AMENDED IN ASSEMBLY MAY 7, 2013

AMENDED IN ASSEMBLY MARCH 19, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 686

Introduced by Assembly Member Quirk

February 21, 2013

An act to ~~amend Section 25201.17~~ *add and repeal Section 25201.18* of the Health and Safety Code, relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 686, as amended, Quirk. Hazardous waste: pharmaceutical ~~cogeneration activities.~~ *facilities.*

~~(1)~~

Existing law requires hazardous waste facilities, including, but not limited to, treatment facilities, to operate under hazardous waste facilities permits or other grants of authorization issued by the Department of Toxic Substances Control. Existing law exempts pharmaceutical neutralization activities from certain requirements of the hazardous waste control laws and certain regulations adopted pursuant to that law if specified conditions are met with regard to the pharmaceutical manufacturing or process development activities, including the management of air emissions and wastes generated as a result of those activities. ~~A violation of the hazardous waste control laws is a crime.~~

This bill would ~~exempt from the hazardous waste control law, and all of the regulations adopted pursuant to that law, pharmaceutical cogeneration activities and the cogeneration fuel components, as defined, if specified conditions are met with regard to certain federal regulations and other requirements for facility construction and if the owner or~~

~~operator of the facility engaged in that activity complies with certain requirements concerning emergency-related training, providing notifications, development of a fuel analysis plan, and maintenance of records. The bill would require the air emissions and wastes generated as a result of those activities to be managed, as specified. Since a violation of the requirements imposed by the bill upon the owner or operator of a facility engaged in pharmaceutical cogeneration activities would be a crime, the bill would impose a state-mandated local program by creating new crimes.~~ *require the department, by January 1, 2015, to develop recommendations for standards and guidelines for the operation of on-site waste management and recycling of hazardous waste at facilities engaged in pharmaceutical manufacturing or pharmaceutical process development. The department would be required, by January 1, 2015, to submit a report to the Legislature on those recommendations, including any recommended statutory and regulatory actions needed to assure the safe and efficient management of waste from pharmaceutical manufacturing or pharmaceutical process development actives. The bill would repeal this report requirement on January 1, 2019.*

~~(2) 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.~~

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

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

SECTION 1. Section 25201.18 is added to the Health and Safety Code, to read:

25201.18. (a) On or before January 1, 2015, the department shall develop recommendations for standards and guidelines for the operation of on-site hazardous waste management and recycling activities at facilities engaged in pharmaceutical manufacturing or pharmaceutical process development. The recommendations shall consider, but are not limited to, all of the following:

(1) Actions to reduce the production and off-site disposal of hazardous waste from pharmaceutical manufacturing operations.

(2) Actions to provide incentives to reduce greenhouse gas emissions through increased energy efficiency.

(3) Recommended permit conditions or other requirements for on-site waste management within a pharmaceutical manufacturing facility to ensure the protection of public health and the environment and that recognize the unique federal and state requirements that apply to pharmaceutical manufacturing.

(b) On or before January 1, 2015, the department shall submit a report to the Legislature in compliance with Section 9795 of the Government Code on the recommendations developed pursuant to subdivision (a), including any recommended statutory and regulatory actions needed to assure the safe and efficient management of hazardous waste from pharmaceutical manufacturing or pharmaceutical process development activities.

(c) This section shall remain in effect only until January 1, 2019, pursuant to Section 10231.5 of the Government Code and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.

~~SECTION 1. Section 25201.17 of the Health and Safety Code is amended to read:~~

~~25201.17. (a) For purposes of this section, the following terms have the following meanings:~~

~~(1) (A) "Cogeneration fuel component" means a material generated by pharmaceutical manufacturing or pharmaceutical process development activities that meets all of the following conditions:~~

~~(i) The material would otherwise be defined as waste or hazardous waste pursuant to this chapter.~~

~~(ii) The materials meet all the physical, viscosity, and constituent specifications for comparable fuel or syngas fuel under paragraph (1) or (2) of subsection (a) of Section 261.38 of Title 40 of the Code of Federal Regulations.~~

~~(iii) The material meets all other criteria in Section 261.38 of Title 40 of the Code of Federal Regulations that exclude comparable and syngas fuels from being classified as a solid waste for purposes of Subpart A (commencing with Section 261.1) of Part 261 of Subchapter 1 of Chapter 1 of Title 40 of the Code of Federal Regulations.~~

~~(B) "Cogeneration fuel component" does not include a material that would otherwise be considered hazardous waste because of the presence of dioxins or furans.~~

~~(2) "Pharmaceutical cogeneration activities" means a pharmaceutical manufacturing facility's onsite utilization of specified manufacturing byproducts to generate steam and electricity to support the facility's pharmaceutical manufacturing process.~~

~~(3) "Pharmaceutical manufacturing or pharmaceutical process development activities" means activities conducted in North American Industry Classification System Code subgroups 325411 and 325412, to the extent they meet either of the following:~~

~~(A) Research, development, and production activities conducted in relation to an investigational new drug application or new drug application as set forth in Part 312 (commencing with Section 312.1) of, and Part 314 (commencing with Section 314.1) of, Subchapter D of Chapter 1 of Title 21 of the Code of Federal Regulations, that is filed with the United States Food and Drug Administration, or research and development activities conducted to support the future filing of an investigational new drug application or new drug application, or research, development, and production activities that are conducted in relation to a filing with a corresponding governmental authority in the European Union, Japan, or Canada that imposes similar requirements.~~

~~(B) The production of a pharmaceutical product, including starting materials, intermediates, and active pharmaceutical intermediates.~~

~~(4) "Pharmaceutical neutralization activities" means the deactivation of a material generated by, or used in, pharmaceutical manufacturing or pharmaceutical process development activities through the addition of a reagent, including, but not limited to, a caustic, before management of the material as a hazardous waste subject to this chapter.~~

~~(5) "Syngas fuel" means synthethesis gas fuel, as specified in paragraph (2) of Subsection (a) of Section 261.38 of Title 40 of the Code of Federal Regulations.~~

~~(b) Pharmaceutical neutralization activities are exempt from any requirement imposed pursuant to this chapter, including any regulation adopted pursuant to this chapter, that relates to generators, tanks, and tank systems, and the requirement to obtain~~

~~a hazardous waste facilities permit or other grant of authorization from the department, except as otherwise provided in subdivision (c), if all of the following conditions are met:~~

~~(1) A permit is not required to conduct neutralization under the federal act pursuant to Section 264.1(g)(5) of Title 40 of the Code of Federal Regulations.~~

~~(2) The pharmaceutical manufacturing or pharmaceutical process development activities are conducted in accordance with the United States Food and Drug Administration's current good manufacturing practices, as set forth in Part 210 (commencing with Section 210.1) of, and Part 211 (commencing with Section 211.1) of, Subchapter C of Chapter 1 of Title 21 of the Code of Federal Regulations.~~

~~(3) The pharmaceutical neutralization activity occurs within a unit that meets the standards of a totally enclosed treatment facility, as defined in Section 260.10 of Title 40 of the Code of Federal Regulations and Section 66260.10 of Title 22 of the California Code of Regulations, that is physically connected to the reactor or vessel where the material being neutralized is created.~~

~~(4) The pharmaceutical neutralization activity is integral to the manufacturing process and occurs within the manufacturing process area and prior to the transfer of the material to a dedicated hazardous waste storage or treatment unit.~~

~~(5) If the pharmaceutical neutralization activity occurs at greater than 15 pounds per square inch gauge pressure, it shall occur within a unit that meets applicable American Society of Mechanical Engineers (ASME) standards for pressure rated vessels, including the ASME requirements for automatic pressure relief in the event of a system failure, including pressure relief valves, burst discs, or equivalent devices.~~

~~(6) The pharmaceutical neutralization activities do not raise the temperature of the hazardous wastes to within 10 degrees Celsius of the boiling point or cause the release of hazardous gaseous emissions, using either constituent-specific concentration limits or calculations.~~

~~(7) The temperature of any unit 100 gallons or larger is automatically monitored, the unit is fitted with a high-temperature alarm system, and, for closed systems, the adding and mixing of in-process and neutralizing solutions are manually controlled.~~

~~(8) The pharmaceutical neutralization activity occurs within a facility that has design or engineering features, including, but not~~

~~limited to, trenches, sumps, berming, sloping, or diking, designed to contain all liquid spills from pharmaceutical manufacturing process and neutralization units.~~

~~(c) An owner or operator of a pharmaceutical neutralization unit exempt under this section shall comply with all of the following requirements:~~

~~(1) The owner or operator shall successfully complete a program of classroom instruction or on-the-job training that includes, at a minimum, instruction for responding effectively to emergencies by familiarizing personnel with emergency procedures, emergency equipment, and emergency systems, including, where applicable, procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment, communications, or alarm systems.~~

~~(2) Within 10 days of commencing initial operation of the unit, or within any other time period that may be required by the CUPA, the owner or operator shall notify the CUPA of the commencement of the operation of the unit under the exemption made pursuant to this section. A CUPA is authorized to, and is required to, implement the requirements specified in this section. If the owner or operator is not under the jurisdiction of a CUPA, the notice shall be sent to the officer of the agency authorized, pursuant to subdivision (e) of Section 25404.3, to implement and enforce the requirements of this chapter listed in paragraph (2) of subdivision (c) of Section 25404.~~

~~(3) The owner or operator shall establish and maintain documentation to substantiate its compliance with all of the requirements and conditions of this section, and shall make the documentation available for inspection upon request of the department or the CUPA.~~

~~(d) Pharmaceutical cogeneration activities and the cogeneration fuel components are exempt from the requirements imposed pursuant to this chapter and the regulations adopted pursuant to this chapter, including, but not limited to, the requirements imposed on generators, tanks, and tank systems, and the requirement to obtain a hazardous waste treatment permit or other grant of authorization from the department, except as otherwise provided in subsection (b) of Section 261.38 of Title 40 of the Code of Federal Regulations, if all of the following conditions are met:~~

~~(1) The pharmaceutical cogeneration activities meet the comparable fuel specifications or syngas fuel specification in Section 261.38 of Title 40 of the Code of Federal Regulations and are conducted in accordance with all conditions specified in that section.~~

~~(2) The pharmaceutical manufacturing or pharmaceutical process development activities are conducted in accordance with the United States Food and Drug Administration's current good manufacturing practices, as set forth in Part 210 (commencing with Section 210.1) of, and Part 211 (commencing with Section 211.1) of, Subchapter C of Chapter 1 of Title 21 of the Code of Federal Regulations.~~

~~(3) The pharmaceutical cogeneration activity occurs within a facility that has design or engineering features, including, but not limited to, trenches, sumps, berming, sloping, or diking that are designed to contain all liquid spills from pharmaceutical manufacturing process and cogeneration units.~~

~~(e) (1) An owner or operator of a facility engaged in pharmaceutical cogeneration activities exempt pursuant to this section shall comply with all of the following requirements, consistent with the requirements specified in Section 261.38 of Title 40 of the Code of Federal Regulations:~~

~~(A) The owner or operator of a facility engaged in pharmaceutical cogeneration activities shall successfully complete a program of classroom instruction or on-the-job training that includes, at a minimum, instruction for responding effectively to emergencies by familiarizing personnel with emergency procedures, emergency equipment, and emergency systems, including, if applicable, procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment, communications, or alarm systems.~~

~~(B) The owner or operator of a facility engaged in pharmaceutical cogeneration activities submits a one-time notice, except as otherwise required by state law or Section 261.38 of Title 40 of the Code of Federal Regulations, to the CUPA in whose jurisdiction the exclusion is being claimed and where the excluded fuel will be used, certifying compliance with the conditions of the exclusion.~~

~~(C) The owner or operator of a facility engaged in pharmaceutical cogeneration activities publishes in a major newspaper of general circulation local to the site where the~~

~~activities take place, prior to the commencement of those activities, a notice entitled "Notification of Burning a Fuel Excluded Under the Resource Conservation and Recovery Act" and containing a brief, general description of the process generating the cogeneration fuel components.~~

~~(D) The owner or operator of a facility engaged in pharmaceutical cogeneration activities develops and follows a written fuel analysis plan that describes the procedures for sampling and analysis of the cogeneration fuel component, in accordance with the requirements of paragraph (4) of subsection (b) of Section 261.38 of Title 40 of the Code of Federal Regulations.~~

~~(E) The owner or operator of a facility engaged in pharmaceutical cogeneration activities maintains all records required by this chapter for a period of three years.~~

~~(2) The requirements of paragraph (1) do not modify any of the requirements specified in Section 261.38 of Title 40 of the Code of Federal Regulations with regard to qualifying for the exclusion from being classified as a solid waste pursuant to that regulation.~~

~~(f) Notwithstanding any other provision of law, all air emissions from a pharmaceutical neutralization unit or generated as a result of any pharmaceutical cogeneration activity shall be managed in accordance with the requirements of the local air pollution control district or air quality management district.~~

~~(g) All wastes generated as a result of pharmaceutical neutralization activities or pharmaceutical cogeneration activities shall be managed as hazardous wastes in accordance with all applicable requirements of this chapter.~~

~~SEC. 2. 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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