

ASSEMBLY THIRD READING
AB 671 (Wood)
As Amended March 15, 2021
Majority vote

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.

Major Provisions

- 1) 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.
- 2) 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.
- 3) Requires covered pharmacist services to be subject to DHCS protocols and utilization controls.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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.

COMMENTS

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 fee-for-service (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 FFS Medi-Cal to one based on actual acquisition cost (AAC). The state had several options to determine the AAC payment methodology under federal guidance. The Medi-Cal FFS AAC reimbursement methodology 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.

DHCS CONTRACTED SPECIALTY PHARMACY STUDY. In response to pharmacy complaints about under-reimbursement of specialty medications, 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 National Average Drug Acquisition Cost 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:

- 1) Brand drug average AAC calculations, in aggregate, are generally equal to, or very close to, the Medi-Cal FFS ingredient cost reimbursement; and,
- 2) Generic drug average AAC calculations, in aggregate, suggest that pharmacies purchase below Medi-Cal FFS ingredient cost reimbursement.

GOVERNOR'S BUDGET MAY REVISION PROPOSAL. The 2021-22 May Revision includes \$12 million total funds (\$4 million General Fund) to implement a Medication Therapy Management (MTM) Program for Specialty Pharmacy Services, effective July 1, 2021. DHCS states MTM is a distinct service or group of services provided by pharmacists, and is especially effective for patients with complex medication therapies, high prescription costs, or having other risk factors that may result in impediments to patient compliance and adherence. A

comprehensive MTM service model contains five key elements: a medication therapy review of the beneficiary's current medications, creation of a personal medication record, development of a medication-related action plan, ongoing interventions and/or referrals to other appropriate health care providers, and documentation of all actions provided by the pharmacy and the associated follow-ups. DHCS has proposed trailer bill language as part of the May Revision related to the MTM program.

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.

Arguments in Support

This bill is sponsored by California Pharmacists Association (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.

Arguments in Opposition

There is no known opposition.

FISCAL COMMENTS

According to the Assembly Appropriations Committee, unknown increased Medi-Cal costs for Disease Management payments to compensate for the costs of dispensing specialty drugs, potentially in excess of \$100 million per year ongoing (General Fund and federal funds).

VOTES**ASM HEALTH: 15-0-0**

YES: Wood, Mayes, Aguiar-Curry, Bigelow, Bonta, Burke, Carrillo, Flora, Maienschein, McCarty, Nazarian, Luz Rivas, Rodriguez, Santiago, Waldron

ASM APPROPRIATIONS: 16-0-0

YES: Lorena Gonzalez, Bigelow, Calderon, Carrillo, Chau, Megan Dahle, Davies, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Holden, Luz Rivas

UPDATED

VERSION: March 15, 2021

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