

State of California—Health and Human Services Agency Department of Health Care Services



NOTICE OF PROPOSED RULEMAKING

SUBJECT: Portable Imaging Services, DHCS-14-011

NOTICE IS HEREBY GIVEN that the Department of Health Care Services (Department) proposes to adopt Sections 51193.1 and 51193.3 and amend Sections 51051, 51113, 51311, 51511.6 and 51531, Title 22, Division 3, Chapter 3 of the California Code of Regulations (CCR), after considering all public comments, objections, and recommendations.

WRITTEN COMMENT PERIOD

Any interested person or his or her 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 Portable Imaging Services, DHCS-14-011 and submit using any of the following methods:

Mail Delivery: Department of Health Care Services

Office of Regulations, MS 0015

P.O. Box 997413

Sacramento, CA 95899-7413

Hand Delivery: Department of Health Care Services

Office of Regulations

1501 Capitol Avenue, Suite 5084

Sacramento, CA 95814

FAX: (916) 440-5748

Email: regulations@dhcs.ca.gov

The written comment period closes at **5:00 p.m.**, **on December 15, 2014**; any written comments, regardless of the method of transmittal, must be received by the Office of Regulations by **5:00 p.m.** on this date for consideration.

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 his or her duly authorized representative, no later than 15 days prior to 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:

Section 20, Health and Safety (H&S) Code; Sections 10725, 14043.75, 14100.1, 14105 and 14124.5, Welfare and Institutions (W&I) Code.

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

Sections 14043, 14043.1, 14043.15, 14043.26, 14043.27, 14043.36, 14105, 14105.3, 14132, 14132.25, 14132.39, 14132.4, 14132.44, 14133, 14133.05, 14133.1 and 14134.5, W&I Code; Section 1206, Business and Professions Code; Statutes of 1982, Chapter 1594, Section 77; Statutes of 1983, Chapter 323, Section 149; Statutes of 1984, Chapter 268, Section 66; Statutes of 1985, Chapter 111, Items 4260-106-001 and 890; Section 33, Chapter 456, Statutes of 1990; Section 149.1, Chapter 323, Statutes of 1993; Statutes of 2004, Chapter 208, Items 4260-101-0001 and 4260-101-0890; Statutes of 2005, Chapters 38, Items 4260-101-0001 and 4260-101-0890; Statutes of 2006, Chapter 48, Items 4260-101-0001 and 4260-101-0890; Sections 1250(k) and 1765.105, H&S Code; and Title 42 United States Code, Section 263a.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Title XIX of the Social Security Act creates the federal Medicaid Program, administered in California by the 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 W&I Code Section 14132(f).

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.

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, 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.

Consistency and Compatibility with Exisitng State Regulations

The Department has conducted an evaluation of the related existing state regulations under CCR, Title 22, Division 3 and has determined that the proposed regulations are consistent with and compatible with those regulations. An automated search of Title 22, Division 3 using the keywords – "x-ray," "portable imaging," "portable x-ray," "portable imaging services," "diagnostic providers," and "diagnostic services" was conducted via Westlaw and yielded no conflicting state regulations.

Regulatory Sections

This regulatory action amends Sections 51051, 51113, 51311, 51511.6 and 51531 and adopts Sections 51193.1 and 51193.3 of Title 22, CCR. This regulatory action will specifically accomplish the following:

- Replace the term "portable x-ray" with the technically correct term "portable imaging";
- Define "portable imaging services" and "portable imaging services provider";
- Clarify the scope of portable imaging services and authorization (payment);
- Specify financial interest and direct care relationship standards; and
- Make non-substantive changes including the addition of cross references, grammatical and punctuation changes, and language amendments for clarity and consistency throughout the impacted regulations.

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 not reimbursable by the State: None.

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.

- B. Costs or Savings to any State Agency: None.
- C. Costs or Savings in Federal Funding to the State: None.
- D. <u>Other Nondiscretionary Costs or Savings Including Revenue Changes Imposed on State or Local Governments</u>: 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 agency 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 business, 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 made the following assessments and 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 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 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 regulations would only affect small businesses (providers) that voluntarily participate in the Medi-Cal program and offer portable imaging services.

Housing Costs Determination

The Department has made the determination that the 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. The proposed regulations are the most effective method in which 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.

ASSISTIVE SERVICES

For individuals with disabilities, the Department can provide assistive services such as the conversion of written materials into Braille, large print, audiocassette and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading or writing assistance. To request these assistive services, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email – regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

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 substance of the regulations described in this notice may be directed to: Janice Spitzer, Chief, Benefits Analysis Section, at (916) 552-9422.

All other inquiries concerning the regulatory action described in this notice may be directed to Lori Manieri, Office of Regulations, at (916) 650-6825; or to the designated backup contact person, Lynette Cordell, at (916) 440-7695.

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 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 from the Office of Regulations.

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's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Materials regarding the 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 or 1-800-735-2929), email regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above.