Assembly Bill No. 830

CHAPTER 479

An act to amend Sections 1367.21 and 1370.4 of the Health and Safety Code, to amend Sections 10123.195 and 10145.3 of the Insurance Code, and to amend Sections 14105.43 and 14133.2 of the Welfare and Institutions Code, relating to drugs and devices.

[Approved by Governor October 11, 2009. Filed with Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 830, Cook. Drugs and devices.

Existing law references various drug compendiums and compendia, including the United States Pharmacopoeia, for purposes of the Knox-Keene Health Care Service Plan Act of 1975, disability insurance, and for Medi-Cal.

This bill would revise these references to include references to a specified compendia, if recognized by the federal Centers for Medicare and Medicaid Services, as specified, or with respect to Medi-Cal, a compendia that is listed in a specified federal Medicaid provision of the federal Social Security Act.

The people of the State of California do enact as follows:

SECTION 1. Section 1367.21 of the Health and Safety Code is amended to read:

1367.21. (a) No health care service plan contract which covers prescription drug benefits shall be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) (A) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition; or

(B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

(g) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(h) If a plan denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under Section 1370.4.

(i) Health care service plan contracts for the delivery of Medi-Cal services under the Waxman-Duffy Prepaid Health Plan Act (Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code) are exempt from the requirements of this section.

SEC. 2. Section 1370.4 of the Health and Safety Code is amended to read:

1370.4. (a) Every health care service plan shall provide an external, independent review process to examine the plan's coverage decisions

regarding experimental or investigational therapies for individual enrollees who meet all of the following criteria:

(1) (A) The enrollee has a life-threatening or seriously debilitating condition.

(B) For purposes of this section, "life-threatening" means either or both of the following:

(i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.

(2) The enrollee's physician certifies that the enrollee has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the enrollee, for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to paragraph (3).

(3) Either (A) the enrollee's physician, who is under contract with or employed by the plan, has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or (B) the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the plan to pay for the services of a nonparticipating physician provided pursuant to this subdivision, that are not otherwise covered pursuant to the plan contact.

(4) The enrollee has been denied coverage by the plan for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3).

(5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service, except for the plan's determination that the therapy is experimental or investigational.

(b) The plan's decision to delay, deny, or modify experimental or investigational therapies shall be subject to the independent medical review process under Article 5.55 (commencing with Section 1374.30) except that, in lieu of the information specified in subdivision (b) of Section 1374.33, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:

(1) The plan shall notify eligible enrollees in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 1374.33.

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by the plan, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the plan contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database of Health Services Technology Assessment Research (HSTAR).

(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

(4) Either of the following reference compendia:

(A) The American Hospital Formulary Service's Drug Information.

(B) The American Dental Association Accepted Dental Therapeutics.

(5) Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(A) The Elsevier Gold Standard's Clinical Pharmacology.

(B) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(C) The Thomson Micromedex DrugDex.

(6) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(7) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

SEC. 3. Section 10123.195 of the Insurance Code is amended to read:

10123.195. (a) No group or individual disability insurance policy issued, delivered, or renewed in this state or certificate of group disability insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state that, as a provision of hospital, medical, or surgical services, directly or indirectly covers prescription drugs shall limit or exclude coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) (A) The drug is prescribed by a contracting licensed health care professional for the treatment of a life-threatening condition; or

(B) The drug is prescribed by a contracting licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the insurer's formulary, if any.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of subdivision (a), if requested by the insurer.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the insurer.

(g) This section shall not apply to a policy of disability insurance that covers hospital, medical, or surgical expenses which is issued outside of California to an employer whose principal place of business is located outside of California.

(h) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(i) If an insurer denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under the Independent Medical Review System of Article 3.5 (commencing with Section 10169).

(j) This section is not applicable to vision-only, dental-only, Medicare or Champus supplement, disability income, long-term care, accident-only, specified disease or hospital confinement indemnity insurance.

SEC. 4. Section 10145.3 of the Insurance Code is amended to read:

10145.3. (a) Every disability insurer that covers hospital, medical, or surgical benefits shall provide an external, independent review process to examine the insurer's coverage decisions regarding experimental or investigational therapies for individual insureds who meet all of the following criteria:

(1) (A) The insured has a life-threatening or seriously debilitating condition.

(B) For purposes of this section, "life-threatening" means either or both of the following:

(i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.

(2) The insured's physician certifies that the insured has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the insured, for which standard therapies would not be medically appropriate for the insured, or for which there is no more beneficial standard therapy covered by the insurer than the therapy proposed pursuant to paragraph (3).

(3) Either (A) the insured's contracting physician has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the insured than any available standard therapies, or (B) the insured, or the insured's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the insured than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the insurer to pay for the services of a noncontracting physician, provided pursuant to this subdivision, that are not otherwise covered pursuant to the contract.

(4) The insured has been denied coverage by the insurer for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3), unless coverage for the specific therapy has been excluded by the insurer's contract.

(5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service except for the insurer's determination that the therapy is experimental or under investigation.

(b) The insurer's decision to deny, delay, or modify experimental or investigational therapies shall be subject to the independent medical review process established under Article 3.5 (commencing with Section 10169) of Chapter 1 of Part 2 of Division 2, except that in lieu of the information specified in subdivision (b) of Section 10169.3, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:

(1) The insurer shall notify eligible insureds in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the insured's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in

addition to any otherwise applicable timeframes contained in subdivision (c) of Section 10169.3.

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the insured than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be covered by the insurer, citing the insured's specific medical condition, the relevant documents, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(2) Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS database of Health Services Technology Assessment Research (HSTAR).

(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

(4) Either of the following reference compendia:

(A) The American Hospital Formulary Service's Drug Information.

(B) The American Dental Association Accepted Dental Therapeutics.

(5) Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(A) The Elsevier Gold Standard's Clinical Pharmacology.

(B) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(C) The Thomson Micromedex DrugDex.

(6) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(7) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

SEC. 5. Section 14105.43 of the Welfare and Institutions Code is amended to read:

14105.43. (a) (1) Notwithstanding other provisions of this chapter, any drug which is approved by the federal Food and Drug Administration for use in the treatment of acquired immunodeficiency syndrome (AIDS) or an AIDS-related condition shall be deemed to be approved for addition to the Medi-Cal list of contract drugs only for the purpose of treating AIDS or an AIDS-related condition, for the period prior to the completion of the procedures established pursuant to Section 14105.33.

(2) In addition to any drug that is deemed to be approved pursuant to paragraph (1), any drug that meets any of the following criteria shall be a Medi-Cal benefit, subject to utilization controls:

(A) Any vaccine to protect against human immunodeficiency virus (HIV) infection.

(B) Any antiviral agent, immune modulator, or other agent to be administered to persons who have been infected with human immunodeficiency virus to counteract the effects of that infection.

(C) Any drug or biologic used to treat opportunistic infections associated with acquired immune deficiency syndrome, that have been found to be medically accepted indications and that has either been approved by the federal Food and Drug Administration or recognized for that use in a compendia listed in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8).

(D) Any drug or biologic used to treat the chemotherapy-induced suppression of the human immune system resulting from the treatment of acquired immune deficiency syndrome.

(3) The department shall add any drug deemed to be approved pursuant to paragraph (1) to the Medi-Cal list of contract drugs or allow the provision of the drug as a Medi-Cal benefit, subject to utilization controls, pursuant to paragraph (2), only if the manufacturer of the drug has executed a contract with the Centers for Medicare and Medicaid Services which provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code.

(b) Any drug deemed to be approved pursuant to paragraph (1) of subdivision (a) shall be immediately added to the Medi-Cal list of contract drugs, and shall be exempt from the contract requirements of Section 14105.33.

(c) If it is determined pursuant to subdivision (c) of Section 14105.39 that a drug to which subdivision (a) applies should not be placed on the Medi-Cal list of contract drugs, that drug shall no longer be deemed to be approved for addition to the list of contract drugs pursuant to subdivision (a).

SEC. 6. Section 14133.2 of the Welfare and Institutions Code is amended to read:

14133.2. (a) The director shall include in the Medi-Cal list of contract drugs any drug approved for the treatment of cancer by the federal Food and Drug Administration, so long as the manufacturer has executed a contract with the Health Care Financing Administration which provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code. These drugs shall be exempt from the contract requirements of Section 14105.33.

(b) In addition to any drug added to the list of contract drugs pursuant to subdivision (a), any drug that meets either of the following criteria and for which the manufacturer has executed a contract with the Health Care Financing Administration that provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code, shall be a Medi-Cal benefit, subject to utilization controls, unless the contract requirements of Section 14105.33 have been complied with:

(1) Any drug approved by the federal Food and Drug Administration for treatment of opportunistic infections associated with cancer.

(2) Any drug or biologic used in an anticancer chemotherapeutic regimen for a medically accepted indication, which has either been approved by the federal Food and Drug Administration, or recognized for that use in a compendia listed in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8).

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