Date of Hearing: March 23, 2021

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 671 Wood – As Amended March 15, 2021

SUBJECT: Medi-Cal: pharmacy benefits.

SUMMARY: Requires the Department of Health Care Services (DHCS) to provide a disease management or similar payment to a pharmacy for specified costs and activities that are associated with dispensing specialty drugs in an amount necessary to ensure beneficiary access, as determined by DHCS based on the results of a DHCS-contracted survey completed during the 2020 calendar year. Specifically, **this bill**:

1) Requires DHCS to provide a disease management or similar payment to a pharmacy pursuant to a contract with DHCS for specified costs and activities that are associated with dispensing specialty drugs in an amount necessary to ensure beneficiary access, as determined by DHCS based on the results of a DHCS-contracted survey completed during the 2020 calendar year.

2) Defines "specialty drugs" by cross reference to existing law to mean drugs determined by DHCS to generally require special handling, complex dosing regimens, specialized self-administration at home by a beneficiary or caregiver, or specialized nursing facility services, or which may include extended patient education, counseling, monitoring, or clinical support.

3) Requires the disease management payment to be in addition to the existing Medi-Cal billable pharmacist services, and the current Medi-Cal prescription drug-related dispensing fee and ingredient cost reimbursement provisions.

4) Requires covered pharmacist services to be subject to DHCS protocols and utilization controls.

5) Requires the DHCS Director to seek any necessary federal approvals to implement this bill, implements this bill only when the necessary federal approvals have been obtained and limits implementation only to the extent that federal financial participation is available.

6) Prohibits this bill from either restricting or prohibiting any services currently provided by pharmacists as authorized by law, including, but not limited to, the Medicaid state plan.

7) Permits DHCS, notwithstanding the rule-making requirements of the Administrative Procedure Act (APA), to implement, interpret, or make specific this bill, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action.

8) Requires DHCS, by July 1, 2023, to adopt regulations in accordance with the requirements of APA. Requires DHCS, commencing July 1, 2022, to provide a status report to the Legislature on a semiannual basis until regulations have been adopted.

EXISTING LAW:

1) Establishes the Medi-Cal program administered by DHCS, under which qualified low-income individuals receive health care services. Requires the purchase of prescribed drugs to be a covered Medi-Cal benefit, subject to the Medi-Cal Contract Drug List (the Medi-Cal CDL is generally the prescription drugs in fee-for-service [FFS] that are available without prior authorization) and utilization controls.

2) Establishes Medi-Cal FFS reimbursement rates for prescription drugs, consisting of a professional dispensing fee (which varies based on volume), and a drug ingredient cost equal to the lowest of the actual acquisition cost (AAC), the federal upper limit (FUL) or the maximum allowable ingredient cost (MAIC).

3) Establishes a list of Medi-Cal services that are covered pharmacist services that may be provided to a Medi-Cal beneficiary, subject to specified requirements:

   a) Furnishing travel medications;
   b) Furnishing naloxone hydrochloride;
   c) Furnishing self-administered hormonal contraception;
   d) Initiating and administering immunizations;
   e) Providing tobacco cessation counseling and furnishing nicotine replacement therapy;
   f) Initiating and furnishing preexposure prophylaxis, limited to no more than a 60-day supply of preexposure prophylaxis to a single patient once every two years; and,
   g) Initiating and furnishing postexposure prophylaxis.

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, this bill will address an issue with Medi-Cal FFS pharmacy reimbursement that exists as a result of a new federally required AAC drug reimbursement cost change. This bill would ensure the availability of high cost specialty drugs and the viability of pharmacies that dispense those drugs to Medi-Cal beneficiaries by providing a disease management payment for high cost specialty medications, such as for mental health and HIV treatment and prevention that includes recognition of the costs of the additional services certain pharmacies provide in dispensing these medications. Certain high-cost brand name prescription drugs used to treat multiple sclerosis (MS), serious mental health conditions, and to treat and prevent HIV are reimbursed by Medi-Cal FFS near or below the cost at which certain community pharmacies acquired the drug. For example, a recent DHCS-contracted report found the brand drug acquisition costs were below reimbursement for MS drugs, and the average dollar amount margin for other brand name drugs for HIV, cystic fibrosis, and to treat serious mental illnesses was very low. The report additionally, identified 15 drugs as examples of "at-risk" that are under-reimbursed by the existing Medi-Cal rate compared to pharmacies' AAC, thereby reducing the availability of these medications and jeopardizing the financial viability of the pharmacies dispensing these medications to patients enrolled in the Medi-Cal program.

2) **BACKGROUND ON MEDI-CAL PRESCRIPTION DRUG COVERAGE.** Outpatient prescription drug coverage is an optional benefit under federal law that all state Medicaid

programs provide. California's Medi-Cal program provides outpatient prescription drug coverage through Medi-Cal managed care (MCMC) plans for the over 10 million people enrolled in a MCMC plan. MCMC plans (with exceptions) typically contract with a pharmacy benefit manager (PBM) for administration of the pharmacy benefit.

Medi-Cal beneficiaries who are not enrolled in a MCMC plan receive their prescription drug coverage through FFS. In addition, certain drugs are "carved out" of the MCMC plan benefit (typically because of cost) and reimbursed through FFS. The carve out varies by MCMC model type and includes antipsychotics, certain cancer and HIV treatment and prevention drugs.

MCMC plans and their contracting PBMs determine pharmacy reimbursement for their enrollees for whom they provide drug coverage. In FFS, Medi-Cal pays pharmacies for two components: a) an amount to cover the estimated cost of the drug, known as the ingredient cost; and, b) an amount to cover the pharmacist's overhead and services to fill the prescription, known as the dispensing fee. As a result of a change in federal law and regulation, the dispensing fee and ingredient cost reimbursement was changed in Medi-Cal (described further below). The state had several options to determine the AAC under federal guidance.

On January 7, 2019, Governor Gavin Newsom issued Executive Order N-01-19 with the stated purpose of achieving cost-savings for drug purchases made by the state. A key component of the Executive Order requires DHCS to transition all Medi-Cal pharmacy services from MCMC plans to FFS by January 1, 2021. This transition, originally scheduled for January 1, 2021 and then April 1, 2021, has been postponed twice. The Administration has not announced a new date for the transition.

3) **FFS MEDI-CAL PHARMACY DRUG REIMBURSEMENT CHANGE.** The federal Patient Protection and Affordable Care Act required states to change their reimbursement methodology for outpatient prescription drugs covered by Medicaid. On February 1, 2016, a regulation (final rule) was released by the Centers for Medicare and Medicaid Services (CMS). Under the final rule, each state is responsible for establishing a Medicaid FFS payment methodology that reimburses outpatient pharmacy providers based on an AAC, plus a professional dispensing fee. The effective date of implementing these requirements was no later than April 1, 2017.

   To prepare for compliance with these requirements, DHCS contracted with Mercer Government Human Services Consulting (Mercer), a part of Mercer Health & Benefits LLC, to conduct an AAC and dispensing fee survey. DHCS proposed to adopt two of the alternatives as outlined in the Mercer report to comply with the requirements of the final rule. The survey concluded that AAC would pay similar to the National Average Drug Acquisition Cost (NADAC) for brand prescription drugs (0.1% less), but 38.2% less for generic drugs. Mercer recommended several options for ingredient cost and dispensing fees, and DHCS recommended one of Mercer's recommendations for the adoption of a higher two-tiered dispensing fee based upon a pharmacy's total claim volume (both Medicaid and non-Medicaid) to replace what was then the dispensing fee of $7.25 for community pharmacies and $8.00 for long-term care pharmacies, as follows:

   a) $13.20 < 90,000 claims yearly; and,
   b) $10.05 ≥ 90,000 claims yearly.

DHCS selected this option in consultation with Mercer because DHCS believed it accurately reflected the disparity in the actual costs of dispensing a medication as it applies to smaller, independent pharmacy owners and the larger multi-store or chain pharmacies. In addition, from an administrative perspective this option could be operationalized through the customary system change processes, allowing a timely implementation. Further, DHCS indicated this option seemed to be the most acceptable to CMS during informal communications with them.

For drug ingredient costs, DHCS recommended adoption of one of Mercer's option for ingredient cost reimbursement using NADAC pricing file, and Wholesale Acquisition Cost (WAC) + 0% as a backup benchmark when a NADAC price is not available. The NADAC and WAC benchmarks would replace Average Wholesale Price (AWP) minus 17% in the reimbursement methodology, which reimbursed the lowest of AWP minus 17%, FUL, MAIC, or the pharmacy's usual and customary charge. DHCS states the Mercer report analysis demonstrated that the NADAC rates were not significantly different from the survey's invoiced acquisition costs for single-source, brand name drugs. DHCS indicated informal discussions with CMS indicated that this option would best meet the intentions of the provisions in the Final Rule.

The two-tiered increased dispensing fee and the ingredient cost reimbursement based on NADAC was codified in SB 97 (Committee on Budget and Fiscal Review), Chapter 52, Statutes of 2018.

4) **LITIGATION OVER MEDI-CAL PHARMACY REIMBURSEMENT.** State Plan Amendment 17-002 to implement the new reimbursement methodology was approved by CMS on August 25, 2017. However, it took time for DHCS to update the FFS claims processing system to reimburse pharmacies using the new methodology. DHCS announced it would make retroactive adjustments for impacted claims with dates of service from the policy effective date of April 1, 2017, through the implementation date of February 23, 2019. The Medi-Cal FFS AAC reimbursement methodology using NADAC drug ingredient cost reimbursement also resulted in several currently "carved out" medications (such as antipsychotics for mental health, HIV treatment and prevention) being reimbursed by Medi-Cal FFS at below the cost at which some community pharmacies acquired the medication.

The California Pharmacists Association (CPhA) sued DHCS in the U.S. District Court over the new AAC methodology and the "clawback" of prior year amounts dating back to April 1, 2017 from subsequent Medi-Cal payments. After one payment with the clawback amount deducted, the clawback was put on hold, while the parties waited for a decision from the U.S. District Court judge. The decision was delayed, and DHCS proposed to resume the clawback in February 2020 while the parties were waiting for a decision from the District Court. CPhA went to court again and the clawback was again temporarily halted.

The US District Court judge subsequently issued a decision denying CPhA's request for a temporary restraining order on February 21, 2020 on the use of the AAC, but expressed concern over the cumulative effect of the AAC methodology in addition to the planned clawback of the past nearly three years of reimbursement. The court expressed concern that the efforts to recoup estimated overpayments may cause significant access problems for Medi-Cal recipients and irreparable harm to CPhA members, and the court required further briefing on the plan to recoup payments retroactively. DHCS' Medi-Cal Estimate for 2021-

22 estimates the amount to be recouped in "overpayments" from pharmacies for the 23-month time period from April 1, 2017 to February 23, 2019 is $206.8 million in total funds ($71 million General Fund).

5) **DHCS CONTRACTED SPECIALTY PHARMACY STUDY**. In response to pharmacy complaints about under-reimbursement of specialty medication, DHCS contracted with Mercer Government Human Services Consulting (Mercer) to research, survey, and analyze specialty disease state drug reimbursement to Medi-Cal FFS pharmacy providers. The purpose of the survey was to compare the NADAC price benchmark against the average AAC in California for a select group of specialty drugs. Additionally, the survey asked specialty pharmacy providers to list specialized services provided to Medi-Cal beneficiaries in order to ensure adherence and compliance, and to monitor positive and negative outcomes from the drug therapy. Six unique drug therapy categories were surveyed, which included drugs used to treat severe mental illness, HIV, autoimmune diseases, cystic fibrosis, multiple sclerosis, and hepatitis C.

   In January 2021, DHCS released the "Medi-Cal Specialty Disease Pharmacy Reimbursement Study." The Mercer findings were that average AAC calculations for reviewed drugs show that the difference between average AAC and FFS reimbursement varies by drug, and that for some National Drug Codes, the pharmacies are able to purchase below the expected FFS reimbursement rate, while others would see the pharmacies' acquisition cost higher than the expected FFS reimbursement rate. General findings from Mercer for drugs reviewed in the specialty categories include:

   a) Brand drug average AAC calculations, in aggregate, are generally equal to, or very close to, the Medi-Cal FFS ingredient cost reimbursement; and,

   b) Generic drug average AAC calculations, in aggregate, suggest that pharmacies purchase below Medi-Cal FFS ingredient cost reimbursement.

   However, the Mercer report found the brand drug average AAC were below reimbursement for MS drugs (pharmacies on average would lose $22.16 per MS unit dispensed), and the average dollar amount margin for other brand drugs was very low ($0.55 for HIV drugs, $3.37 for serious mental illness drugs and $1.10 for cystic fibrosis). The Mercer survey identified 15 drugs as examples of "at-risk" that are under-reimbursed by the existing Medi-Cal rate compared to pharmacies' AAC.

   In addition to the medication costs, the Mercer survey asked selected pharmacies to complete a survey detailing the specialty services provided to gain an understanding of the additional services provided to members receiving specialty drugs. These additional services were able to be funded under the margin provided by the prior reimbursement methodology. Because the brand name medications are costly and used to treat serious medical conditions, the additional services were aimed at encouraging patient adherence and monitoring. The aggregate summary of the most-common additional services mentioned include the following:

   a) Compliance packaging to promote medication adherence;
   b) Patient engagement technologies, 24/7/365 operating hours;
   c) Free delivery, text messaging program, clinical personnel available 24/7;

d) Therapeutic intervention;
e) Access to complex drug regimens enabling patients to be discharged in a timely manner;
f) Providing delivery to complicated cases at specific hospitals to prevent readmission; and,
g) In-home assessments for patients with bleeding disorders and patients who require immunoglobulin treatments, and management of complex infusions

In releasing the results of the survey, DHCS indicated it would analyze the identified specialty services not reimbursed by Medi-Cal and, in the coming months, would also engage pharmacy stakeholders and MCMC plans to further discuss and assess possible policy approaches and payment mechanisms.

6) **SUPPORT.** This bill is sponsored by CPhA, which writes that patients afflicted with chronic illnesses rely heavily on pharmacists to help manage their disease. These patients require medications referred to as "specialty drugs." These specialty drugs are often classified as high cost, high complexity medications that require special handling and packaging, as well as close monitoring of the patients. These medications include drugs that treat HIV, behavioral health, cancer and chronic diseases that require costly care. CPhA writes that, as a result of a recent reimbursement change, pharmacists have been reimbursed below the cost of acquisition for these medications. This under reimbursement makes it difficult for them to continue to provide these medications to patients, which ultimately negatively impacts access. This possibility was noted recently in a report issued by DHCS. In addition to reimbursement issues, pharmacists are not currently reimbursed for the time required to provide appropriate care to patients who require specialty medications: HIV; diabetes; and, behavioral health. In addition to community pharmacies being located in underserved communities, pharmacists provide care where their patients live as documented recently by CPhA. CPhA writes that reimbursing pharmacists for disease management will help maintain this important network of Medi-Cal provider's ability to provide care to those Californians the state has rightfully committed to ensure equity in health care.

7) **RELATED LEGISLATION.** AB 1178 (Irwin) prohibits the DHCS Medi-Cal prior authorization requirement for any drug prescribed for the treatment of a serious mental illness (SMI), as defined, for a period of 365 days after the initial prescription has been dispensed for a person over 18 years of age who is not under the transition jurisdiction of the juvenile court. Requires DHCS to automatically approve a prescription for a drug for the treatment of a SMI if DHCS verifies a record of a paid claim that documents a diagnosis of a SMI within 365 days before the date of that prescription for a person over 18 years of age who is not under the transition jurisdiction of the juvenile court. Requires DHCS to authorize a pharmacist to dispense a 90-day supply of a drug prescribed for the treatment of a SMI if that prescription drug is included on the Medi-Cal CDL and the prescription otherwise conforms to applicable formulary requirements, including that the patient has filled at least a 30-day supply for the same prescription in the previous 90 days, and to dispense an early refill prescribed for the treatment of a SMI if that prescription drug is included in the Medi-Cal CDL and the prescription otherwise conforms to prescribed standards, such as limiting the number of refills to no more than three in a calendar year. AB 1178 is pending hearing in the Assembly Health Committee.

8) **PREVIOUS LEGISLATION.** AB 2100 (Wood) would have authorized DHCS to provide a disease management or similar payment to a pharmacy pursuant to a contract with DHCS for the costs and activities associated with dispensing specialty drugs in an amount necessary to

ensure beneficiary access, as determined by DHCS based on the results of the survey completed during the 2020 calendar year. Requires DHCS to provide a Medi-Cal beneficiary with the opportunity to seek an Independent Prescription Drug Medical Review for outpatient prescription drug denials, modifications or delays based on medical necessity, or if the drug is denied as being experimental or investigational, modeled on the current independent medical review process for licensed health plans. Requires DHCS to provide continuity of prescription drug coverage if a beneficiary is taking a particular drug through a MCMC plan and that drug is no longer covered under the contract drug list in FFS Medi-Cal for a minimum of 180 days or until the drug is no longer prescribed, whichever is shorter. Requires additional information on the Medi-Cal FFS pharmacy benefit on rebates, pharmacy participation, costs, and appeals to be included in the Medi-Cal Budget Estimate. AB 2100 was vetoed by Governor Newsom. In his veto message, the Governor wrote the following:

> First, it is premature to consider a disease management payment for Medi-Cal specialty drugs. DHCS is processing the results of a recent survey of specialty drug acquisition costs to determine what types of services are provided in association with the dispensing of specialty drugs. Until the results of the survey have been analyzed, DHCS will not know whether reimbursement for disease management services, or other supplemental services, are medically necessary for certain beneficiaries, and under what circumstances.
>
> Second, while I am supportive of additional transparency efforts regarding the implementation of the Medi-Cal Rx program, the requirements of this bill are too prescriptive. I am instead directing DHCS to post additional information on its website regarding implementation of Medi-Cal Rx to enable the public and stakeholders to assess the transition of the Medi-Cal prescription drug benefit from managed care to FFS.
>
> Third, while I am supportive of efforts to enhance Medi-Cal beneficiary protections, issues regarding consumer protections under Medi-Cal Rx can be addressed administratively with input from the Legislature and stakeholders, to ensure that appropriate protections and reporting requirements are in place when Medi-Cal Rx is implemented. I am directing DHCS to convene stakeholders no later than July 1, 2021, to explore options and approaches for additional public reporting of administrative hearing decisions pertaining to outpatient prescription drug benefits, which will help assess whether additional changes to the grievance and appeals process are warranted.
>
> Finally, DHCS has developed a Pharmacy Transition Policy for Medi-Cal Rx to allow Medi-Cal beneficiaries to continue receiving their existing prescription medications without having to get additional prior authorizations for 180 days after the transition begins. As we work toward a health care delivery system that provides coverage and access through a unified financing system, we must also align policies and processes across our public and private delivery systems to provide California's health care consumers with a consistent experience and minimal side effects. Such efforts should be considered as part of those conversations.

REGISTERED SUPPORT / OPPOSITION:

Support

California Pharmacists Association (sponsor)

APLA Health
California Council for the Advancement of Pharmacy
California Life Sciences Association
California Retailers Association
National Association of Chain Drug Stores

Opposition

None on file.

Analysis Prepared by: Scott Bain / HEALTH / (916) 319-2097