

INITIAL STATEMENT OF REASONS

Title XIX of the Social Security Act creates the federal Medicaid Program, administered in California by the Department of Health Care Services (Department) as the California Medical Assistance (Medi-Cal) program. The Social Security Act, Sections 1902 and 1905, require that the Medi-Cal program provide certain health care services, including, but not limited to, hospital inpatient and hospital outpatient services, nursing facility services, physician services, and x-ray and laboratory services. Specifically, Title 42, United States Code, Section 1396d(a)(3) indicates that x-ray and laboratory services are covered medical assistance, as further set forth in Title 42 Code of Federal Regulations, Section 440.30. The state authority for the foregoing is contained in Welfare & Institutions (W&I) Code Section 14132(f).

STATEMENT OF PURPOSE AND RATIONALE/PROBLEM BEING ADDRESSED

The Medi-Cal program covers specified services, when rendered by a Medi-Cal provider (defined under Title 22, California Code of Regulations (CCR) Section 51051), including physicians, hospital outpatient departments, clinical laboratories, and portable x-ray services providers. These Medi-Cal providers shall meet the standards for participation in the Medi-Cal program as specified in Section 51200 et seq. As specified under Section 51501(b), these providers shall receive payments for services covered under the Medi-Cal program only when the providers have met these standards and the requirements for payment under Article 7 (commencing with Section 51501).

Portable x-ray services are covered under the Medi-Cal program as x-ray services when rendered by a portable x-ray services provider, as specified in Title 22, CCR, Section 51311. However, existing regulations do not include definitions for “portable x-ray services” or “portable x-ray services providers.” This regulatory action proposes to define these services and providers, in addition to updating the terminology throughout the affected CCR Sections. Specifically, “portable x-ray services” will appropriately be called “portable imaging services” and “portable x-ray services providers” will appropriately be called “portable imaging services providers.” This terminology change is the result of the evolution of medical technology and is now the recognized terminology used in the diagnostic industry today. In addition to these changes in terminology, this regulatory proposal will also update other requirements for portable imaging services related to authorization and payment.

BENEFITS AND 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, Basic Health Care), to afford qualifying individuals (such as the aged or disabled) covered health care services in a manner equitable to the general public and without duplication of benefits available under other federal or state laws.

Within Chapter 7, W&I Code Section 14124.5 further specifies that the Director may promulgate regulations as are necessary or proper to carry out the purpose and intent of this Chapter, which includes implementation of the uniform schedule of health care benefits under the Medi-Cal program, as described under W&I Code Section 14131 et seq., including x-ray services under W&I Code Section 14132(f).

The amendments proposed through this regulatory action will clarify the x-ray services (i.e. portable imaging services) that are available under the Medi-Cal program. These amendments will directly benefit providers (e.g. Physicians, Portable Imaging Services Providers, et al.) through the adoption of current and defined terminology and by providing clarity regarding the scope of services, authorization, and requirements for payment, which in turn facilitate the delivery of these health care services to beneficiaries. In addition to meeting the goals of the authorizing statutes (as described above), these proposed regulations ensure 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, funding and the authorized schedule of benefits.

The specific purpose and rationale for the proposed amendments are as follows:

Section 51051

Subsection (b) is proposed to be amended as follows:

- 1) To revise the phrase "Comprehensive Perinatal Providers," which inadvertently excluded the term "Services," and to include this term to accurately reflect the title of the Comprehensive Perinatal Services Program.
- 2) To add a "/" where it was previously inadvertently omitted between "Home Health Agencies/Hospices."
- 3) To delete the term "X-ray" and replace it with the term "Imaging" that is technically accurate and recognized in the diagnostic industry today, so the phrase will read "Portable Imaging Services..." "Imaging" more accurately describes the services that may be performed by this provider. The term "X-ray" implies that radiation is utilized for all the services; however diagnostic ultrasound, echocardiographic, and non-invasive vascular examinations are performed without radiation. "Imaging" is a more accurate and inclusive term than "X-ray."
- 4) To add the word "Providers" at the end of "Portable Imaging Services" so that the phrase will read "Portable Imaging Services Providers," simply to clarify that these services are rendered by "providers," and for consistency with similar phrases under Subsection (b) and the definition as proposed under Title 22, CCR Section 51193.3.

Section 51113

The proposed amendment is to change the word "X-ray" to "imaging." This amendment is necessary to clearly describe what type of outpatient services do not need to be provided on the premises of a hospital outpatient facility. This change is necessary to

update terminology that is recognized and used in the industry today as medical technology has evolved.

Section 51193.1

The adoption of this section is proposed to define “portable imaging services” because a definition does not currently exist. The adoption of this definition will clearly state the meaning of this phrase as it is used by the Department. The adoption of this definition will also ensure that the use of this phrase is clear and consistent when used throughout the regulations, and there is a clear description of the type of service as it is rendered by qualified providers, thus enabling the Department to monitor the provision of and payment for these services, while in turn protecting the Medi-Cal Program from fraud and abuse.

This definition is necessary to accurately describe the examinations provided under this service classification and the manner in which these services are provided, via portable diagnostic equipment. These examinations are currently the industry standard for portable imaging services. As described above, these services are labeled “portable imaging” as opposed to “x-ray” since the latter term implies that radiation is utilized for all the services; however, diagnostic ultrasound, echocardiographic, and non-invasive vascular examinations are performed without radiation, thus portable imaging is a more appropriate (inclusive) term.

Section 51193.3

This section is proposed to define “portable imaging services provider,” because a definition does not currently exist. The adoption of this definition will clearly state the meaning of this phrase as it is used by the Department. The adoption of this definition will also ensure that the use of this phrase is clear and consistent when used throughout the regulations and there is a clear description of the type of individual that would qualify as this type of provider, thus enabling the Department to determine qualifying applicants for Medi-Cal enrollment and to protect the Medi-Cal Program from fraud and abuse.

Section 51311

This section is proposed to be amended to ensure that portable imaging services are provided in accordance with provisions under Section 51531 and proposed Sections 51193.1 and 51193.3.

The title of Section 51311 is proposed to be amended to include the phrase “Portable Imaging” in order to update the terminology to that which is recognized and utilized in the industry today, as medical technology has evolved. The term “Radioisotope” is proposed to be deleted because there is nothing in the section referring to “radioisotope” except in the title.

Subsection (a) is proposed to be amended to include the phrase “/her,” to be gender neutral and to include the term “the,” for grammatical accuracy.

Subsection (b) is proposed to be amended as follows:

- 1) To replace the term “X-ray” throughout this subsection [and Subsection (c)], with the phrase “imaging services” to update the terminology, as described above, and to be consistent with proposed Sections 51193.1 and 51193.3.
- 2) “Portable imaging” is added in front of the term “services” for clarity and consistent use of this phrase throughout the regulations. The phrase “rendered by portable X-ray providers” is removed because it is not necessary due to the addition of the phrase “portable imaging.” The phrase “that services” is removed and the phrase “when they are” is added, for sentence flow. The phrase “shall not require prior authorization” is removed because it is not necessary due to other revised language in Subsection (b). It is clear that prior authorization for portable imaging services is not required in a skilled nursing facility (SNF) or intermediate care facility (ICF), per W&I Code Section 14132(f). Additionally, the phrase “are covered without” is replaced with “do not require” for purposes of clarity. Prior authorization is not required for emergency services.
- 3) To delete, “subject to the submission of a written statement with the claim for services to support the emergency,” and include a period after the term “authorization” because submission of a written statement with the claim is no longer a requirement. Enrolled providers are allowed to self-certify by checking a box on the claim certifying that emergency services were provided. A Treatment Authorization Request (TAR) must be submitted for portable imaging services rendered by a portable imaging services provider to establish that these services are medically necessary except in the circumstances described in 2) above. Medical necessity must always be documented on the TAR. This process assures review for medical necessity, and therefore, the prevention of fraud and abuse under the Medi-Cal program.
- 4) To remove the last sentence: “The following procedures and examinations are covered as portable x-ray services:” along with Subsections (b)(1), (b)(2), and (b)(3). This part of the section is no longer needed as the definition of “portable imaging services” is proposed under Section 51193.1.

Subsections (c), (c)(4), (c)(6), and (c)(7) are proposed to be amended to include minor grammatical edits including replacing the term “which” with “that” and deleting the term “that” under Subsection (c)(4). Subsection (c)(6) includes a correction in punctuation and the term “and” is included; the period is changed to a semicolon for consistency throughout the listing under (c). Subsection (c)(7) is also proposed to be amended to include a non-substantive change, replacing the phrase “because there is a necessity for” with “and require” for the purpose of clarity. Lastly under Subsection (c)(7), the term “radiologic” is changed to “radiology” because this is the terminology most commonly used when referring to a “facility.”

Subsection (d) is proposed to specify further conditions which must be met in order for portable imaging services to be a covered benefit. These provisions are necessary to prevent fraud and abuse under the Medi-Cal Program.

Subsection (d)(1) is established so the provider ordering the portable imaging services cannot have a financial interest in the business providing the portable imaging services, which would be a conflict of interest and could lead to fraud and abuse under the Medi-Cal Program.

Subsection (d)(2) is established so the patient receiving the portable imaging services is under the direct care of the provider who ordered the portable imaging services, and not the portable imaging services provider, which would be a conflict of interest and could lead to fraud and abuse under the Medi-Cal Program.

Section 51511.6

Subsection (a) includes a non-substantive change that replaces the term “defined” to “described” in order to more accurately reflect the contents under Section 51335.6(a).

Subsection (f)(8) includes a nonsubstantive punctuation change. A period is changed to a semicolon and the term “and” is included.

Subsection (f)(9) is proposed to be amended to change the word “x-ray” to “imaging.” This amendment is necessary to update terminology that is recognized and used in the industry today as medical technology has evolved.

Section 51531

This section is proposed to be amended to ensure that payment for portable imaging services is based upon and consistent with provisions, scope of benefits, and standards established under Section 51311 and proposed Sections 51193.1 and 51193.3.

The title of Section 51531 is proposed to be amended to include the terms “portable” and “imaging” and exclude the term “X-ray” in order to update the terminology to that which is recognized and utilized in the industry today, as medical technology has evolved. The term “payment” is included in the title of Section 51531 (Payment for Portable Imaging Services), as located under Article 7, Payment for Services and Supplies, to simply distinguish it from Section 51193.1, which is the definition of “Portable Imaging Services,” found under Article 2, Definitions.

Subsections (a), (b) and (c) are proposed to be amended to remove the term “X-ray” and replace it with the phrase “portable imaging” and where appropriate related terms such as “provider” or “services” for clarity and the reasons described above in Sections 51193.1 and 51193.3.

Subsection (b) is proposed to be amended as follows:

- 1) To include a non-substantive change, replacing the phrase “as set forth” with “accordance with,” for consistency with the use of this phrase [to match language used under Section 51511.6(d)].
- 2) To include a cross reference to proposed Section 51193.1 that defines portable imaging services, along with the existing reference to Section 51311(b). Including the definition of portable imaging services along with the setting in which the services are provided in one convenient location provides clarity for the affected public.

Subsection (b)(1) is proposed to be amended to include three non-substantive changes as follows:

- 1) To remove the term “either,” which is not necessary;
- 2) To add the terms “interpreting” and “and/” because services may be billed by a physician who provides the professional service of interpreting the examination and by a portable imaging services provider who provides the technical service of performing the imaging; and
- 3) To remove the term “(Radiologist)” because “interpreting physician” is the accurate term to use and “Radiologist” is included as an “interpreting physician.”

Subsection (c) is proposed to include the terms “a” and “provider” that were missing from existing regulation text. Subsection (c) is also amended to specify that claims shall include the name and information of specific practitioners, the “portable imaging services provider and ordering provider.” The ordering provider is included because this provider orders the portable imaging services. The term “service” is removed because it is not necessary due to the preceding amendment. Subsection (c) also includes a non-substantive grammatical change, replacing “was” with “are.”

STATEMENTS OF DETERMINATION

ALTERNATIVES CONSIDERED

The Department has determined 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 action is proposed, or 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. The proposed regulations are the most effective way to update existing regulatory provisions related to portable imaging services and to adopt new related definitions. This regulatory proposal will provide convenient access to this information in one location (the CCR) for providers of these services and beneficiaries who receive these services.

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.

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.

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 of new businesses or the 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

Medi-Cal is a public health program that provides health care services for low-income individuals who choose to enroll and participate in the program. This proposed regulatory action will affect only those providers who administer portable imaging services and the beneficiaries who receive these services through the Program. The amendments proposed through this regulatory action that define/update terminology and clarify scope of services and criteria for authorization and payment, are not anticipated to have an impact on the creation or elimination of jobs, the creation of new businesses, the elimination of existing business or the expansion of businesses in California.

Benefits of the Proposed Regulations

The Department has determined that the proposed regulations will not affect worker safety or the state's environment. However, the proposed regulations will benefit the health and welfare of California residents by maintaining the continuity of the Medi-Cal program through the provision of comprehensive health care services for low-income individuals such as families with children, seniors, persons with disabilities, children in foster care and pregnant women. The proposed regulations will specify what portable imaging services are and who can provide these services, as well as requirements related to authorization and eligibility for payment, which in turn will facilitate the delivery of these vital health care services to beneficiaries. This regulatory proposal supports the proper and efficient administration of the Medi-Cal program in accordance with Federal and State laws.

EFFECT ON SMALL BUSINESSES

The Department has determined that the proposed regulations would only impact small businesses (providers) that voluntarily participate in the Medi-Cal Program and offer portable imaging services.

HOUSING COSTS DETERMINATION

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