

Introduced by Senator McPherson

February 25, 2000

An act to amend Section 14105.39 of the Welfare and Institutions Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1968, as introduced, McPherson. Medi-Cal: drugs.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services, pursuant to which medical benefits are provided to public assistance recipients and certain other low-income persons.

Existing law, until January 1, 2000, provides for the provision of drugs that are reimbursed through the Medi-Cal program without prior authorization when they are on an approved list of contract drugs.

Existing law, until January 1, 2000, authorizes the State Department of Health Services to enter into contracts with manufacturers of single-source and multiple-source drugs under the Medi-Cal program, and specifies procedures for the implementation of that authority.

Under existing law, until January 1, 2001, a manufacturer of a new single-source drug may request inclusion of its drug on the list of contract drugs if certain conditions are met.

This bill would revise the conditions that must be met by the drug manufacturer in order to request that the drug be placed on the list of contract drugs.

This bill would also extend the effective period of that provision to January 1, 2002.

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

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

1 SECTION 1. Section 14105.39 of the Welfare and
2 Institutions Code is amended to read:
3 14105.39. (a) (1) A manufacturer of a new
4 single-source drug may request inclusion of its drug on
5 the list of contract drugs pursuant to Section 14105.33
6 provided all of the following conditions are met:
7 (A) The request is made within 12 months of approval
8 for marketing by the federal Food and Drug
9 Administration.
10 (B) The manufacturer agrees to negotiate a contract
11 with the department to provide the drug at the
12 manufacturer's best price.
13 (C) (i) The manufacturer provides the department
14 with necessary information, as specified by the
15 department, in the request.
16 (ii) Notwithstanding clause (i), either of the following
17 may be submitted by the manufacturer in lieu of the
18 Summary Basis of Approval prepared by the federal Food
19 and Drug Administration for that drug:
20 (I) The federal Food and Drug Administration's
21 approval or approvable letter for the drug and federal
22 Food and Drug Administration's approved labeling.
23 (II) The federal Food and Drug Administration's
24 medical officers' and pharmacologists' reviews and the
25 federal Food and Drug Administration's approved
26 labeling.
27 (D) The department had concluded contracting for
28 the therapeutic category in which the drug is included
29 prior to approval of the drug by the federal Food and
30 Drug Administration.
31 (2) Within 90 days from receipt of the request, the
32 department shall evaluate the request using the criteria
33 identified in subdivision (d), and shall submit the drug to
34 the Medi-Cal Contract Drug Advisory Committee.



1 (b) Any petition for the addition to or deletion of a
2 drug to the Medi-Cal drug formulary submitted prior to
3 July 31, 1990, shall be deemed to be denied. A
4 manufacturer who has submitted a petition deemed
5 denied may request inclusion of that drug on the list of
6 contract drugs provided all of the following conditions are
7 met:

8 (1) The manufacturer agrees to negotiate for a
9 contract with the department to provide the drug at the
10 manufacturer's best price.

11 (2) The manufacturer provides the department with
12 necessary information, as specified by the department, in
13 the request.

14 (3) The manufacturer submits the request to the
15 department prior to October 1, 1990.

16 (c) Any new drug designated as having an important
17 therapeutic gain and approved for marketing by the
18 federal Food and Drug Administration on or after July 31,
19 1990, shall immediately be included on the list of contract
20 drugs for a period of three years provided that all of the
21 following conditions are met:

22 (1) The manufacturer offers the department its best
23 price.

24 (2) The drug ~~is typically~~ *may be* administered in an
25 outpatient setting.

26 (3) The drug is prescribed only for the indications and
27 usage specified in the federal Food and Drug
28 Administration approved labeling.

29 (4) The drug is determined by the director to be safe,
30 relative to other drugs in the same therapeutic category
31 on the list of contract drugs.

32 (d) (1) To ensure that the health needs of Medi-Cal
33 beneficiaries are met consistent with the intent of this
34 chapter, the department shall, when evaluating a
35 decision to execute a contract, and when evaluating drugs
36 for retention on, addition to, or deletion from, the list of
37 contract drugs, use all of the following criteria:

38 (A) The safety of the drug.

39 (B) The effectiveness of the drug.

40 (C) The essential need for the drug.



1 (D) The potential for misuse of the drug.

2 (E) The cost of the drug.

3 (2) The deficiency of a drug when measured by one of
4 these criteria may be sufficient to support a decision that
5 the drug should not be added or retained, or should be
6 deleted from the list. However, the superiority of a drug
7 under one criterion may be sufficient to warrant the
8 addition or retention of the drug, notwithstanding a
9 deficiency in another criterion.

10 (e) (1) A manufacturer of single-source drugs denied
11 a contract pursuant to this section or Section 14105.33 or
12 14105.37, may file an appeal of that decision with the
13 director within 30 calendar days of the department's
14 written decision.

15 (2) Within 30 calendar days of the manufacturer's
16 appeal, the director shall request a recommendation
17 regarding the appeal from the Medi-Cal Contract Drug
18 Advisory Committee. The committee shall provide its
19 recommendation in writing, within 30 calendar days of
20 the director's request.

21 (3) The director shall issue a final decision on the
22 appeal within 30 calendar days of the recommendation.

23 (f) Deletions made to the list of contract drugs,
24 including those made pursuant to Section 14105.37, shall
25 become effective no sooner than 30 days after publication
26 of the changes in provider bulletins.

27 (g) Changes made to the list of contract drugs under
28 this or any other section are exempt from the
29 requirements of the Administrative Procedure Act
30 (Chapter 3.5 (commencing with Section 11340), Chapter
31 4 (commencing with Section 11370), and Chapter 5
32 (commencing with Section 11500) of Part 1 of Division 3
33 of Title 2 of the Government Code), and shall not be
34 subject to the review and approval of the Office of
35 Administrative Law.

36 (h) This section shall remain in effect only until
37 January 1, ~~2001~~ 2002, and as of that date is repealed, unless



1 a later enacted statute, which is enacted before January
2 1, ~~2001~~ 2002, deletes or extends that date.

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