Emergency Use Authorization Toolkit

Evolving Policy Issues

Summer 2011

The public health response to the 2009 H1N1 influenza pandemic made clear a number of challenges, gaps, and barriers associated with the increased use of Emergency Use Authorizations (EUA) during the response. The HHS, FDA, and CDC have been actively working with state and local public health agencies to understand and address the issues identified. This document highlights some of the evolving legal and policy issues related to EUAs and medical countermeasures generally.[1]

Emergency Use Authorizations

Circumstances for Issuing an EUA and State/Local Planning

States have consistently raised concerns about the need for advanced or earlier information about what countermeasures will be subject to an EUA and the requirements for states in storing, distributing, and dispensing these products. While acknowledging that the EUA process is still a relatively new one for all parties, states are seeking earlier information from which they can better prepare for operating under an EUA. Since final EUA conditions are established when the EUA is issued, public health officials will not know all of the expected requirements of a particular authorization in advance of an emergency. As a result, state and local officials will have to comply with EUA conditions for which they might not be able to effectively plan.

It is not possible to anticipate all the possible EUAs that might arise because the decision to issue an EUA is event-specific. In addition to issuing EUAs (e.g., during the H1N1 pandemic; for mass dispensing of doxycycline), the FDA has been working with other federal agencies to develop "pre-EUAs" to minimize delays in issuing EUAs during an emergency. While the law does not allow the FDA to preauthorize an EUA before the determination and declaration of an emergency, the process of submitting an EUA request can begin before the actual emergency occurs. A pre-EUA request can be submitted to the FDA based on likely situations such as potential anthrax attacks or smallpox outbreaks. Planners speculate about what the emergency might be and the products that could be used in those situations. A pre-EUA allows the FDA to begin work on fact sheets and other documentation. If an emergency is declared and the EUA is formally requested, the FDA can conduct a final review of the pre-EUA materials and make any substantive changes as needed.

Stockpile Issues

Storing SNS Assets

Ongoing questions have arisen about who is responsible at the state and local levels for storing unused Strategic National Stockpile (SNS) countermeasures before, during, and after an event. Especially of concern has been the costs for storage and if these will be paid for or reimbursed by the federal government. State and local public health authorities are responsible for the costs associated with items that have been distributed from SNS stockpiles. The FDA requires that all medical countermeasures such as antivirals—including those received from the SNS—must be stored according to Current Good Manufacturing Practices (CGMPs), including labeled storage conditions. In certain circumstances, such as some of the antiviral medications covered under the H1N1 EUAs, CGMP and labeled storage condition requirements were waived based on FDA's knowledge about product stability for specified durations of time (e.g., two weeks) to facilitate movement of product.

Impact of State Pharmacy Laws on Stored SNS Assets

For SNS assets stored in the states, states have questioned whether states' pharmacy laws for conditions of storage, monitoring, and accounting for pharmaceuticals apply to these countermeasures. The FDA has stated that state restrictions that directly conflict with what is permitted in the EUA are preempted by federal law. States should

review their applicable pharmacy laws to determine where state law may or may not conflict with federal requirements.

Shelf Life Extension Program

Developing a SLEP-Like Program for States

State-maintained stockpiles are not currently eligible for participation in the federal Shelf Life Extension Program (SLEP). As required by the May 2006 *National Strategy for Pandemic Influenza: Implementation Plan*, a work group of federal agencies and the states conducted preliminary assessments of including state stockpiles in the federal SLEP program; however, the group determined that it is not currently feasible to add states to SLEP. In addition to the 2006 evaluation, the HHS has been analyzing the feasibility of creating a separate SLEP-like program for extending state stockpiles. The Biomedical Advanced Research and Development Authority (BARDA) within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) has been evaluating the infrastructure necessary to support a new program for states and analyzing the comparative cost effectiveness of shelf-life testing to repurchasing for state inventories. Cost factors to be considered include laboratory testing, storage site inspection, state personnel, relabeling for extended products, destruction for products not extended, and transportation for products being tested or destroyed. The HHS, BARDA, and the states are conducting a detailed analysis with state-specific data in 2011.

Labeling and Relabeling of Medical Countermeasures

Relabeling Stored Countermeasures

States have raised questions about the requirement to relabel medications held in non-SNS stockpiles (i.e., state, local, or regional caches) that have been shelf-life-extended through an EUA (e.g., Tamiflu). Because of the financial costs involved in relabeling, states have expressed interest in including information for consumers, healthcare professionals, and other dispensers when such medications are distributed indicating that a particular product/lot number has an extended shelf life in lieu of relabeling the products. The FDA has expressed its intention to forego enforcement action regarding relabeling requirements for specific products that had been shelf-life-extended so long as these products were stored under labeled storage conditions. The agency did this last year when it provided disposition information on its website on June 22, 2010, regarding the specified lots of Tamiflu and Relenza that had been authorized for use beyond their labeled expiration date during the H1N1 response. However, to minimize confusion on the part of healthcare professionals and patients, the FDA recommended that, before dispensing, the identified lots be relabeled/repackaged by an FDA-registered firm in accordance with applicable CGMP requirements. FDA has included information in authorized fact sheets for recipients indicating that certain products are authorized for use even though they have an expired date on the package.

States as Certified Relabelers

Given FDA requirements for relabeling countermeasures and significant budget constraints, some states have inquired about whether it is possible for states to become certified relabelers as a cost saving measure. The FDA has reported that medical product relabelers must be registered with the FDA and comply with all CGMP requirements that apply to their operations, among other things. The FDA also inspects establishments engaged in relabeling or other manufacturing or processing activities to ensure compliance with applicable CGMP requirements.

States have also inquired if it is possible for the states to self-certify that they meet CGMP requirements. The FDA has stated that the feasibility of any alternative mechanisms for ensuring that state relabeling efforts comply with applicable CGMPs (i.e., self-certification) must be further evaluated and will likely depend on a number of factors, such as the nature of the products or operations involved. Aside from self-certification, states will first need to assess their ability to comply with the applicable CGMP requirements, including whether it is cost-effective for them to do so.

Notes:

[1] Materials relating to FDA views were adapted from Borio L. Food and Drug Administration. July 25, 2011 Letter to William G. Burel, CDC et al regarding answers to questions raised during December 2010 *Federal, State, and Local Public Health Preparedness* meeting in Baltimore, MD. Available at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm234336.htm. Accessed January 31, 2012.

This document was compiled from July-September 2011 and reflects the laws and programs current at the time. It reflects only selected portions of the laws relevant to public health emergencies; it is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.