

INITIAL STATEMENT OF REASONS

The purpose of the Department of Health Care Services (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, which 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 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

¹ [core elements of an mtm practice.pdf \(pharmacist.com\)](https://www.cdph.ca/Programs/OPA/Pages/NR19-002.aspx)

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.

DETAILED STATEMENT OF REASONS: PURPOSE AND RATIONALE

Section 51105.1. Pharmacist Services.

Subsection (a) is adopted to define the term “pharmacist services.” This definition is necessary to implement W&I Code section 14132.968 that authorizes the Department to adopt regulations to include pharmacist services as benefits under the Medi-Cal program.

“Pharmacist services” include eight specific services, which are covered benefits when rendered by a pharmacist. These services are further described in proposed subsections (a)(1)-(8) below.

Subsection (a)(1) is adopted to specify that furnishing travel medications, as authorized by B&P Code section 4052(a)(10)(A)(iii), is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(A). This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1746.5 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052(a)(10)(A)(iii). The duplication of W&I Code section 14132.968(b)(1)(A) and cross-reference to California Code of Regulations, title 16, section 1746.5 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(2) is adopted to specify that furnishing naloxone hydrochloride, as authorized by B&P Code section 4052.01, is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(B). This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1746.3 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052.01. The duplication of the W&I Code section 14132.968(b)(1)(B) and cross-reference to California Code of Regulations, title 16, section 1746.3 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(3) is adopted to specify that furnishing self-administered hormonal contraception, as authorized by B&P Code section 4052.3(a), is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(C). This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1746.1 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052.3(a). The duplication of the W&I Code section 14132.968(b)(1)(C) and cross-reference to California Code of Regulations, title 16, section 1746.1 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(4) is adopted to specify that initiating and administering immunizations, as authorized by B&P Code section 4052.8, is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(D). This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1746.4 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052.8. The duplication of the W&I Code section

14132.968(b)(1)(D) and cross-reference to California Code of Regulations, title 16, section 1746.4 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(5) is adopted to specify that tobacco cessation counseling and furnishing nicotine replacement therapy, as authorized by B&P Code section 4052.9, is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(E). This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1746.2 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052.9. The duplication of the W&I Code section 14132.968(b)(1)(E) and cross-reference to California Code of Regulations, title 16, section 1746.2 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(6) is adopted to specify that initiating and furnishing HIV preexposure prophylaxis, as authorized by B&P Code section 4052.02, is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(F) that also limits these services to no more than a 60-day supply of HIV preexposure prophylaxis to a single beneficiary once every two years. This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1747 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052.02. The duplication of the W&I Code section 14132.968(b)(1)(F) and cross-reference to California Code of Regulations, title 16, section 1747 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(7) is adopted to specify that initiating and furnishing HIV postexposure prophylaxis, as authorized by B&P Code section 4052.03, is a covered pharmacist service. This proposed language is consistent with W&I Code section 14132.968(b)(1)(G). This subsection also provides a cross-reference to California Code of Regulations, title 16, section 1747 that was adopted by the California State Board of Pharmacy to implement B&P Code section 4052.03. The duplication of the W&I Code section 14132.968(b)(1)(G) and cross-reference to California Code of Regulations, title 16, section 1747 are necessary to provide a convenient location that clearly specifies the requirements the pharmacists must follow in the delivery of this pharmacist service.

Subsection (a)(8) is adopted to specify that MTM in conjunction with dispensing specialty drugs, is a covered pharmacist service as authorized in W&I Code section 14132.968(b)(1)(H). This subsection provides a cross-reference to W&I Code section 14132.969 that is necessary to provide a convenient location that specifies how MTM is administered and reimbursed.

Subsection (b) is adopted to specify that pharmacist services do not include services that are associated with a “professional dispensing fee” incurred in the transaction of dispensing a drug. Pharmacist services include the professional services provided by pharmacists in the evaluation and management of a beneficiary; whereas services

associated with a professional dispensing fee are the professional services provided by pharmacists in the dispensing of a drug on the legal prescription of a licensed practitioner. The cross-reference to W&I Code section 14105.45 that defines “professional dispensing fee” is included for the clarity and convenience of the regulated public.

Section 51105.2. Medication Therapy Management or MTM.

This section is adopted to define the term “Medication Therapy Management” or “MTM.” This definition is necessary to implement W&I Code section 14132.968 that authorizes the Department to take regulatory action to implement pharmacist services as benefits under the Medi-Cal program. The definition includes a cross reference to W&I Code section 14132.969(g)(1) that clearly defines this term. The cross reference within this definition aligns the meaning of the term as used in the regulations with its meaning in statute.

Section 51105.3 Specialty Drugs.

This section is adopted to define “specialty drugs.” This definition is necessary to implement W&I Code section 14132.968 that authorizes the Department to take regulatory action to implement pharmacist services as benefits under the Medi-Cal program. The definition includes a cross reference to W&I Code section 14132.969(g)(2) that clearly defines this term. The cross reference within this definition aligns the meaning of the term as used in the regulations with its meaning in statute.

Section 51226. Pharmacy.

The section is amended to include a new designation of (a) for the existing provision due to the proposed addition of subsection (b).

Subsection (b) is added to specify that a pharmacy shall enter into a contractual agreement with the Department to provide and be eligible for reimbursement for MTM. This is necessary to clearly state this standard for provider participation and reimbursement. A pharmacy must be under contract to ensure that MTM is reliably and appropriately provided and this requirement is consistent with W&I Code section 14132.969(c). A cross-reference to W&I Code section 14132.969(c) is included for the clarity and convenience of the regulated public.

Section 51227. Pharmacist.

The section is amended to include a new designation of (a) for the existing provision due to the proposed addition of subsection (b).

The phrase “Business and Professions Code” is added before the word “section” to establish a consistent grammatical style for referring to statutes through this regulatory proposal. The term “state” is not capitalized for consistency with the use of this term throughout the regulations and the term “he” is replaced with “the pharmacist” to use gender-neutral language and to eliminate the use of the gender-specific pronoun.

Subsection (b) is added to include the requirement that a pharmacist be enrolled as an ordering, referring, and prescribing (ORP) provider under the Medi-Cal program before rendering a pharmacist service. Both the pharmacist and the pharmacy must be enrolled in the Medi-Cal program in order to submit claims for reimbursement for pharmacist services and this requirement is consistent with W&I Code section 14132.968(c). A cross-reference to W&I Code section 14132.968(c) is included for the clarity and convenience of the regulated public.

Section 51313.7. Pharmacist Services.

This section is adopted to add pharmacist services as covered Medi-Cal benefits when rendered by pharmacists who are acting pursuant to applicable professional licensing statutes and regulations. This section is necessary to implement W&I Code sections 14132.968 and 14132.969, establish the scope of these covered benefits, and specify that pharmacist services are subject to the specific limitations identified within the regulations. This section is also consistent with SPA TN No. 21-0028, Limitations on Attachment 3.1-A, Page 12a.7 and Limitations on Attachment 3.1-B, Page 12a.7 (effective July 1, 2021).

51313.8. Medication Therapy Management.

This section is adopted specifically for Medication Therapy Management that is a pharmacist service and covered Medi-Cal benefit. MTM is subject to the list of specialty drugs, criteria, protocols, and limitations specified on the Department's Medi-Cal Providers website at <https://mcweb.apps.prd.cammis.medi-cal.ca.gov/>. This section is necessary to implement W&I Code section 14132.969(b)(1), (2) and (4) and includes reference to the Department's Medi-Cal Providers website for the clarity and convenience of the regulated public. The Department established this website as a resource for providers to have timely access to useful information pertaining to the delivery of services under the Medi-Cal program. As specified in W&I Code section 14132.969(f), the Department is authorized to implement and interpret this section pertaining to MTM, without taking regulatory action.

Section 51476.3. Pharmacist Services Records.

This section is adopted to specify the documentation and record maintenance and availability requirements in the rendering of pharmacist services. These provisions are necessary to ensure that pharmacists and pharmacies establish, maintain, and have readily available documentation that substantiates the rendering of pharmacist services, which is required to be eligible for payment.

Subsection (a) is adopted as a lead in for the following description of documentation and record maintenance requirements that must be followed by a pharmacist when rendering pharmacist services.

Subsection (a)(1) is adopted to require a pharmacist to document the delivery of pharmacist services at or around the time the services are rendered to a beneficiary. The requirement to create the documentation at or near the time of service helps to ensure a more accurate beneficiary record and is consistent with best practices in the

delivery of health care. This subsection mirrors language from California Code of Regulations, title 22, section 51476(a) and is necessary to ensure consistent enforcement of a standard record maintenance practice across the Medi-Cal program.

Subsection (a)(2) is adopted to specify that a pharmacist who renders pharmacist services must comply with existing record maintenance and availability laws and regulations including those specific to Medi-Cal providers as described in California Code of Regulations, title 22, section, 51476 and W&I Code section 14124.1. This subsection also requires a pharmacist to follow all applicable professional licensing statutes and regulations, including the specific references to California Code of Regulations, title 16, sections 1746.1, 1746.2, 1746.3, 1746.4, 1746.5, and 1747. These cross-references to specific statutes and regulatory sections provide pharmacists with detailed record retention and availability requirements that must be met when rendering pharmacist services and are included for the clarity and convenience of the regulated public. These record maintenance requirements are necessary to clearly substantiate the medical need and delivery of pharmacist services.

Subsection (a)(3) is adopted to specify that a pharmacist must maintain written evidence of the completion of any certification, training, or education as required by applicable professional licensing statutes and regulations. This subsection is necessary to protect the health and safety of beneficiaries by ensuring that pharmacists can substantiate that they have completed required and necessary training and education to maintain their licensure and provide pharmacist services. Cross-references to California Code of Regulations, title 16, sections 1746.1, 1746.2, 1746.3, 1746.4, 1746.5, and 1747, which specify the training requirements pertaining to the delivery of pharmacist services are included for the clarity and convenience of the regulated public.

Subsection (b) is adopted to specify that a pharmacy, where pharmacist services are rendered, must comply with existing records maintenance and availability laws and regulations including those specific to Medi-Cal providers as described in California Code of Regulations, title 22, section 51476 and W&I Code section 14124.1. This subsection requires a pharmacy to follow all applicable professional licensing statutes and regulations, including the specific references to California Code of Regulations, title 16, sections 1707.1, 1717, 1746.1, 1746.2, 1746.3, 1746.4, 1746.5, and 1747.

These cross-references to specific statutes and regulatory sections provide pharmacies with detailed record retention and availability requirements that must be met with the delivery of pharmacist services and are included for the clarity and convenience of the regulated public. These record maintenance requirements are necessary to clearly substantiate the medical need and delivery of pharmacist services.

Section 51476.4. Claim Submission Requirements for Pharmacist Services.

This section is adopted to establish the conditions that pertain to claim submissions for pharmacist services and to indicate that affected parties shall also comply with other legal claims requirements that are specified outside of these regulations.

Subsection (a) is added to specify that only a pharmacy may submit a claim for a pharmacist service and further describes the acceptable formats for the claim submission. The requirement that a Medi-Cal pharmacy provider submit the claim for reimbursement, on behalf of the pharmacist rendering the service, is consistent with W&I Code section 14132.968(c). Cross-references to California Code of Regulations, title 22, sections 51502 and 51502.1 are included for the clarity and convenience of the regulated public. Section 51502 outlines (manual form) billing requirements and section 51502.1 delineates the requirements for electronic claims submission, either of which may be used to submit a claim for a pharmacist service.

Subsection (b) is added to require that the claim include the rendering pharmacist's national provider identifier (NPI). The NPI is necessary because of the implementation of the HIPAA (Public Law 104-191, title II, sections 1175 and 1178). Specifically, the HIPAA Administrative Simplification provisions require health care providers to use their assigned unique 10-digit numeric identifier with all their administrative and financial transactions, including claims submissions, pursuant to title 45, Code of Federal Regulations, section 162.406.

Subsection (c) is added to specify that a claim must not include a claim for a drug component. This is necessary because a claim for pharmacist services only covers the delivery of the pharmacist service that includes the evaluation and management of the beneficiary and not the cost for a drug component. This provision is consistent with W&I Code section 14132.968(b) that outlines the covered pharmacist services, which do not include dispensing services and is consistent with the Reimbursement Methodology for Licensed Pharmacist Services, as specified in SPA TN No. 22-0013, Attachment 4.19-B, Page 3P (effective January 1, 2022).

Section 51505.4. Pharmacist Services.

This section is adopted to specify provisions related to payment for the rendering of pharmacist services.

Subsection (a)(1) is added to describe the rate of reimbursement for pharmacist services that is 85% of the fee schedule for physician rates under the Medi-Cal program (except for MTM as specified in W&I Code section 14132.969) and subject to the payment reductions specified in W&I Code section 14105.192. A cross reference to Section 51105.1(a)(8), the description of MTM as a pharmacist service, is included for the clarity and convenience of the regulated public. This rate of reimbursement is consistent with W&I Code section 14132.968(a)(3) and with the Reimbursement Methodology for Licensed Pharmacist Services, as specified in SPA TN No. 22-0013, Attachment 4.19-B, Page 3P (effective January 1, 2022). Reimbursement for pharmacist services is also subject to statutorily-mandated payment reductions. Therefore, a cross-reference to W&I Code section 14105.192 is included for the clarity and convenience of the regulated public. Reference to the Department's Medi-Cal Providers website (<https://mcweb.apps.prd.cammis.medi-cal.ca.gov/>) is also included for the clarity and convenience of the regulated public. The Department established this website as a resource for providers to have timely access to useful information

pertaining to the delivery and reimbursement for services under the Medi-Cal program. The Department is authorized to adopt and publish updated rates/fee schedules and procedure codes without taking regulatory action as provided for in W&I Code section 14105.05.

Subsection (a)(2) is added to describe the rate of reimbursement for MTM, which is the rate established in the contract between the pharmacy and the Department that is subject to the payment reductions specified in W&I Code section 14105.192. A pharmacy must be under contract to ensure that MTM is reliably and appropriately provided and this requirement is consistent with W&I Code section 14132.969(c). A cross-reference to W&I Code section 14132.969(c) is included for the clarity and convenience of the regulated public. Reimbursement for MTM is also subject to statutorily mandated payment reductions. Therefore, a cross-reference to W&I Code section 14105.192 is included for the clarity and convenience of the regulated public. Reference to the Department's Medi-Cal Providers website (<https://mcweb.apps.prd.cammiis.medi-cal.ca.gov/>) is also included for the clarity and convenience of the regulated public. The Department established this website as a resource for providers to have timely access to useful information pertaining to the delivery and reimbursement for services under the Medi-Cal program. The Department is authorized to adopt and publish updated rates/fee schedules and procedure codes without taking regulatory action as provided for in W&I Code section 14105.05.

Subsection (b)(1) is added to specify that covered pharmacist services (except for MTM that is described in subsection (c) below), are limited in the number of visits allowed for an existing patient of the pharmacy location within a specific time period, unless accompanied by written substantiation. Pharmacist services rendered to an existing patient of a pharmacy location up to six times in a 90-day period are eligible for payment without written substantiation.

This provision applies to an "existing patient of the pharmacy location" that is consistent with the American Medical Association's (AMA) Current Procedural Terminology (CPT) Manual, Evaluation and Management Services Guidelines, as described in subsection (d) below.

The establishment of utilization controls is typical with the provision of Medi-Cal services and is consistent with W&I Code section 14132.968(b)(2); and this specific limitation is consistent with SPA TN No. 21-0028, Limitations on Attachment 3.1-A, Page 12a.7 and Limitations on Attachment 3.1-B, Page 12a.7 (effective July 1, 2021). Such utilization controls are necessary to support the delivery of only essential health care services and maintain Medi-Cal program integrity.

Subsection (b)(2)(A) is added to specify that a claim for pharmacist services (except for MTM that is described in subsection (c) below), provided more than six times in a 90-day period requires a pharmacy to submit written substantiation to be eligible for payment. When pharmacist services rendered exceed the limitation set in subsection (b)(1), a pharmacy is required to submit written substantiation to demonstrate the

medical necessity for these additional pharmacist services. The establishment of utilization controls is typical with the provision of Medi-Cal services and is consistent with W&I Code section 14132.968(b)(2); and this specific limitation is consistent with SPA TN No. 21-0028, Limitations on Attachment 3.1-A, Page 12a.7 and Limitations on Attachment 3.1-B, Page 12a.7 (effective July 1, 2021). Such utilization controls are necessary to support the delivery of only essential health care services and maintain Medi-Cal program integrity.

Subsection (b)(2)(B) is added to specify the type of information that shall be included in the written substantiation specified in subsection (b)(2)(A). In order to qualify for payment, the written substantiation must describe the beneficiary's acute or chronic condition that requires frequent visits to monitor the beneficiary's condition to decrease hospitalizations. This requirement is necessary to ensure the pharmacy provides the Department with essential information to evaluate the medical necessity of the pharmacist service and authorize payment of the claim.

Subsection (b)(2)(C) is added to specify that claims for the administration of immunizations rendered pursuant to section 51105.1(a)(4) are not subject to the limitation specified in subsection (b)(1) nor the requirement for written substantiation specified in subsection (b)(2)(A). For years, B&P Code section 4052 has authorized pharmacists to administer immunizations pursuant to a protocol with a prescriber. B&P Code section 4052.8 authorizes pharmacists to independently initiate and administer immunizations to patients 3 years of age and older. Because the act of administering an immunization has been within a pharmacist's scope of practice for many years it differs from the other pharmacist services specified in W&I Code section 14132.968 and since it is not an evaluation and management service, it is not subject to the same limitations as the other pharmacist services.

Subsection (c)(1) is added to specify that claims for MTM provided to a beneficiary up to six times in a 365-day period shall be eligible for payment without written substantiation. The establishment of utilization controls is typical with the provision of Medi-Cal services and is consistent with W&I Code sections 14132.968(b)(2) and 14132.969(b)(1); and this specific limitation is consistent with SPA TN No. 21-0028, Limitations on Attachment 3.1-A, Page 12a.7a and Limitations on Attachment 3.1-B, Page 12a.7a (effective July 1, 2021). Such utilization controls are necessary to support the delivery of only essential health care services and maintain Medi-Cal program integrity.

Subsection (c)(2) is added to specify that claims for MTM with a treatment duration that is less than six months shall be limited to one claim per treatment month. The establishment of utilization controls is typical with the provision of Medi-Cal services and is consistent with W&I Code sections 14132.968(b)(2) and 14132.969(b)(1); and this specific limitation is consistent with SPA TN No. 21-0028, Limitations on Attachment 3.1-A, Page 12a.7a and Limitations on Attachment 3.1-B, Page 12a.7a (effective July 1, 2021). Such utilization controls are necessary to support the delivery of only essential health care services and maintain Medi-Cal program integrity.

Subsection (c)(3)(A) is added to specify that claims for MTM provided in excess of the limitations specified in subsections (c)(1) and (2) require written substantiation submitted by a pharmacy with the claim to be eligible for payment. When MTM is provided in excess of these limitations, a pharmacy is required to submit written substantiation to demonstrate the medical necessity for the additional MTM. The establishment of utilization controls is typical with the provision of Medi-Cal services and is consistent with W&I Code sections 14132.968(b)(2) and 14132.969(b)(1); and this specific limitation is consistent with SPA TN No. 21-0028, Limitations on Attachment 3.1-A, Page 12a.7a and Limitations on Attachment 3.1-B, Page 12a.7a (effective July 1, 2021). Such utilization controls are necessary to support the delivery of only essential health care services and maintain Medi-Cal program integrity.

Subsection (c)(3)(B) is added to specify the type of information that shall be included in the written substantiation specified in subsection (c)(3)(A). In order to qualify for payment, the written substantiation must describe the beneficiary's acute or chronic condition that requires frequent visits to monitor the beneficiary's condition to decrease hospitalizations. This requirement is necessary to ensure the pharmacy provides the Department with essential information to evaluate the medical necessity of the MTM and authorize payment of the claim.

Subsection (d) is added to specify the meaning of "existing patient of the pharmacy location" that is used in subsection (b)(1). This description is necessary to distinguish this type of beneficiary who has received pharmacist services from a specific pharmacy within the past three years, as described in subsection (b)(1), above. This definition is consistent with the definition of established patient in the American Medical Association's Current Procedural Terminology (CPT) Manual, Evaluation and Management Services Guidelines. (See page 15 of the AMA Code and Guidelines Changes)

(www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf)

Documents Relied Upon

1. State Plan Amendment (SPA) TN No. 21-0028, effective July 1, 2021

([CA 21-0028 Approval Package.pdf](#))

2. State Plan Amendment (SPA) TN No. 22-0013, effective January 1, 2022

([SPA 22-0013 Approval \(ca.gov\)](#))

3. American Medical Association, Current Procedural Terminology (CPT) Manual, Evaluation and Management Services Guidelines, AMA Code and Guidelines Changes, p. 15.

(www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf)

4. Medication Therapy Management in Pharmacy Practice, Core Elements of an MTM Service Model, Version 2.0 March 2008, Page 3.

([core elements of an mtm practice.pdf \(pharmacist.com\)](#))

STATEMENTS OF DETERMINATION

(a) Alternatives Considered

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 this regulatory action is proposed, would be as effective and less burdensome to affected private persons than the regulatory 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.

(b) Local Mandate Determination

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.

(c) Economic Impact Analysis/Assessment

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.

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 within the State of California.
2. The creation or elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of 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/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.

(d) 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.

(e) Housing Costs Determination

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