



October 6, 2014

Michele Leonhart  
Administrator  
Drug Enforcement Administration  
Lincoln Place-East  
700 Army Navy Drive  
Arlington, Virginia 22202

***RE: Disposal of Controlled Substances Final Rule published September 9, 2014***

Dear Ms. Leonhart:

As the organizations representing more than 5,000 hospitals and health systems across the country, we respectfully urge you to delay the effective date of October 9, 2014 for provisions in the final rule on Disposal of Controlled Substances that would adversely affect hospitals. We do so based on serious concerns about certain provisions in the rule that are not readily compatible with employee and patient safety protocols, will require months of employee retraining and new technology that does not meet agency standards or is not widely available, as well as necessitate the redeployment of current staff or the addition of new staff, among other significant hurdles.

We fully support the goals of the law on which the regulations are based – to expand the options available to communities to dispose of controlled substances, including certain prescription drugs, to prevent their diversion and misuse. For hospitals, however, allowing only 30 days in which to implement a complex web of requirements that are tangential to the laudable goals of the law itself is neither reasonable nor prudent.

All hospitals treat seriously ill patients, some of whom require medications that are controlled substances. These include pain medications during and following surgery, medications to control seizures and medications to treat acute episodes of mental health disorders, such as Bipolar Disorder, among others.

We recognize the importance of disposing properly of such substances to prevent diversion and misuse. However, the regulations make it nearly impossible to safely do so for small amounts left over in syringes, IV solutions or medicated patches. The problem is two-fold. First, it is impossible to accurately quantify such small amounts to satisfy the regulations that apply to “reverse distributors” (companies that can be hired to properly dispose of left-over medications). These companies that would otherwise provide disposal services simply cannot accept or dispose of medications in these quantities because of certain record keeping requirements in the regulations.

Second, we are aware of no technology that meets DEA standards that would allow hospitals to properly dispose of these small quantities of left-over medications on site. Virtually no hospitals have incinerators, for commendable environmental reasons, and there appear to be no companies that currently meet DEA standards to provide disposal services by chemical means. This combination of issues leaves hospitals with few, if any, practical options.

In addition, and even more disturbing, the record keeping and disposal requirements that apply to these same medications do not appear readily compatible with the goals of prudent employee and patient safety requirements, such as those found in the Occupational Safety and Health Administration’s directives to dispose of syringes promptly and Medicare’s Condition of Participation Requirements related to infection control standards for rapid disposal of syringes and not transporting them elsewhere in the hospital for further handling. That is because the DEA regulations can be read as requiring syringes containing medications to be moved from room to room or capped and uncapped in order to properly log them. Such an approach presents real and unacceptable hazards for employees and patients.

The definition of employee in the rule also has serious implications for hospitals. That is because physicians with privileges and agency nurses, who are used by virtually every hospital, would be disqualified from participating in proper disposal and logging procedures. Nearly every hospital has on staff physicians with privileges who are not employees and uses agency nurses to ensure that patients are properly cared for. If they are not permitted to assist with disposal and logging procedures, then, at best, staff will need to be re-deployed to handle these duties, new staff will need to be hired or other arrangements made for these purposes. Any of the accommodations will be costly and require significant time to implement.

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In addition to seeking a reasonable delay to the provisions of the rule adversely impacting hospitals, we respectfully request an opportunity to meet with you at your earliest opportunity and discuss practical solutions to these issues that can both accomplish the laudable goals in the law and effectively addresses the employee and patient safety concerns as well as those related to excessive costs and disruption.

Thank you for your attention to this important matter.

Sincerely,

America's Essential Hospitals  
American Hospital Association  
Association of American Medical Colleges  
Catholic Health Association of the United States  
Children's Hospital Association  
Federation of American Hospitals  
National Association of Psychiatric Health Systems  
Premier healthcare alliance  
VHA Inc.

cc: The Honorable Sylvia Burwell  
Attorney General Eric Holder  
Senator Patrick Leahy  
Senator Charles Grassley  
Senator Amy Klobuchar