AMENDED IN ASSEMBLY JANUARY 5, 2016 AMENDED IN ASSEMBLY MAY 4, 2015 AMENDED IN ASSEMBLY MARCH 16, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 73

Introduced by Assembly Member Waldron

December 18, 2014

An act to add Section 14133.06 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, as amended, Waldron. Prescriber Prevails Act. Patient Access to Prescribed Antiretroviral Drugs for HIV/AIDS Treatment Act.

Existing law establishes the Medi-Cal program, administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Existing law specifies the benefits provided pursuant to the program, including the purchase of prescribed drugs that are covered subject to utilization controls. Utilization controls include a requirement that the treatment provider obtain prior authorization for providing medical treatment, as specified.

This—bill would, bill, to the extent permitted by federal law, would provide that—drugs in specified therapeutic drug classes that are prescribed by a Medi-Cal beneficiary's treating provider are covered Medi-Cal benefits. The bill would require, except as specified, that a Medi-Cal managed care plan cover the drug if the treating provider demonstrates that the drug is medically necessary, not on the Medi-Cal

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managed care plan formulary, and consistent with federal rules and regulations for labeling and use, under which circumstances if medically necessary antiretroviral drugs used in the treatment of HIV/AIDS is prescribed by a Medi-Cal beneficiary's treating provider for that purpose, and coverage for that prescribed drug is denied by a Medi-Cal managed care plan in which the beneficiary is enrolled, that denial shall be reviewed in accordance with the bill. This bill would provide that if the treating provider demonstrates, consistent with federal law, that in his or her reasonable, professional judgment, the drug is medically necessary and consistent with the federal Food and Drug Administration's labeling and use rules and regulations, as specified, the beneficiary would be entitled to an automatic urgent appeal, as defined.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

- SECTION 1. This act shall be known, and may be cited as, the Prescriber Prevails Patient Access to Prescribed Antiretroviral Drugs for HIV/AIDS Treatment Act.
- 4 SEC. 2. Section 14133.06 is added to the Welfare and 5 Institutions Code, to read:
- 14133.06. (a) It is the intent of the Legislature in enacting this section that a Medi-Cal beneficiary shall have prompt access to medically necessary drugs for use in the treatment of the conditions specified in this section and that have been approved by the federal Food and Drug Administration for the treatment of those conditions, including drugs that are not on the formulary of the
- 12 Medi-Cal managed care plan or that are subject to prior 13 authorization. 14 (b) To the extent permitted by federal law, if a drug in any of
- (b) To the extent permitted by federal law, if a drug in any of
 the following therapeutic drug classes is prescribed by a Medi-Cal
 beneficiary's treating provider, that drug shall be covered under
 the Medi-Cal program:
- 18 (1) Antiretroviral drugs for HIV/AIDS.
- 19 (2) Antipsychotics.
- 20 (3) Antirejection drugs.
- 21 (4) Drugs used to treat seizures or epilepsy.

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(e) (1) A drug is covered pursuant to this section if the treating provider demonstrates, consistent with federal law, that in his or her reasonable, professional judgment, the drug is medically necessary and consistent with the federal Food and Drug Administration's labeling and use rules and regulations, as supported in at least one of the official compendia, as defined in Section 1927(g)(1)(B)(i) of the federal Social Security Act (42 U.S.C. Sec. 1396r-8(g)(1)(B)(i)), and the drug is not on the formulary for the Medi-Cal managed care plan.

- (2) In a case in which a plan denies coverage for a drug prescribed under this section, the beneficiary shall be entitled to an automatic urgent appeal. For purposes of this paragraph, "automatic urgent appeal" means an appeal in which the plan immediately notifies the department of the denial of coverage, and the beneficiary is not required to take any further action. An automatic urgent appeal shall be resolved within 48 hours after denial by the plan. The 48-hour period specified in this paragraph shall be in addition to any time prescribed by federal law.
- (3) Medi-Cal managed care plans shall continue to develop formularies and may also administer prior authorization programs for the drugs specified in subdivision (b). Providers prescribing those drugs may be required to provide the plans with requested information or clinical documentation to support prior authorization requests. The plans may continue to provide a temporary three-day supply of medication when medically necessary.
- (4) Consistent with federal law, if a Medi-Cal managed care plan is unable to complete a prior authorization due to missing information or because the prescriber's reasonable, professional judgment has not been adequately demonstrated, as required under this subdivision, the plan shall issue a notice of action to the provider and the beneficiary. The plan shall include in the notice of action a description of the information that is required from the provider or the beneficiary in order for the plan to complete the authorization, and the beneficiary's rights regarding appeal and fair hearing options, and independent review by the Department of Managed Health Care.
- SEC. 2. Section 14133.06 is added to the Welfare and Institutions Code, to read:
- 14133.06. (a) It is the intent of the Legislature in enacting this section that a Medi-Cal beneficiary shall have prompt access to

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medically necessary antiretroviral drugs for use in the treatment of HIV/AIDS that have been approved by the federal Food and Drug Administration for that purpose, including drugs that are not on the formulary of a Medi-Cal managed care plan or that are subject to prior authorization.

- (b) To the extent permitted by federal law, if a drug used in the treatment of HIV/AIDS as described in subdivision (a) is prescribed by a Medi-Cal beneficiary's treating provider for the treatment of HIV/AIDS, and coverage for that prescribed drug is denied by a Medi-Cal managed care plan in which the beneficiary is enrolled, that denial shall be reviewed in accordance with this section.
- (c) (1) The denial by a Medi-Cal managed care plan of a drug prescribed for the treatment of HIV/AIDS and approved by the federal Food and Drug Administration for use in the treatment of HIV/AIDS is subject to the urgent appeal process described in paragraph (2) if the treating provider demonstrates, consistent with federal law, that in his or her reasonable, professional judgment, the drug is medically necessary and consistent with the federal Food and Drug Administration's labeling and use rules and regulations, as supported in at least one of the official compendia identified in Section 1927(g)(1)(B)(i) of the federal Social Security Act (42 U.S.C. Sec. 1396r-8(g)(1)(B)(i)), and the drug is not on the formulary for the Medi-Cal managed care plan.
- (2) In a case in which a plan denies coverage for a drug prescribed for the treatment of HIV/AIDS and approved by the federal Food and Drug Administration for use in the treatment of HIV/AIDS, the beneficiary shall be entitled to an urgent appeal in accordance with paragraph (1). For purposes of this section, "urgent appeal" means an appeal in which the beneficiary, or treatment provider with the consent of the beneficiary, requests an appeal either orally or in writing. An urgent appeal shall be resolved by the plan within 24 hours after the plan receives the request. The 24-hour period specified in this paragraph shall be in addition to any time prescribed by federal law.