

AMENDED IN ASSEMBLY AUGUST 1, 2016
AMENDED IN ASSEMBLY AUGUST 24, 2015
AMENDED IN SENATE JUNE 1, 2015
AMENDED IN SENATE APRIL 6, 2015

SENATE BILL

No. 447

Introduced by Senator Allen

February 25, 2015

An act to ~~add Section 1222.1 to the Health and Safety Code, and to amend Sections 14043.17 and 24005~~ *amend Section 14132.01* of the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

SB 447, as amended, Allen. Medi-Cal: clinics:—~~enrollment applications: drugs, devices, and supplies.~~

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 persons receive health care benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid provisions.

The Medi-Cal program administers a program known as the Family Planning, Access, Care, and Treatment (Family PACT) Program, to provide comprehensive clinical family planning services to any person who has a family income at or below 200% of the federal poverty level and who is eligible to receive those services. *Existing law specifies various requirements relating to reimbursement for the provision of drugs and supplies under the Medi-Cal program and the Family PACT Program that are applicable to licensed community clinics, free clinics, or intermittent clinics. Existing law requires reimbursement for drugs*

and supplies covered under the Medi-Cal program and the Family PACT Program and provided by these clinics to be the lesser of the amount billed or the Medi-Cal reimbursement rate and caps reimbursement at the net cost of the drugs or products as provided by retail pharmacies under the Medi-Cal program. Existing law sets the costs for drugs and supplies covered under those programs at an aggregate amount equivalent to the sum of the actual acquisition cost of a drug or supply plus a clinic dispensing fee not to exceed \$12 per billing unit, as specified. Existing law also sets the cost for a take-home drug that is dispensed for use by the patient within a specific timeframe of 5 or fewer days from the date medically indicated at the actual acquisition cost for that drug plus a clinic dispensing fee, not to exceed \$17 per prescription.

~~Existing law requires the State Department of Health Care Services to approve the application of an affiliate clinic, as defined, for enrollment into the Family PACT Program within 30 days of receiving the application, as specified. Existing law also requires the State Department of Public Health to implement a process that allows an applicant for licensure as a primary care clinic, as defined, to submit an application for review of the clinic's qualifications for enrollment and certification in the Medi-Cal program, and, among others, the Family PACT Program. Existing law requires the State Department of Health Care Services, within 30 days after receiving confirmation of certification for enrollment of an affiliate clinic in the Medi-Cal program, to enroll the clinic in the Medi-Cal program retroactive to the date of certification.~~

~~This bill would eliminate the requirement that the State Department of Health Care Services approve an application for enrollment into the Family PACT Program, and would instead require a primary care clinic or an affiliate clinic that is seeking to enroll in the program to submit an application to the State Department of Public Health. The bill would require a clinic not enrolled in the Medi-Cal program to submit a consolidated application for enrollment in both the Medi-Cal program and the Family PACT program, and would require a clinic already enrolled in the Medi-Cal program to submit an application for enrollment in the Family PACT Program. The bill would require the State Department of Public Health to review that application to certify the clinic for enrollment in those programs, as applicable, and to notify the State Department of Health Care Services of that certification within 15 days after it is granted. The bill would require the State Department of Health Care Services to enroll the clinic in those programs within~~

~~15 days after receiving notification from the State Department of Public Health, as specified. The bill would require the State Department of Public Health to develop consolidated application forms, as specified.~~

This bill would also require reimbursement for devices covered under the Medi-Cal Program and the Family PACT Program. The bill would revise the reimbursement formula described above and would instead specify separate reimbursement formulas for contraceptive drugs, devices, and supplies, and non-contraceptive drugs, devices, and supplies. The bill would, for contraceptive drugs, devices, and supplies, require a clinic to bill the Medi-Cal program and the Family PACT Program at the Medi-Cal reimbursement rate. The bill would, for non-contraceptive drugs, devices, and supplies, require a clinic to bill the Medi-Cal program or the Family PACT Program at the lesser of the clinic's usual charge made to the general public, or its cost, defined as an aggregate amount equivalent to the sum of the actual acquisition cost of the drug, device, or supply plus a clinic dispensing fee. The bill would provide that the clinic dispensing fee shall be determined by the department, as specified, or, if not determined by the department, shall be the difference between the actual acquisition cost and the Medi-Cal reimbursement rate. The bill would require reimbursement for non-contraceptive drugs, devices, and supplies to be the lesser of the amount billed, as described above, or the Medi-Cal reimbursement rate, and would cap reimbursement at the net cost of the drug, device, or supply when provided by retail pharmacies under the Medi-Cal program. The bill would require the department to seek federal approval of any state plan amendments necessary to implement these provisions. The bill would require the department, by July 1, 2018, to adopt regulations to implement these provisions, as specified. Until those regulations are adopted the bill would require the department to implement these provisions by provider bulletins or similar instructions and provide the Legislature with a semiannual status report, as specified.

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 14132.01 of the Welfare and Institutions
- 2 Code is amended to read:

1 14132.01. (a) Notwithstanding any other ~~provision of law, a~~
 2 community clinic or free clinic licensed pursuant to subdivision
 3 (a) of Section 1204 of the Health and Safety Code or an intermittent
 4 clinic operating pursuant to subdivision (h) of Section 1206 of the
 5 Health and Safety Code, that has a valid license pursuant to Article
 6 13 (commencing with Section 4180) of Chapter 9 of Division 2
 7 of the Business and Professions Code shall bill and be reimbursed,
 8 as described in this section, for ~~drugs~~ *drugs, devices, and supplies*
 9 covered under the Medi-Cal program and Family PACT ~~Waiver~~
 10 Program.

11 (b) ~~(1)~~ A clinic described in subdivision (a) shall bill the
 12 Medi-Cal program and Family PACT ~~Waiver~~ Program for ~~drugs~~
 13 *contraceptive drugs, devices, and supplies* covered under those
 14 programs at the lesser of cost or the clinic's usual charge made to
 15 the general public. *Medi-Cal reimbursement rate.*

16 (2) ~~For purposes of this section, "cost" means an aggregate~~
 17 ~~amount equivalent to the sum of the actual acquisition cost of a~~
 18 ~~drug or supply plus a clinic dispensing fee not to exceed twelve~~
 19 ~~dollars (\$12) per billing unit as identified in either the Family~~
 20 ~~PACT Policies, Procedures, and Billing Instructions Manual, or~~
 21 ~~the Medi-Cal Inpatient/Outpatient Provider Manual governing~~
 22 ~~outpatient clinic billing for drugs and supplies, as applicable. For~~
 23 ~~purposes of this section, "cost" for a take-home drug that is~~
 24 ~~dispensed for use by the patient within a specific timeframe of five~~
 25 ~~or less days from the date medically indicated means actual~~
 26 ~~acquisition cost for that drug plus a clinic dispensing fee, not to~~
 27 ~~exceed seventeen dollars (\$17) per prescription. Reimbursement~~
 28 ~~shall be at the lesser of the amount billed or the Medi-Cal~~
 29 ~~reimbursement rate, and shall not exceed the net cost of these drugs~~
 30 ~~or supplies when provided by retail pharmacies under the Medi-Cal~~
 31 ~~program.~~

32 (c) (1) *A clinic described in subdivision (a) shall bill the*
 33 *Medi-Cal program or the Family PACT Program for*
 34 *non-contraceptive drugs, devices, and supplies covered under*
 35 *those programs at the lesser of cost or the clinic's usual charge*
 36 *made to the general public.*

37 (2) *For purposes of this subdivision only, "cost" means an*
 38 *aggregate amount equivalent to the actual acquisition cost of a*
 39 *non-contraceptive drug, device, or supply plus a clinic dispensing*
 40 *fee as determined by the department and identified in either the*

1 *Medi-Cal Provider Manual or the Family PACT Policies,*
2 *Procedures, and Billing Instructions Manual. If the department*
3 *does not identify a clinic dispensing fee in either the Medi-Cal*
4 *Provider Manual or the Family PACT Policies, Procedures, and*
5 *Billing Instructions Manual, the clinic dispensing fee shall be the*
6 *difference between the actual acquisition cost and the Medi-Cal*
7 *reimbursement rate.*

8 (3) *Reimbursement for non-contraceptive drugs, devices, and*
9 *supplies shall be the lesser of the amount billed or the Medi-Cal*
10 *reimbursement rate, and shall not exceed the net cost of the*
11 *non-contraceptive drugs, devices, and supplies when provided by*
12 *retail pharmacies under the Medi-Cal program.*

13 (e)

14 (d) A clinic described in subdivision (a) that furnishes services
15 free of charge, or at a nominal charge, as defined in subsection (a)
16 of Section 413.13 of Title 42 of the Code of Federal Regulations,
17 or that can demonstrate to the department, upon request, that it
18 serves primarily low-income patients, and its customary practice
19 is to charge patients on the basis of their ability to pay, shall not
20 be subject to reimbursement reductions based on its usual charge
21 to the general public.

22 (d)

23 (e) Federally qualified health centers and rural health clinics
24 that are clinics as described in subdivision (a) may bill and be
25 reimbursed as described in this section, upon electing to be
26 reimbursed for pharmaceutical goods and services *drugs, devices,*
27 *and supplies delivered through their dispensaries* on a
28 fee-for-service basis, as permitted by subdivision (k) of Section
29 14132.100.

30 (e)

31 (f) A clinic that otherwise meets the qualifications set forth in
32 subdivision (a), that is eligible to, but that has elected not to, utilize
33 drugs purchased under the 340B Discount Drug Program for its
34 Medi-Cal patients, shall provide notification to the Health
35 Resources and Services Administration's Office of Pharmacy
36 Affairs that it is utilizing non-340B drugs for its Medi-Cal patients
37 in the manner and to the extent required by federal law.

38 (g) *The department shall seek federal approval of any state plan*
39 *amendments necessary to implement this section.*

1 (h) Notwithstanding Chapter 3.5 (commencing with Section
2 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
3 the department may implement this section by means of provider
4 bulletins or similar instructions until the time any necessary
5 regulations are adopted. Thereafter, by July 1, 2018, the
6 department shall adopt regulations in accordance with the
7 requirements of Chapter 3.5 (commencing with Section 11340) of
8 Part 1 of Division 3 of Title 2 of the Government Code. Until those
9 regulations have been adopted, the department shall provide a
10 status report to the Legislature on a semiannual basis and pursuant
11 to Section 9795 of the Government Code.

12 (i) This section shall be implemented only if and to the extent
13 that federal financial participation is available and any necessary
14 federal approvals have been obtained.

15 **SECTION 1.** Section 1222.1 is added to the Health and Safety
16 Code, to read:

17 1222.1. (a) (1) As part of the application for licensure either
18 as a primary care clinic, as described in subdivision (a) of Section
19 1204, or as an affiliate clinic, as described in Section 1218.1, the
20 department shall accept a consolidated application for enrollment
21 in both the Medi-Cal program and the Family PACT Program that
22 is submitted by a clinic pursuant to subparagraph (A) of paragraph
23 (1) of subdivision (t) of Section 24005 of the Welfare and
24 Institutions Code. The department shall review the clinic's
25 qualifications for enrollment in both the Medi-Cal program and
26 the Family PACT Program, and, if approved, shall transmit its
27 certification for enrollment in both programs to the State
28 Department of Health Care Services within 15 calendar days of
29 the date approval is granted.

30 (2) The department shall accept an application for enrollment
31 in both the Medi-Cal program and the Family PACT Program, or
32 for enrollment in the Family PACT Program, from a licensed
33 primary care clinic, as described in subdivision (a) of Section 1204,
34 or from a licensed affiliate clinic, as described in Section 1218.1.
35 The department shall review the clinic's qualifications for
36 enrollment in the Medi-Cal program and the Family PACT
37 Program, as applicable, and, if approved, shall transmit its
38 certification for enrollment in those programs to the State
39 Department of Health Care Services within 15 calendar days of
40 the date approval is granted.

1 ~~(b) If a clinic submits an initial application for enrollment in~~
2 ~~both the Medi-Cal program and the Family PACT Program~~
3 ~~pursuant to paragraph (1) or (2) of subdivision (a), the department~~
4 ~~shall apply the same certification date to its approval for enrollment~~
5 ~~in both programs.~~

6 ~~(c) No later than June 30, 2016, the department shall develop a~~
7 ~~consolidated Medi-Cal program and Family PACT Program initial~~
8 ~~application form, and a Family PACT Program initial application~~
9 ~~form for a clinic already enrolled in the Medi-Cal program, subject~~
10 ~~to all of the following:~~

11 ~~(1) The department shall not require an applicant for enrollment~~
12 ~~in the Family PACT Program to disclose any additional information~~
13 ~~beyond what was required of a community clinic for enrollment~~
14 ~~in the Family PACT Program as of December 31, 2014.~~

15 ~~(2) The department shall not require an applicant to attend a~~
16 ~~provider orientation if the applicant is owned by a nonprofit~~
17 ~~corporation that owns at least one other primary care clinic that~~
18 ~~has held an active enrollment in the Family PACT Program for~~
19 ~~the immediately preceding five years, and during that period has~~
20 ~~had no demonstrated history of a repeated or uncorrected violation~~
21 ~~of this chapter or any regulation adopted after the enactment of~~
22 ~~this chapter that poses an immediate jeopardy to a patient, as that~~
23 ~~term is defined in subdivision (f) of Section 1218.1.~~

24 ~~(d) Nothing in this section shall be construed to modify the~~
25 ~~requirement that the department issue a license to an affiliate clinic~~
26 ~~within 30 days of receipt of a completed application, as set forth~~
27 ~~in subdivision (d) of Section 1218.1.~~

28 ~~(e) A subsequent change to information reported on the initial~~
29 ~~application described in this section shall be reported to the~~
30 ~~centralized application unit of the department within 35 calendar~~
31 ~~days. The department shall review the clinic's changes, and, if~~
32 ~~approved, shall transmit its approval to the State Department of~~
33 ~~Health Care Services within 15 calendar days after approval is~~
34 ~~granted. A provider that reports a change under this section other~~
35 ~~than a change of ownership shall not be required to reenroll in~~
36 ~~either the Medi-Cal program or the Family PACT Program.~~

37 ~~SEC. 2. Section 14043.17 of the Welfare and Institutions Code~~
38 ~~is amended to read:~~

39 ~~14043.17. (a) Notwithstanding any other law, within 15~~
40 ~~calendar days of receiving confirmation of certification for~~

1 enrollment as a Medi-Cal provider for a primary care clinic, as
2 described in subdivision (a) of Section 1204 of the Health and
3 Safety Code, or an affiliate primary care clinic that is licensed
4 pursuant to Section 1218.1 of the Health and Safety Code, the
5 department shall provide written notice to the applicant informing
6 the applicant that its Medi-Cal enrollment is approved.

7 (b) The department shall enroll the primary care clinic or the
8 affiliate clinic retroactive to the date of certification.

9 (c) This section shall not be construed to limit the department's
10 authority pursuant to Section 14043.37, 14043.4, or 14043.7 to
11 conduct background checks, preenrollment inspections, or
12 unannounced visits.

13 SEC. 3.— Section 24005 of the Welfare and Institutions Code is
14 amended to read:

15 24005. (a) This section shall apply to the Family Planning,
16 Access, Care, and Treatment (Family PACT) Program identified
17 in subdivision (aa) of Section 14132 and this program.

18 (b) Only licensed medical personnel with family planning skills,
19 knowledge, and competency may provide the full range of family
20 planning medical services covered in this program.

21 (c) Medi-Cal enrolled providers, as determined by the
22 department, shall be eligible to provide family planning services
23 under the program when these services are within their scope of
24 practice and licensure. Those clinical providers electing to
25 participate in the program and approved by the department shall
26 provide the full scope of family planning education, counseling,
27 and medical services specified for the program, either directly or
28 by referral, consistent with standards of care issued by the
29 department.

30 (d) The department shall require providers to enter into clinical
31 agreements with the department to ensure compliance with
32 standards and requirements to maintain the fiscal integrity of the
33 program. Provider applicants, providers, and persons with an
34 ownership or control interest, as defined in federal Medicaid
35 regulations, shall be required to submit to the department their
36 social security numbers to the full extent allowed under federal
37 law. All state and federal statutes and regulations pertaining to the
38 audit or examination of Medi-Cal providers shall apply to this
39 program.

1 ~~(e) Clinical provider agreements shall be signed by the provider~~
2 ~~under penalty of perjury. The department may screen applicants~~
3 ~~at the initial application and at any reapplication pursuant to~~
4 ~~requirements developed by the department to determine provider~~
5 ~~suitability for the program.~~

6 ~~(f) The department may complete a background check on clinical~~
7 ~~provider applicants for the purpose of verifying the accuracy of~~
8 ~~information provided to the department for purposes of enrolling~~
9 ~~in the program and in order to prevent fraud and abuse. The~~
10 ~~background check may include, but not be limited to, unannounced~~
11 ~~onsite inspection prior to enrollment, review of business records,~~
12 ~~and data searches. If discrepancies are found to exist during the~~
13 ~~preenrollment period, the department may conduct additional~~
14 ~~inspections prior to enrollment. Failure to remediate significant~~
15 ~~discrepancies as prescribed by the director may result in denial of~~
16 ~~the application for enrollment. Providers that do not provide~~
17 ~~services consistent with the standards of care or that do not comply~~
18 ~~with the department's rules related to the fiscal integrity of the~~
19 ~~program may be disenrolled as a provider from the program at the~~
20 ~~sole discretion of the department.~~

21 ~~(g) The department shall not enroll any applicant who, within~~
22 ~~the previous 10 years:~~

23 ~~(1) Has been convicted of any felony or misdemeanor that~~
24 ~~involves fraud or abuse in any government program, that relates~~
25 ~~to neglect or abuse of a patient in connection with the delivery of~~
26 ~~a health care item or service, or that is in connection with the~~
27 ~~interference with, or obstruction of, any investigation into health~~
28 ~~care related fraud or abuse.~~

29 ~~(2) Has been found liable for fraud or abuse in any civil~~
30 ~~proceeding, or that has entered into a settlement in lieu of~~
31 ~~conviction for fraud or abuse in any government program.~~

32 ~~(h) In addition, the department may deny enrollment to any~~
33 ~~applicant that, at the time of application, is under investigation by~~
34 ~~the department or any local, state, or federal government law~~
35 ~~enforcement agency for fraud or abuse. The department shall not~~
36 ~~deny enrollment to an otherwise qualified applicant whose felony~~
37 ~~or misdemeanor charges did not result in a conviction solely on~~
38 ~~the basis of the prior charges. If it is discovered that a provider is~~
39 ~~under investigation by the department or any local, state, or federal~~
40 ~~government law enforcement agency for fraud or abuse, that~~

1 provider shall be subject to immediate disenrollment from the
2 program.

3 (i) (1) The program shall disenroll as a program provider any
4 individual who, or any entity that, has a license, certificate, or other
5 approval to provide health care, which is revoked or suspended
6 by a federal, California, or other state's licensing, certification, or
7 other approval authority, has otherwise lost that license, certificate,
8 or approval, or has surrendered that license, certificate, or approval
9 while a disciplinary hearing on the license, certificate, or approval
10 was pending. The disenrollment shall be effective on the date the
11 license, certificate, or approval is revoked, lost, or surrendered.

12 (2) A provider shall be subject to disenrollment if the provider
13 submits claims for payment for the services, goods, supplies, or
14 merchandise provided, directly or indirectly, to a program
15 beneficiary, by an individual or entity that has been previously
16 suspended, excluded, or otherwise made ineligible to receive,
17 directly or indirectly, reimbursement from the program or from
18 the Medi-Cal program and the individual has previously been listed
19 on either the Suspended and Ineligible Provider List, which is
20 published by the department, to identify suspended and otherwise
21 ineligible providers or any list published by the federal Office of
22 the Inspector General regarding the suspension or exclusion of
23 individuals or entities from the federal Medicare and Medicaid
24 programs, to identify suspended, excluded, or otherwise ineligible
25 providers.

26 (3) The department shall deactivate, immediately and without
27 prior notice, the provider numbers used by a provider to obtain
28 reimbursement from the program when warrants or documents
29 mailed to a provider's mailing address, its pay to address, or its
30 service address, if any, are returned by the United States Postal
31 Service as not deliverable or when a provider has not submitted a
32 claim for reimbursement from the program for one year. Prior to
33 taking this action, the department shall use due diligence in
34 attempting to contact the provider at its last known telephone
35 number and to ascertain if the return by the United States Postal
36 Service is by mistake and shall use due diligence in attempting to
37 contact the provider by telephone or in writing to ascertain whether
38 the provider wishes to continue to participate in the Medi-Cal
39 program. If deactivation pursuant to this section occurs, the

1 provider shall meet the requirements for reapplication as specified
2 in regulation.

3 (4) For purposes of this subdivision:

4 (A) “Mailing address” means the address that the provider has
5 identified to the department in its application for enrollment as the
6 address at which it wishes to receive general program
7 correspondence.

8 (B) “Pay to address” means the address that the provider has
9 identified to the department in its application for enrollment as the
10 address at which it wishes to receive warrants.

11 (C) “Service address” means the address that the provider has
12 identified to the department in its application for enrollment as the
13 address at which the provider will provide services to program
14 beneficiaries.

15 (j) Subject to Article 4 (commencing with Section 19130) of
16 Chapter 5 of Part 2 of Division 5 of Title 2 of the Government
17 Code, the department may enter into contracts to secure consultant
18 services or information technology including, but not limited to,
19 software, data, or analytical techniques or methodologies for the
20 purpose of fraud or abuse detection and prevention. Contracts
21 under this section shall be exempt from the Public Contract Code.

22 (k) Except as provided in Section 1222.1 of the Health and
23 Safety Code, enrolled providers shall attend specific orientation
24 approved by the department in comprehensive family planning
25 services. Enrolled providers who insert IUDs or contraceptive
26 implants shall have received prior clinical training specific to these
27 procedures.

28 (l) Upon receipt of reliable evidence that would be admissible
29 under the administrative adjudication provisions of Chapter 5
30 (commencing with Section 11500) of Part 1 of Division 3 of Title
31 2 of the Government Code, of fraud or willful misrepresentation
32 by a provider under the program or commencement of a suspension
33 under Section 14123, the department may do any of the following:

34 (1) Collect any State-Only Family Planning program or Family
35 Planning, Access, Care, and Treatment Program overpayment
36 identified through an audit or examination, or any portion thereof
37 from any provider. Notwithstanding Section 100171 of the Health
38 and Safety Code, a provider may appeal the collection of
39 overpayments under this section pursuant to procedures established
40 in Article 5.3 (commencing with Section 14170) of Chapter 7 of

1 Part 3 of Division 9. Overpayments collected under this section
2 shall not be returned to the provider during the pendency of any
3 appeal and may be offset to satisfy audit or appeal findings, if the
4 findings are against the provider. Overpayments shall be returned
5 to a provider with interest if findings are in favor of the provider.

6 ~~(2) Withhold payment for any goods or services, or any portion~~
7 ~~thereof, from any State-Only Family Planning program or Family~~
8 ~~Planning, Access, Care, and Treatment Program provider. The~~
9 ~~department shall notify the provider within five days of any~~
10 ~~withholding of payment under this section. The notice shall do all~~
11 ~~of the following:~~

12 ~~(A) State that payments are being withheld in accordance with~~
13 ~~this paragraph and that the withholding is for a temporary period~~
14 ~~and will not continue after it is determined that the evidence of~~
15 ~~fraud or willful misrepresentation is insufficient or when legal~~
16 ~~proceedings relating to the alleged fraud or willful~~
17 ~~misrepresentation are completed.~~

18 ~~(B) Cite the circumstances under which the withholding of the~~
19 ~~payments will be terminated.~~

20 ~~(C) Specify, when appropriate, the type or types of claimed~~
21 ~~payments being withheld.~~

22 ~~(D) Inform the provider of the right to submit written evidence~~
23 ~~that is evidence that would be admissible under the administrative~~
24 ~~adjudication provisions of Chapter 5 (commencing with Section~~
25 ~~11500) of Part 1 of Division 3 of Title 2 of the Government Code,~~
26 ~~for consideration by the department.~~

27 ~~(3) Notwithstanding Section 100171 of the Health and Safety~~
28 ~~Code, a provider may appeal a withholding of payment under this~~
29 ~~section pursuant to Section 14043.65. Payments withheld under~~
30 ~~this section shall not be returned to the provider during the~~
31 ~~pendency of any appeal and may be offset to satisfy audit or appeal~~
32 ~~findings.~~

33 ~~(m) As used in this section:~~

34 ~~(1) "Abuse" means either of the following:~~

35 ~~(A) Practices that are inconsistent with sound fiscal or business~~
36 ~~practices and result in unnecessary cost to the Medicaid program,~~
37 ~~the Medicare program, the Medi-Cal program, including the Family~~
38 ~~Planning, Access, Care, and Treatment Program, identified in~~
39 ~~subdivision (aa) of Section 14132, another state's Medicaid~~
40 ~~program, or the State-Only Family Planning program, or other~~

1 health care programs operated, or financed in whole or in part, by
2 the federal government or any state or local agency in this state or
3 any other state.

4 (B) Practices that are inconsistent with sound medical practices
5 and result in reimbursement, by any of the programs referred to
6 in subparagraph (A) or other health care programs operated, or
7 financed in whole or in part, by the federal government or any
8 state or local agency in this state or any other state, for services
9 that are unnecessary or for substandard items or services that fail
10 to meet professionally recognized standards for health care.

11 (2) “Fraud” means an intentional deception or misrepresentation
12 made by a person with the knowledge that the deception could
13 result in some unauthorized benefit to himself or herself or some
14 other person. It includes any act that constitutes fraud under
15 applicable federal or state law.

16 (3) “Provider” means any individual, partnership, group,
17 association, corporation, institution, or entity, and the officers,
18 directors, owners, managing employees, or agents of any
19 partnership, group, association, corporation, institution, or entity,
20 that provides services, goods, supplies, or merchandise, directly
21 or indirectly, to a beneficiary and that has been enrolled in the
22 program.

23 (4) “Convicted” means any of the following:

24 (A) A judgment of conviction has been entered against an
25 individual or entity by a federal, state, or local court, regardless
26 of whether there is a post-trial motion or an appeal pending or the
27 judgment of conviction or other record relating to the criminal
28 conduct has been expunged or otherwise removed.

29 (B) A federal, state, or local court has made a finding of guilt
30 against an individual or entity.

31 (C) A federal, state, or local court has accepted a plea of guilty
32 or nolo contendere by an individual or entity.

33 (D) An individual or entity has entered into participation in a
34 first offender, deferred adjudication, or other program or
35 arrangement where judgment of conviction has been withheld.

36 (5) “Professionally recognized standards of health care” means
37 statewide or national standards of care, whether in writing or not,
38 that professional peers of the individual or entity whose provision
39 of care is an issue, recognize as applying to those peers practicing
40 or providing care within a state. When the United States

1 Department of Health and Human Services has declared a treatment
2 modality not to be safe and effective, practitioners that employ
3 that treatment modality shall be deemed not to meet professionally
4 recognized standards of health care. This definition shall not be
5 construed to mean that all other treatments meet professionally
6 recognized standards of care.

7 (6) “Unnecessary or substandard items or services” means those
8 that are either of the following:

9 (A) Substantially in excess of the provider’s usual charges or
10 costs for the items or services.

11 (B) Furnished, or caused to be furnished, to patients, whether
12 or not covered by Medicare, Medicaid, or any of the state health
13 care programs to which the definitions of applicant and provider
14 apply, and which are substantially in excess of the patient’s needs,
15 or of a quality that fails to meet professionally recognized standards
16 of health care. The department’s determination that the items or
17 services furnished were excessive or of unacceptable quality shall
18 be made on the basis of information, including sanction reports,
19 from the following sources:

20 (i) The professional review organization for the area served by
21 the individual or entity.

22 (ii) State or local licensing or certification authorities.

23 (iii) Fiscal agents or contractors, or private insurance companies.

24 (iv) State or local professional societies.

25 (v) Any other sources deemed appropriate by the department.

26 (7) “Enrolled or enrollment in the program” means authorized
27 under any and all processes by the department or its agents or
28 contractors to receive, directly or indirectly, reimbursement for
29 the provision of services, goods, supplies, or merchandise to a
30 program beneficiary.

31 (n) In lieu of, or in addition to, the imposition of any other
32 sanctions available, including the imposition of a civil penalty
33 under Sections 14123.2 or 14171.6, the program may impose on
34 providers any or all of the penalties pursuant to Section 14123.25,
35 in accordance with the provisions of that section. In addition,
36 program providers shall be subject to the penalties contained in
37 Section 14107.

38 (o) (1) Notwithstanding any other provision of law, every
39 primary supplier of pharmaceuticals, medical equipment, or
40 supplies shall maintain accounting records to demonstrate the

1 manufacture, assembly, purchase, or acquisition and subsequent
2 sale, of any pharmaceuticals, medical equipment, or supplies, to
3 providers. Accounting records shall include, but not be limited to,
4 inventory records, general ledgers, financial statements, purchase
5 and sales journals, and invoices, prescription records, bills of
6 lading, and delivery records.

7 (2) For purposes of this subdivision, the term “primary supplier”
8 means any manufacturer, principal labeler, assembler, wholesaler,
9 or retailer.

10 (3) Accounting records maintained pursuant to paragraph (1)
11 shall be subject to audit or examination by the department or its
12 agents. The audit or examination may include, but is not limited
13 to, verification of what was claimed by the provider. These
14 accounting records shall be maintained for three years from the
15 date of sale or the date of service.

16 (p) Each provider of health care services rendered to any
17 program beneficiary shall keep and maintain records of each service
18 rendered, the beneficiary to whom rendered, the date, and such
19 additional information as the department may by regulation require.
20 Records required to be kept and maintained pursuant to this
21 subdivision shall be retained by the provider for a period of three
22 years from the date the service was rendered.

23 (q) A program provider applicant or a program provider shall
24 furnish information or copies of records and documentation
25 requested by the department. Failure to comply with the
26 department’s request shall be grounds for denial of the application
27 or automatic disenrollment of the provider.

28 (r) A program provider may assign signature authority for
29 transmission of claims to a billing agent subject to Sections 14040,
30 14040.1, and 14040.5.

31 (s) Moneys payable or rights existing under this division shall
32 be subject to any claim, lien, or offset of the State of California,
33 and any claim of the United States of America made pursuant to
34 federal statute, but shall not otherwise be subject to enforcement
35 of a money judgment or other legal process, and no transfer or
36 assignment, at law or in equity, of any right of a provider of health
37 care to any payment shall be enforceable against the state, a fiscal
38 intermediary, or carrier.

39 (t) (1) (A) Notwithstanding any other law, a primary care clinic,
40 as described in subdivision (a) of Section 1204 of the Health and

1 Safety Code, or an affiliate clinic, as described in Section 1218.1
2 of the Health and Safety Code, that is seeking to enroll as a
3 provider in both the Medi-Cal program and the Family PACT
4 Program, shall submit one consolidated application for enrollment
5 in both the Medi-Cal program and the Family PACT Program to
6 the State Department of Public Health, using the forms described
7 in Section 1222.1 of the Health and Safety Code. The effective
8 date of enrollment for a clinic enrolling in both programs at the
9 same time shall be the date the State Department of Public Health
10 certifies the clinic for enrollment in those programs.

11 (B) A primary care clinic, as described in subdivision (a) of
12 Section 1204 of the Health and Safety Code, or an affiliate clinic,
13 as described in Section 1218.1 of the Health and Safety Code, that
14 is enrolled in the Medi-Cal program and that is seeking to enroll
15 as a provider in the Family PACT Program, shall submit an
16 application for enrollment in the Family PACT Program to the
17 State Department of Public Health using the forms described in
18 Section 1222.1 of the Health and Safety Code. The effective date
19 of enrollment in the Family PACT program for a clinic that was
20 enrolled in the Medi-Cal program at the time it applied to the
21 Family PACT Program shall be the date the State Department of
22 Public Health certifies the clinic for enrollment in the Family PACT
23 Program.

24 (2) Within 15 calendar days of receiving notification from the
25 State Department of Public Health that a clinic described in
26 subparagraph (A) or (B) of paragraph (1) is certified for enrollment,
27 the department shall enroll the clinic in the Family PACT Program.

28 (3) A subsequent change to information reported on the initial
29 enrollment application described in this subdivision shall be
30 reported to the State Department of Public Health in a manner
31 determined by the State Department of Public Health within 35
32 calendar days. Within 15 calendar days of receiving notification
33 from the State Department of Public Health that a clinic's reported
34 changes are approved, the department shall update the clinic's
35 provider master file for the Medi-Cal program and the Family
36 PACT Program enrollments, as applicable. A provider described
37 in this subdivision that reports a change other than a change of
38 ownership shall not be required to reenroll in either the Medi-Cal
39 program or the Family PACT Program.

1 ~~(u) Providers, or the enrolling entity, shall make available to all~~
2 ~~applicants and beneficiaries prior to, or concurrent with,~~
3 ~~enrollment, information on the manner in which to apply for~~
4 ~~insurance affordability programs, in a manner determined by the~~
5 ~~State Department of Health Care Services. The information~~
6 ~~provided shall include the manner in which applications can be~~
7 ~~submitted for insurance affordability programs, information about~~
8 ~~the open enrollment periods for the California Health Benefit~~
9 ~~Exchange, and the continuous enrollment aspect of the Medi-Cal~~
10 ~~program.~~

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