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RN 18 02014 PAGE 1

An act to amend and repeal Section 14105.46 of, and to add Section 14105.465 to, the Welfare and Institutions Code, relating to Medi-Cal.



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## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 14105.46 of the Welfare and Institutions Code is amended to read:

14105.46. (a) For purposes of this section:

(1) "Covered entity" means a provider defined as a covered entity in Section 256b of Title 42 of the United States Code.

(2) "340B" means the discount drug purchasing program described in Section 256b of Title 42 of the United States Code.

(b) A covered entity shall dispense only 340B drugs to Medi-Cal beneficiaries.

(c) If a covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary. If a covered entity dispenses a drug purchased at regular drug wholesale rates pursuant to this subdivision, the covered entity is required to maintain documentation of their inability to obtain the 340B drug.

(d) A covered entity shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01.

(e) A covered entity shall identify a 340B drug on the claim submitted to the Medi-Cal program for reimbursement.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(g) This section shall become inoperative upon the effective date specified in a written notification by the director to the applicable fiscal and policy committees of the Legislature that all applicable federal approvals have been obtained to implement Section 14105.465. The department shall post the director's notification on its Internet Web site. This section shall be repealed 90 days following the effective date specified in the notification provided pursuant to this subdivision.

SEC. 2. Section 14105.465 is added to the Welfare and Institutions Code, to read:

14105.465. (a) (1) "Covered entity" means a provider defined as a covered entity in Section 256b of Title 42 of the United States Code.

(2) "340B Program" means the discount drug purchasing program described in Section 256b of Title 42 of the United States Code.

(b) Notwithstanding any other law and in accordance with subdivision (h), the department shall seek federal approval to prohibit any covered entity from dispensing or administering any drug to any Medi-Cal beneficiary or other individual in any other program eligible for federal drug rebates pursuant to Section 1396r-8 of Title 42 of the United States Code that the covered entity purchased through the 340B Program.

(c) If the department determines that federal approval is not available under subdivision (b), the department shall instead seek federal approval for either or both of the following, notwithstanding any other law and in accordance with subdivision (h):



(1) To prohibit or otherwise limit the use of contract pharmacies by a covered entity participating in the Medi-Cal program, including, but not limited to, the fee-for-service and Medi-Cal managed care delivery systems.

(2) To prohibit or otherwise limit certain types of covered entities, as determined by the department, from dispensing or administering any specified covered drug to a Medi-Cal beneficiary that the applicable covered entity purchased through the 340B Program. Subject to any necessary federal approvals, the department may apply that prohibition or limitation to the entirety of the Medi-Cal program or to a segment thereof, including, but not limited to, the fee-for-service and Medi-Cal managed care delivery systems, and any other program eligible for federal drug rebates pursuant to Section 1396r-8 of Title 42 of the United States Code.

(d) A covered entity, limited pursuant to subdivision (b) or (c) as applicable, shall bill Medi-Cal its usual and customary charge.

(e) For covered entities that the department requires or allows to dispense or administer a drug purchased through the 340B Program, as applicable, the covered entity shall bill the following:

(1) Medi-Cal an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional dispensing fee, or other associated fees authorized in federal or state law and published in all-county letters, provider bulletins, or similar instructions.

(2) A managed care plan an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional dispensing fee, or other associated fees pursuant to a contract entered into between the covered entity and the Medi-Cal managed care plan.

(f) If a covered entity required to use 340B drugs pursuant to subdivision (e) is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary. If a covered entity dispenses a drug purchased at regular drug wholesale rates pursuant to this subdivision, the covered entity is required to maintain documentation of its inability to obtain the 340B drug, in the form and manner specified by the department.

(g) A covered entity shall identify a 340B drug on the claim submitted to the Medi-Cal program or to a managed care plan for reimbursement, in the form and manner specified by the department.

(h) (1) The department shall seek any necessary federal approvals, as applicable, to implement this section.

(2) This section shall not be implemented until the applicable necessary federal approvals are obtained. If, and only to the extent, federal approval is obtained to implement either subdivision (b) or (c), as applicable, the department shall implement either subdivision on a prospective basis according to the effective date identified in the applicable federal approval obtained. The department shall seek an effective date for dates of service commencing at least 90 days from the date the applicable federal approval is obtained, but no sooner than January 1, 2019.

(3) This section shall be implemented only to the extent that any necessary federal approvals are obtained and federal financial participation is available and is not otherwise jeopardized.



(i) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2023, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

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## LEGISLATIVE COUNSEL'S DIGEST

Bill No.  
as introduced, \_\_\_\_\_.  
General Subject: Discount drug purchasing program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services and 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 federal law, known as the 340B discount drug purchasing program, generally requires pharmaceutical manufacturers participating in Medicaid to give discounts on pharmaceutical drugs to covered entities serving the Medicaid population.

The Medi-Cal program requires a covered entity to dispense a drug purchased through the 340B program only to a Medi-Cal beneficiary. If a covered entity is unable to purchase a drug for a Medi-Cal beneficiary through the 340B program, the covered entity may dispense a drug purchased at a regular drug wholesale rate, but existing law limits the amount the covered entity may charge the Medi-Cal program for reimbursement of the purchase of the drug. Existing federal law prohibits a covered entity from requesting payment pursuant to the 340B program with respect to a drug that is subject to payment of a rebate from a pharmaceutical manufacturer to the state.

This bill would require the department to seek federal authorization to prohibit a covered entity from dispensing a drug purchased through the 340B program to a Medi-Cal beneficiary or other individual participating in another program that is eligible for federal drug rebates. If the department determines that this federal approval is not available, the bill would require the department to instead seek federal approval to limit the use of contract pharmacies by covered entities, as specified, or to authorize the department to limit the types of drugs purchased through the 340B program that covered entities may dispense to Medi-Cal beneficiaries, or both. Upon receiving a type of federal approval, the bill would require a covered entity to seek reimbursement from the Medi-Cal program in a modified process, as specified.

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

