintain an adequate network of pharmacy providers, reimburse 340B entities at a higher rate than the 340B price. However, it is likely 340B entities receive a significant amount of revenue from the incremental difference between costs and managed care reimbursement, as this feature is the primary method utilized by the 340B program to assist safety net clinics and providers to stretch scarce funding resources to care for underserved populations.

SB 17 Increases Prescription Drug Price Transparency. SB 17 (Hernandez), Chapter 603, Statutes of 2017, 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.

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 the Office of Statewide Health Planning and Development (OSHPD), which in turn 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.

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 for publication:

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 prior calendar year.
 - b. The company from which the drug was acquired, the date, and the purchase price.
 - c. The year the drug was introduced and the price 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 non-innovator multiple source drug, or a single source drug.
 - f. A description of changes or improvements, if any, that necessitate the increase.
 - g. Volume of sales of the manufacturer's drug in the U.S. for the previous year.

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 for publication:

1. A description of the marketing and pricing plans used in the launch of the new drug;
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; and,
4. The date and price of acquisition if the drug was not developed by the manufacturer.

Health Plan Expenditures on High Cost and High Utilization Drugs. SB 17 also requires health plans to annually file with the Department of Managed Health Care (DMHC) the following information for publication:

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

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

- The percent of premiums attributable to drug costs for each category of prescription drugs;
- The year-over-year increase for each category;
- The year-over-year increase 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; and,
- Information on use of a pharmacy benefits manager (PBM), if any, including which components of prescription drug coverage are managed by the PBM.

GOVERNOR'S PROPOSAL

Executive Order on Prescription Drug Purchasing. On January 7, 2019, the Governor issued Executive Order N-01-19, ordering state departments to implement several directives intended to reduce the cost of prescription drugs for both public and private purchasers.

1. *Transition of Medi-Cal Prescription Drug Benefits to Fee-For-Service.* The Executive Order directs the Department of Health Care Services (DHCS) to take all necessary steps to transition all pharmacy services currently provided by Medi-Cal managed care plans into the Medi-Cal fee-for-service delivery system. The transition, which would be completed by January 2021, is intended to create additional negotiating leverage on behalf of the state's 13.2 million Medi-Cal beneficiaries. According to the Administration, this transition would standardize the Medi-Cal drug benefit, reduce confusion among beneficiaries without sacrificing quality or outcomes, and result in hundreds of millions of dollars in additional savings beginning in the 2021-22 fiscal year. There are no savings or transition costs for this purpose reflected in the Governor's January budget for the 2019-20 fiscal year.
2. *Statewide Review of Drug Purchasing Initiatives.* The Executive Order directs DHCS, in consultation with the California Pharmaceutical Collaborative (CPC), to review all state purchasing initiatives and consider additional options to maximize the state's bargaining power, including the Medi-Cal program. The review, which may include recommended changes to state law or other procurement or reimbursement processes, will be completed by July 12, 2019.
3. *Prioritization of Drugs and Implementation of Bulk Purchasing Arrangements.* The Executive Order directs the Department of General Services (DGS), in collaboration with the CPC, to develop a prioritized list of prescription drugs for future bulk purchasing initiatives or for renegotiation of existing purchasing arrangements with manufacturers. The prioritization would be based on the level of competition for the drug in the marketplace and consideration of the 25 highest-cost drugs. The department will provide a written report to the Governor's Office by March 15, 2019.

Once DGS and the CPC have developed a prioritized list, these two entities will develop and implement bulk purchasing arrangements for high-priority drugs. The department will encourage local governments to participate in the bulk purchasing arrangement through proactive outreach and will provide a written status report to the Governor's Office by April 12, 2019. The Executive Order also directs DGS and the CPC to develop a framework for private purchasers, such as small businesses, health plans, and the self-insured to opt into the state bulk purchasing program. DGS will provide a written report

recommending any necessary legislative changes to the Governor’s Office by May 17, 2019.

Timeline of Deliverables in Governor’s Executive Order on Prescription Drugs		
Report/Action	Completion Date	Department/Entity
Priority list of drugs recommended for bulk purchasing or renegotiation	March 15, 2019	Department of General Services CA Pharmaceutical Collaborative
Status report of development and implementation of bulk purchasing arrangement for high-priority drugs	April 12, 2019	Department of General Services CA Pharmaceutical Collaborative
Status report and recommended statutory changes to enable private purchasers to participate in state purchasing program	May 17, 2019	Department of General Services CA Pharmaceutical Collaborative
Review of state prescription drug purchasing initiatives and recommended statutory or process changes	July 12, 2019	Department of Health Care Services CA Pharmaceutical Collaborative
Transition of all pharmacy services from Medi-Cal managed care to fee-for-service delivery system	January 2021	Department of Health Care Services

According to the Executive Order, the DGS and CPC reports and updates regarding implementation of the bulk purchasing program are due to the Governor’s Office on the dates referenced. It is unclear whether the Administration intends to make these documents public. The Executive Order is similarly silent regarding the publication of the DHCS and CPC review of state purchasing initiatives, stating only that the department shall complete its review by the July 12, 2019 deadline.

In addition to these deliverables, the Executive Order directs all agencies under the Governor’s executive authority, and encourages all other agencies, to cooperate to the fullest extent permitted under law by providing data and other information to DGS to develop its priority list of drugs recommended for bulk purchasing or renegotiation.

ISSUES TO CONSIDER

Existing Programs Currently Leverage State Purchasing Power for Prescription Drugs. California state departments and safety net health care providers are currently part of several initiatives that serve to leverage state purchasing power or state and federal law to lower the cost of prescription drugs. These initiatives include the Medi-Cal federal and state supplemental drug rebate programs, the DGS Common Drug Formulary for non-Medi-Cal state departments, and the 340B drug discount program for safety net clinics, public hospitals, family planning clinics, and ADAP providers. The state will likely realize significant additional savings from moving Medi-

Cal beneficiary drug utilization from the managed care delivery system, in which it is only eligible for federal drug rebates, to the fee-for-service delivery system, in which it will also be eligible for state supplemental rebates. However, it is unclear the extent to which making these drugs eligible for additional rebates will affect pre-rebate pricing decisions made by manufacturers.

Will Increasing Purchasing Power Alone Make A Significant Impact? The Governor's Executive Order to establish a bulk purchasing program differ in key ways from the programs currently administered by DGS. In particular, the Executive Order directs DGS to encourage local governments to participate in the program and to develop a framework to allow private purchasers to participate, as well. These features will increase the number of covered individuals for whom the bulk purchasing program will negotiate prescription drug prices, which is likely to help reduce costs. However, the Administration has not described how this program would contend with the cost of drugs under patent protection or otherwise without a generic alternative. Bulk purchasing programs are generally successful when they are empowered to deny coverage for a particular drug unless the manufacturer is willing to negotiate a reasonable price. It is unclear how the Administration's proposal would approach negotiations with sole-source manufacturers, which are often among the highest-cost prescription drugs, without compromising access to those drugs. The Legislature may wish to consider whether other, more effective options exist to address the availability of sole-source drugs, particularly generics or brand name drugs that are no longer patent-protected.

Impacts on Existing Prescription Drug Programs. While the proposed transition of Medi-Cal pharmacy services from managed care to the fee-for-service delivery system would likely result in significant state rebates, there may be a significant negative impact on safety net providers in California that rely on revenue received by providing drugs through the 340B program to Medi-Cal managed care beneficiaries. In evaluating the Governor's proposal, the Legislature may wish to consider how to address these negative impacts, as these providers deliver a significant portion of the care provided to Medi-Cal beneficiaries and other low-income or uninsured Californians.