An act to amend Sections 14105.31 and 14134 of, to amend and repeal Section 14133.22 of, and to add Section 14105.334 to, the Welfare and Institutions Code, relating to Medi-Cal.
THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 14105.31 of the Welfare and Institutions Code is amended to read:

14105.31. For purposes of the Medi-Cal contract drug list, the following definitions shall apply:

(a) “Single-source drug” means a drug that is produced and distributed under an original New Drug Application approved by the federal Food and Drug Administration. This shall include a drug marketed by the innovator manufacturer and any cross-licensed producers or distributors operating under the New Drug Application, and shall also include a biological product, except for vaccines, marketed by the innovator manufacturer and any cross-licensed producers or distributors licensed by the federal Food and Drug Administration pursuant to Section 262 of Title 42 of the United States Code. A drug ceases to be a single-source drug when the same drug in the same dosage form and strength manufactured by another manufacturer is approved by the federal Food and Drug Administration under the provisions for an Abbreviated New Drug Application.

(b) “Best price” means the negotiated price, or the manufacturer’s lowest price available to any foreign or domestic class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities within the United States, entities, that contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits, shall be based upon the manufacturer’s commonly used retail package sizes for the drug sold by wholesalers to retail pharmacies.

(c) “Manufacturer” means any person, partnership, corporation, or other institution or entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, labeling, relabeling, and distribution of drugs.

(d) “Price escalator” means a mutually agreed-upon price specified in the contract, to cover anticipated cost increases over the life of the contract.

(e) “Medi-Cal pharmacy costs” or “Medi-Cal drug costs” means all reimbursements to pharmacy providers for services or merchandise, including single-source or multiple-source prescription drugs, over-the-counter medications, and medical supplies, or any other costs billed by pharmacy providers under the Medi-Cal program.

(f) “Medicaid rebate” means the rebate payment made by drug manufacturers pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8).

(g) “State rebate” means the amount negotiated between the manufacturer and the department for reimbursement by the manufacturer, as specified in the contract, in addition to the Medicaid rebate.

(h) “Date of mailing” means the date that is evidenced by the postmark date by the United States Postal Service or other common mail carrier on the envelope.

(i) The amendments made to this section by the act that added this subdivision shall be effective no sooner than January 1, 2021.
(j) This section shall be implemented only to the extent that any necessary federal approvals are obtained and federal financial participation is available.

SEC. 2. Section 14105.334 is added to the Welfare and Institutions Code, to read:

14105.334. (a) Notwithstanding any other law, upon approval of the Department of Finance, the department shall seek the necessary federal approvals to establish and administer a drug rebate program to collect rebate payments from drug manufacturers with respect to drugs furnished to selected populations of California residents that are ineligible for full-scope Medi-Cal benefits under this chapter.

(b) The department shall administer the drug rebate program for qualified non-Medi-Cal populations consistent with the applicable requirements and procedures of the federal Medicaid Drug Rebate Program implemented pursuant to Section 14105.33 and Section 1396r-8 of Title 42 of the United States Code.

(c) The department, in consultation with the Department of Finance, shall determine the non-Medi-Cal populations to be included in the drug rebate program administered pursuant to this section based on the level to which the department can demonstrate that their inclusion furthers the goals and objectives of the Medi-Cal program, increases the efficiency and economy of the Medi-Cal program, and sufficiently benefits the Medi-Cal population as a whole.

(d) The department shall seek any federal approvals from the federal Centers for Medicare and Medicaid Services, via submission of State Plan Amendments or other applicable mechanism, it deems necessary to implement this section. 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.

(e) 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, in whole or in part, by means of provider bulletins or other similar instructions, without taking regulatory action.

(f) For purposes of implementing this section, the department may enter into exclusive or nonexclusive contracts, or amend existing contracts, on a bid or negotiated basis with manufacturers of single-source and multiple-source drugs. Contracts entered into or amended pursuant to this section shall be exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, Section 19130 of the Government Code, Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, and the State Administrative Manual, and shall be exempt from the review or approval of any division of the Department of General Services. Contracts entered into or amended pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(g) Any rebate payments collected from manufacturers pursuant to this section shall be deposited in the Medi-Cal Drug Rebate Fund, created pursuant to Section 14105.36.

SEC. 3. Section 14133.22 of the Welfare and Institutions Code is amended to read:

14133.22. (a) Prescribed drugs shall be limited to no more than six per month, unless prior authorization is obtained.
(b) The limit in subdivision (a) shall not apply to patients receiving care in a
nursing facility.
(c) The limit in subdivision (a) shall not apply to drugs for family planning.
(d) The department may issue Medi-Cal cards that contain labels for prescribed
drugs to implement this section.
(e) In carrying out this section, the department may contract either directly, or
through the fiscal intermediary, for pharmacy consultant staff necessary to accomplish
the treatment authorization request reviews.
(f) This section shall become inoperative on January 1, 2021, and shall be repealed
on July 1, 2021, unless a later enacted statute, enacted before that date, deletes or
extends that date.

SEC. 4. Section 14134 of the Welfare and Institutions Code is amended to read:
14134. (a) Except for any prescription, refill, visit, service, device, or item for
which the program’s payment is ten dollars ($10) or less, in which case no copayment
shall be required, a recipient of services under this chapter shall be required to make
copayments not to exceed the maximum permitted under federal regulations or federal
waivers, as follows:

(1) Copayment of five dollars ($5) shall be made for nonemergency services
received in an emergency department or emergency room when the services do not
result in the treatment of an emergency medical condition or inpatient admittance. For
the purposes of this section, “nonemergency services” means services not required to,
as appropriate, medically screen, examine, evaluate, or stabilize an emergency medical
condition that manifests itself by acute symptoms of sufficient severity, including
severe pain, so that the absence of immediate medical attention could reasonably be
expected to result in any of the following:
(A) Placing the individual’s health, or, with respect to a pregnant woman, the health of the
woman or her pregnant individual or pregnant individual’s unborn child, in serious jeopardy.
(B) Serious impairment to bodily functions.
(C) Serious dysfunction of any bodily organ or part.
(2) Copayment of one dollar ($1) shall be made for each drug prescription or
refill.
(3) Copayment of one dollar ($1) shall be made for each visit for services under
subdivisions (a) and (h) of Section 14132.
(4) The copayment amounts set forth in paragraphs (1), (2), and (3) (1) and (2)
may be collected and retained, or waived by the provider.
(5) The department shall not reduce the reimbursement otherwise due to providers
as a result of the copayment. The copayment amounts shall be in addition to any
reimbursement otherwise due to the provider for services rendered under this program.
(6) This section does not apply to emergency services, family planning services,
or to any services received by any of the following:
(A) A child in AFDC-Foster Care, as defined in Section 11400.
(B) A person who is an inpatient in a health facility, as defined in Section 1250 of the Health and Safety Code.

(C) A person 18 years of age or under.

(D) A woman receiving perinatal care.

(7) Paragraph (2) does not apply to a person 65 years of age or over.

(8) A provider of service shall not deny care or services to an individual solely because of that person’s inability to copay under this section. However, an individual shall remain liable to the provider for any copayment amount owed.

(9) This section shall not apply to preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force provided by a physician or other licensed practitioner of the healing arts, or any approved adult vaccines and their administration recommended by the Advisory Committee on Immunization Practices. Pursuant to Section 1905(b) of the federal Social Security Act (42 U.S.C. Sec. 1396d(b)), these services shall be provided without any cost sharing by the beneficiary in order for the state to receive an increased federal medical assistance percentage for these services.

(b) The department shall seek any federal waivers necessary to implement this section. The provisions for which appropriate federal waivers cannot be obtained shall not be implemented, but provisions for which waivers are either obtained or found to be unnecessary shall be unaffected by the inability to obtain federal waivers for the other provisions.

(c) The director shall adopt regulations necessary to implement this section as emergency regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The adoption of the regulations shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. The director shall transmit these emergency regulations directly to the Secretary of State for filing and the regulations shall become effective immediately upon filing. Upon completion of the formal regulation adoption process and prior to the expiration of the 120 day duration period of emergency regulations, the director shall transmit directly to the Secretary of State for filing the adopted regulations, the rulemaking file, and the certification of compliance as required by subdivision (e) of Section 11346.1 of the Government Code.

(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code and subdivision (c), the department may implement, interpret, or make specific the amendments made to this section by the act that added this subdivision, in whole or in part, by means of policy letter, provider bulletin, or other similar instruction, without taking regulatory action.

(e) The amendments made to this section by the act that added this subdivision shall be effective no sooner than January 1, 2021.

(f) This section shall be implemented only to the extent any necessary federal approvals are obtained and federal financial participation is available.

SEC. 5. The Legislature finds and declares that Section 2 of this act, which adds Section 14105.334 to the Welfare and Institutions Code, imposes a limitation on the public’s right of access to the meetings of public bodies or the writings of public
officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to facilitate manufacturer participation and deliver affordable prescription drugs to low-income Californians, it is necessary to protect the confidentiality of trade secrets and pricing information.

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LEGISLATIVE COUNSEL’S DIGEST

Bill No. as introduced, ______.
General Subject: Medi-Cal: pharmacy.

(1) Existing law establishes the Medi-Cal program, administered by the State Department of Health Care Services and under which health care services are provided to qualified low-income persons pursuant to a schedule of benefits, which includes pharmacy benefits, through various health care delivery systems, including fee-for-service and managed care. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

Existing law authorizes the department to enter into contracts with drug manufacturers, based on the manufacturer’s best price for purposes of the Medi-Cal program, under which qualified low-income individuals receive health care services. Under existing law, “best price” is defined to mean the negotiated price, or the manufacturer’s lowest available price, to any specified entity within the United States.

This bill instead defines “best price” to mean the negotiated price for any specified entity, including entities both within and outside of the United States.

(2) Existing law authorizes the department, among other things, to enter into contracts with certain drug manufacturers that provide for state rebates for drugs covered under the Medi-Cal program. Under existing law, the department is entitled to various drug rebates, including federal rebates in accordance with certain conditions.

This bill authorizes the department, upon approval by the Department of Finance, to seek the necessary federal approvals to establish and administer a drug rebate program to collect rebate payments from drug manufacturers for drugs furnished to selected populations of California residents who are ineligible for full-scope Medi-Cal.

(3) Existing law limits prescribed drugs under the Medi-Cal program to not more than 6 drugs per month, unless prior authorization is obtained, and except under specified circumstances.

This bill repeals that provision.

(4) Existing law requires Medi-Cal beneficiaries to make set copayments for specified services, including a $1 copayment for a drug prescription or refill, and prohibits the department from reducing the provider reimbursement as a result of the copayment.

This bill would repeal the copayment requirement for a drug prescription or refill.

(5) Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.