Assembly Bill No. 1098

CHAPTER 322

An act to amend Sections 1241, 1265, 1287, 1301, and 1324 of, and to add Sections 1269.5, 1281.1, 1282.2, 1282.3, and 1311 to, the Business and Professions Code, to amend Sections 186.2 and 923 of the Penal Code, and to amend Sections 14040, 14040.5, 14043.1, 14043.2, 14043.36 14043.37, 14043.65, 14043.7, 14043.75, 14100.75, 14107, 14107.11, 14124.1, 14124.2, 14170, 14170.8, 14171.6, and 24005 of, and to add Sections 14040.1, 14043.34, 14043.61, 14043.62, and 14123.25 to, the Welfare and Institutions Code, relating to health.

[Approved by Governor September 5, 2000. Filed with Secretary of State September 7, 2000.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1098, Romero. Health.

Existing law contains provisions governing the licensure and registration of clinical laboratories, which are administered by the State Department of Health Services.

This bill would make various modifications to these requirements, including the provision of additional grounds for denial, suspension, or revocation of licensure or registration, and exemptions from clinical laboratory provisions relating to the retention of records.

The bill would make it a crime, punishable as specified, to engage in willful or wanton disregard of a person's safety that exposes the person to a substantial risk of, or that causes, serious bodily injury, by affecting the integrity of a biological specimen or a clinical laboratory test or examination result, through improper collection, handling, storage, or labeling of the specimen, or the erroneous transcription or reporting of test or examination results.

The bill would also make it unlawful, and subject to criminal penalties, for any person to: (1) except where exempt, provide any form of payment or gratuity for human blood or any other biological specimen provided for the purpose of clinical laboratory testing or practice, (2) solicit, or provide any form of payment or gratuity to, another person for the procurement of that person's blood or any other specimen from his or her body, or (3) unless authorized to do so, to perform venipuncture, skin puncture, or arterial puncture to collect a biological specimen.

Existing law authorizes the Attorney General to convene the grand jury to investigate and consider certain criminal matters.

This bill would authorize the Attorney General to convene the grand jury to investigate, consider, and indict for activities subject to

penalties under the bill related to defrauding or submitting false information to the Medi-Cal program.

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 defines a provider for the purposes of the Medi-Cal program.

This bill would revise the definition of a provider for that purpose.

Existing law provides for the State-Only Family Planning Program, under which family planning services are provided to eligible individuals.

Existing law also establishes the Family Planning Access, Care, and Treatment Waiver Program, as part of the Medi-Cal program.

The bill would enact various provisions relating to billing for Medi-Cal and family planning services, including provisions relating to provider billing agents.

Existing law provides that any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing Medi-Cal program services or merchandise, knowingly submits false information for the purpose of obtaining greater compensation than that to which he or she is legally entitled, or knowingly submits false information for the purpose of obtaining authorization for obtaining Medi-Cal program services or merchandise is guilty of a crime.

This bill would, instead, make it a crime for any person, including a Medi-Cal provider, an applicant for provider status, or a billing agent, to engage in specified activities related to defrauding or submitting false information to the Medi-Cal program, punishable as prescribed.

The bill would also permit, subject to specified requirements, the forfeiture of property of persons engaging in these activities.

Because the bill creates additional crimes, the bill would constitute a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

SECTION 1. Section 1241 of the Business and Professions Code is amended to read:

1241. (a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California

for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.

(2) Public health laboratories, as defined in Section 1206.

(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.

(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.

(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.

(6) Those that register with the State Department of Health Services pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes when the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:

(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to

determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.

(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.

(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.

(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.

(7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.

(c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Health Services in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of Health Services.

SEC. 2. Section 1265 of the Business and Professions Code is amended to read:

1265. (a) (1) A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.

(2) A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the department. The department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA

requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

(b) An application for a clinical laboratory license or registration shall include the name or names of the owner or the owners, the name or names of the laboratory director or directors, the name and location of the laboratory, a list of the clinical laboratory tests or examinations performed by the laboratory by name and total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance, or proficiency testing purposes). The application shall also include a list of the tests and the test kits, methodologies, and laboratory equipment used, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures, and any other relevant information as may be required by the department. If the laboratory is performing tests subject to a provider-performed microscopy certificate, the name of the provider or providers performing those tests shall be included on the application. Application shall be made by the owners of the laboratory and the laboratory directors prior to its opening. A license or registration to conduct a clinical laboratory if the owners are not the laboratory directors shall be issued jointly to the owners and the laboratory directors and the license or registration shall include any information as may be required by the department. The owners and laboratory directors shall be severally and jointly responsible to the department for the maintenance and conduct thereof or for any violations of this chapter and regulations pertaining thereto.

(c) The department shall not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.

(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

(1) Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.

(2) Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction, may file

a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.

(4) Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

(e) (1) A license or registration shall be valid for one year unless revoked or suspended. A clinical laboratory license or registration shall be automatically revoked 30 days from a major change of laboratory directorship or ownership. The clinical laboratory shall be required to submit a completed application for a new clinical laboratory license or registration within those 30 days or cease engaging in clinical laboratory practice.

(2) If a clinical laboratory intends to continue to engage in clinical laboratory practice during the 30 days after a major change in directorship occurs and before the laboratory license or registration is automatically revoked, the laboratory owner may appoint an interim director who meets the requirements of this chapter and CLIA. The interim director shall be appointed within five business days of the major change of the directorship. Written notice shall be provided to the department of the appointment of the laboratory director pursuant to this paragraph within five business days of the appointment.

(f) If the department does not within 60 days after the date of receipt of the application issue a license or registration, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant by certified mail addressed to the applicant at his or her last known address.

(g) The department shall be notified in writing by the laboratory owners or delegated representatives of the owners and the laboratory directors of any change in ownership, directorship, name, or location, including the addition or deletion of laboratory owners or laboratory directors within 30 days. However, notice of change in ownership shall be the responsibility of both the current and new owners. Laboratory owners and directors to whom the current license or registration is issued shall remain jointly and severally responsible to the department for the operation, maintenance, and conduct of the clinical laboratory and for any violations of this chapter or the regulations adopted thereunder, including any failure to provide the notifications required by this subdivision, until proper notice is received by the department. In addition, failure of the laboratory owners and directors to notify the department within 30 days of any change in laboratory directors, including any additions or deletions, shall result in the automatic revocation of the clinical laboratory's license or registration.

(h) The withdrawal of an application for a license or registration or for a renewal of a license, or registration, issuable under this chapter, shall not, after the application has been filed with the department, deprive the department of its authority to institute or continue a proceeding against the applicant for denial of the license, registration, or renewal upon any ground provided by law or to enter an order denying the license, registration, or renewal upon any such ground, unless the department consents in writing to the withdrawal.

(i) The suspension, expiration, or forfeiture by operation of law of a license or registration issued under this chapter, or its suspension, forfeiture, or cancellation by order of the department or by order of a court of law, or its surrender without the written consent of the department, shall not deprive the department of its authority to institute or continue an action against a license or registration issued under this chapter or against the laboratory owner or laboratory director upon any ground provided by law or to enter an order suspending or revoking the license or registration issued under this chapter.

(j) (1) Whenever a clinical laboratory ceases operations, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify the department of this fact, in writing, within 30 calendar days from the date a clinical laboratory ceases operation. For purposes of this subdivision, a laboratory ceases operations when it suspends the performance of all clinical laboratory tests or examinations for 30 calendar days at the location for which the clinical laboratory is licensed or registered.

(2) (A) Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.

(B) For purposes of this subdivision, ‘‘medical records’’ means the test requisition or test authorization, or the patient’s chart or medical record, if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.

(C) For purposes of this subdivision, ‘‘laboratory records’’ means records showing compliance with CLIA and this chapter during a laboratory’s operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all

invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.

(D) Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.

(3) The department or any person injured as a result of a laboratory's abandonment or failure to retain records pursuant to this section may bring an action in a court of proper jurisdiction for any reasonable amount of damages suffered as a result thereof.

SEC. 3. Section 1269.5 is added to the Business and Professions Code, to read:

1269.5. The department may deny, suspend, or revoke any license, registration, or certificate issued under this chapter for performance by unlicensed laboratory personnel of any activity that is not authorized by Section 1269.

SEC. 4. Section 1281.1 is added to the Business and Professions Code, to read:

1281.1. It is unlawful for any person, including a person who owns, operates, or directs a clinical laboratory, to provide, offer, or solicit, any form of payment or gratuity for human blood or any other biological specimen provided for the purpose of clinical laboratory testing or clinical laboratory practice, unless the person is serving as an agent of a clinical laboratory or another facility legally utilizing those specimens only for purposes of research or teaching or for quality assurance purposes, or is an entity licensed under Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code.

SEC. 5. Section 1282.2 is added to the Business and Professions Code, to read:

1282.2. It is unlawful for any person to perform venipuncture, skin puncture, or arterial puncture to collect a biological specimen unless he or she is authorized to do so under this chapter, the regulations adopted thereunder, or under other provisions of law.

SEC. 6. Section 1282.3 is added to the Business and Professions Code, to read:

1282.3. (a) It is unlawful for any person to act with willful or wanton disregard for a person's safety that exposes the person to a substantial risk of, or that causes, great bodily injury by affecting the integrity of a clinical laboratory test or examination result through improper collection, handling, storage, or labeling of the biological specimen or the erroneous transcription or reporting of clinical laboratory test or examination results.

(b) Notwithstanding Section 1287, a violation of this section shall be punished, upon first conviction, by imprisonment in a county jail for a period of not more than one year, or by imprisonment in a state prison for 16 months, or two or three years, by a fine not exceeding fifty thousand dollars ($50,000), or by both this fine and

imprisonment. A second or subsequent conviction is punishable by imprisonment in the state prison for two, four, or six years, by a fine not exceeding fifty thousand dollars ($50,000), or by both this fine and imprisonment.

(c) The enforcement remedies provided under this section are not exclusive, and shall not preclude the use of any other criminal or civil remedy. However, an act or omission punishable in different ways by this section and any other provision of law shall not be punished under more than one provision. Under those circumstances, the penalty to be imposed shall be determined as set forth in Section 654 of the Penal Code.

SEC. 7. Section 1287 of the Business and Professions Code is amended to read:

1287. (a) Any person who violates any provision of this chapter is guilty of a misdemeanor punishable upon conviction by imprisonment in the county jail for a period not exceeding six months or by fine not exceeding one thousand dollars ($1,000) or by both.

(b) (1) Notwithstanding subdivision (a), a violation of Section 1281.1 is a public offense and is punishable upon conviction by imprisonment in the county jail for not more than one year, or by a fine not exceeding ten thousand dollars ($10,000), or by both that imprisonment and fine.

(2) Notwithstanding subdivision (a), a violation of Section 1282.2 is a public offense and is punishable upon conviction by imprisonment in the county jail for not more than one year, or by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(3) The enforcement remedies provided under this section are not exclusive, and shall not preclude the use of any other criminal or civil remedy. However, an act or omission punishable in different ways by this section and any other provision of law shall not be punished under more than one provision. Under those circumstances, the penalty to be imposed shall be determined as set forth in Section 654 of the Penal Code.

SEC. 8. Section 1301 of the Business and Professions Code is amended to read:

1301. (a) The annual renewal fee for a clinical laboratory license or registration set under this chapter shall be paid during the 30-day period before the expiration date of the license or registration. Failure to pay the annual fee in advance during the time the license remains in force shall, ipso facto, work a forfeiture of said license after a period of 60 days from the expiration date of the license or registration.

(b) (1) The department shall give written notice to all persons licensed pursuant to Sections 1260, 1260.1, 1261, 1261.5, 1262, 1264, or 1270 30 days in advance of the regular renewal date that a renewal fee has not been paid. In addition, the department shall give written

notice to licensed clinical laboratory bioanalysts or doctoral degree specialists and clinical laboratory scientists or limited clinical laboratory scientists by registered or certified mail 90 days in advance of the expiration of the fifth year that a renewal fee has not been paid and if not paid before the expiration of the fifth year of delinquency the licensee may be subject to reexamination.

(2) If the renewal fee is not paid for five or more years, the department may require an examination before reinstating the license, except that no examination shall be required as a condition for reinstatement if the original license was issued without an examination. No examination shall be required for reinstatement if the license was forfeited solely by reason of nonpayment of the renewal fee if the nonpayment was for less than five years.

(3) If the license is not renewed within 60 days after its expiration, the licensee, as a condition precedent to renewal, shall pay the delinquency fee identified in subdivision (*l*) of Section 1300, in addition to the renewal fee in effect on the last preceding regular renewal date. Payment of the delinquency fee will not be necessary if within 60 days of the license expiration date the licensee files with the department an application for inactive status.

SEC. 9. Section 1311 is added to the Business and Professions Code, to read:

1311. The department shall have three years from the date of a violation of this chapter or of a regulation adopted thereunder to file a civil or administrative action.

SEC. 10. Section 1324 of the Business and Professions Code is amended to read:

1324. Except for a person or entity whose license was revoked automatically under Section 1265, no person or entity who has owned or operated a clinical laboratory that had its license or registration revoked may, within two years of the revocation of the license or registration, own or operate a laboratory for which a license or registration has been issued under this chapter.

SEC. 11. Section 186.2 of the Penal Code is amended to read:

186.2. For purposes of this chapter, the following definitions apply:

(a) ''Criminal profiteering activity'' means any act committed or attempted or any threat made for financial gain or advantage, which act or threat may be charged as a crime under any of the following sections:

(1) Arson, as defined in Section 451.

(2) Bribery, as defined in Sections 67, 67.5, and 68.

(3) Child pornography or exploitation, as defined in subdivision (b) of Section 311.2, or Section 311.3 or 311.4, which may be prosecuted as a felony.

(4) Felonious assault, as defined in Section 245.

(5) Embezzlement, as defined in Sections 424 and 503.

(6) Extortion, as defined in Section 518.

(7) Forgery, as defined in Section 470.

(8) Gambling, as defined in Sections 337a to 337f, inclusive, and Section 337i, except the activities of a person who participates solely as an individual bettor.

(9) Kidnapping, as defined in Section 207.

(10) Mayhem, as defined in Section 203.

(11) Murder, as defined in Section 187.

(12) Pimping and pandering, as defined in Section 266.

(13) Receiving stolen property, as defined in Section 496.

(14) Robbery, as defined in Section 211.

(15) Solicitation of crimes, as defined in Section 653f.

(16) Grand theft, as defined in Section 487.

(17) Trafficking in controlled substances, as defined in Sections 11351, 11352, and 11353 of the Health and Safety Code.

(18) Violation of the laws governing corporate securities, as defined in Section 25541 of the Corporations Code.

(19) Any of the offenses contained in Chapter 7.5 (commencing with Section 311) of Title 9, relating to obscene matter, or in Chapter 7.6 (commencing with Section 313) of Title 9, relating to harmful matter that may be prosecuted as a felony.

(20) Presentation of a false or fraudulent claim, as defined in Section 550.

(21) False or fraudulent activities, schemes, or artifices, as described in Section 14107 of the Welfare and Institutions Code.

(22) Money laundering, as defined in Section 186.10.

(23) Offenses relating to the counterfeit of a registered mark, as specified in Section 350.

(24) Offenses relating to the unauthorized access to computers, computer systems, and computer data, as specified in Section 502.

(25) Conspiracy to commit any of the crimes listed above, as defined in Section 182.

(26) Engaging in a pattern of criminal gang activity, as defined in subdivision (e) of Section 186.22.

(b) ''Pattern of criminal profiteering activity'' means engaging in at least two incidents of criminal profiteering, as defined by this act, that meet the following requirements:

(1) Have the same or a similar purpose, result, principals, victims, or methods of commission, or are otherwise interrelated by distinguishing characteristics.

(2) Are not isolated events.

(3) Were committed as a criminal activity of organized crime.

Acts that would constitute a ''pattern of criminal profiteering activity'' may not be used by a prosecuting agency to seek the remedies provided by this chapter unless the underlying offense occurred after the effective date of this chapter and the prior act occurred within 10 years, excluding any period of imprisonment, of

the commission of the underlying offense. A prior act may not be used by a prosecuting agency to seek remedies provided by this chapter if a prosecution for that act resulted in an acquittal.

(c) ''Prosecuting agency'' means the Attorney General or the district attorney of any county.

(d) ''Organized crime'' means crime that is of a conspiratorial nature and that is either of an organized nature and seeks to supply illegal goods and services such as narcotics, prostitution, loan sharking, gambling, and pornography, or that, through planning and coordination of individual efforts, seeks to conduct the illegal activities of arson for profit, hijacking, insurance fraud, smuggling, operating vehicle theft rings, or systematically encumbering the assets of a business for the purpose of defrauding creditors. ''Organized crime'' also means crime committed by a criminal street gang, as defined in subdivision (f) of Section 186.22. ''Organized crime'' also means false or fraudulent activities, schemes, or artifices, as described in Section 14107 of the Welfare and Institutions Code.

(e) ''Underlying offense'' means an offense enumerated in subdivision (a) for which the defendant is being prosecuted.

SEC. 12. Section 923 of the Penal Code is amended to read:

923. (a) Whenever the Attorney General considers that the public interest requires, he or she may, with or without the concurrence of the district attorney, direct the grand jury to convene for the investigation and consideration of those matters of a criminal nature that he or she desires to submit to it. He or she may take full charge of the presentation of the matters to the grand jury, issue subpoenas, prepare indictments, and do all other things incident thereto to the same extent as the district attorney may do.

(b) Whenever the Attorney General considers that the public interest requires, he or she may, with or without the concurrence of the district attorney, petition the court to impanel a special grand jury to investigate, consider, or issue indictments for any of the activities subject to fine, imprisonment, or asset forfeiture under Section 14107 of the Welfare and Institutions Code. He or she may take full charge of the presentation of the matters to the grand jury, issue subpoenas, prepare indictments, and do all other things incident thereto to the same extent as the district attorney may do. If the evidence presented to the grand jury shows the commission of an offense or offenses for which jurisdiction would be in a county other than the county where the grand jury is impaneled, the Attorney General, with or without the concurrence of the district attorney in the county with jurisdiction over the offense or offenses, may petition the court to impanel a special grand jury in that county. Notwithstanding any other provision of law, upon request of the Attorney General, a grand jury convened by the Attorney General pursuant to this subdivision may submit confidential information obtained by that grand jury, including, but not limited to documents

and testimony, to a second grand jury that has been impaneled at the request of the Attorney General pursuant to this subdivision in any other county where venue for an offense or offenses shown by evidence presented to the first grand jury is proper. All confidentiality provisions governing information, testimony, and evidence presented to a grand jury shall be applicable except as expressly permitted by this subdivision. The Attorney General shall inform the grand jury that transmits confidential information and the grand jury that receives confidential information of any exculpatory evidence, as required by Section 939.71. The grand jury that transmits information to another grand jury shall include the exculpatory evidence disclosed by the Attorney General in the transmission of the confidential information. The Attorney General shall inform both the grand jury transmitting the confidential information and the grand jury receiving that information of their duties under Section 939.7. A special grand jury convened pursuant to this subdivision shall be in addition to the other grand juries authorized by this chapter or Chapter 2 (commencing with Section 893).

(c) Upon certification by the Attorney General, a statement of the costs directly related to the impanelment and activities of the grand jury pursuant to subdivision (b) from the presiding judge of the superior court where the grand jury was impaneled shall be submitted for state reimbursement of the costs to the county.

SEC. 13. Section 14040 of the Welfare and Institutions Code is amended to read:

14040. (a) Each contract for fiscal intermediary services shall allow, to the extent practicable, providers to utilize electronic means for transmitting claims to the fiscal intermediary contractor. Means of transmission, and the manner and format used, shall be approved by the director. In determining which electronic means are acceptable, the director shall consider magnetic tape, computer-to-computer via telephone, diskettes, and any other methods which may become available through technological advancements.

(b) A provider, as defined in Section 14043.1, may assign signature authority for transmission of claims to the provider's authorized representative or the registered billing agent of the provider identified to the department pursuant to subdivision (c) of Section 14040.5.

(c) The department shall develop reasonable standards for participation and continued participation by providers and billing agents in the use of claims transmission methods utilized pursuant to this section. These standards shall be designed to ensure that providers and billing agents submit technically complete claims and to reduce the potential for fraud and abuse. The department shall notify providers and billing agents of any planned changes to the claims transmission standards prior to the implementation of the

changes. A ''technically complete claim'' means any billing request for payment from a provider or the billing agent of the provider, including an original claim, claim inquiry, or appeal, that is submitted on the correct Medi-Cal claim form or electronic billing format, is fully and accurately completed, and includes all information and documentation required to be submitted on or with the claim pursuant to Medi-Cal billing and documentation requirements.

(d) To the extent required by federal and state law, the fiscal intermediary shall retain claim data submitted by providers or the billing agent of the provider pursuant to this section. The department shall, however, return to a provider or the billing agent of the provider original tapes, diskettes, and any other similar devices that are used by the provider or the billing agent of the provider pursuant to this section.

(e) In order to reduce the amount of paperwork or attachments which are required to be completed by a provider or the billing agent of the provider submitting a claim for reimbursement under this chapter to the fiscal intermediary, the department shall direct the fiscal intermediary to investigate and develop the means to incorporate as much information as possible on the electronic format.

(f) Each provider and billing agent submitting claims shall be responsible for ensuring that each claim submitted for reimbursement for services, goods, supplies, or merchandise rendered or supplied by the provider to a Medi-Cal beneficiary or under the Medi-Cal program meets the standards established by the department pursuant to this section.

SEC. 14. Section 14040.1 is added to the Welfare and Institutions Code, to read:

14040.1. (a) ''Billing agent'' or ''billing agent of the provider'' means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, owners, managing employees, or agents of any partnership, group, association, corporation, institution, or entity, that submits claims on behalf of the provider, as defined in Section 14043.1, for reimbursement for services, goods, supplies, or merchandise rendered or provided directly or indirectly to a Medi-Cal beneficiary or under the Medi-Cal program. As used in this section a billing agent shall not include an authorized representative of a provider billing solely for that provider, a provider wholly owned entity billing solely for the provider, or a clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code or exempt from licensure pursuant to subdivision (c) of Section 1206 of the Health and Safety Code when preparing and submitting claims for services provided on behalf of the clinic. For purposes of this subdivision, an authorized representative shall be either an individual who is an employee of the provider or an individual with a familial relationship to the provider. For purposes of this section and Section 14040.5, an authorized

representative, a provider wholly owned entity billing solely for the provider, or a clinic that is licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code or exempt from licensure pursuant to subdivision (c) of Section 1206 of the Health and Safety Code, when preparing and submitting claims for services provided on behalf of the clinic, shall be considered a provider.

(b) The department shall establish standards for the registration or continued registration of each billing agent. The standards shall establish time periods, no longer than a year from the date the standards become effective, after which, no billing agent shall submit a claim on behalf of a provider, as defined in Section 14043.1, for reimbursement for services, goods, supplies, or merchandise rendered or provided directly or indirectly by the provider to a Medi-Cal beneficiary or under the Medi-Cal program, unless that billing agent has been registered with the department. The department shall establish the standards for the registration or continued registration of billing agents pursuant to this subdivision, in consultation with interested parties, by the adoption of emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The adoption of these emergency regulations or readoption of the regulations shall be deemed to be an emergency necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340 of Part 1 of Division 3 of Title 2 of the Government Code, emergency regulations adopted or readopted pursuant to this subdivision shall be exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations.

(c) The department may complete a background check on applicants for registration or continued registration as a billing agent, for the purpose of verifying the accuracy of information provided by an applicant for registration or continued registration as a billing agent or in order to prevent fraud and abuse. The background check may include, but not be limited to, onsite inspection, review of business records, and data searches.

(d) As a condition of registration, or continued registration, as a billing agent, an applicant for registration as a billing agent shall provide to the department a surety bond of not less than fifty thousand dollars ($50,000). This subdivision shall become operative only if the director executes a declaration, that shall be retained by the director, stating that the surety bonds described in this paragraph are commercially offered throughout the state and by more than one vendor.

SEC. 15. Section 14040.5 of the Welfare and Institutions Code is amended to read:

14040.5. (a) A provider may, by written contract, do either of the following:

(1) Authorize a billing agent to submit claims, including electronic claims, on behalf of the provider for reimbursement for services, goods, supplies, or merchandise provided by the provider to the Medi-Cal program or a Medi-Cal beneficiary.

(2) Assign signature authority for transmission of the claims by the authorized billing agent.

(b) If a contract as described in subdivision (a) is entered into, the contract shall meet the requirements of Section 447.10 of Title 42 of the Code of Federal Regulations or shall have been approved by the federal Health Care Financing Administration for purposes of the Medicare program.

(c) Any provider intending to use a billing agent to submit claims for reimbursements to the Medi-Cal program shall provide, at least 30 days prior to the submission of any claims for reimbursement by the billing agent, written notification to the director of the name, including known legal and any known fictitious or ''doing business as'' names used by the billing agent, the address, and the telephone number of the billing agent.

(d) Billing agents shall register with the director and shall obtain a unique identifier prior to submitting any claims for reimbursement. This unique identifier shall be part of each claim for reimbursement submitted by the billing agent.

(e) (1) Any Medi-Cal claim submitted by a billing agent or provider failing to comply with the requirements of this section or Section 14040 or 14040.1, or the regulations adopted pursuant to these sections, shall be subject to denial by the director.

(2) The director may deny, suspend, or revoke the registration or continued registration of a billing agent based upon any of the following grounds:

(A) Failure of the billing agent to comply with this section or Section 14040.1 or the regulations adopted under these sections.

(B) Involvement of a billing agent in illegal submission of claims.

(C) The billing agent is under investigation for fraud or abuse, as defined in Section 14043.1, by the department or any federal, state, or local law enforcement agency.

(3) The director may immediately revoke or suspend the registration or continued registration of a billing agent upon the involvement of that billing agent in the filing of false or misleading information on claims submitted for services allegedly rendered, or when a billing agent has demonstrated a pattern of filing claims that are not technically complete claims as defined in subdivision (c) of Section 14040. The director shall not take action to revoke or suspend a billing agent's registration or continued registration when the

falsity or misleading nature of the information was the result of the provider's actions and not the billing agent's.

(4) Proceedings for suspension or revocation of the registration or continued registration of a billing agent pursuant to this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, except that hearings may be conducted by departmental hearing officers appointed by the director. The director may periodically contract with the Office of Administrative Hearings to conduct these hearings.

(5) The director shall provide written notification outlining the reasons for the proposed action to the billing agent 30 days in advance of a proposed suspension or revocation and shall allow the billing agent to demonstrate within those 30 days by comment why the suspension or revocation notice should not be issued.

(6) If after consideration of the billing agent's comment, the director determines that the suspension or revocation is nonetheless warranted, the director shall notify the billing agent of the suspension or revocation and the effective date thereof and at the same time shall serve the billing agent with an accusation. In addition, the director shall send each provider utilizing the services of the billing agent written notice of the suspension or revocation of the billing agent. The suspension or revocation of the billing agent shall take effect 15 days from the date of the notification of the billing agent and service of the accusation. To the extent allowed by federal law, the director may waive any claims submission requirement to assist a provider in submitting or resubmitting claims to the Medi-Cal program when they are delayed because of a billing agent's suspension or revocation. Upon receipt of a notice of defense by the billing agent, the director shall set the matter for hearing within 30 days of the receipt of the notice. The suspension or revocation shall remain in effect until the hearing is completed and the director has made a final determination on the merits. The suspension or revocation shall, however, be deemed vacated if the director fails to make a final determination on the merits within 60 days of the completion of the original hearing.

(7) Paragraph (4) of this subdivision shall not apply where the suspension or revocation of a billing agent is based upon the conviction for any crime involving fraud, abuse of the Medi-Cal program, or suspension from the federal Medicare or medicaid programs, or where the billing agent has entered into a settlement in lieu of conviction for fraud or abuse in any government program, within the previous 10 years. In those instances, suspension or revocation shall be automatic and not subject to administrative appeal or hearing. In those instances, the director shall send each provider utilizing the services of the billing agent written notice of the automatic suspension or revocation of the billing agent. To the

extent allowed by federal law, the director may waive any claims submission requirement to assist a provider in submitting or resubmitting claims to the Medi-Cal program when they are delayed because of a billing agent's automatic suspension or revocation.

(8) Notwithstanding Section 100171 of the Health and Safety Code, proceedings for the denial of the registration of a billing agent pursuant to this section shall be conducted in accordance with Section 14043.65. This subdivision shall not apply where the denial is based upon conviction of any crime involving fraud or abuse of the Medi-Cal program or the federal medicaid or Medicare programs, or exclusion by the federal government from the medicaid or Medicare programs. In this case, the denial shall be automatic and not subject to administrative appeal or hearing.

(f) For purposes of this section, ''billing agent'' has the same meaning as defined in Section 14040.1.

(g) As used in this section ''provider'' has the same meaning as defined in Section 14043.1.

SEC. 16. Section 14043.1 of the Welfare and Institutions Code is amended to read:

14043.1. As used in this article:

(a) ''Abuse'' means either of the following:

(1) Practices that are inconsistent with sound fiscal or business practices and result in unnecessary cost to the federal medicaid and Medicare programs, the Medi-Cal program, another state's medicaid program, or other health care programs operated, or financed in whole or in part, by the federal government or any state or local agency in this state or any other state.

(2) Practices that are inconsistent with sound medical practices and result in reimbursement by the federal medicaid and Medicare programs, the Medi-Cal program or other health care programs operated, or financed in whole or in part, by the federal government or any state or local agency in this state or any other state, for services that are unnecessary or for substandard items or services that fail to meet professionally recognized standards for health care.

(b) ''Applicant'' means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, owners, managing employees, or agents thereof, that applies to the department for enrollment as a provider in the Medi-Cal program.

(c) ''Convicted'' means any of the following:

(1) A judgment of conviction has been entered against an individual or entity by a federal, state, or local court, regardless of whether there is a posttrial motion or an appeal pending or the judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed.

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

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

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

(d) ''Fraud'' means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or herself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

(e) ''Provider'' means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, owners, managing employees, or agents of any partnership, group association, corporation, institution, or entity, that provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary and that has been enrolled in the Medi-Cal program.

(f) ''Enrolled or enrollment in the Medi-Cal program'' means authorized under any and all processes by the department or its agents or contractors to receive, directly or indirectly, reimbursement for the provision of services, goods, supplies, or merchandise to a Medi-Cal beneficiary.

(g) ''Professionally recognized standards of health care'' means statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a state. When the United States Department of Health and Human Services has declared a treatment modality not to be safe and effective, practitioners that employ that treatment modality shall be deemed not to meet professionally recognized standards of health care. This definition shall not be construed to mean that all other treatments meet professionally recognized standards of care.

(h) ''Unnecessary or substandard items or services'' means those that are either of the following:

(1) Substantially in excess of the provider's usual charges or costs for the items or services.

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

(A) The professional review organization for the area served by the individual or entity.

(B) State or local licensing or certification authorities.

(C) Fiscal agents or contractors, or private insurance companies.

(D) State or local professional societies.

(E) Any other sources deemed appropriate by the department.

SEC. 17. Section 14043.2 of the Welfare and Institutions Code is amended to read:

14043.2. (a) Whether or not regulations for certification are adopted under Section 14043.15, in order to be enrolled as a provider, or for enrollment as a provider to continue, an applicant or provider may be required to sign a provider agreement and shall disclose all information as required in federal medicaid regulations and any other information required by the department. Applicants, providers, and persons with an ownership or control interest, as defined in federal medicaid regulations, shall submit their social security number or numbers to the department, to the full extent allowed under federal law. The director may designate the form of a provider agreement by provider type. Failure to disclose the required information, or the disclosure of false information, shall result in denial of the application for enrollment or shall make the provider subject to temporary suspension from the Medi-Cal program, which shall include temporary deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program.

(b) The director shall notify the provider of the temporary suspension and deactivation of the provider's Medi-Cal provider number or numbers and the effective date thereof. Notwithstanding Section 100171 of the Health and Safety Code and Section 14123, proceedings after the imposition of sanctions provided for in subdivision (a) shall be in accordance with Section 14043.65.

SEC. 18. Section 14043.34 is added to the Welfare and Institutions Code, to read:

14043.34. (a) As a condition of a pharmacy's participation in the Medi-Cal program, the pharmacy shall have in stock and regularly dispense prescription drugs.

(b) For purposes of this section, ''prescription drugs'' means any drug unsafe for self use by a person, and includes either of the following:

(1) Any drug that bears the legend: ''R_x Only'' or ''Caution: federal law prohibits dispensing without prescription'' or words of similar import.

(2) Any other drug that by federal or state law can be lawfully dispensed by the prescription of a licensed physician and surgeon.

SEC. 19. Section 14043.36 of the Welfare and Institutions Code is amended to read:

14043.36. (a) The department shall not enroll any applicant that has been convicted of any felony or misdemeanor involving fraud or abuse in any government program, or related to neglect or abuse of a patient in connection with the delivery of a health care item or service, or in connection with the interference with or obstruction of any investigation into health care related fraud or abuse or that has been found liable for fraud or abuse in any civil proceeding, or that has entered into a settlement in lieu of conviction for fraud or abuse in any government program, within the previous 10 years. In addition, the department may deny enrollment to any applicant that, at the time of application, is under investigation by the department or any state, local, or federal government law enforcement agency for fraud or abuse pursuant to Subpart A (commencing with Section 455.12) of Part 455 of Title 42 of the Code of Federal Regulations. The department shall not deny enrollment to an otherwise qualified applicant whose felony or misdemeanor charges did not result in a conviction solely on the basis of the prior charges. If it is discovered that a provider is under investigation by the department or any state, local, or federal government law enforcement agency for fraud or abuse, that provider shall be subject to temporary suspension from the Medi-Cal program, which shall include temporary deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program.

(b) The director shall notify in writing the provider of the temporary suspension and deactivation of the provider's Medi-Cal provider number or numbers, which shall take effect 15 days from the date of the notification. Notwithstanding Section 100171 of the Health and Safety Code, proceedings after the imposition of sanctions provided for in subdivision (a) shall be in accordance with Section 14043.65.

SEC. 20. Section 14043.37 of the Welfare and Institutions Code is amended to read:

14043.37. The department may complete a background check on applicants for the purpose of verifying the accuracy of the information provided to the department for purposes of enrolling in the Medi-Cal program and in order to prevent fraud and abuse. The background check may include, but is not limited to, the following:

(a) Onsite inspection prior to enrollment.

(b) Review of business records.

(c) Data searches.

SEC. 21. Section 14043.61 is added to the Welfare and Institutions Code, to read:

14043.61. (a) A provider shall be subject to suspension if claims for payment are submitted under any provider number used by the provider to obtain reimbursement from the Medi-Cal program for the services, goods, supplies, or merchandise provided, directly or indirectly, to a Medi-Cal beneficiary, by an individual or entity that

is suspended, excluded, or otherwise ineligible because of a sanction to receive, directly or indirectly, reimbursement from the Medi-Cal program and the individual or entity is listed on either the Suspended and Ineligible Provider List, published by the department, to identify suspended and otherwise ineligible providers, or any list published by the federal Office of Inspector General regarding the suspension or exclusion of individuals or entities from the federal Medicare and medicaid programs, to identify suspended, excluded, or otherwise ineligible providers.

(b) Notwithstanding Section 100171 of the Health and Safety Code, the imposition of the sanction provided for in subdivision (a) shall be appealable in accordance with Section 14043.65.

SEC. 22. Section 14043.62 is added to the Welfare and Institutions Code, to read:

14043.62. (a) The department shall deactivate, immediately and without prior notice, the provider numbers used by a provider to obtain reimbursement from the Medi-Cal program when warrants or documents mailed to a provider's mailing address or its pay to address, if any, or its service or business address, are returned by the United States Postal Service as not deliverable or when a provider has not submitted a claim for reimbursement from the Medi-Cal program for one year. Prior to taking this action the department shall use due diligence in attempting to contact the provider at its last known telephone number and ascertain if the return by the United States Postal Service is by mistake or shall use due diligence in attempting to contact the provider by telephone or in writing to ascertain whether the provider wishes to continue to participate in the Medi-Cal program. If deactivation pursuant to this section occurs, the provider shall meet the requirements for reapplication as specified in this article or the regulations adopted thereunder.

(b) For purposes of this section:

(1) ''Mailing address'' means the address that the provider has identified to the department in its application for enrollment as the address at which it wishes to receive general program correspondence.

(2) ''Pay to address'' means the address that the provider has identified to the department in its application for enrollment as the address at which it wishes to receive warrants.

(3) ''Service or business address'' means the address that the provider has identified to the department in its application for enrollment as the address at which the provider will provide services to program beneficiaries.

SEC. 23. Section 14043.65 of the Welfare and Institutions Code is amended to read:

14043.65. (a) Notwithstanding any other provision of law, any applicant whose application for enrollment as a provider or whose certification is denied; or any provider who is denied continued

enrollment or certification, who has been temporarily suspended, who has had payments withheld, who has had one or more provider numbers used to obtain reimbursement from the Medi-Cal program deactivated pursuant to this article or Section 14107.11, or who has had a civil penalty imposed pursuant to Section 14123.25; or any billing agent, as defined in Section 14040, when the billing agent's registration has been denied pursuant to subdivision (e) of Section 14040.5, may appeal this action by submitting a written appeal, including any supporting evidence, to the director or the director's designee. Where the appeal is of a withholding of payment pursuant to Section 14107.11, the appeal to the director or the director's designee shall be limited to the issue of the reliability of the evidence supporting the withhold and shall not encompass fraud or abuse. The appeal procedure shall not include a formal administrative hearing under the Administrative Procedure Act and shall not result in reactivation of any deactivated provider numbers during appeal. An applicant, provider, or billing agent that files an appeal pursuant to this section shall submit the written appeal along with all pertinent documents and all other relevant evidence to the director or to the director's designee within 60 days of the date of notification of the department's action. The director or the director's designee shall review all of the relevant materials submitted and shall issue a decision within 90 days of the receipt of the appeal. The decision may provide that the action taken should be upheld, continued, or reversed, in whole or in part. The decision of the director or the director's designee shall be final. Any further appeal shall be required to be filed in accordance with Section 1085 of the Code of Civil Procedure.

(b) No applicant whose application for enrollment, as a provider, has been denied pursuant to Section 14043.2, 14043.36, or 14043.4 may reapply for a period of three years from the date the application is denied. Where the provider has appealed the denial, the three-year period shall commence upon the date of final action by the director or the director's designee.

SEC. 24. Section 14043.7 of the Welfare and Institutions Code is amended to read:

14043.7. (a) The department may make unannounced visits to any applicant or to any provider for the purpose of determining whether enrollment, continued enrollment, or certification is warranted, or as necessary for the administration of the Medi-Cal program. At the time of the visit, the applicant or provider shall be required to demonstrate an established place of business appropriate and adequate for the services billed or claimed to the Medi-Cal program, as relevant to his or her scope of practice, as indicated by, but not limited to, the following:

(1) Being open and available to the general public.

(2) Having regularly established and posted business hours.

(3) Having adequate supplies in stock on the premises.

(4) Meeting all local laws and ordinances regarding business licensing and operations.

(5) Having the necessary equipment and facilities to carry out day-to-day business for his or her practice.

(b) An unannounced visit pursuant to subdivision (a) shall be prohibited with respect to clinics licensed under Section 1204 of the Health and Safety Code, clinics exempt from licensure under Section 1206 of the Health and Safety Code, health facilities licensed under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, and natural persons licensed or certified under Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act, or the Chiropractic Initiative Act, unless the department has reason to believe that the provider will defraud or abuse the Medi-Cal program or lacks the organizational or administrative capacity to provide services under the program.

(c) Failure to remediate significant discrepancies in information provided to the department by the provider or significant discrepancies that are discovered as a result of an announced or unannounced visit to a provider, for purposes of enrollment, continued enrollment, or certification pursuant to subdivision (a) shall make the provider subject to temporary suspension from the Medi-Cal program, which shall include temporary deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. The director shall notify in writing the provider of the temporary suspension and deactivation of provider numbers, which shall take effect 15 days from the date of the notification. Notwithstanding Section 100171 of the Health and Safety Code, proceedings after the imposition of sanctions in this paragraph shall be in accordance with Section 14043.65.

SEC. 25. Section 14043.75 of the Welfare and Institutions Code is amended to read:

14043.75. The director may, in consultation with interested parties, by regulation, adopt, readopt, repeal, or amend additional measures to prevent or curtail fraud and abuse. Regulations adopted, readopted, repealed, or amended pursuant to this section shall be deemed emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). These emergency regulations shall be deemed necessary for the immediate preservation of the public peace, health and safety, or general welfare. Emergency regulations adopted, amended, or repealed pursuant to this section shall be exempt from review by the Office of Administrative Law. The emergency regulations authorized by this section shall be submitted to the Office of

Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations.

SEC. 26. Section 14100.75 of the Welfare and Institutions Code is amended to read:

14100.75. (a) (1) Each provider and each applicant, as defined in Section 14043.1, when applying for enrollment and continued enrollment, shall provide, to the department, a bond, or other security satisfactory to the department, of an amount determined by the department, pursuant to regulations adopted by the department.

(2) The department, in determining the amount of bond or security required by paragraph (1), shall base the determination on the level of estimated billings, and shall not be less than twenty-five thousand dollars ($25,000).

(3) This subdivision shall become operative only if the director executes a declaration, that shall be retained by the director, stating that the surety bonds described in this paragraph are commercially offered throughout the state and by more than one vendor.

(b) (1) After three years of continuous operation as a provider, a Medi-Cal provider may apply to the department for an exemption from the requirements of subdivision (a).

(2) The department shall adopt regulations establishing conditions for the approval or denial of applications for exemption pursuant to paragraph (1).

(c) The department shall establish a mechanism to track rates of participation among providers who are subject to the requirement of subdivision (a) to determine if the requirement is a deterrent to Medi-Cal program participation among provider applicants.

(d) Subdivisions (a) and (b) shall not apply to natural persons licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act, or the Chiropractic Initiative Act, or to any clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code, or exempt from licensure under subdivision (c) of Section 1206 of the Health and Safety Code, to any health facility licensed under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, or to any provider that is operated by a city, county, school district, county office of education, or state special school, or any professional corporation practicing pursuant to the Moscone-Knox Professional Corporation Act provided for pursuant to Part 4 (commencing with Section 13400) of Division 3 of Title 1 of the Corporations Code.

(e) Nothing in this section shall relieve an applicant or provider of durable medical equipment or home health agency services from complying with subdivisions (a) and (b) of Sections 14100.8 and 14100.9, as applicable.

SEC. 27. Section 14107 of the Welfare and Institutions Code is amended to read:

14107. (a) Any person, including any applicant or provider as defined in Section 14043.1, or billing agent, as defined in Section 14040.1, who engages in any of the activities identified in subdivision (b) is punishable by imprisonment as set forth in subdivisions (c) , (d), and (e), by a fine not exceeding three times the amount of the fraud or improper reimbursement or value of the scheme or artifice, or by both this fine and imprisonment.

(b) The following activities are subject to subdivision (a):

(1) A person, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise under this chapter or Chapter 8 (commencing with Section 14200).

(2) A person knowingly submits false information for the purpose of obtaining greater compensation than that to which he or she is legally entitled for furnishing services or merchandise under this chapter or Chapter 8 (commencing with Section 14200).

(3) A person knowingly submits false information for the purpose of obtaining authorization for furnishing services or merchandise under this chapter or Chapter 8 (commencing with Section 14200).

(4) A person knowingly and willfully executes, or attempts to execute, a scheme or artifice to do either of the following:

(A) Defraud the Medi-Cal program or any other health care program administered by the department or its agents or contractors.

(B) Obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, the Medi-Cal program or any other health care program administered by the department or its agents or contractors, in connection with the delivery of or payment for health care benefits, services, goods, supplies, or merchandise.

(c) A violation of subdivision (a) is punishable by imprisonment in a county jail, or in the state prison for two, three, or five years.

(d) If the execution of a scheme or artifice to defraud as defined in paragraph (4) of subdivision (b) is committed under circumstances likely to cause or that do cause two or more persons great bodily injury, as defined in Section 12022.7 of the Penal Code, or serious bodily injury, as defined in paragraph (4) of subdivision (f) of Section 243 of the Penal Code, a term of four years, in addition and consecutive to the term of imprisonment imposed in subdivision (c), shall be imposed for each person who suffers great bodily injury or serious bodily injury.

The additional terms provided in this subdivision shall not be imposed unless the facts showing the circumstances that were likely to cause or that did cause great bodily injury or serious bodily injury to two or more persons are charged in the accusatory pleading and admitted or found to be true by the trier of fact.

(e) If the execution of a scheme or artifice to defraud, as defined in paragraph (4) of subdivision (b) results in a death which constitutes a second degree murder, as defined in Section 189 of the Penal Code, the offense shall be punishable, upon conviction, pursuant to subdivision (a) of Section 190 of the Penal Code.

(f) Any person, including an applicant or provider as defined in Section 14043.1, or billing agent, as defined in Section 14040.1, who has engaged in any of the activities subject to fine or imprisonment under this section, shall be subject to the asset forfeiture provisions for criminal profiteering.

(g) Pursuant to Section 923 of the Penal Code, the Attorney General may convene a grand jury to investigate and indict for any of the activities subject to fine, imprisonment, or asset forfeiture under this section.

(h) The enforcement remedies provided under this section are not exclusive and shall not preclude the use of any other criminal or civil remedy. However, an act or omission punishable in different ways by this section and other provisions of law shall not be punished under more than one provision, but the penalty to be imposed shall be determined as set forth in Section 654 of the Penal Code.

SEC. 28. Section 14107.11 of the Welfare and Institutions Code is amended to read:

14107.11. (a) Upon receipt of reliable evidence that would be admissible under the administrative adjudication provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, of fraud or willful misrepresentation by a provider as defined in Section 14043.1, under the Medi-Cal program or the commencement of a suspension under Section 14123, the department may do any of the following:

(1) Collect any Medi-Cal program overpayment identified through an audit or examination, or any portion thereof from any provider. Notwithstanding Section 100171 of the Health and Safety Code, a provider may appeal the collection of overpayments under this section pursuant to procedures established in Article 5.3 (commencing with Section 14170). Overpayments collected under this section shall not be returned to the provider during the pendency of any appeal and may be offset to satisfy audit or appeal findings if the findings are against the provider. Overpayments will be returned to a provider with interest if findings are in favor of the provider.

(2) Withhold payment for any goods, services, supplies, or merchandise, or any portion thereof. The department shall notify the provider within five days of any withholding of payment under this section. The notice shall do all of the following:

(A) State that payments are being withheld in accordance with this subdivision and that the withholding is for a temporary period and will not continue after it is determined that the evidence of fraud

or willful misrepresentation is insufficient or when legal proceedings relating to the alleged fraud or willful misrepresentation are complete.

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

(C) Specify, when appropriate, the type or types of claims for which payment is being withheld.

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

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

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

(c) For purposes of this section, ‘‘provider’’ means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, employees, or agents thereof, that provide services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary, and that has been enrolled in the Medi-Cal program.

SEC. 29. Section 14123.25 is added to the Welfare and Institutions Code, to read:

14123.25. (a) In lieu of, or in addition to, the imposition of any other sanction available to it, including the sanctions and penalties authorized under Section 14123.2 or 14171.6, and as the ‘‘single state agency’’ for California vested with authority to administer the Medi-Cal program, the department shall exercise the authority granted to it in Section 1002.2 of Title 42 of the Code of Federal

Regulations, and may also impose the mandatory and permissive exclusions identified in Section 1128 of the federal Social Security Act (42 U.S.C. Sec. 1320a-7), and its implementing regulations, and impose civil penalties identified in Section 1128A of the federal Social Security Act (42 U.S.C. Sec. 1320a-7a), and its implementing regulations, against applicants and providers, as defined in Section 14043.1 or against billing agents, as defined in Section 14040.1. The department may also terminate, or refuse to enter into, a provider agreement authorized under Section 14043.2 with an applicant or provider, as defined in Section 14043.1, upon the grounds specified in Section 1866(b)(2) of the federal Social Security Act (42 U.S.C. Sec. 1395cc(b)(2). Notwithstanding Section 100171 of the Health and Safety Code or any other provision of law, any appeal by an applicant, provider, or billing agent of the imposition of a civil penalty, exclusion, or other sanction pursuant to this subdivision shall be in accordance with Section 14043.65, except that where the action is based upon conviction for any crime involving fraud or abuse of the Medi-Cal, medicaid, or Medicare programs, or exclusion by the federal government from the medicaid or Medicare programs the action shall be automatic and not subject to appeal or hearing.

(b) In addition, the department may impose the intermediate sanctions identified in Section 1846 of the Social Security Act (42 U.S.C. Sec. 1395w-2), and its implementing regulations, against any provider that is a clinical laboratory, as defined in Section 1206 of the Business and Professions Code. The imposition and appeal of this intermediate sanction shall be in accordance with Article 8 (commencing with Section 1065) of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.

SEC. 30. Section 14124.1 of the Welfare and Institutions Code is amended to read:

14124.1. Each provider, as defined in Section 14043.1, of health care services rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, shall keep and maintain records of each such service rendered, the beneficiary or person to whom rendered, the date the service was rendered, and such additional information as the department may by regulation require. Records herein required to be kept and maintained shall be retained by the provider for a period of three years from the date the service was rendered.

SEC. 31. Section 14124.2 of the Welfare and Institutions Code is amended to read:

14124.2. (a) (1) During normal working hours, the department may make any examination of the books and records of, and may visit and inspect the premises or facilities of, those identified in paragraphs (2) and (3), that it may deem necessary to carry out the provisions of this chapter or Chapter 8 (commencing with Section 14200) and regulations adopted thereunder, or the law under which

the department or its agents or contractors administer any other health care program.

(2) Any applicant or provider, as defined in Section 14043.1, pertaining to services, goods, supplies, or merchandise rendered or supplied, directly or indirectly, or to be rendered or supplied, directly or indirectly, to any beneficiary under this chapter or Chapter 8 (commencing with Section 14200).

(3) Any person or entity that provides services, goods, supplies, or merchandise, directly or indirectly, under, or seeks reimbursement from, any other health care program administered by the department or its agents or contractors.

(b) (1) Applicants, providers, or others receiving or seeking reimbursement under the Medi-Cal program or other health care programs administered by the department or its agents or contractors shall furnish information or copies of records and documentation upon request by the department. Unannounced visits to request this information shall be reserved for those exceptional situations where arrangement of an appointment beforehand is clearly not possible or is clearly inappropriate to the nature of the intended visit. Only those related books and records of each service rendered, the beneficiary to whom rendered, the date, and additional information as the department may by regulation require shall be subject to the requirement of furnishing copies. This information may include records to support and document the recipient's eligibility for services and, to the extent necessary, records to provide proof of the quantity and receipt of the services, and that the services were provided by proper personnel. Providers and others subject to this section shall be reimbursed for reasonable photocopying-related expenses as determined by the department. Failure to comply with the requests for information or records made pursuant to this section shall be grounds for immediate suspension of the provider or others subject to this section under subdivision (b) of Section 14123 or under the other health care programs administered by the department or its agents or contractors.

(2) Any copies furnished pursuant to this section shall be used only to investigate and pursue criminal, civil, or administrative sanctions for Medi-Cal fraud or abuse, including the provision of dental services that are below or less than the standard of acceptable quality as prescribed by subdivision (f) of Section 14123, or fraud or abuse under any other health care program administered by the department or its agents or contractors and the copies shall be destroyed when that purpose has been satisfied. This section shall not be construed to prohibit the referral of investigative findings, including copies of books and records, to the appropriate federal, state, or local licensing, certifying, regulatory, or prosecutorial authority.

(c) For purposes of this section and Section 14124.1, ‘‘provider’’ shall be defined as follows:

(1) ‘‘Provider’’ shall have the meaning contained in Section 14043.1.

(2) ‘‘Provider’’ shall also include any person or entity under contract with the provider, as defined in paragraph (1), to assist in the application process or eligibility determination.

SEC. 32. Section 14170 of the Welfare and Institutions Code is amended to read:

14170. (a) (1) Amounts paid for services provided to Medi-Cal beneficiaries shall be audited by the department in the manner and form prescribed by the department. The department shall maintain adequate controls to ensure responsibility and accountability for the expenditure of federal and state funds. Cost reports and other data submitted by providers to a state agency for the purpose of determining reasonable costs for services or establishing rates of payment shall be considered true and correct unless audited or reviewed by the department within 18 months after July 1, 1969, the close of the period covered by the report, or after the date of submission of the original or amended report by the provider, whichever is later. Moreover the cost reports and other data for cost reporting periods beginning on January 1, 1972, and thereafter shall be considered true and correct unless audited or reviewed within three years after the close of the period covered by the report, or after the date of submission of the original or amended report by the provider, whichever is later.

(2) (A) Nothing in this section shall be construed to limit the correction of cost reports or rates of payment when inaccuracies are determined to be the result of intent to defraud, or when a delay in the completion of an audit is the result of willful acts by the provider or inability to reach agreement on the terms of final settlement.

(B) Nothing in this section shall be construed to preclude the department from further review of cost reports and other data for cost reporting periods beginning on January 1, 1998, after the three-year period contained in paragraph (1) of subdivision (a), where after the three-year period the department discovers information not customarily contained in these cost reports and other data for the fiscal periods in question that indicates the provider may have engaged in practices that have resulted in overreimbursement.

(3) Notwithstanding any other provision of law, nursing facilities and all categories of intermediate care facilities for the developmentally disabled which have received and are receiving funds for salary increases pursuant to Sections 14110.6 and 14110.7 shall maintain payroll and personnel records for examination by auditors from the department and the Labor Commissioner beginning March 1985 until the records have been audited, or until December 31, 1992, whichever occurs first.

(b) Notwithstanding any other provision of law, costs reported for reimbursement purposes relative to Medi-Cal beneficiaries in nursing facilities that are distinct parts of acute care hospitals shall be audited by the department at least annually. The audits may be performed on a sample basis and, when the sample is statistically reliable, as determined by the department, may be used for ratesetting purposes.

SEC. 33. Section 14170.8 of the Welfare and Institutions Code is amended to read:

14170.8. (a) Notwithstanding any other provision of law, every primary supplier of pharmaceuticals, medical equipment, or supplies shall maintain accounting records to demonstrate the manufacture, assembly, purchase, or acquisition and subsequent sale, of any pharmaceuticals, or medical equipment, or supplies to providers, as defined in Section 14043.1. Accounting records shall include, but not be limited to, inventory records, general ledgers, financial statements, purchase and sales journals and invoices, prescription records, bills of lading, and delivery records. For purposes of this section the term ''primary suppliers'' shall mean any manufacturer, principal labeler, assembler, wholesaler, or retailer.

(b) Accounting records maintained pursuant to subdivision (a) shall be subject to audit or examination by the department or its agents. This audit or examination may include, but is not limited to, verification of what was claimed by the provider. These accounting records shall be maintained for three years from the date of sale or the date of service.

(c) This section shall not apply to any clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code or to any manufacturer of prescription drugs registered with the federal Food and Drug Administration in accordance with Section 510 of the Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360).

SEC. 34. Section 14171.6 of the Welfare and Institutions Code is amended to read:

14171.6. (a) (1) Any provider, as defined in paragraph (3), that obtains reimbursement under this chapter to which it is not entitled shall be subject to interest charges or penalties as specified in this section.

(2) When it is established upon audit that the provider has not received reimbursement to which the provider is entitled, the department shall pay the provider interest assessed at the rate, and in the manner, specified in subdivision (g) of Section 14171.

(3) For purposes of this section, ''provider'' means any provider, as defined in Section 14043.1.

(b) When it is established upon audit that the provider has claimed payments under this chapter to which it is not entitled, the provider shall pay, in addition to the amount improperly received, interest at the rate specified by subdivision (h) of Section 14171.

(c) (1) When it is established upon audit that the provider claimed payments related to services or costs that the department had previously notified the provider in an audit report that the costs or services were not reimbursable, the provider shall pay, in addition to the amount improperly claimed, a penalty of 10 percent of the amount improperly claimed after receipt of the notice, plus the cost of the audit.

(2) In addition to the penalty and costs specified by paragraph (1), interest shall be assessed at the rate specified in subdivision (h) of Section 14171.

(3) Providers that wish to preserve appeal rights or to challenge the department's positions regarding appeal issues may claim the costs or services and not be reimbursed therefor if they are identified and presented separately on the cost report.

(d) (1) When it is established that the provider fraudulently claimed and received payments under this chapter, the provider shall pay, in addition to that portion of the claim that was improperly claimed, a penalty of 300 percent of the amount improperly claimed, plus the cost of the audit.

(2) In addition to the penalty and costs specified by paragraph (1), interest shall be assessed at the rate specified by subdivision (h) of Section 14171.

(3) For purposes of this subdivision, a fraudulent claim is a claim upon which the provider has been convicted of fraud upon the Medi-Cal program.

(e) Nothing in this section shall prevent the imposition of any other civil or criminal penalties to which the provider may be liable.

(f) Any appeal to any action taken pursuant to subdivision (b), (c), or (d) is subject to the administrative appeals process provided by Section 14171.

(g) As used in this section, ''cost of the audit'' includes actual hourly wages, travel, and incidental expenses at rates allowable by rules adopted by the State Board of Control and applicable overhead costs that are incurred by employees of the state in administering this chapter with respect to the performance of audits.

(h) This section shall not apply to any clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code, clinics exempt from licensure under Section 1206 of the Health and Safety Code, health facilities licensed under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, or to any provider that is operated by a city, county, or school district.

SEC. 35. Section 24005 of the Welfare and Institutions Code is amended to read:

24005. (a) This section shall apply to the Family Planning Access Care and Treatment Waiver program identified in subdivision (aa) of Section 14132 and this program.

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

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

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

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

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

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

(1) Has been convicted of any felony or misdemeanor that involves fraud or abuse in any government program, that relates to neglect or abuse of a patient in connection with the delivery of a health care item or service, or that is in connection with the

interference with, or obstruction of, any investigation into health care related fraud or abuse.

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

(h) In addition, the department may deny enrollment to any applicant that, at the time of application, is under investigation by the department or any local, state, or federal government law enforcement agency for fraud or abuse. The department shall not deny enrollment to an otherwise qualified applicant whose felony or misdemeanor charges did not result in a conviction solely on the basis of the prior charges. If it is discovered that a provider is under investigation by the department or any local, state, or federal government law enforcement agency for fraud or abuse, that provider shall be subject to immediate disenrollment from the program.

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

(2) A provider shall be subject to disenrollment if claims for payment are submitted under any provider number used by the provider to obtain reimbursement from the program for the services, goods, supplies, or merchandise provided, directly or indirectly, to a program beneficiary, by an individual or entity that has been previously suspended, excluded, or otherwise made ineligible to receive, directly or indirectly, reimbursement from the program or from the Medi-Cal program and the individual has previously been listed on either the Suspended and Ineligible Provider List, which is published by the department, to identify suspended and otherwise ineligible providers or any list published by the federal Office of the Inspector General regarding the suspension or exclusion of individuals or entities from the federal Medicare and medicaid programs, to identify suspended, excluded, or otherwise ineligible providers.

(3) The department shall deactivate, immediately and without prior notice, the provider numbers used by a provider to obtain reimbursement from the program when warrants or documents mailed to a provider's mailing address, its pay to address, or its service address, if any, are returned by the United States Postal Service as not deliverable or when a provider has not submitted a claim for reimbursement from the program for one year. Prior to taking this

action, the department shall use due diligence in attempting to contact the provider at its last known telephone number and to ascertain if the return by the United States Postal Service is by mistake and shall use due diligence in attempting to contact the provider by telephone or in writing to ascertain whether the provider wishes to continue to participate in the Medi-Cal program. If deactivation pursuant to this section occurs, the provider shall meet the requirements for reapplication as specified in regulation.

(4) For purposes of this subdivision:

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

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

(C) ''Service address'' means the address that the provider has identified to the department in its application for enrollment as the address at which the provider will provide services to program beneficiaries.

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

(k) Enrolled providers shall attend specific orientation approved by the department in comprehensive family planning services. Enrolled providers who insert IUDs or contraceptive implants shall have received prior clinical training specific to these procedures.

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

(1) Collect any State-Only Family Planning program or Family Planning Access Care and Treatment Waiver program overpayment identified through an audit or examination, or any portion thereof from any provider. Notwithstanding Section 100171 of the Health and Safety Code, a provider may appeal the collection of overpayments under this section pursuant to procedures established in Article 5.3 (commencing with Section 14170) of Part 3 of Division 9. Overpayments collected under this section shall not be returned to the provider during the pendency of any appeal and may be offset to satisfy audit or appeal findings, if the findings are against the

provider. Overpayments shall be returned to a provider with interest if findings are in favor of the provider.

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

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

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

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

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

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

(m) As used in this section:

(1) ''Abuse'' means either of the following:

(A) Practices that are inconsistent with sound fiscal or business practices and result in unnecessary cost to the medicaid program, the Medicare program, the Medi-Cal program, including the Family Planning Access Care and Treatment Waiver program, identified in subdivision (aa) of Section 14132, another state's medicaid program, or the State-Only Family Planning program, or other health care programs operated, or financed in whole or in part, by the federal government or any state or local agency in this state or any other state.

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

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

(3) ‘‘Provider’’ means any individual, partnership, group, association, corporation, institution, or entity, and the officers, directors, owners, managing employees, or agents of any partnership, group, association, corporation, institution, or entity, that provides services, goods, supplies, or merchandise, directly or indirectly, to a beneficiary and that has been enrolled in the program.

(4) ‘‘Convicted’’ means any of the following:

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

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

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

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

(5) ‘‘Professionally recognized standards of health care’’ means statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a state. When the United States Department of Health and Human Services has declared a treatment modality not to be safe and effective, practitioners that employ that treatment modality shall be deemed not to meet professionally recognized standards of health care. This definition shall not be construed to mean that all other treatments meet professionally recognized standards of care.

(6) ‘‘Unnecessary or substandard items or services’’ means those that are either of the following:

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

(B) Furnished, or caused to be furnished, to patients, whether or not covered by Medicare, medicaid, or any of the state health care programs to which the definitions of applicant and provider apply, and which are substantially in excess of the patient’s needs, or of a quality that fails to meet professionally recognized standards of health care. The department’s determination that the items or services furnished were excessive or of unacceptable quality shall be

made on the basis of information, including sanction reports, from the following sources:

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

(ii) State or local licensing or certification authorities.

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

(iv) State or local professional societies.

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

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

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

(o) (1) Notwithstanding any other provision of law, every primary supplier of pharmaceuticals, medical equipment, or supplies shall maintain accounting records to demonstrate the manufacture, assembly, purchase, or acquisition and subsequent sale, of any pharmaceuticals, medical equipment, or supplies, to providers. Accounting records shall include, but not be limited to, inventory records, general ledgers, financial statements, purchase and sales journals, and invoices, prescription records, bills of lading, and delivery records.

(2) For purposes of this subdivision, the term ''primary supplier'' means any manufacturer, principal labeler, assembler, wholesaler, or retailer.

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

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

(q) A program provider applicant or a program provider shall furnish information or copies of records and documentation requested by the department. Failure to comply with the

department's request shall be grounds for denial of the application or automatic disenrollment of the provider.

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

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

SEC. 36. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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