

NOTICE OF PROPOSED RULEMAKING

SUBJECT: Pharmacist Services, DHCS-19-002

NOTICE IS HEREBY GIVEN that the Department of Health Care Services (Department) proposes to adopt sections 51105.1, 51105.2, 51105.3, 51313.7, 51313.8, 51476.3, 51476.4, and 51505.4, and amend sections 51226 and 51227 under title 22, division 3, chapter 3, of the California Code of Regulations, after considering all public comments, objections, and recommendations.

WRITTEN COMMENT PERIOD

Any interested person or their duly authorized representative may submit written comments to the Department relevant to the regulatory action described in this notice.

Please label any comments as pertaining to **Pharmacist Services, DHCS-19-002** and submit using any of the following methods:

Mail: Department of Health Care Services
Office of Legal Services, Regulations, MS 0015
P.O. Box 997413
Sacramento, CA 95899-7413

FAX: (916) 440-5748

Email: regulations@dhcs.ca.gov

The written comment period closes on **February 5, 2025**. Any written comments, regardless of the method of delivery, must be received by **February 5, 2025**, to be considered for review.

Written comments should include the author's contact information so the Department can provide notification of any further changes to the regulation proposal.

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a hearing if a written request for a public hearing is received from any interested person or their duly authorized representative, no later than 15 days before the close of the written comment period, pursuant to Government Code section 11346.8.

The Department shall consider all comments received regarding the proposal equally, whether submitted in writing or through oral testimony at a public hearing.

AUTHORITY AND REFERENCE

These regulations are being proposed under the following authorities:

Sections 10725, 14105, 14105.05, 14105.45, 14124.5 and 14132.968, Welfare and Institutions Code.

These proposed regulations implement, interpret, or make specific the following:

Sections 14059, 14105, 14105.05, 14105.45, 14124.1, 14124.2, 14132, 14132.968 and 14132.969, Welfare and Institutions Code; and section 162.406, title 45, Code of Federal Regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The purpose of the Department is to provide equitable access to quality health care leading to a healthy California for all. In support of this purpose, the Department administers many health care programs including California's State Medicaid program known as the Medi-Cal program. The Pharmacy Benefits Division is responsible for setting policy and coverage for outpatient pharmacy services for the Medi-Cal program that includes the development and promulgation of regulations for these services, such as pharmacist services.

Related and Existing Laws and Regulations

The Pharmacy Law, under chapter 9 (commencing with section 4000) of division 2 of the Business and Professions (B&P) Code provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. The Pharmacy Law specifies procedures and functions that a pharmacist is authorized to perform. Since 2013, those procedures and functions expanded to include the following pharmacist services: furnishing travel medications (B&P Code section 4052(a)(10)(A)(iii)), naloxone hydrochloride (B&P Code section 4052.01), self-administered hormonal contraception (B&P Code section 4052.3(a)), and nicotine replacement therapy (B&P Code section 4052.9); initiating and administering immunizations (B&P Code section 4052.8); providing tobacco cessation counseling (B&P Code section 4052.9); initiating and furnishing Human Immunodeficiency Virus (HIV) preexposure and HIV postexposure prophylaxis (B&P Code sections 4052.02 and 4052.03); and providing Medication Therapy Management (MTM) in conjunction with dispensing specialty drugs (Welfare and Institutions (W&I) Code section 14132.968 – as described further below).

The California State Board of Pharmacy has regulations in title 16, division 17 of the California Code of Regulations that specify the requirements a pharmacist must follow when engaging in these additional procedures and functions, except for MTM, that does not currently have implementing regulations.

In 2016, the Legislature added section 14132.968 to the W&I Code. This section added these pharmacist services, except for MTM, to the Medi-Cal schedule of benefits together with authorization for reimbursement for these services. These services are subject to Department protocols and utilization controls, as well as Centers for Medicare & Medicaid Services (CMS) approval. CMS initially authorized these services through

approval of State Plan Amendment (SPA) TN No. 21-0028 (effective July 1, 2021), that was superseded, in part, by SPA 22-0013 (effective January 1, 2022).

In 2021, the Legislature amended W&I Code section 14132.968 to add MTM as a pharmacist service provided in conjunction with specialty drugs; and section 14132.969 was also added to authorize reimbursement to pharmacies for MTM provided by pharmacists.

W&I Code section 14105.05 authorizes the Department to update procedure-coding systems required for compliance with federal Medicaid requirements or the federal Health Insurance Portability and Accountability Act (HIPAA). This statute also authorizes the Department to establish corresponding reimbursement rates for these updated procedure codes. The Department may adopt these procedure codes and reimbursement rates without taking regulatory action. Further, the Department may publish these updated procedure codes and corresponding reimbursement rates in the Medi-Cal Provider Manual or a similar publication.

Statement of Purpose/Problem to be Addressed

These proposed regulations are essential to implement, interpret, and make specific W&I Code sections 14132.968 and 14132.969 that authorize these pharmacist services as Medi-Cal benefits that are eligible for reimbursement. This proposed regulatory action is required to meet the mandate of W&I Code section 14132.968 that the Department promulgate regulations to implement this section.

This regulatory proposal is necessary to establish a clear framework for the delivery of pharmacist services under the Medi-Cal program. These provisions specify how, where, and under what circumstances a pharmacist may render these services and be eligible for reimbursement. The provisions also include references to the relevant professional licensing statutes and regulations that apply to pharmacists and pharmacies to further support clarity.

This regulatory proposal is necessary to ensure that beneficiaries have continued access to these critical pharmacist services (including MTM and specialty drugs), which prevent medication-related problems that are a significant public health issue within the healthcare system. Estimates suggest that more than 1.5 million preventable medication-related adverse events occur each year in the United States, accounting for an excess of \$177 billion in medication-related morbidity and mortality costs.¹

Anticipated Benefits or Goals of the Regulations

This regulatory proposal supports the purpose and intent of the Medi-Cal program as specified under W&I Code section 14000 et seq., chapter 7, to afford qualifying individuals such as the aged and other persons (including those persons who lack

¹ [core elements of an mtm practice.pdf \(pharmacist.com\)](https://www.pharmacist.com/core-elements-of-an-mtm-practice.pdf)

sufficient annual income to meet the costs of health care) with covered health care and related social services, in a manner equitable to the general public and without duplication of benefits available under other federal or state laws.

Within chapter 7, section 14124.5 specifies that the Director may, in accordance with section 10725, promulgate regulations as are necessary or proper to carry out the purpose and intent of chapter 7, including implementation of the uniform schedule of health care benefits under the Medi-Cal program, as described under section 14131 et seq., that includes sections 14132.968 and 14132.969 that provide for pharmacist services. Additionally, within chapter 7, section 14105 specifies that the Director shall prescribe policies and regulations for the administration of the chapter, which include the establishment of reimbursement rates for payment of health care services, such as pharmacist services.

The inclusion of these new regulations and amendments to existing regulations will directly support pharmacists who render these pharmacist services as well as pharmacies where these services are rendered through the adoption of current benefit information and provisions related to claims and payment. This in turn facilitates the convenient delivery of these pharmacist services to beneficiaries who can access these services and medications from pharmacists without having to make an appointment to be seen by a doctor. Similar to Medi-Cal covered services provided by nurses, physician assistants, and other non-physician medical providers, a pharmacist consults with a beneficiary, assesses their need for a medication, immunization, or MTM, then selects and provides it as appropriate. Pharmacist services fit into the current pharmacy workflow model, where a beneficiary could request or be recommended a service at a pharmacy, similar to how immunizations are offered on a walk-in basis.

This regulatory proposal implements pharmacist services that will not only ensure more timely access to preventive care, but will also support efforts to do the following: decrease opioid-related deaths by increasing access to naloxone; prevent unintended pregnancies; increase rates of tobacco cessation; increase immunization rates; reduce illnesses contracted due to travel; and expand access and remove barriers for treatments used in the prevention of HIV to reduce and ultimately eliminate new HIV infections in California and decrease HIV infections nationwide.

Furthermore, providing MTM and its availability will further optimize clinical outcomes for beneficiaries who take specialty drugs, are on multiple medications including over-the-counter, herbal, or dietary supplements, or those who have multiple or serious health or mental health conditions. MTM is also anticipated to improve health outcomes of beneficiaries who are at risk of treatment failure due to noncompliance, nonadherence, or other factors found to affect drug therapy outcomes negatively, leading to high-cost Emergency Room (ER) visits and hospitalizations. MTM prevents medication-related problems, improves patient health, slows the progression of disease, reduces ER visits, and reduces hospitalizations and related costs. The accessibility of MTM ensures the availability of high-cost specialty drugs and the viability of pharmacies that dispense these drugs to beneficiaries, supporting the continued access to these services.

In addition to meeting the goals of the authorizing statutes as described above, these proposed regulations support the proper and efficient administration of the Medi-Cal program in accordance with the federal and state laws that govern the program's rules of participation and funding.

Consistency and Compatibility with Existing State Regulations

The Department has conducted an evaluation of the related existing state regulations under California Code of Regulations, title 22, division 3, chapter 3 and has determined that the proposed regulations are consistent with and compatible with those regulations. An automated search of title 22, using the following keywords "pharmacy," "pharmacies," "pharmacist," and "pharmacist services," was conducted via Westlaw and yielded no conflicting state regulations.

Regulation Sections

This proposed regulatory action adopts sections 51105.1, 51105.2, 51105.3, 51313.7, 51313.8, 51476.3, 51476.4, and 51505.4, and amends sections 51226 and 51227 under California Code of Regulations, title 22, division 3, chapter 3, to accomplish the following:

- Define pharmacist services, medication therapy management, and specialty drugs.
- Amend standards for participation in the Medi-Cal program for a pharmacy and pharmacists.
- Establish the scope of pharmacist services, including MTM.
- Describe pharmacist services records maintenance and availability; and claim submission requirements.
- Establish and direct providers to reimbursement rates for pharmacist services; and describe claim limitations and written substantiation requirements.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

FISCAL IMPACT STATEMENT

- A. Costs to any Local Agency or School District that is required to be reimbursed Under Part 7 (commencing with Section 17500), Division 4 of the Government Code: None.

Costs to any Local Agency or School District that is not reimbursable by the State: None.

- B. Costs or Savings to any State Agency:

Savings to the General Fund (GF) is expected to phase in over several years. For FY 2022-23, FY 2023-24, FY 2024-25, FY 2025-26, and FY 2026-27 is:

Fiscal Years	TF	GF	FF
FY 2022-23	(\$27,098,000)	(\$9,727,000)	(\$17,371,000)
FY 2023-24	(\$25,135,000)	(\$9,064,000)	(\$16,071,000)
FY 2024-25	(\$23,696,000)	(\$8,578,000)	(\$15,118,000)
FY 2025-26	(\$23,446,000)	(\$8,494,000)	(\$14,952,000)
FY 2026-27	(\$23,437,000)	(\$8,491,000)	(\$14,946,000)

C. Costs or Savings in Federal Funding to the State:

Savings to the Federal Fund (FF) is expected to phase in over several years. For FY 2022-23, FY 2023-24, FY 2024-25, FY 2025-26, and FY 2026-27 is:

Fiscal Years	TF	GF	FF
FY 2022-23	(\$27,098,000)	(\$9,727,000)	(\$17,371,000)
FY 2023-24	(\$25,135,000)	(\$9,064,000)	(\$16,071,000)
FY 2024-25	(\$23,696,000)	(\$8,578,000)	(\$15,118,000)
FY 2025-26	(\$23,446,000)	(\$8,494,000)	(\$14,952,000)
FY 2026-27	(\$23,437,000)	(\$8,491,000)	(\$14,946,000)

D. Other Nondiscretionary Costs or Savings Including Revenue Changes Imposed on State or Local Agencies: None.

All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action:

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

MANDATES ON LOCAL AGENCIES OR SCHOOL DISTRICTS

The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with section 17500) of division 4 of the Government Code.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT AFFECTING BUSINESSES

The Department has made an initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT (ANALYSIS)

In accordance with Government Code section 11346.3(b)(1), the Department has determined that the proposed regulations would not significantly affect the following:

1. The creation or elimination of jobs in California.
2. The creation or elimination of businesses in California.
3. The expansion of businesses currently doing business in California.

IMPACT ON JOBS AND BUSINESSES

The proposed regulatory action clarifies and adds specificity to the current pharmacist regulations. These regulations authorize pharmacist services including MTM to be eligible for Medi-Cal reimbursement. This proposed regulatory action will only affect pharmacies and pharmacists who participate in the Medi-Cal program and provide pharmacist services, as specified. There is no significant impact to the state in the creation or elimination of businesses or jobs; however, MTM is expected to have a positive economic impact and enhance the financial viability of pharmacies who provide MTM.

BENEFITS OF THE PROPOSED REGULATION

The Department has determined that the proposed regulations will not affect worker safety or the state's environment. However, the proposed regulations will benefit pharmacists and pharmacies administratively by offering clear and current pharmacist services benefit, claims, and reimbursement information. This in turn will benefit the health and welfare of California's residents by continued delivery of these critical services. These regulations support the proper and efficient administration of the Medi-Cal program in accordance with the federal and state laws that govern the program's rules of participation and funding.

EFFECT ON SMALL BUSINESSES

The Department has determined that small businesses are assumed to be impacted because MTM reimbursement will have a positive economic impact and enhance the financial viability of pharmacies who choose to participate in the Medi-Cal program and provide MTM.

HOUSING COSTS DETERMINATION

The Department has made the determination that the proposed regulations would have no impact on housing costs.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Regulations pertaining to Medi-Cal benefits, including those related to pharmacists and pharmacies are located in California Code of Regulations, title 22, chapter 3, Health Care Services. Using this regulatory proposal to include provisions for pharmacist services is the most effective and convenient way to provide updated information directly to affected parties, including Medi-Cal providers and beneficiaries. This proposed regulatory action is also necessary to meet the mandate of W&I Code section 14132.968 that the Department promulgate regulations to implement this section.

ASSISTIVE SERVICES

For individuals with disabilities, the Department will provide assistive devices, including sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of training or meeting materials into braille, large print, audio or electronic format. To request these services, copies in an alternative format or language services, all free of charge, please call or write:

Department of Health Care Services
Office of Legal Services, Regulations MS 0015
P.O. Box 997413
Sacramento, CA 95899-7413
Program Phone Number: (916) 440-7695
Program Email: regulations@dhcs.ca.gov

Please note that the range of assistive services available may be limited if requests are received less than ten working days prior to the meeting or event.

The Department shall provide, upon request from a person with a visual disability or other disability for which effective communication is required under state or federal law, a narrative description of the additions to, and deletions from, the California Code of Regulations or other publication in a manner that allows for accurate translation by reading software used by the visually impaired. Providing this description may require extending the period of public comment for the proposed action pursuant to Government Code Section 11346.6.

CONTACT PERSONS

Inquiries regarding the proposed regulations described in this notice may be directed to Sylvana Ho of the Pharmacy Benefits Division at (916) 345-8651.

All other inquiries concerning the action described in this notice may be directed to Greg Rodriguez of the Office of Legal Services, Regulations, at (916) 345-8396, or to the designated backup contact person, Jasmin Delacruz, at (916) 345-8418.

AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Legal

Services, Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request.

The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available by the Department at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Materials regarding the regulatory action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) are posted to the Department's Internet site at:

<http://www.dhcs.ca.gov/formsandpubs/laws/Pages/ProposedRegulations.aspx>.

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons be mailed to you, please call (916) 440-7695 (or California Relay at 711), email – regulations@dhcs.ca.gov, or write to Office of Legal Services, Regulations at the address noted above.