#### AMENDED IN SENATE JUNE 6, 2011

CALIFORNIA LEGISLATURE-2011-12 REGULAR SESSION

# **ASSEMBLY BILL**

## No. 399

#### **Introduced by Assembly Member Bonnie Lowenthal**

February 14, 2011

An act to amend Section 5024.2 of the Penal Code, relating to corrections. An act to amend Sections 14105.192, 14105.45, and 14105.451 of the Welfare and Institutions Code, relating to Medi-Cal.

#### LEGISLATIVE COUNSEL'S DIGEST

AB 399, as amended, Bonnie Lowenthal. Corrections: offender pharmacies. Medi-Cal: pharmacy providers: drug reimbursement.

Existing law provides for the Medi-Cal program, which is 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 requires reimbursement to Medi-Cal pharmacy providers for drugs, as prescribed.

This bill would modify the way in which reimbursement to Medi-Cal pharmacy providers is calculated by, in part, authorizing the department to establish a new reimbursement methodology based on average acquisition cost. This bill would make other related changes.

Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that may incorporate specified features, including a statewide pharmacy administration system with direct authority and responsibility for program administration and oversight, and a multidisciplinary,

statewide Pharmacy and Therapeutics Committee with specified responsibilities.

This bill would, instead, require a comprehensive pharmacy services program to incorporate those specified features.

Existing law authorizes the department to operate and maintain a centralized pharmacy distribution center and states that the centralized pharmacy distribution center and institutional pharmacies should be licensed as pharmacies by the California State Board of Pharmacy and should meet all applicable regulations applying to a pharmacy.

This bill would, instead, require that the centralized pharmacy distribution center and institutional pharmacies be licensed as pharmacies by the California State Board of Pharmacy and meet all applicable regulations applying to a pharmacy.

Existing law states that the centralized pharmacy distribution center should maintain a system of quality control checks on each process used to package, label, and distribute medications, and that the department should ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable laws, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department's inmate patients.

This bill would, instead, require the centralized pharmacy distribution center to maintain a system of quality control checks on each process used to package, label, and distribute medications, and would require the department to ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable laws, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department's inmate patients.

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. Section 14105.192 of the Welfare and Institutions
 Code is amended to read:

3 14105.192. (a) The Legislature finds and declares the 4 following:

5 (1) Costs within the Medi-Cal program continue to grow due

6 to the rising cost of providing health care throughout the state and

also due to increases in enrollment, which are more pronounced
 during difficult economic times.

3 (2) In order to minimize the need for drastically cutting 4 enrollment standards or benefits during times of economic crisis,

5 it is crucial to find areas within the program where reimbursement

6 levels are higher than required under the standard provided in
7 Section 1902(a)(30)(A) of the federal Social Security Act and can

8 be reduced in accordance with federal law.

9 (3) The Medi-Cal program delivers its services and benefits to

10 Medi-Cal beneficiaries through a wide variety of health care

11 providers, some of which deliver care via managed care or other

12 contract models while others do so through fee-for-service 13 arrangements.

(4) The setting of rates within the Medi-Cal program is complex
and is subject to close supervision by the United States Department
of Health and Human Services.

(5) As the single state agency for Medicaid in California, the
department has unique expertise that can inform decisions that set
or adjust reimbursement methodologies and levels consistent with
the requirements of federal law.

21 (b) Therefore, it is the intent of the Legislature for the 22 department to analyze and identify where reimbursement levels 23 can be reduced consistent with the standard provided in Section 24 1902(a)(30)(A) of the federal Social Security Act and consistent 25 with federal and state law and policies, including any exemptions 26 contained in the provisions of the act that added this section, 27 provided that the reductions in reimbursement shall not exceed 10 28 percent on an aggregate basis for all providers, services and 29 products.

30 (c) Notwithstanding any other provision of law, the director 31 shall adjust provider payments, as specified in this section.

32 (d) (1) Except as otherwise provided in this section, payments
33 shall be reduced by 10 percent for Medi-Cal fee-for-service benefits
34 for dates of service on and after June 1, 2011.

35 (2) For managed health care plans that contract with the
36 department pursuant to this chapter or Chapter 8 (commencing
37 with Section 14200), except contracts with Senior Care Action
38 Network and AIDS Healthcare Foundation, payments shall be
39 reduced by the actuarial equivalent amount of the payment
40 reductions specified in this section pursuant to contract

amendments or change orders effective on July 1, 2011, or
 thereafter.
 (3) Payments shall be reduced by 10 percent for non-Medi-Cal

4 programs described in Article 6 (commencing with Section 124025)

4 programs described in Article 6 (commencing with Section 124023) 5 of Charten 2 of Part 2 of Division 106 of the Health and Safety

5 of Chapter 3 of Part 2 of Division 106 of the Health and Safety

6 Code, and Section 14105.18, for dates of service on and after June7 1, 2011. This paragraph shall not apply to inpatient hospital

8 services provided in a hospital that is paid under contract pursuant

9 to Article 2.6 (commencing with Section 14081).

10 (4) (A) Notwithstanding any other provision of law, the director

11 may adjust the payments specified in paragraphs (1) and (3) of

12 this subdivision with respect to one or more categories of Medi-Cal

13 providers, or for one or more products or services rendered, or any

14 combination thereof, so long as the resulting reductions to any

15 category of Medi-Cal providers, in the aggregate, total no more 16 than 10 percent.

(B) The adjustments authorized in subparagraph (A) shall be
 implemented only if the director determines that, for each affected
 product, service or provider category, the payments resulting from

20 the adjustment comply with subdivision (m).

21 (e) Notwithstanding any other provision of this section, 22 payments to hospitals that are not under contract with the State

23 Department of Health Care Services pursuant to Article 2.6

24 (commencing with Section 14081) for inpatient hospital services

25 provided to Medi-Cal beneficiaries and that are subject to Section

26 14166.245 shall be governed by that section.

(f) Notwithstanding any other provision of this section, thefollowing shall apply:

(1) Payments to providers that are paid pursuant to Article 3.8(commencing with Section 14126) shall be governed by that article.

31 (2) (A) Subject to subparagraph (B), for dates of service on and

32 after June 1, 2011, Medi-Cal reimbursement rates for intermediate

care facilities for the developmentally disabled licensed pursuantto subdivision (e), (g), or (h) of Section 1250 of the Health and

35 Safety Code, and facilities providing continuous skilled nursing

36 care to developmentally disabled individuals pursuant to the pilot

37 project established by Section 14132.20, as determined by the

38 applicable methodology for setting reimbursement rates for these

39 facilities, shall not exceed the reimbursement rates that were

40 applicable to providers in the 2008–09 rate year.

1 (B) (i) If Section 14105.07 is added to the Welfare and 2 Institutions Code during the 2011–12 Regular Session of the 3 Legislature, subparagraph (A) shall become inoperative.

4 (ii) If Section 14105.07 is added to the Welfare and Institutions 5 Code during the 2011–12 Regular Session of the Legislature, then 6 for dates of service on and after June 1, 2011, payments to intermediate care facilities for the developmentally disabled 7 8 licensed pursuant to subdivision (e), (g), or (h) of Section 1250 of 9 the Health and Safety Code, and facilities providing continuous 10 skilled nursing care to developmentally disabled individuals 11 pursuant to the pilot project established by Section 14132.20, shall 12 be governed by the applicable methodology for setting 13 reimbursement rates for these facilities and by Section 14105.07. 14 (g) The department may enter into contracts with a vendor for 15 the purposes of implementing this section on a bid or nonbid basis. 16 In order to achieve maximum cost savings, the Legislature declares 17 that an expedited process for contracts under this subdivision is 18 necessary. Therefore, contracts entered into to implement this 19 section and all contract amendments and change orders shall be exempt from Chapter 2 (commencing with Section 10290) of Part 20

21 2 Division 2 of the Public Contract Code.

(h) To the extent applicable, the services, facilities, and
payments listed in this subdivision shall be exempt from the
payment reductions specified in subdivision (d) as follows:

(1) Acute hospital inpatient services that are paid under contracts
pursuant to Article 2.6 (commencing with Section 14081).

(2) Federally qualified health center services, including those
facilities deemed to have federally qualified health center status
pursuant to a waiver pursuant to subsection (a) of Section 1115 of
the federal Social Security Act (42 U.S.C. Sec. 1315(a)).

31 (3) Rural health clinic services.

32 (4) Payments to facilities owned or operated by the State33 Department of Mental Health or the State Department of34 Developmental Services.

(5) Hospice services.

35

36 (6) Contract services, as designated by the director pursuant to37 subdivision (k).

38 (7) Payments to providers to the extent that the payments are

39 funded by means of a certified public expenditure or an

40 intergovernmental transfer pursuant to Section 433.51 of Title 42

1 of the Code of Federal Regulations. This paragraph shall apply to

2 payments described in paragraph (3) of subdivision (d) only to the

3 extent that they are also exempt from reduction pursuant to 4 subdivision (l).

5 (8) Services pursuant to local assistance contracts and

- 6 interagency agreements to the extent the funding is not included
- 7 in the funds appropriated to the department in the annual Budget8 Act.

9 (9) Breast and cervical cancer treatment provided pursuant to
10 Section 14007.71 and as described in paragraph (3) of subdivision
11 (a) of Section 14105.18 or Article 1.5 (commencing with Section
104160) of Chapter 2 of Part 1 of Division 103 of the Health and

13 Safety Code.

14 (10) The Family Planning, Access, Care, and Treatment (Family

15 PACT) Program pursuant to subdivision (aa) of Section 14132.

(i) Subject to the exception for services listed in subdivision(h), the payment reductions required by subdivision (d) shall apply

18 to the benefits rendered by any provider who may be authorized

19 to bill for the service, including, but not limited to, physicians,

20 podiatrists, nurse practitioners, certified nurse-midwives, nurse 21 anesthetists, and organized outpatient clinics.

(j) Notwithstanding any other provision of law, for dates of service on and after June 1, 2011, Medi-Cal reimbursement rates applicable to the following classes of providers shall not exceed the reimbursement rates that were applicable to those classes of providers in the 2008–09 rate year, as described in subdivision (f)

27 of Section-14105.91 14105.191, reduced by 10 percent:

28 (1) Intermediate care facilities, excluding those facilities 29 identified in paragraph (2) of subdivision (f). For purposes of this

identified in paragraph (2) of subdivision (f). For purposes of thissection, "intermediate care facility" has the same meaning as

SU section, intermediate care facility has the same meaning as

31 defined in Section 51118 of Title 22 of the California Code of 32 Regulations.

33 (2) Skilled nursing facilities that are distinct parts of general

34 acute care hospitals. For purposes of this section, "distinct part"

35 has the same meaning as defined in Section 72041 of Title 22 of

36 the California Code of Regulations.

37 (3) Rural swing-bed facilities.

38 (4) Subacute care units that are, or are parts of, distinct parts of

39 general acute care hospitals. For purposes of this subparagraph,

"subacute care unit" has the same meaning as defined in Section
 51215.5 of Title 22 of the California Code of Regulations.

3 (5) Pediatric subacute care units that are, or are parts of, distinct 4 parts of general acute care hospitals. For purposes of this 5 subparagraph, "pediatric subacute care unit" has the same meaning 6 as defined in Section 51215.8 of Title 22 of the California Code 7 of Regulations.

8 (6) Adult day health care centers.

9 (7) Freestanding pediatric subacute care units, as defined in
10 Section 51215.8 of Title 22 of the California Code of Regulations.
11 (k) 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 and administer this section by
means of provider bulletins, or similar instructions, without taking

15 regulatory action.

16 (*l*) The reductions described in this section shall apply only to

17 payments for services when the General Fund share of the payment

18 is paid with funds directly appropriated to the department in the

19 annual Budget Act and shall not apply to payments for services

20 paid with funds appropriated to other departments or agencies.

(m) Notwithstanding any other provision of this section, the payment reductions and adjustments provided for in subdivision (d) shall be implemented only if the director determines that the payments that result from the application of this section will comply with applicable federal Medicaid requirements and that federal financial participation will be available.

(1) In determining whether federal financial participation is
available, the director shall determine whether the payments
comply with applicable federal Medicaid requirements, including
those set forth in Section 1396a(a)(30)(A) of Title 42 of the United
States Code.

32 (2) To the extent that the director determines that the payments 33 do not comply with the federal Medicaid requirements or that 34 federal financial participation is not available with respect to any 35 payment that is reduced pursuant to this section, the director retains 36 the discretion to not implement the particular payment reduction 37 or adjustment and may adjust the payment as necessary to comply

38 with federal Medicaid requirements.

39 (n) The department shall seek any necessary federal approvals40 for the implementation of this section.

1 (o) This section shall not be implemented until federal approval 2 is obtained. When federal approval is obtained, the payments 3 resulting from the application of subdivision (d) shall be 4 implemented retroactively to June 1, 2011, or on such other date 5 or dates as may be applicable.

(p) Adjustments to pharmacy drug product reimbursement 6 7 pursuant to this section shall no longer apply when the department 8 determines that the average acquisition cost methodology has been

9 fully implemented pursuant to Section 14105.45.

10 SEC. 2. Section 14105.45 of the Welfare and Institutions Code is amended to read: 11

14105.45. (a) For purposes of this section, the following 12 13 definitions shall apply:

(1) "Average manufacturers price" means the price reported to 14 15 the department by the Centers for Medicare and Medicaid Services

pursuant to Section 1927 of the Social Security Act (42 U.S.C. 16

17 Sec. 1396r-8). In the event an average manufacturer's price is not

available, the department shall use the direct price as the average 18 19 manufacturer's price.

(1) "Average acquisition cost" or "AAC" means the cost or 20

21 basis for reimbursement to pharmacy providers for drug products.

22 The AAC shall be the average of the invoice costs paid by

individual pharmacies to wholesalers, manufacturers, or 23 24

distribution centers for individual drug products based on the 25 11-digit National Drug Code (NDC) number.

(2) "Average wholesale price" or "AWP" means the price for 26 27 a drug product listed as the average wholesale price in the 28 department's primary price reference source.

29 (3) "Direct price" means the price for a drug product purchased 30 by a pharmacy directly from a drug manufacturer listed in the

31 department's primary reference source.

32 (4) "Estimated acquisition cost" means the department's best 33 estimate of the price generally and currently paid by providers for 34 a drug product sold by a particular manufacturer or principal labeler

35 in a standard package.

(3) "Estimated acquisition cost" or "EAC" means the AAC of 36 37 the drug or, in cases where no AAC is available, the wholesale 38 acquisition cost plus not less than 3 percent.

39 (5) 1 (4) "Federal upper limit" or "FUL" means the maximum per 2 unit reimbursement when established by the Centers for Medicare

3 and Medicaid Services and published by the department in

- 4 Medi-Cal pharmacy provider bulletins and manuals.
- 5 (6)

6 (5) "Generically equivalent drugs" means drug products with 7 the same active chemical ingredients of the same strength, quantity, 8 and dosage form, and of the same generic drug name, as determined 9 by the United States Adopted Names (USAN) and accepted by the 10 federal Food and Drug Administration (FDA), as-those drug 11 products having the same chemical ingredients therapeutically 12 equivalent in the FDA Approved Drug Products with Therapeutic 13 Equivalent Evaluations (the Orange Book). 14 (7)

(6) "Legend drug" means any drug whose labeling states
"Caution: Federal law prohibits dispensing without prescription,"
"Rx only," or words of similar import.

18 (8) "Maximum allowable ingredient cost" (MAIC) means the

maximum amount the department will reimburse Medi-Cal
 pharmacy providers for generically equivalent drugs.

21 (9)

(7) "Innovator multiple source drug," "noninnovator multiple
source drug," and "single source drug" have the same meaning as
those terms are defined in Section 1396r-8(k)(7) of Title 42 of the

25 United States Code.

26 (10)

27 (8) "Nonlegend drug" means any drug whose labeling does not 28 contain the statement referenced in paragraph (7) (6).

29 (11) "Selling price" means the price used in the establishment

30 of the estimated acquisition cost. The department shall base the

31 selling price on the average manufacturer's price plus a percent

32 markup determined by the department to be necessary for the

33 selling price to represent the average purchase price paid by retail

34 pharmacies in California. The selling price shall not be considered

35 confidential and shall be subject to disclosure under the California

36 Public Records Act (Chapter 3.5 (commencing with Section 6250)

37 of Division 7 of Title 1 of the Government Code).

38 (12) "Volume weighted average" means the aggregated average

39 volume for generically equivalent drugs, weighted by each drug's

40 percentage of the total volume in the Medi-Cal fee-for-service

1 program during the previous six months. For purposes of this

2 paragraph, volume is based on the standard billing unit used for
 3 the generically equivalent drugs.

4 (9) "Pharmacy warehouse" means a physical location licensed

5 as a wholesaler for prescription drugs that acts as a central
6 warehouse and performs intracompany sales or transfers of those
7 drugs to a group of pharmacies under common ownership and

8 control.

9 (10) "Specialty pharmacy drug" means a drug that generally 10 requires special handling, complex dosing regimens, administration

11 by self-administration in the home or by a provider in the home,

- 12 clinic, or a practitioner's office, patient education, special 13 monitoring, or clinical support.
- 14 (11) "Wholesaler" means a drug wholesaler that is engaged in 15 wholesale distribution of prescription drugs to retail pharmacies

16 in California.

17 (13)

18 (12) "Wholesaler acquisition cost" or "WAC" means the price 19 for a drug product listed as the wholesaler acquisition cost in the

20 department's primary price reference source.

21 (b) (1) Reimbursement to Medi-Cal pharmacy providers for

legend and nonlegend drugs shall consist of the estimated
 acquisition cost of the drug plus a professional fee for dispensing.

24 The professional fee shall be seven dollars and twenty-five cents

25 (\$7.25) per dispensed prescription. The professional fee for legend

26 drugs dispensed to a beneficiary residing in a skilled nursing

27 facility or intermediate care facility shall be eight dollars (\$8) per

28 dispensed prescription. For purposes of this paragraph "skilled

29 nursing facility" and "intermediate care facility" shall have the

30 same meaning as defined in Division 5 (commencing with Section

31 70001) of Title 22 of the California Code of Regulations.

32 (2) The department shall establish the estimated acquisition cost
 33 of legend and nonlegend drugs as follows:

34 (A) For single source and innovator multiple source drugs, the

35 estimated acquisition cost shall be equal to the lowest of the 36 average wholesale price minus 17 percent, the selling price, the

50 average wholesale price minus 17 percent, the senting pr

37 federal upper limit, or the MAIC.

38 (B) For noninnovator multiple source drugs, the estimated

39 acquisition cost shall be equal to the lowest of the average

1 wholesale price minus 17 percent, the selling price, the federal 2 upper limit, or the MAIC. 3 (3) For purposes of paragraph (2), the department shall establish 4 a list of MAICs for generically equivalent drugs, which shall be 5 published in pharmacy provider bulletins and manuals. The 6 department shall establish a MAIC only when three or more 7 generically equivalent drugs are available for purchase and 8 dispensing by retail pharmacies in California. The department shall 9 update the list of MAICs and establish additional MAICs in 10 accordance with all of the following: 11 (A) The department shall base the MAIC on the mean of the 12 average manufacturer's price of drugs generically equivalent to 13 the particular innovator drug plus a percent markup determined 14 by the department to be necessary for the MAIC to represent the 15 average purchase price paid by retail pharmacies in California. 16 (B) If average manufacturer prices are unavailable, the 17 department shall establish the MAIC in either of the following 18 ways: 19 (i) Based on the volume weighted average of wholesaler 20 acquisition costs of drugs generically equivalent to the particular 21 innovator drug plus a percent markup determined by the department 22 to be necessary for the MAIC to represent the average purchase 23 price paid by retail pharmacies in California. 24 (ii) Pursuant to a contract with a vendor for the purpose of 25 surveying drug price information, collecting data, and calculating 26 a proposed MAIC. 27 (C) The department may enter into contracts with a vendor for 28 the purpose of this section on a bid or nonbid basis. In order to 29 achieve maximum cost savings, the Legislature declares that an 30 expedited process for contracts under this section is necessary. 31 Therefore, contracts entered into on a nonbid basis shall be exempt 32 from Chapter 2 (commencing with Section 10290) of Part 2 of 33 **Division 2 of the Public Contract Code.** 34 (D) The department shall update MAICs at least every three 35 months and notify Medi-Cal providers at least 30 days prior to the 36 effective date of a MAIC. 37 (E) The department shall establish a process for providers to 38 seek a change to a specific MAIC when the providers believe the 39 MAIC does not reflect current available market prices. If the 40 department determines a MAIC change is warranted, the

1	department may update a specific MAIC prior to notifying
2	providers.
3	(F) In determining the average purchase price, the department
4	shall consider the provider-related costs of the products that
5	include, but are not limited to, shipping, handling, storage, and
6	delivery. Costs of the provider that are included in the costs of the
7	dispensing shall not be used to determine the average purchase
8	price.
9	(c) The department shall update the Medi-Cal claims processing
10	system to reflect the selling price of drugs not later than 30 days
11	after receiving the average manufacturer's price.
12	(d) In order to maintain beneficiary access to prescription drug
13	services, no later than 30 days after the department initially
14	implements selling price as a component of estimated acquisition
15	cost, pursuant to paragraph (2) of subdivision (b), the department
16	shall make a one-time adjustment to the dispensing fees paid to
17	pharmacy providers in accordance with paragraph (1) of
18	subdivision (b). This change shall only be made if selling price
19	results in a lower aggregate drug reimbursement. Any increase in
20	dispensing fee made pursuant to this subdivision shall not exceed
21	the aggregate savings associated with the implementation of selling
22	price. At least 30-days prior to implementing the dispensing fee
23	increase, the department shall issue a copy of the department's
24	request for federal approval pursuant to subdivision (e), to the
25	chairperson in each house that considers appropriations and the
26	Chairperson of the Joint Legislative Budget Committee, or
27	whatever lesser time the Chairperson of the Joint Legislative
28	Budget Committee or his or her designee may determine.
29	(b) (1) Reimbursement to Medi-Cal pharmacy providers for
30	legend and nonlegend drugs shall not exceed the lowest of all of
31	the following:
32	(A) The FUL for certain multiple source drugs as established
33	and published by the federal Centers for Medicare and Medicaid
34	Services (CMS) plus a reasonable dispensing fee.
35	(B) The EAC for the drug plus a reasonable dispensing fee.
36	(C) The provider's usual and customary charge to the general
37	public for the drug.
20	(D) East los and made and damage that do not home a FIII

- 38 (D) For legend and nonlegend drugs that do not have a FUL,
  39 AAC, or WAC, the AWP minus \_\_\_\_\_ percent, plus a reasonable
  40 dispensing fee.

1 (2) (A) Until the department implements the average acquisition 2 cost methodology pursuant to paragraph (3) and the reasonable 3 dispensing fee is established pursuant to subparagraph (B), retail 4 pharmacy providers shall be paid a professional fee of seven 5 dollars and twenty-five cents (\$7.25) per dispensed prescription. 6 The professional fee for legend drugs dispensed to a beneficiary 7 residing in a skilled nursing facility or intermediate care facility 8 shall be eight dollars (\$8) per dispensed prescription. For purposes 9 of this section, "skilled nursing facility" and "intermediate care 10 facility" shall have the same meaning as defined in Division 5 11 (commencing with Section 70001) of Title 22 of the California 12 Code of Regulations. 13 (B) When the AAC methodology is implemented pursuant to paragraph (3), the department shall pay pharmacy providers the 14 15 dispensing fee established pursuant to this subparagraph, including 16 payment to retail pharmacy providers of the annually adjusted 17 dispensing fee if the fee is greater than seven dollars and 18 twenty-five cents (\$7.25). The reasonable dispensing fee shall be 19 established as follows:

20 (i) At least 60 days prior to implementing the AAC methodology, 21 the department shall complete a cost-of-dispensing study and shall

22 make the results available to all retail pharmacy providers.

23 (ii) The retail pharmacy factors and elements used for the 24 cost-of-dispensing study to determine the dispensing fee shall be 25 agreed upon and negotiated with retail pharmacies.

26 (iii) The cost-of-dispensing study shall include a separate 27 determination of the cost of dispensing specialty drugs. The 28 department shall establish a separate reasonable dispensing fee 29 for dispensing specialty drugs.

30 (iv) The department shall begin paying retail pharmacy 31 providers the dispensing fee, including the dispensing fee for 32 specialty drugs determined by the cost-of-dispensing study, at the 33 time of implementation of the AAC methodology.

34 (v) The January after implementation of the AAC methodology, 35 and each January thereafter, the department shall conduct a cost 36 of dispensing study and pay retail pharmacy providers the 37 dispensing fee determined by the cost-of-dispensing study, or 38 alternatively, the department shall annually, on January 1 of each 39 year, adjust the dispensing fee based on the Bureau of Labor 40 Employment Cost Index (ECI).

1 (3) For the purposes of paragraph (1), the department may

2 establish the average acquisition cost for single source drugs,
3 innovator multiple source drugs, and noninnovator multiple source

4 drugs.

5 (A) The department may, at its discretion, establish average 6 acquisition cost in one of the following ways:

(i) Based on a national pricing benchmark obtained from the
federal Centers for Medicare and Medicaid Services or on a similar
benchmark listed in the department's primary price reference
source adjusted by the department to ensure that the average

11 acquisition price represents the average purchase price paid by12 retail pharmacies in California.

(ii) Based on the proposed average acquisition cost as
calculated by the vendor pursuant to a contract described in
paragraph (4).

16 (B) The average acquisition cost shall be the net cost to 17 individually enrolled retail pharmacy provider locations and shall 18 include additional costs included on the pharmacy providers' 19 invoices. In establishing the AAC, the department or the vendor

20 shall conduct a survey of enrolled pharmacies, or wholesalers

21 when applicable, at least every three months to collect drug

acquisition cost information including, but not limited to, pharmacyinvoices from individual retail pharmacy locations.

(i) Retail pharmacy warehouses shall not be required to submit
 pharmacy invoices.

(ii) At the time of survey, a retail pharmacy provider location
may be exempt from having to provide pharmacy invoices if the
information is not reasonably available or retrievable due to
circumstances outside the control of the retail pharmacy provider
location.

(iii) An individual retail pharmacy location surveyed pursuant
to this subparagraph shall have the option of having the department
collect the pharmacy invoices from its wholesale drug distributor.

(iv) Individual retail pharmacy locations may not be surveyed
 more than once every two years.

36 (v) Survey information, including pharmacy invoices, provided
37 to the department or a vendor pursuant to this section shall be

38 used solely for the purposes of establishing the average acquisition

39 cost pursuant to this section, shall be confidential, and shall be

40 exempt from disclosure under the California Public Records Act

1 (Chapter 3.5 (commencing with Section 6250) of Division 7 of

2 *Title 1 of the Government Code), and shall be destroyed within*3 *four months after the survey is completed.*

4 (C) Average acquisition costs established pursuant to this 5 paragraph shall be implemented for payment to retail pharmacy 6 providers not more than 10 business days after completion of the 7 survey.

8 (4) For the purposes of paragraph (3), the department may 9 contract with a vendor for the purpose of surveying drug price 10 information, collecting data from individual retail pharmacy 11 locations, or their wholesalers if applicable, and calculating a 12 proposed average acquisition cost.

13 <del>(e)</del>

(c) The director shall implement this section in a manner that
is consistent with federal Medicaid law and regulations. The
director shall seek any necessary federal approvals for the
implementation of this section. This section shall be implemented
only to the extent that federal approval is obtained.

19 <del>(f)</del>

20 (d) Notwithstanding Chapter 3.5 (commencing with Section

21 11340) of Part 1 of Division 3 of Title 2 of the Government Code,

22 the department may take the actions specified in this section by

23 providing not less than 60 days prior notice to retail pharmacy

24 *providers* by means of a provider bulletin or notice, policy letter,

25 or other similar instructions, without taking regulatory action.

26 (g) The department shall issue a Medi-Cal pharmacy

reimbursement fact sheet to the chairperson of the committee in
 each house of the Legislature that considers appropriations no later

than March 1, 2008. The reimbursement fact sheet shall contain,

30 but not be limited to, available data and information regarding the

31 change in reimbursement due to the federal Deficit Reduction Act

32 of 2005 implementation of average manufacturer's price based

33 federal upper limits, the implementation of selling price, change

34 in the average wholesale price reported to the department by the

35 primary price reference source, change in pharmacy dispensing

36 fees, prescription drug volume trends, and the number of active

37 Medi-Cal pharmacy providers. The fact sheet shall also contain

38 general information and definitions regarding drug pricing

39 terminology and a description of pharmacy claims processing in

40 Medi-Cal.

1 (e) The department may enter into contracts with a vendor for 2 the purposes of implementing this section on a bid or nonbid basis. 3 In order to achieve maximum cost savings, the Legislature declares 4 that an expedited process for contracts under this section is 5 necessary. Therefore, contracts entered into to implement this section, and all contract amendments and change orders, shall be 6 7 exempt from Chapter 2 (commencing with Section 10290) of Part 8 2 of Division 2 of the Public Contract Code. 9 (f) (1) The rates provided for in this section shall be implemented only if CMS determines that the rates will comply 10 with applicable federal Medicaid requirements and that federal 11 12 financial participation will be available. (2) In assessing whether federal financial participation is 13 available, the director shall comply with the CMS determination 14 15 on whether the rates comply with applicable federal Medicaid requirements, including those set forth in Section 1396a(a)(30)(A)16 17 of Title 42 United States Code.

(3) To the extent that the director determines that the rates do
not comply with applicable federal Medicaid requirements or that
federal financial participation is not available with respect to any
rate of reimbursement described in this section, the director retains

the discretion not to implement that rate and may revise the rateas necessary to comply with federal Medicaid requirements.

(g) The director shall seek any necessary federal approvals for
 the implementation of this section. The director shall not implement

26 any rate revised pursuant to paragraph (3) of subdivision (f) until

27 after the director has sought and received approval from CMS.

(h) Adjustments to pharmacy drug product reimbursement made
 pursuant to Section 14105.192 shall no longer apply when the
 department determines that the average acquisition cost

31 methodology has been fully implemented.

32 SEC. 3. Section 14105.451 of the Welfare and Institutions Code 33 is amended to read:

34 14105.451. (a) (1) The Legislature finds and declares all of 35 the following:

36 (A) The United States Department of Health and Human37 Services has identified the critical need for state Medicaid agencies

37 Services has identified the critical need for state interface agencies 38 to establish pharmacy reimbursement rates based on a pricing

39 benchmark that reflects actual acquisition costs.

1 (B) The Medi-Cal program currently uses a methodology based 2 on average wholesale price (*AWP*).

3 (C) Investigations by the federal Office of Inspector General 4 have found that average wholesale price is inflated relative to 5 average acquisition cost.

6 (2) Therefore, it is the intent of the Legislature to enact 7 legislation by August 1, 2011, that provides for development of a 8 new reimbursement methodology that will enable the department 9 to achieve savings while continuing to reimburse pharmacy 10 providers in compliance with federal law.

(b) The department may require providers, manufacturers, and
wholesalers to submit any data the director determines necessary
or useful in preparing for the transition from a methodology based
on average wholesale price to a methodology based on actual
acquisition cost.

(c) If the AWP ceases to be listed by the department's primary
price reference source vendor, the department may direct the fiscal
intermediary to establish a process with the primary price
reference source vendor to temporarily report the AWP, consistent

20 with the definition of AWP in Section 14105.45. If this process is

established, it shall be limited in scope and duration, and shall
cease when the department has fully implemented the average

cease when the department has fully implemented the averageacquisition cost methodology pursuant to Section 14105.45.

- 24 SECTION 1. Section 5024.2 of the Penal Code is amended to 25 read:
- 26 5024.2. (a) The Department of Corrections and Rehabilitation
   27 is authorized to maintain and operate a comprehensive pharmacy
- 28 services program for those facilities under the jurisdiction of the
- 29 department that is both cost effective and efficient, that program
- 30 shall incorporate all of the following:
- 31 (1) A statewide pharmacy administration system with direct
   32 authority and responsibility for program administration and
   33 oversight.
- 34 (2) Medically necessary pharmacy services using professionally
- and legally qualified pharmacists, consistent with the size and the
   scope of medical services provided.
- 37 (3) Written procedures and operational practices pertaining to
- 38 the delivery of pharmaceutical services.
- 39 (4) A multidisciplinary, statewide Pharmacy and Therapeutics
- 40 Committee responsible for all of the following:

- 1 (A) Developing and managing a department formulary. 2 (B) Standardizing the strengths and dosage forms for 3 medications used in department facilities. 4 (C) Maintaining and monitoring a system for the review and 5 evaluation of corrective actions related to errors in prescribing, dispensing, and administering medications. 6 7 (D) Conducting regular therapeutic category reviews for 8 medications listed in the department formulary. 9 (E) Evaluating medication therapies and providing input to the development of disease management guidelines used in the 10 11 department. (5) A requirement for the use of generic medications, when 12 available, unless an exception is reviewed and approved in 13 accordance with an established nonformulary approval process. 14 15 (6) Use of an enterprise-based pharmacy operating system that provides management with information on prescription workloads, 16 17 medication utilization, prescribing data, and other key pharmacy 18 information. 19 (b) The department is authorized to operate and maintain a centralized pharmacy distribution center to provide advantages of 20 21 scale and efficiencies related to medication purchasing, inventory 22 control, volume production, drug distribution, workforce utilization, 23 and increased patient safety. The centralized pharmacy distribution 24 center and institutional pharmacies shall be licensed as pharmacies 25 by the California State Board of Pharmacy and shall meet all 26 applicable regulations applying to a pharmacy. 27 (1) To the extent it is cost effective and efficient, the centralized 28 pharmacy distribution center should include systems to do the 29 following: 30 (A) Order and package bulk pharmaceuticals and prescription and stock orders for all department correctional facilities. 31 32 (B) Label medications as required to meet state and federal 33 prescription requirements. 34 (C) Provide barcode validation matching the drug to the specific 35 prescription or floor stock order. (D) Sort completed orders for shipping and delivery to 36 37 department facilities. 38 (2) Notwithstanding any other requirements, the department
- 39 centralized pharmacy distribution center is authorized to do the
- 40 following:

1 (A) Package bulk pharmaceuticals into both floor stock and 2 patient-specific packs. 3 (B) Reclaim, for reissue, unused and unexpired medications. 4 (C) Distribute the packaged products to department facilities 5 for use within the state corrections system. 6 (3) The centralized pharmacy distribution center shall maintain 7 a system of quality control checks on each process used to package, 8 label, and distribute medications. The quality control system may 9 include a regular process of random checks by a licensed 10 pharmacist. 11 (c) The department may investigate and initiate potential 12 systematic improvements in order to provide for the safe and 13 efficient distribution and control of, and accountability for, drugs 14 within the department's statewide pharmacy administration system, 15 taking into account factors unique to the correctional environment. 16 (d) The department shall ensure that there is a program providing 17 for the regular inspection of all department pharmacies in the state 18 to verify compliance with applicable law, rules, regulations, and 19 other standards as may be appropriate to ensure the health, safety, 20 and welfare of the department's inmate patients. 21 (e) On March 1, 2012, and each March 1 thereafter, the 22 department shall report all of the following to the Joint Legislative 23 Budget Committee, the Senate Committee on Appropriations, the 24 Senate Committee on Budget and Fiscal Review, the Senate 25 Committee on Health, the Senate Committee on Public Safety, the 26 Assembly Committee on Appropriations, the Assembly Committee 27 on Budget, the Assembly Committee on Health, and the Assembly 28 **Committee on Public Safety:** 29 (1) The extent to which the Pharmacy and Therapeutics 30 Committee has been established and achieved the objectives set 31 forth in this section, as well as the most significant reasons for 32 achieving or not achieving those objectives. 33 (2) The extent to which the department is achieving the objective 34 of operating a fully functioning and centralized pharmacy distribution center, as set forth in this section, that distributes 35 36 pharmaceuticals to every adult prison under the jurisdiction of the

- 37 department, as well as the most significant reasons for achieving
- 38 or not achieving that objective.

- 1 (3) The extent to which the centralized pharmacy distribution
- center is achieving cost savings through improved efficiency and
   distribution of unit dose medications.
- 4 (4) A description of planned or implemented initiatives to
- 5 accomplish the next 12 months' objectives for achieving the goals
- 6 set forth in this section, including a fully functioning and
- 7 centralized pharmacy distribution center that distributes
   8 pharmaceuticals to every adult facility under the jurisdiction of
- 9 the department.
- 10 (5) The costs for prescription pharmaceuticals for the previous
- 11 fiscal year, both statewide and at each adult prison under the
- 12 jurisdiction of the department, and a comparison of these costs
- 13 with those of the prior fiscal year.
- 14 (f) The requirement for submitting a report imposed under
- 15 subdivision (e) is inoperative on March 1, 2016, pursuant to Section
- 16 10231.5 of the Government Code.

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