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EDMUND G. BROWN JR.
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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
DPH-15-012 Limited Permit X-ray Bone Densitometry Category –
Whole Body Composition & Terminology Change
Notice Published: January 26, 2018

PUBLIC PROCEEDINGS

The California Department of Public Health (Department) is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement overview section of this notice.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing 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.

WRITTEN COMMENT PERIOD

Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on March 12, 2018, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "**DPH-15-012 Limited Permit X-ray Bone Densitometry Category – Whole Body Composition & Terminology Change**" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission: (916) 440-5747;
3. By Postal Service: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814;



4. Hand-delivered: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, “**DPH-15-012 Limited Permit X-ray Bone Densitometry Category – Whole Body Composition & Terminology Change**” author’s name and mailing address.

Authority and Reference

The Department is proposing to adopt, amend, or repeal, as applicable, Title 17, California Code of Regulations, sections 30400, 30413, 30417, 30418, 30419, 30420, 30427, 30427.2, 30435, 30442, 30443, 30447 and 30461, under the authority provided in sections 114870 and 131200 of the Health and Safety Code. This proposal implements, interprets and makes specific sections 106965, 106975, 106990, 107045, 114845, 114850, 114870, 114880, 131050, 131051 and 131052 of the Health and Safety Code.

Summary of the Proposal

This proposal amends regulations as recommended by the Radiologic Technology Certification Committee (RTCC), clarifying that Whole Body Composition (WBC) procedures (i.e. the measurement of total and regional whole body fat and lean tissue mass) are within the existing scope of the X-ray Bone Densitometry (XBD) Permit Category, and changing the XBD terminology to Dual Energy X-ray Absorptiometry (DEXA). Nonsubstantial changes are also made.

Informative Digest/Policy Statement Overview

Problem Statement: The existing limited permit scope of the XBD Permit category fails to clarify whether the permit holder is authorized to perform WBC procedures when so ordered by a licentiate of the healing arts. The existing name of the XBD permit is inconsistent with current industry and international terminology and usage.

Objectives: Broad objectives of this proposed regulatory action are to:

- Clarify that the scope of practice for the XBD permit category includes performance of WBC procedures.
- Address RTCC’s recommendation regarding WBC procedures.
- Revise terminology so it is consistent with industry and international usage.

Benefits: Anticipated benefits from this proposed regulatory action are:

- Clarification that the scope of practice for the XBD permit category includes performance of WBC procedures.
- Implementation of RTCC’s recommendation regarding WBC procedures.
- Consistent terminology with industry and international usage.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations:

The Department evaluated this proposal and determined that, if adopted, it will not be inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations. An Internet search of other state agency regulations determined that no other state regulation addresses the same subject matter.

Program Background

The Radiologic Technology Act (RT Act), codified in Health and Safety Code (H&S Code), sections 106965 through 107120 and sections 114840 through 114896, was enacted into California law in 1969. The RT Act was enacted to protect the public from excessive or improper exposure to ionizing radiation by establishing standards of education, training, and experience for persons who use X-rays on human beings and to prescribe means for assuring that these standards are met. The RT Act requires that any individual who uses X-rays on human beings meet certain standards of education, training, and experience. The Department (successor to the Department of Health Services) is authorized under the RT Act to promulgate regulations to implement the Act's provisions. (H&S Code 114870, 131055 & 131200.¹) The regulations implementing the RT Act are codified in Title 17, California Code of Regulations (CCR), sections 30400 et seq. (17 CCR 30400².)

Pursuant to the RT Act, the Department permits individuals as limited permit X-ray technicians in specific limited permit categories. (17 CCR 30442.) Limited permits are permits authorizing the holder to conduct radiologic technology limited to the performance of certain procedures or the application of X-ray to specific areas of the human body, except for a mammogram. (H&S Code 114850(e); 17 CCR 30443.) An individual granted a limited permit is called a limited permit X-ray technician (XT). (17 CCR 30400(a)(27).)

The RT Act also created the Radiologic Technology Certification Committee (RTCC) to assist, advise, and make recommendations for the establishment of rules and regulations necessary to insure the proper administration and enforcement of the RT Act. (H&S Code 114855.) This advisory committee consists of six licensed physician and surgeons, a licensed podiatrist and chiropractor, two certified radiologic technologists, and a radiological physicist. (H&S Code 114860.) Each member is appointed by the Department Director from at least three nominees for each position submitted by appropriate professional associations and societies. (H&S Code 114855.) Lastly, any regulations adopted by the Department, as recommended by RTCC, shall be adopted only after consultation with and approval of the committee by six affirmative

¹ This short format "H&S Code 131055" for a given Health and Safety Code section will be used throughout this document for brevity.

² The short format "17 CCR 30400" for a given regulation will be used throughout this document for brevity.

votes of those present at an official meeting of the committee. (H&S Code 114880.)

The XBD limited permit category was adopted in 1997 as recommended by the RTCC to address health industry and technological changes in the types of radiation sources used to perform densitometric measurements. Historically, such measurements used radioactive sources, which are not within the purview of the RT Act. However, radiation machine sources (i.e. X-ray machines) replaced radioactive source use. This source change, from radioactive to X-ray machine, brought such usage within the purview of the RT ACT.

Prior to 1997, operation of XBD equipment was limited to use by either: a certified supervisor and operator (17 CCR 30400(a)(10)) holding either a radiography supervisor and operator permit (17 CCR 30464) or a radiology supervisor and operator certificate (17 CCR 30462); a certified diagnostic radiologic technologist (17 CCR 30400(a)(8)); or, a holder of a special permit (17 CCR 30402). By adopting the XBD limited permit category, healthcare access increased as new qualified individuals were added to the workforce.

Currently, XBD focuses on the application of X-ray to the skeleton for measuring bone density, an indicator of medical conditions such as osteoporosis. At the RTCC's October 13, 2013 public meeting (Reference 1), the RTCC determined that the scope of practice for the XBD permit category should include performance of WBC procedures, and that the name of the permit should be changed to body densitometry. Department staff analyzed the recommendation, prepared material (Reference 2) and proposed regulations, and presented its conclusions and alternatives for the RTCC's consideration at the RTCC's April 2, 2014 public meeting. The RTCC discussed the two presented alternatives and approved the alternative as proposed in this regulatory action. As presented to (Reference 2) and approved by the RTCC, WBC means the measurement of total and regional whole body fat and lean tissue mass.

The authority and reference citations of sections being amended, resulting in nonsubstantial changes pursuant to 1 CCR 100, reflect the reorganization of the Department of Health Services into the Department of Health Care Services and the Department of Public Health, pursuant to Senate Bill 162. (Stats. 2006, ch. 241.)

The regulations interpreting, specifying, or implementing the RT Act are in title 17, California Code of Regulations, sections 30400 et seq. The proposed changes are:

Amend **section 30400** to address the RTCC's recommendation to include WBC procedures within the existing scope of the XBD Permit Category and to change the term "X-ray Bone Densitometry" to "Dual Energy X-ray Absorptiometry" for consistency with industry and international usage.

Amend **section 30413**. Subsection (a)(4) is amended for consistency with the redesignation of section 30427.2 to section 30427, resulting in no regulatory effect.

Amend **section 30417**. “X-ray Bone Densitometry” terminology (subsection (e)) is changed to “DEXA” for consistency with industry and international usage, as recommended by the RTCC.

Amend **section 30418**. Subsection (d)(1) is amended for consistency with the redesignation of section 30427.2 to section 30427, resulting in no regulatory effect.

Amend **section 30419**. Subsection (c) is amended to correctly refer to section 30418(d), addressing didactic instructors, instead of section 30418(c), which addresses qualifications of program directors for radiologic technologist fluoroscopy permit schools. This change results in no regulatory effect.

Amend **section 30420**. Subsection (a)(4)(B) is amended to correctly refer to the provision addressing investigational levels, by changing the reference to subsection (b)(5), which does not exist, to subsection (a)(5), resulting in no regulatory effect.

Redesignate **section 30427.2** to **section 30427** and amend to address the RTCC’s recommendation. “X-ray Bone Densitometry” terminology (found in the introductory paragraph and subsection (a)(3)) is changed to “DEXA” for consistency with industry and international usage, as recommended by the RTCC. The section is redesignated as section 30427, resulting in no regulatory effect.

Amend **section 30435**. Subsection (b) is amended for consistency with the redesignation of section 30427.2 to section 30427, resulting in no regulatory effect.

Amend **section 30442** to address the RTCC’s recommendation. “X-ray Bone Densitometry” terminology (subsection (g)) is changed to “DEXA” for consistency with industry and international usage, as recommended by the RTCC.

Amend **section 30443** to address the RTCC’s recommendation. “X-ray Bone Densitometry” terminology (subsection (g)) is changed to “DEXA,” and the phrase “or body” is added for consistency with this proposal and with industry and international usage, as recommended by the RTCC.

Amend **section 30447** to address the RTCC’s recommendation. “X-ray Bone Densitometry” terminology (subsection (b)) is changed to “DEXA” for consistency with this proposal and with industry and international usage, as recommended by the RTCC.

Amend **section 30461** to address the RTCC’s recommendations and to make nonsubstantial corrections.

MANDATED BY FEDERAL LAW OR REGULATIONS

None

FORMS INCORPORATED BY REFERENCE

None.

OTHER STATUTORY REQUIREMENTS

None.

BUSINESS REPORTING REQUIREMENT

None.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

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. Thus, there will be no significant adverse economic impact on California businesses.

FISCAL IMPACT ASSESSMENT

- A. Mandate on local agencies and school districts: None

- B. Cost or savings to any state agency: None

- C. Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None

- D. Cost or savings in federal funding to the state: None

- E. Impact on private persons or businesses directly affected: None

- F. Other nondiscretionary cost or savings imposed on local agencies: None

STATEMENTS OF DETERMINATIONS and ECONOMIC IMPACT ASSESSMENT

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulation 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.

The Department has determined that the regulations affect the following as described:

1. **The creation or elimination of jobs within the State of California.** Because this proposal clarifies the limited permit scope of practice for the DEXA, as

- proposed, permit category, it may create new job opportunities for existing and future permit holders.
2. **The creation of new businesses or the elimination of existing businesses within the State of California.** Though new businesses may be created to offer DEXA services due to expansion of an individual's DEXA permit scope, no significant effect is expected, due to the limited nature of such services. Elimination of existing businesses is not expected since the individual's permit scope would expand instead of diminish.
 3. **The expansion of businesses currently doing business within the State of California.** Though businesses may be able to offer additional services with existing staff, in that an individual's permit scope expands, no significant effect is expected.
 4. **The benefits of the regulation to the health and welfare of California residents, and increases worker safety.** This proposal provides benefits to the health and welfare of California residents and increases worker safety, because it ensures only qualified individuals perform WBC procedures. This proposal would not significantly affect the state's environment, because the radiation energy emitted from the use of X-ray equipment dissipates to normal atomic structures without environmental contamination.

EFFECT OF HOUSING

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

EFFECT ON SMALL BUSINESS

The Department has determined that there would be an effect on small businesses because they will be legally required to comply with the regulation. If the small business fails to comply with the regulation, the small business may incur a detriment in the form of a civil penalty. Under the proposed regulations, however, small businesses are expected to have a larger pool of individuals that can perform WBC procedures. This will likely allow for greater compliance by small businesses and may decrease violations and thus civil penalties assessed.

Consideration of Reasonable Alternatives

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, or would be as effective and less burdensome to affected private persons than the proposed regulatory action, or would be more cost-effective to affected private persons and equally effective in addressing the RTCC's recommendations.

Documents Relied Upon (References)

1. RTCC meeting minutes of October 23, 2013.
2. Handout for RTCC April 2, 2014 meeting.

3. National Health and Nutrition Examination Survey, Centers for Disease Control and Prevention:
 - a. Plan and Operations, 1999-2010, August 2013; Accessed November 8, 2017: http://www.cdc.gov/nchs/data/series/sr_01/sr01_056.pdf
 - b. Technical Documentation for the 1999-2004 Dual Energy X-ray Absorptiometry (DXA) Multiple Imputation Data Files, February 2008; Accessed November 8, 2017: https://wwwn.cdc.gov/nchs/data/nhanes/dxa/dxa_techdoc.pdf
 - c. Body Composition Procedures Manual, December 2000; Accessed November 8, 2017: <http://www.cdc.gov/nchs/data/nhanes/bc.pdf>
4. International Atomic Energy Agency, Dual Energy X Ray Absorptiometry for Bone Mineral Density and Body Composition Assessment, IAEA Human Health Series No. 15; 2010. Accessed November 8, 2017: http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1479_web.pdf

CONTACT PERSON

Inquiries regarding the subject matter in this notice may be directed to Phillip Scott of the Department's Radiologic Health Branch, at (916) 440-7978. Inquiries regarding the regulatory process described in this notice should be directed to Dawn Basciano, Office of Regulations, at (916) 440-7367, or to the designated backup contact person, Linda Cortez (916) 440-7807.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS

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 order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7367 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the 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.

FINAL STATEMENT OF REASONS

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed here: www.cdph.ca.gov.