



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

December 21, 2015

Gina McCarthy
Administrator
Environmental Protection Agency
Attn: Office of Resource Conservation and Recovery (5304P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Subject: Management Standards for Hazardous Waste Pharmaceuticals, EPA–HQ–RCRA–2007–0932

Dear Administrator McCarthy:

On behalf of our nearly 400 member hospital and health systems, the California Hospital Association (CHA) is pleased to submit comments on the federal Environmental Protection Agency (EPA) Management Standards for Hazardous Waste: Pharmaceuticals proposed rule issued September 25. The proposed rule establishes sector-specific regulations for the management of hazardous waste pharmaceuticals by health care facilities, including hospitals, clinics, retail pharmacies and reverse distributors. CHA appreciates EPA's commitment to addressing stakeholder concerns raised in previous rulemaking and revisiting this important topic. Moreover, CHA appreciates the additional 30 days provided to vet these proposals with member hospitals and health systems and respond to the agency with our comments.

CHA is generally supportive of the proposed sector-specific requirements that further clarify current regulation and address gaps in the intersection between EPA and Drug Enforcement Administration regulation. During the comment period, CHA convened a workgroup of health care facilities experts to review and analyze the proposed rule. In doing so, CHA spent considerable time considering existing state law and regulation issued by the California Department of Toxic Substance Control and the California Department of Public Health Medical Waste Management Program. CHA also conducted a survey of the workgroup to solicit input and feedback on operational challenges presented by the current polices, if any.

Currently, the California Department of Toxic Substance Control enforces federal Resource Conservation and Recovery Act (RCRA) requirements, as well as California hazardous waste requirements. Non-RCRA pharmaceutical waste, however, is enforced by the California Department of Public Health Medical Waste Management Program. **While CHA is supportive of the direction and policies set forth in the proposed rule, we are concerned about the interpretation and application of the policies in California — in particular how the two regulatory agencies will proceed in application, review and enforcement. CHA is concerned that without additional time for implementation, hospitals will be unable to comply.**

Understanding the complexities and overlap between federal and state law in California is particularly challenging for hospitals, health systems and other health care facilities. The complexity lies in having two state agencies with oversight responsibilities introducing the opportunity for inconsistent interpretation and application. This is further complicated with additional review by the California

Department of Public Health Center for Health Care Quality that has oversight for survey and certification.

While CHA has reached out to state oversight agencies to offer our assistance in reviewing and responding to this rule, we believe EPA should provide additional resources to state agencies to ensure shared understanding of these new regulations. We also believe EPA should provide technical assistance to state agencies, ensuring that both state and federal regulations can be complied with in an efficient manner. In addition, we believe EPA is well positioned to assist state agencies in developing resources to help educate hospitals and other health care facilities about how best to operationalize these new requirements within the framework of existing state law and regulation. **CHA urges EPA to develop technical assistance for states to smooth operational implementation. In addition, we believe EPA should work with the Centers for Medicare & Medicaid Services to ensure understanding of these rules in the context of the Medicare Conditions of Participation for hospitals. Education of hospital surveyors will be necessary at the federal and state level.**

Most importantly, CHA urges EPA to delay the effective date of the final rule to no earlier than one year from its release. CHA believes that state agencies need additional time prior to the effective date of the final rule to both understand the opportunities and challenges these new policies present, and develop resources to educate hospitals and health care facilities on compliance.

CHA is committed to working with our state agencies, but believes that, in light of the scope of these regulations and a myriad of state regulations, additional time is needed. Hospitals and other health care facilities will need time to understand the new requirements and then develop policies and procedures to ensure operational compliance. Hospitals will also need to determine the impact on existing waste disposal programs. For example, the final rule may affect contracts with waste haulers for medical waste (California) and hazardous waste. Contracts may need to be restructured, especially those based on minimal pick-up volumes for certain waste streams or those involving single and/or multiple company(ies) that pick up medical, chemical and pharmaceutical waste. Also, some waste vendors provide reusable waste containers for non-RCRA pharmaceutical waste disposal in California. Hospitals in California will need time to evaluate how to best manage their RCRA waste and what container management solutions existing waste vendors can provide for hospitals in California. In addition, such a program change will require time and resources to train thousands of health care workers to implement these new standards, including frontline health care workers and pharmacists if point-of-generation segregation and containerization practices are affected. In these times of health care systems that include multiple hospitals with numerous community clinics and practices, developing standardized training resources and curricula is an arduous, time consuming task. Time will be needed for hospitals to review their existing hazardous waste program and the new sector based rule to determine which hazardous waste management method best works for their operations and file updated notification of hazardous waste activities with EPA and Cal EPA.

California hospitals have a long history of working with state and federal environmental regulators and are good stewards in managing their various waste streams. **Hospitals are committed to compliance and to improving the protection of our environment; however, additional time is needed, by both state agencies and healthcare facilities, to ensure we do this efficiently and within the framework of existing state law.** CHA appreciates the opportunity to comment on these proposed rules. If you have any questions, please do not hesitate to contact Cheri Hummel, vice president emergency management and facilities, at chummel@calhospital.org or (916) 552-7681, or me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/

Alyssa Keefe

Vice President Federal Regulatory Affairs