

Coping with and Mitigating the Effects of Shortages of Emergency Medications

December 2012



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ASTHO is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, and the District of Columbia, and the more than 100,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, formulate and influence sound public health policy and ensure excellence in state-based public health practice. ASTHO's primary function is to track, evaluate, and advise members on the impact and formation of public or private health policy that may affect them and to provide them with guidance and technical assistance on improving the nation's health.

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BACKGROUND

According to the U.S. Department of Health and Human Services, over the last six years shortages of key cardiovascular, anesthetic, analgesic, and anti-infective drugs have quadrupled and such drugs are often in short supply. It is estimated that nearly 40 percent of the drugs in shortage affect the delivery of emergency care, due principally to the lack of sufficient and timely availability of sterile injectable drugs used in the emergency care setting.¹ While the emergency care drug shortage impact is not being felt equally in all jurisdictions (it is generally acknowledged that distributors can react very quickly to ameliorate truly local spot shortages), nevertheless, these shortages have become a national public health and homeland security concern.

At times, the impact of the drug shortages situation is so acute that it has been reported that a facility's management first becomes aware that an issue is evolving when ordered drugs are missing from a shipment and put on back order. The hospital or EMS unit then finds itself without any inventory of that medication. Patient comfort and safety can be put at risk when emergency care providers are forced to implement contingency response strategies including delaying treatments, reallocating scarce resources, or resorting to backup treatment regimens. When a sufficient amount of the preferred drug is not available, healthcare workers may need to resort to third- or fourth-line agents that may not be as effective, which they are unaccustomed to using and may be uncomfortable administering without training. Summarizing a 2011 survey of hospital pharmacy staff conducted by the Institute of Safe Medication Practice, an April 2012 Medication Safety Alert pertinently stated, "Nearly a hundred practitioners took our short survey and strengthened our belief that the ongoing drug shortage crisis is exacting a significant toll on patient safety."²

The U.S. Food and Drug Administration (FDA) continues to work with the drug manufacturers to address and prevent drug shortages—which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations—to communicate the issue, and to help restore availability. Executive Order 13588, "Reducing Prescription Drug Shortages," signed by President Obama on Oct. 31, 2011, and Title X of the Food and Drug Administration Safety and Innovation Act of 2012, signed into law on July 7, 2012, have increased industry requirements to notify FDA of impending shortages to provide additional lead time to thwart them or at least lessen their impact.

Despite these best efforts, this problem is expected to persist until the root causes associated with domestic and global drug production capacity and product quality are addressed. As such, government

¹ ASPR. *The Impact of the National Drug Shortage on Emergency Care*. Proceedings Report, April 2012.

² Institute of Safe Medication Practices. "A Shortage of Everything Except Errors: Harm Associated with Drug Shortage." Medication Safety Alert, April 19, 2012.

officials and providers of emergency medical services and trauma care must work together to face and cope with the challenges presented by drug shortages to mitigate to the fullest extent possible, if not eliminate, the adverse impact on patient care, while working within a regulatory framework intended to protect healthcare consumers but which may not be readily adaptive to this unanticipated situation.

PURPOSE

Until such time as the root causes of the emergency care drug shortage are addressed and sufficient, reliable supplies of first-line medications are readily available, public health and other governmental officials, emergency medical services personnel, and emergency/trauma care providers must work collaboratively to identify and apply reasonable coping strategies and tactics to mitigate the impact of the shortage on patient care. This document attempts to capture and summarize the current best thinking of national thought leaders in these fields and is intended to serve as a guide to actionable options for consideration. It must be stressed that this document does not reflect a consensus and should not be construed as formal guidance. Rather, it is a compendium of various contingency planning or “coping” approaches currently being followed or considered by certain practitioners in the field and deemed worthy of sharing with the community of practice for individual assessment and consideration before being implemented. For a variety of reasons, not every option will be viable for all entities and each must be examined in the context of a facility’s or agency’s controlling policies and legal/regulatory construct.

The information in this paper was gleaned in large part from a two-day workshop of national subject matter experts, including physicians, paramedics, nurses, pharmacists, and public health emergency planners (hereafter referred to as the “work group”), which was conducted in mid-July 2012. Approximately 40 experts representing the following national organizations were convened to help identify plausible coping strategies and tactics for consideration by the public health, EMS, and emergency/trauma care sectors:

- American College of Emergency Physicians
- National Association of State EMS Officials
- National Association of Emergency Medical Technicians
- Association of State and Territorial Health Officials
- The Institute of Medicine
- American Pharmacists Association
- American Association of Poison Control Centers
- Trauma Center Association of America

- Federation of State Medical Boards
- Emergency Services Coalition for Medical Preparedness
- Association of Critical Care Transport
- National EMS Managers Association
- Emergency Nurses Association
- Canadian Association of Paramedic Chiefs
- Paramedic Association of Canada

Key federal agency representatives from relevant operating divisions/units also participated as observers and technical resources from the following departments:

- Department of Health and Human Services
- Department of Transportation
- Department of Homeland Security

This document is intended to serve as a guide to a number of useful resources and tools identified during an environmental scan or provided by workshop participants. Links and references can be found in Appendix A.

A FRAMEWORK FOR CONTINGENCY PLANNING

The work group recognized that the recently released Institute of Medicine report entitled *Crisis Standards of Care—A Systems Framework for Catastrophic Disaster Response*³ (the “framework”), while principally drafted to support broader disaster planning and response efforts, serves as the most appropriate and useful approach to systematically and methodically addressing the drug shortage issue and other health and medical matters when demand for needed resources far exceeds availability. As so aptly emphasized in this framework, “the duty to plan for such incidents is an ethical imperative.” This framework also recognizes that resource shortages and the demand for healthcare service delivery is not an “all or none” phenomenon, but rather a continuum from a conventional to contingency and, in the worst-case scenario, a crisis response effort. The current issues related to drug shortages clearly transcend the conventional response capabilities of healthcare and EMS agencies and vividly illustrate the need for contingency planning elucidated in this document.

The IOM framework is presented as a seven-volume set of stand-alone resource manuals for all stakeholders involved in disaster response. Three of the volumes directly target the sectors of interest

³ Institute of Medicine of the National Academies. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*. Washington, DC: National Academies Press, 2012.

regarding emergency drug shortages: state and local government (public health), EMS, and hospitals (www.iom.edu/Reports/2012/Crisis-Standards-of-Care-A-Systems-Framework-for-Catastrophic-Disaster-Response.aspx). The work group strongly recommends use of this resource to guide planning and mitigation efforts to manage and minimize the impact of drug shortages.

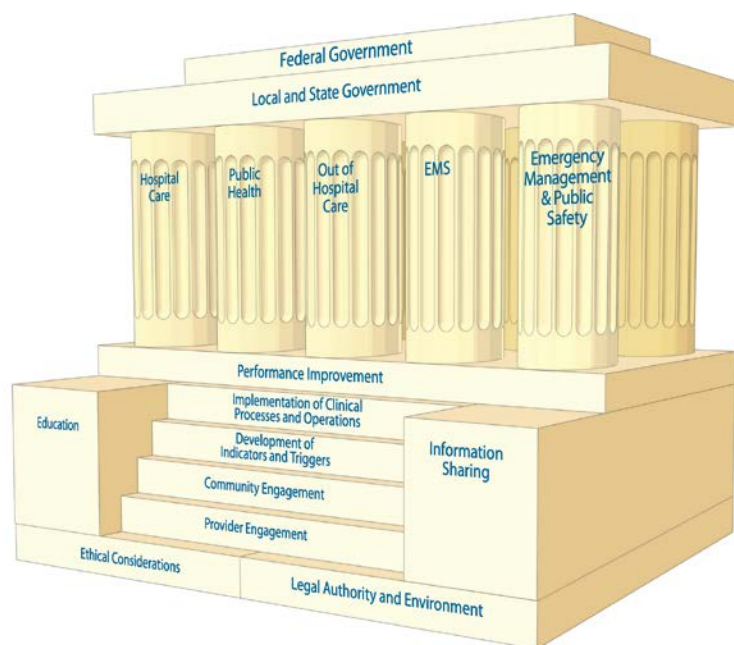
The framework reflects five key elements of crisis planning that are applicable no matter the degree of severity of the event being contemplated:

1. The consideration of foundational ethical underpinnings.
2. The development of community and provider engagement, education, and communications.
3. The role of legal authority and environment.
4. The need for resource shortage indicators and triggers.
5. The importance of clinical processes and operations.

The conceptual model of the framework depicted below would be very helpful in the development and implementation of plans to mitigate the effects of the drug shortage issue. Even though it refers to “catastrophic disaster response,” the model’s utility is in highlighting a systems approach required to mitigate such a complex, multifaceted issue that has implications along many steps of the healthcare delivery timeline. The model depicts a strong foundation of key guiding principles, the steps needed to successfully implement a response to the problem, and the pillars of the system, which clearly capture the three sectors of interest (public health, EMS, and hospital based emergency/trauma care). It is capped by the recognition for governmental overarching authority responsible for oversight and, in some cases, ensuring that plan development and execution occurs.

Conceptualizing a Systems Framework for Catastrophic Disaster Response⁴

⁴ Ibid. Reprinted courtesy of the National Academy of Sciences.



The framework describes a very useful and adaptable continuum from conventional to crisis care, depending on the demands placed on the system and its component parts by the incident—in this case, emergency care drug shortages. The three segments of the continuum are defined as follows:

Conventional: “The spaces, staff, and **supplies** (emphasis added) used are consistent with the daily practices within the institution. These spaces and practices are used during a major mass casualty incident (or in this case, a drug shortage situation) that triggers activation of the facility emergency operations plan.”

Contingency: “The spaces, staff, and **supplies** (emphasis added) used are NOT consistent with daily practices but provide care that is functionally equivalent to usual patient care. These spaces or practices may be used temporarily during a major mass casualty incident or on a more sustained basis during a disaster (when the demands of the incident exceed community resources, in this case during emergency care drug shortages).”

Crisis: “Adaptive spaces, staff, and **supplies** (emphasis added) are not consistent with usual standards of care but provide sufficiency of care in the context of a disaster (i.e., provide the best possible care to patients given the circumstances and resources available). Crisis capacity activation constitutes a significant adjustment to standards of care.”

It was the judgment of the work group that at the present time, the national EMS/emergency-trauma care system is in the **contingency** phase of this continuum (recognizing that there may be some regional and even facility-to-facility variation) and a concerted effort, through the possible use of the various coping options presented in this paper, would be beneficial in stabilizing the shortage’s impact and retarding, even preventing, the situation from escalating to the crisis phase through effective conservation, adaptation, and substitution with the objective of providing functionally equivalent care.

As visually portrayed in the graphic on the following page, the goal is to intervene early to stabilize the situation and avoid escalation of the problem (e.g., moving to the right of the continuum into the “crisis” phase), which would cause more deviation from the conventional standard of care.

Allocation of Specific Resources Along the Care Capacity Continuum⁵

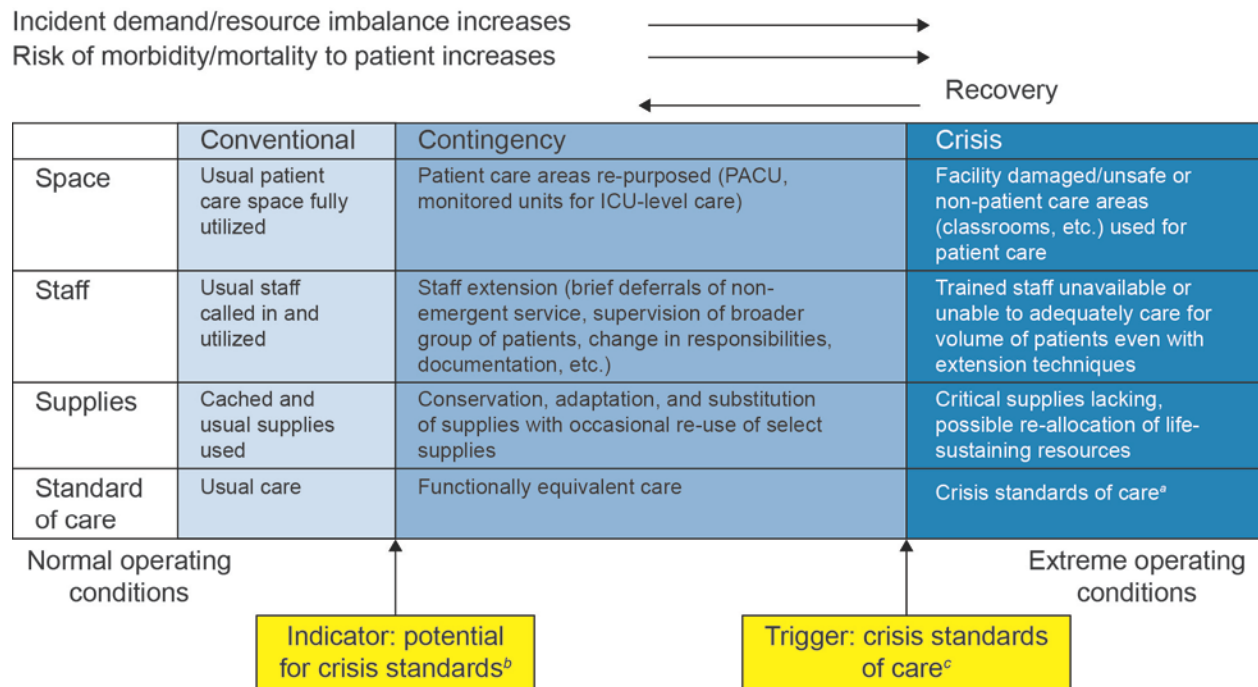


FIGURE 2-2

Allocation of specific resources along the care capacity continuum.

NOTE: ICU = intensive care unit; PACU = postanesthesia care unit.

^a Unless temporary, requires state empowerment, clinical guidance, and protection for triage decisions and authorization for alternate care sites/techniques. Once situational awareness achieved, triage decisions should be as systematic and integrated into institutional process, review, and documentation as possible.

^b Institutions consider impact on the community of resource use (consider “greatest good” versus individual patient needs—e.g., conserve resources when possible), but patient-centered decision making is still the focus.

^c Institutions (and providers) must make triage decisions—balancing the availability of resources to others and the individual patient’s needs—shift to community-centered decision making.

SOURCE: IOM, 2009, p. 53.

The framework can be used to assist states and local jurisdictions in stabilizing the drug shortage situation and avoiding escalation of the problem to the crisis stage. One key foundational element of the framework is the suggestion that state and local jurisdictions form a medical advisory committee. This committee, consisting of regional representatives from public health, emergency management, EMS, healthcare systems, community-based practitioners, and public safety, will be tasked with examining and developing a complete picture of the current local and regional drug shortage situation. The inclusion of neighboring states in the shortage analysis will not only ensure a complete picture but will also assist in the development of regional coping strategies that address the drug shortage, paying close attention to the importance of not depleting the supply chain. Existing committees could be used to fulfill this role by simply expanding their charge and membership, as warranted. This would be a more efficient use of resources and also contribute to a more integrated systems approach to planning.

⁵ Ibid. Reprinted courtesy of the National Academy of Sciences.

The medical advisory committee can also be used as technical advisors to provide analysis for potential modification of medical treatment, triage, and protocols. An example of this may involve the approval of medication alternatives due to drug shortages. The state EMS agency and/or medical director can use the committee's subject matter expertise to determine the new medication recommendation and ensure legality. The committee can also be used to provide recommendations on specific medications and assist state EMS agencies and other impacted healthcare entities with an understanding of their jurisdictional authority.

The framework also identifies a suite of strategies to address resource shortfalls. They are:

- **Prepare:** Planning and training for responses and emergency patient care; anticipating potential resource shortfalls and likely adaptive strategies.
- **Substitute:** Using functionally equivalent device or supply.
- **Conserve:** Placing restrictions on the use of therapies or interventions to preserve supply.
- **Reuse:** Re-using a device with appropriate cleaning, disinfection, or sterilization.
- **Reallocate:** Prioritizing of therapy to those patients with the best chance of a good outcome, most likely to benefit, or who require the least resource investment.

One illustration of how this framework is translated to a real-world application is the guide prepared by the Minnesota Healthcare System Preparedness Program, "Patient Care—Strategies for Scarce Resource Situations" (www.health.state.mn.us/oep/healthcare/standards.pdf). Assembled as a card set, it is intended to serve as a decision support tool and is designed to facilitate a structured approach to resource shortfalls at a healthcare facility. It is shown as a matrix displaying core clinical categories (e.g., Medication Administration), continuum capacity (e.g., Conventional, Contingency, and Crisis), and mitigation strategies (e.g. Substitute, Conserve, and Adapt), and key examples.⁶

The table on the following page highlights a number of the recommendations contained in the Minnesota tool as it pertains to Medication Administration.

⁶ Minnesota Department of Health, Office of Emergency Preparedness, Minnesota Healthcare System Preparedness Program. "Patient Care—Strategies for Scarce Resource Situations." Revised March 2012.

Examples of Strategies Using IOM Framework to Address Resource Shortfalls to Achieve Functionally Equivalent Care⁷

Conservation

- ☐ Restrict use of certain classes if limited stocks likely to run out (restrict use of prophylactic/empiric antibiotics after low risk wounds, etc.)
- ☐ Do without; consider impact if medications not taken during shortage (statins, etc.)
- ☐ Decrease dose; consider using smaller doses of medications in high demand/likely to run out (reduce doses of medications allowing blood pressure or glucose to run higher to ensure supply of medications adequate for anticipated duration of shortage)
- ☐ Allow use of personal medications (e.g., inhalers, oral medications) in hospital

Substitution

- ☐ Analgesia: Consider lorazepam for propofol
- ☐ Anti-infective: Consider cephalosporins, gentamicin, or clindamycin for unavailable broad-spectrum antibiotic
- ☐ Metered dose inhalers instead of nebulized medications

Adaptation

- ☐ Administer medications by gravity drip rather than IV pump if needed
- ☐ Consider use of select medications beyond expiration date (*legal protection such as FDA approval or waiver required)
- ☐ Emphasize oral, nasogastric, subcutaneous routes of medication administration
- ☐ Consider use of veterinary medications when alternative treatments are not available (*legal protection such as FDA approval or waiver required)

ACTIONABLE COPING STRATEGIES AND TACTICS—A MENU OF OPTIONS TO BE CONSIDERED

In the face of a shortage of critical emergency care drugs, systems, facilities, and practitioners will need to act promptly and responsibly to mitigate potential adverse consequences and provide the best possible care to patients. For many, this will be one of a number of concerns that require active management. It is also confounded and complicated by a series of legal, regulatory, and institutional policy and practice barriers and considerations that must be successfully navigated with the ultimate objective of providing the best quality care to the patient while remaining compliant with and true to the spirit of controlling laws, regulations, policies, and clinical standards of care and practice.

To assist policymakers, emergency planners, and clinicians and practitioners in this sometimes daunting task, the work group identified a series of strategies and tactics that, in their professional judgment, could be actionable and worthy of consideration. They are presented as just one resource to support ongoing planning and decision-making in this regard; they are not proffered as recommendations, nor do they carry any formal endorsement from the participating organizations and agencies. This resource should be used with conscious attention to and in the context of the prevailing jurisdictional and institutional legal, ethical, clinical, and administrative doctrines. Furthermore, the options presented do not carry with them any legal advice or prioritization, nor are they weighted with regard to importance or impact.

⁷ *Ibid.*

Increasing Situational Awareness and Visibility of Supply Availability

Heavily embracing the old adage “knowledge is power,” it is imperative that all three sectors increase their awareness, understanding, and attention to the drug shortage issue, both nationally and, more importantly, locally. This is a dynamic, not static, situation. Different types of drugs will go in and out of shortage, and the extent and duration of a shortage may also vary geographically.

At the national, even global, level there are two highly regarded and heavily utilized resources that provide relatively real-time information on reported shortages. They are:

- The U.S. Food and Drug Administration’s Drug Shortage Program: www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm. FDA maintains an index of drugs in shortage as reported by the drug industry, resources and fact sheets for consumers and health professionals, and a portal to report a drug shortage being experienced.
- The American Society of Health-System Pharmacists Drug Shortage Resource Center: www.ashp.org/shortages. ASHP maintains a resource center containing a list of current and resolved drug product bulletins, as well as bulletins on drugs no longer available.

Interested parties are encouraged to periodically visit these sites for updates and utilize the social media services available to receive information. Additionally, healthcare providers are reminded and encouraged to report shortages to the FDA Drug Shortage Program, particularly if they are experiencing a shortage that is not already listed on the program’s website.

Closer to home, planners, responders, and clinicians should consider treating potential or real emergency care drug shortages as a standing element of national security preparedness and readiness. They should utilize existing infrastructure and relationships among public health, EMS, and emergency/trauma care to exchange information and collaboratively plan and initiate mitigation actions, to the extent possible. This could include:

- *Advisory Committee(s)*: To ensure integrated preparedness efforts across jurisdictions, state and territorial health agencies receiving federal public health and healthcare preparedness funds are required to establish and maintain advisory committees comprised of senior officials from governmental and nongovernmental organizations involved in homeland security, healthcare, public health, and behavioral health. These well-established advisory committees include senior jurisdictional officials responsible for the administration of Department of Homeland Security preparedness grants and ASPR and CDC preparedness cooperative agreements as well as representation from emergency medical services, emergency management, medical examiner’s office, hospital association or local system, and quite often additional disciplines such as legal counsel and finance, local officials, and citizens.
- *Healthcare Coalition(s)*: Healthcare coalitions consist of one or more hospitals, at least one of which shall be a designated trauma center; one or more other local healthcare facilities, including clinics, health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; and one or more political subdivisions. Healthcare coalitions focus on

collaboration during preparedness efforts and develop priorities, goals, and objectives, which could also capture emergency care drug shortages.⁸

- *Partnerships and Other Standing Committees:* Additionally, many formalized partnerships exist between governmental, public, healthcare, and non-healthcare interested parties that provide an appropriate forum for information exchange, as do other standing bodies such as medical coordination centers/committees and regional disaster medical advisory committees.

Another way to increase situational awareness is to include drug shortage status as one of the data reporting elements in existing jurisdictional databases and dashboards (e.g., the State Medical Asset Resource Tracking Tool [SMARTT], or a “home-grown” platform such as New Jersey’s Hippocrates) that systematically capture, manage, display, and disseminate important information on facility status, asset availability, service disruption, and so forth and provide valuable decision support to public health and healthcare planners and responders. Given the potential impact of emergency care drug shortages or scarcity on national health security, if conditions worsen, field intelligence on shortage conditions should also be considered reportable to state fusion centers for information analysis and sharing. In Georgia, the Commissioner of Public Health asked all EMS services throughout the state to report daily to the Office of EMS/Trauma any drug shortages that had occurred or were imminent. The Office of EMS used the web survey tool Survey Monkey to maintain situational awareness statewide of the shortage issues.⁹

It is also important that EMS and emergency/trauma care personnel make it known when a drug shortage situation has occurred that may have had a deleterious impact on patient care and treatment. Such incidents should be immediately reported through established employer procedures and chain of command as well as to the relevant jurisdictional regulatory agency, in accordance with established regulation, directives, and policies and protocols, when applicable. For example, one California jurisdiction requires the medical director be notified when treatment standards were adjusted due to drug shortages. In turn, the medical director will inform the patient, the receiving hospital, FDA, and the Drug Enforcement Agency (DEA) of the incident in writing.¹⁰ Additionally, the National Association of Emergency Medical Technicians, in collaboration with the Center for Leadership, Innovation, and Research in EMS, has developed an anonymous system for EMS practitioners to report patient safety incidents by answering a series of questions online. The purpose of the system is to collect and aggregate data that will then be analyzed and used in the development of EMS policies and procedures, and for use in training, educating, and preventing similar events. This reporting system is called the EMS Voluntary Event Notification Tool (EVENT). For more information and to view the tool, please visit

⁸ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. FY 2011 Hospital Preparedness Program Guidance.

⁹ Written communication from J. Patrick O’Neal, MD, Director of Health Protection, Georgia Department of Public Health. Nov. 30, 2012.

¹⁰ A California jurisdiction requires its Advanced Life Support (ALS) providers to request approval for the use of expired medications for patient care. Following medical director approval, the most recently expired medications are to be used for 30 days or less. Additionally, the medical director will inform, in writing, the patient, receiving hospital, USDA, and DEA, as appropriate, that an extended expiration drug was administered during care.

www.emseventreport.org. EMS providers experiencing drug shortage incidents having an impact on patient safety should consider reporting the details of the occurrence to EVENT.

Remember, we all have a professional duty to anticipate, plan, and communicate.

Taking Action to Avoid Shortages

The FDA defines a drug shortage as “a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level.”¹¹ Stated another way, it’s not having what you need (the preferred course of treatment) in the indicated dosage and formulation when it must be administered. There are several steps EMS and hospital administrators could consider to avoid or delay shortages of preferred drugs. They include:

- *Set Up Sentinels in Inventory Management Systems:* Have the necessary triggers and indicators properly calibrated to get sufficient advance warning of a drug that is approaching depletion with enough lead time to take action.
- *Modify Purchase Amounts:* Just-in-time procurement practices are very sensitive to fluctuations in product availability from manufacturers and distributors. Facilities should consider purchasing more liberal amounts of key drugs as a way to possibly mitigate some of the impacts of “no notice” shortages (allowing them to benefit from a little more time to plan and initiate contingencies or possibly ride it out if it is a short-term, transient shortage). A word of caution: ***Do not hoard.*** Over-purchasing quantities of key drugs is counterproductive given its impact on supply and will exacerbate the “haves and have-nots” scenario. It also puts extra strain on material managers to ensure that products are used before their expiration date, should in-house demand not be in sync with the increased supply.
- *Broaden Procurement Options:* Facilities/systems could consider expanding their business relationships beyond their current suppliers. This may pay dividends in that end users have additional sources of product to turn to. Group purchasing cooperatives, including larger regional collaboratives, may also be a path to explore, possibly garnering more favorable consideration from manufacturers and suppliers (such as preference given due to size of procurement actions and more favorable volume-based pricing to help with cost containment). Such collaboratives could also leverage the influence of existing and maturing healthcare coalitions and possibly improve materiel management, resulting in waste reduction. Another collateral benefit mentioned by the work group is improved coordination and communication among state and private healthcare sector players. Procurement officials may also want to consider remaining in closer contact with manufacturers’ representatives to get direct updates on supply availability and also to directly communicate to them the facility/system status and the level of criticality that may exist due to actual or impending shortages. Of course, there are downsides to this approach, the most obvious one being that with an insufficient, finite supply

¹¹ FDA Manual of Policies and Procedures. MAPP 6003.1, Office of New Drugs. *Drug Shortage Management*. Feb. 3, 2012.

of drug(s), these approaches may provide relief to some but increase the magnitude of the shortage for others.

- *Share*: It is quite possible that situations will be encountered where the transfer of drugs from one facility to another (or from a hospital to an EMS unit) to alleviate a facility shortage is not only necessary but feasible, both within a facility and between facilities. In many areas of the country, EMS units may be struggling to maintain sufficient supplies of emergency care drugs necessary for advanced life support. Hospitals should consider giving priority assistance to EMS units by making available caches of critical drugs that are in shortage. This option is based on the premise that proper and sufficient pre-hospital care is essential to the ultimate patient outcome and, if accomplished, would lessen the burden on hospital's emergency department/trauma care team. In addition, EMS personnel, unlike physicians and hospital staff, have less latitude for alternative medication options due to scope of practice, education, and training requirements and resources. This type of mutual aid should be supported by the development of pre-event policies, procedures, and agreements. The inter-facility transfer of certain drugs is also governed by state and federal regulation. As such, the prevailing and situation-relevant laws and regulations should be examined to ensure that noncompliant actions are not unknowingly taken. DEA does permit the inter-facility transfer of certain scheduled, controlled, dangerous substances between two DEA registrants as long as sufficient documentation is maintained in accordance with 21CFR13.05.11 et seq. (www.deadiversion.usdoj.gov/21cfr/cfr/2105cfrt.htm). For C-2 drugs, a form 222 must be completed, and for C-3 through C-5 drugs, an invoice must be completed to document the transaction.¹² Facilities considering this approach are strongly encouraged to consult with their local DEA office prior to initiating transfers (www.justice.gov/dea/about/Domesticoffices.shtml).

Tapping into Existing Federal and State Stockpiles

The U.S. government maintains the Strategic National Stockpile (SNS) as a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration supplies, airway maintenance supplies, and medical/surgical items. Some states also maintain supplemental supplies of pharmaceuticals and other medical materiel referred to as state stockpiles. These stocks are maintained to support a jurisdiction's response to specific threat scenarios and some have suggested that they might provide temporary relief of drug shortages. These formularies are not designed to meet the needs of day-to-day pharmaceutical requirements. As such, in evaluating shortages to date, there has been little overlap between these stocks of drugs and the drugs found to be in short supply. Additionally, the individual medication supply would be quickly depleted if used for normal operations, providing only temporary relief of a drug shortage and leaving the stockpile unprepared for its original purpose.

SNS materiel is held in a variety of configurations designed to allow for its most effective deployment and use. The SNS generally holds inventory in a network of strategically located repositories chosen to allow rapid deployment in clinically relevant timeframes. Some SNS assets have also been pre-deployed

¹² Telephone conversation with the DEA Office of Drug Diversion, Liaison and Policy Unit, Nov. 14, 2012.

to allow immediate use by a jurisdiction. One specific example of the pre-deployment strategy is the CHEMPACK, which provides forward-placed caches of chemical nerve agent antidotes and related materials to hospitals and EMS units.

To receive SNS assets other than CHEMPACKs, generally a request is made by an authorized representative of a specific jurisdiction. Requests for assets may be routed through the CDC Emergency Operations Center or the HHS Secretary's Operation Center. Small, specific requests may be approved by CDC, resulting in immediate release of the requested SNS materiel to jurisdiction. Requests for larger amounts of assets require additional adjudication but can also be processed in a rapid manner. CHEMPACKs can be "opened" (i.e., specific contents taken out of the security storage units for emergency use) by a jurisdiction in cases of immediate need with subsequent reporting to CDC.

Potential benefits of using disaster stockpiles include: they are readily available, they may address immediate patient needs, they are either pre-deployed or can be made available within clinically relevant timeframes, and they are largely under government (public sector) control, ensuring equitable and objective allocation. Limitations include a less than optimal correlation between SNS formularies and emergency care drugs typically in shortage, regulatory complexities that require either an Emergency Use Authorization or Investigational New Drug approval prior to use, the cost associated with Drug Enforcement Agency site licensure requirements to access and store scheduled medications, and issues associated with billing for the costs of the drugs administered since facilities are not allowed to charge for material drawn from the SNS. Another challenge present in using SNS and/or state stockpiles resources is ensuring that the restocking of materials used occurs rapidly for potentially more serious emergencies and within limited budgetary resources. The release of a stockpiled drug could also exacerbate the immediate drug shortage problem by having to rapidly replenish stocks of an emergency care drug that is already in very short supply.

On March 16, 2012, CDC's Division of Strategic National Stockpile issued a memorandum to clarify procedures for accessing diazepam and atropine sulfate included in the CHEMPACK containers forward deployed across the nation. In face of the reported shortage, CDC did grant permission to use CHEMPACK countermeasures under the following conditions:

1. The removal of stockpile materiel is for a life-saving measure.
2. An alternative means of procurement is not available in a timely manner to support a medical emergency.
3. Product removed and used from CHEMPACK cache cannot be charged to patient.
4. Product removed by the case(s) only. Any unused portion of product will not be returned to CHEMPACK container.

EMS and hospital emergency planners are encouraged to discuss this option with their respective state or territorial Strategic National Stockpile coordinator.

Establishing and Institutionalizing a Suite of Contingencies for Clinical Care

EMS and emergency/trauma care professionals must be prepared with a “Plan B” should they face a drug shortage, despite their best efforts to avoid one. This plan should serve as a reliable decision-support tool by clearly articulating the various options, indicating priority or criticality, laying out conditions under which they will be executed, and other operational considerations. One such guideline developed in California is shown below and was discussed during the work group meeting in July. While the work group does not endorse this specific tool, it does illustrate an approach of careful examination and consideration and one way to facilitate structured and informed decision-making and action when a drug shortage coping intervention needs to be initiated. The tool has also been slightly modified by adding the last column, “Strategy,” to link the various decision points to the IOM Crisis Standards of Care framework.

Drug Shortage Mitigation Algorithm (Prioritized by Patient Safety)

Decision Point	Comment	Intervention/Contingency	Strategy*
1	Baseline SOP	None: Continue with current policies/procedures	Plan & Prepare
2a	Does not require Medication changes	Utilize Expired Medications	Adapt
2b	Does not require Medication changes	Utilize Compounded Medications	Adapt
2c	Does not require Medication changes	Discontinue use of Medication for interventions with questionable utility	Conserve
3	Requires new Dose Calculations & Training	Utilize the Same Drug with a Different Concentration	Substitute
4	Requires New Dose Calculations & Training	Utilize the Same Drug given via a different route (oral vs. IV)	Substitute
5	Requires New Dose Calculations & Training	Utilize a different drug from the same class (Versed™ vs. Valium™)	Substitute
6	Requires New Dose Calculations & Training	Utilize a different drug from a different class (Phenergan™ vs. Zofran™)	Substitute
7	Does Not Require Medication Changes	Stay in Service without the Medication (Failed Mitigation)	Transition to Crisis Care

**IOM Crisis Standards of Care Framework, 2012*

As can be seen from examining this algorithm, a number of interventions or contingencies have been listed that were also identified by the work group as being potentially feasible and actionable. These correlate to the strategies elucidated in the IOM framework, based on an approach that emphasizes substitution, adaptation, and re-use as means to avoid having to limit allocation of resources based on lack of availability. A brief discussion of each of these contingencies follows.

- *Using Expired Medications:* The work group held a fairly strong opinion that under proper conditions and if clinical circumstances dictated, using out-of-date drugs would be one potentially viable option, especially if the clinician was faced with the decision of using an expired drug versus no drug at all, taking into account the effectiveness of the drug and the seriousness of the patient's condition. The work group felt that favorable data exist for many classes of drugs regarding stability and efficacy beyond expiration, that this option provides dosing consistency, that the drug would be readily available thus avoiding delays in administration, and that it would aid in reducing unnecessary waste of a limited resource. The problems associated with this approach include safety and effectiveness issues, regulatory noncompliance issues, public perception and mistrust, fear of potential liability, and the impracticality of facilities sponsoring and conducting their own product stability tests to determine the acceptability of the expired drug.

When considering this option, it is important to have a full understanding of the fairly complex regulatory framework, both at the federal and state levels, that should be factored into an assessment before this approach is initiated. Federal law and FDA regulations require that drug product manufacturers assign an expiration date for drugs marketed in the United States. For drugs approved by FDA, the expiration date is determined based on FDA review of stability data from studies performed by the manufacturer. These studies are designed to show that a properly stored drug does not degrade to the point that it no longer meets its stability specifications within the labeled expiry period—that is, it can be expected to remain safe and effective for the labeled period of time when properly stored.

Experience has shown that, in some cases, drug products may remain stable beyond their labeled expiration date. For instance, a drug product manufacturer may have stability data that supports a longer shelf life than what is initially established. In limited instances, where adequate stability data can be obtained, FDA has exercised enforcement discretion on a case-by-case basis to enable distribution and use of a product beyond its labeled expiration to alleviate drug shortages of medically necessary products. In these cases, FDA reviewed stability data showing that the product would remain safe and effective for a certain time frame beyond expiry, and Dear Healthcare Provider letters were sent out to notify practitioners of the expiry extension and the overlabeling of product (reflecting a revised expiration date). FDA cannot, however, support an across-the-board extension for all products or particular classes or categories of products in the absence of such data.

In addition to FDA jurisdiction and interests, the Centers for Medicare and Medicaid Services (CMS) regulations, 42 CFR 482.25(b)(3), states, "Outdated, mislabeled, or otherwise unusable

drugs and biologicals must not be available for patient use.” The Joint Commission’s Medication Management Standards require that a hospital safely store medications (Standard MM.03.01.01), and the standard’s Element of Performance 2 requires that hospitals safely store all medications according to the manufacturers’ recommendations or, in the absence of such recommendations, do so in accordance with a pharmacist’s instructions. It is the Joint Commission’s interpretation that if an expired medication is present (e.g., “stored”) in a covered facility, even if sequestered from other “in date” medications, it would be a violation of the above-cited Joint Commission standards, since it is available for use.

Because state pharmacy laws also govern the dispensing and dating of pharmaceuticals, they should be considered in any approach that involves use of medicines past their labeled expiration date. In particular, state/local professional (e.g., medical, pharmacy, nursing, etc.) boards should be consulted. Some states have exercised their regulatory discretion authority to relax or waive regulations to allow providers such as EMS units to use expired medications under certain conditions. For example, the state of Utah has approved an expiration date extension program for critical medications in short supply. Under this procedure, approved medications are authorized to be used for up to six months following their labeled expiration. The protocol allows each Utah EMS agency and its medical director the discretion to approve or deny the use of expired medication use in a shortage.¹³

Regarding the stability of drugs beyond their expiration date, drug product stability characteristics can differ from product to product. Product stability is also dependent on storage conditions (e.g., light, temperature, humidity, etc.), with some drugs more sensitive than others. In the case of emergency care drugs, storage conditions might vary significantly (e.g., storage in an ambulance compared to storage in a pharmacy). In the absence of acceptable stability data and information about product storage, the strength, quality, and purity of an expired product at the time of use cannot be ensured. That being said, facilities faced with the challenge and choice of using an expired drug when medically necessary should, to the fullest extent possible, make an evidence-based decision. Drug manufacturers should be contacted for beyond expiration product stability data. If this cannot be accomplished, peer-reviewed journals and compendia should be consulted, although it should be mentioned that FDA would not likely endorse relying on these sources as the basis for extending an expiration date. Four that are widely used are the American Hospital Formulary Service (AHFS) *Drug Information*, Trissel’s *2 Clinical Pharmaceutics Database*, Trissel’s *Handbook on Injectable Drugs*, and the *King Guide to Parenteral Admixtures*.¹⁴

When considering this option:

¹³ Utah Bureau of EMS and Preparedness Drug Shortage Protocol, October 2012.

¹⁴ Institute of Safe Medication Practices. “Results of Our Survey on Drug Storage, Stability, Compatibility, and Beyond Use Dating.” Medication Safety Alert, March 22, 2012.

- Examine and refine inventory management practices to minimize the amount of expired drugs on hand.
 - Determine the regulatory requirements of and level of enforcement discretion being exercised by the jurisdiction's professional board(s) and federal regulatory bodies such as FDA and CMS.
 - Establish clear, documented institutional guidance and authority governing this practice.
 - Contact the drug manufacturer to learn more about the stability characteristics as a means to make a more informed decision on a drug-by-drug basis.
 - Maintain patient record documentation including a reference to a clinical assessment determination of medical necessity and that patient benefit clearly outweighed known or theoretical risk(s).
- *Using Compounded Medications:* The increased use of compounding pharmacies has been identified as one other means to increase drug availability. It can result in immediate availability of a product that is not commercially available and is especially useful as it pertains to addressing the individual medical needs of certain special populations. The disadvantages identified include product safety and efficacy concerns due to poorly compounded drugs, as evidenced by the recent multistate fungal meningitis outbreak associated with mass produced commercially compounded drugs (www.fda.gov/Drugs/DrugSafety/FungalMeningitis/default.htm#), increased expense, and a shorter shelf life, possibly resulting in potential wastage. In addition, it is an option not widely or readily available to all due to regional and geographic limitations. Other general concerns expressed by the work group that are worthy of consideration when exploring this option were potential liability due to human error in the compounding process resulting in impact on patient safety, the current framework of state regulatory oversight and FDA policy regarding this process, and the concern that the compounded product is not produced in full accordance with current good manufacturing practices for drugs. If this avenue is being considered, it is strongly recommended that facilities consult with the state board of pharmacy having jurisdiction over the commercial compounding pharmacy of interest to ascertain the current level of regulatory oversight provided (i.e., adequacy of state regulations and inspection and enforcement program) and the compounder's compliance track record before making a decision. A list of state boards of pharmacy contacts can be found at the National Association of Boards of Pharmacy website, www.nabp.net/boards-of-pharmacy/.

New Jersey has developed guidelines to assist its specialty care, mobile intensive care, and air medical units in obtaining waivers associated with mandated on-board medications. Documentation must demonstrate a multi-tiered, good-faith effort to obtain the needed medications. As an additional requirement, the agency must have used compounding as an alternative for at least 30 days with no indication of resupply in the near future before a waiver

would be issued to allow mobile intensive care units to operate without the mandatory medication formulary, indicating one application of this contingency to mitigate a shortage.¹⁵

- *Conservation, Including Tiered Utilization (Priority Given to Select Patients with Medical Necessity), Discontinued Use of Medical Intervention with Questionable Utility, and Adjusting Dosage Concentration (“Titrate to Effect”) and/or Route of Delivery:* This approach allows for prudent conservation of a scarce resource with the goal of preserving sufficient preferred treatment courses for life-threatening situations or special medical populations where treatment alternatives are limited or nonexistent. It also allows treatment with the same drug, thus avoiding the need to pursue substitution (discussed below). Potential areas of concern associated with this approach include managing perceptions of inequity, the need to have a strong ethical framework behind and supporting treatment decisions, sub-optimal treatment, and a fear of increased exposure to liability and potential litigation among healthcare practitioners and entities.
- *Substitution—Utilizing a Different Drug from the Same Class or a Different Drug from a Different Class:* By expanding a facility’s formulary of both in-class and out-of-class drugs, this option provides an alternative path for treatment when the preferred drug is not readily available or is being reserved for more medically-critical situations. In general, same-class drugs would be preferable to drugs from a different class, as this should minimize differences in side effect profiles and staff training requirements. The benefit of this approach is that it does allow for timely treatment rather than delaying or forgoing drug administration. It may also reduce the potential for inappropriate hoarding of first-order medications that are in limited supply. Drawbacks that must be seriously considered are the possible lack of practitioner familiarity and professional competence with rarely or never before administered third- and fourth-line drugs, possibly resulting in medical errors and jeopardizing patient safety (including side effects and drug interactions); the alternative drug may not be a clinically viable option or FDA-approved for some special needs populations (e.g., pediatrics); the imperative need for additional clinician education and training that carries with it a cost and time commitment; and the burden of increased procurement costs and storage space and expense to accommodate the expanded formulary.

Massachusetts allows for substitute concentrations when typical dosage forms are unavailable. All temporary substitutions must be approved by the service provider’s affiliate hospital’s medical and pharmacy directors. The protocol requires that the substitute used deliver the standard amount of active medication and be packaged to prevent medication errors as best possible.¹⁶

¹⁵ Waiver issued for New Jersey Administrative Code 8:41-6.1-014, July 1, 2012.

¹⁶ Memorandum from Massachusetts State EMS Director, Jan. 17, 2012.

- *Sparing—Using Multi-Dose Vials of Medications on Multiple Patients:* When a EMS unit or healthcare facility is faced with the dilemma of not having sufficient single-use vials of a scarce medication or not having any at all, consideration may be given to using multi-dose vials of that medication for multiple patients. Like some of the other options, this will result in a readily available drug of choice and could decrease costs and product waste. Some of the disadvantages, or at least challenges, that must be overcome are the potential for product contamination, dosing errors, and diversion, as well as establishing guidelines and improved practices for proper vial storage once opened and maintaining increased documentation requirements.

Establishing a Culture of Awareness and Understanding and a Discipline of Inclusion and Integrated Response to Drug Shortages

Drug shortages impact all levels and components of a healthcare enterprise, from executives to operations, clinical care, communications and outreach, and the healthcare consumer. Every effort should be taken to prevent being caught short or taken by surprise. Furthermore, the EMS and emergency/trauma care sectors should seize every opportunity to leverage existing resources and infrastructure to support drug shortage mitigation and coping strategies. Ideas generated by the work group include:

- *Proactively Maintain and Share a Real-Time List of Drugs in Shortage with All Who Have a Need to Know:* This will undoubtedly allow clinicians to anticipate possible practice adjustments and consider alternative treatments prior to an emergent need, will achieve better than just-in-time (or “at the moment”) notification of the shortage, facilitate resource sharing to the extent possible, and inform future policy decisions. It would be useful to have a pre-designated list of suggested substitutions collaboratively developed by the pharmacy and medical staffs. A brief summary of side effects and contraindications could also be listed for those substitute medications that are uncommonly used
- *Optimize Use of Decision-Support Tools:* Modify electronic medical records to provide and capture important information on alternative drug treatment regimens during times of shortage. Expanding data sets could also be considered as a way to record use of alternative treatment modalities resulting from a drug shortage, which could have value as it pertains to potential concerns over malpractice and other liabilities, inform future policymaking, support future research, and serve as one means to trigger escalated (or de-escalated) contingency planning.
- *Address Drug Shortage Issues as a Standing Part of the Curricula for In-Service Training and Continuing Education Activities for Nurses, Physicians, Pharmacists, and EMS Personnel:* Expanded education and training is the lynchpin to successful implementation of any and all of the coping strategies identified in this paper. It is proactive and progressive; will minimize confusion, frustration, and conflict; and will reduce medical errors and adverse patient

outcomes. It will also build stronger collaboration between hospital and pre-hospital care providers. The development and sharing of model protocols and training modules would result in increased consistency across healthcare systems and geopolitical jurisdictions, save time and improve coordination, and, with more rigorous development, could contain extremely valuable and helpful evidence-based options. Additionally, the engagement of medical specialty organizations in communicating recommendations of preferred alternative medications when the primary or preferred drug is unavailable enhances patient safety, especially for patient populations with functional or other special needs.

- *Institute Awareness Level Training for the Non-Clinician:* Policy- and decisionmakers at the executive and senior management/operations level must have a full appreciation of the impact drug shortages will have on a facility or operation. This awareness will provide them with the requisite sensitivity to the issue and empower them to support, maybe even champion, appropriate policy development, procurement actions, and advocacy efforts.
- *Inform the Public:* It is important for the public to receive timely, accurate, and objective information on the status of the emergency care drug shortage issue and its potential impact on patient care and safety. Too much is at stake to allow public trust to erode simply as a result of inability, unwillingness, or failure to communicate and help the public understand the issue, recalibrate their expectations under these conditions, and, if necessary, make informed decisions as a healthcare consumer. Be up front about this issue, let the public know what a facility or unit is doing to cope with it, and counter the shortage with the assurance that patient comfort and safety is the paramount consideration. Where more durable changes to healthcare delivery are envisioned as a result of persistent drug shortages, public participation that demonstrates important community values may be helpful in guiding the development of ongoing prioritization schemes. Volume 6 of the aforementioned IOM *Crisis Standards of Care* framework addresses public engagement and contains useful guidelines and templates to assist in this important activity.

REGULATORY CONSIDERATIONS

A discussion on drug shortage issues would not be complete without a brief review of state regulatory implications. It is vital that regulated entities such as EMS providers and hospitals maintain direct, frequent contact with their jurisdictional regulatory bodies such as the department of public health and boards of medicine and pharmacy to discuss the impact caused by the shortage, difficulties in complying with applicable rules and regulations, and the potential need for regulatory relief to allow for contingencies to be operationalized when it is determined to be in the best interests of the patient. Conversely, state regulatory agencies, after validating the “ground truth,” should consider using proper enforcement discretion and other authorized means to provide assistance in the form of regulatory relief when the benefits of such relief (e.g., temporary suspension or modification of specific

requirements) is determined to outweigh the perceived risk. Two specific areas of interest include the authorized use of expired drugs and waiving the par requirements for medical caches during times of documented shortage. Regarding the former, many state regulatory agencies do not have the authority to issue a blanket waiver to allow for the use of expired medications, nor would it be prudent to do so. They will, however, use discretion before taking an enforcement action if the attempts to acquire the subject drug(s) are documented properly by the EMS provider. For example, in Texas, the state regulatory agency requires providers to have a statement from their medical director that will demonstrate to the department that the medical director is aware of the situation: “If the department receives a complaint that a provider is using expired drugs or expired drugs are found on an ambulance during an inspection, the department will require the EMS organization to provide documentation from the manufacturer and the provider’s medical director regarding the shortage of the specific drug(s) before considering an enforcement action. DSHS [the Texas Department of State Health Services] is recommending that the documentation is on any ambulance that has expired drugs approved by the Medical Director.”¹⁷ Arizona¹⁸ and Tennessee¹⁹ have also used discretion for would-be citations issued during inspections. Arizona will allow the suspension of a citation during inspection if the EMS agency provides documentation showing a good faith effort to obtain the needed medications with no success. If the required documents are provided, the EMS Bureau will not cite the deficiency for 90 days. Tennessee also requires good faith effort documentation. In addition, if a therapeutic equivalent substitution is written by the medical director, the new protocol must be placed in each unit’s onboard protocol book for reference.

IN CLOSING

It is our sincere hope that this collection of peer-generated suggestions for coping with the ongoing emergency care drug shortage issue will be of assistance to you and your facility, agency, or organization as you attempt to mitigate its consequences. It is our plan to periodically update this document as more is learned about the impacts of the shortage and an evidence base for impactful coping strategies and tactics is developed. As such, we welcome your feedback on the utility of this guide and suggestions for enhancement and improvement. Additionally, we hope to soon establish a compendium of resources from the field that can be shared among the public health, EMS, and emergency/trauma care community of practice. All comments and submission of candidate resources should be forwarded to infocenter@astho.org.

¹⁷ Texas Department of State Health Services. Drug Shortage Statement for the Website. Available at www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=35824&id=3979&terms=drug+shortage+statement.

¹⁸ Arizona Guidance Document 104-PHS-EMS, Drug Shortages. Available at www.azdhs.gov/diro/admin_rules/guidancedocs/GD-104-DrugShortages.pdf.

¹⁹ Tennessee State Medical Director and EMS Director Memo to All EMS Service Directors and Medical Directors.

Appendix A

State Resources

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- Texas Medical Board, “Texas Medical Board Statement on Drug Shortages.” Feb. 24, 2012. Available at www.tmb.state.tx.us/news/press/2012/120224.php. Accessed 1/17/2013.

Expiration Date Extension

- Orange County (California) Emergency Medical Services, “Emergency Extension for Expiration of Selected Field Medications.” Available at www.astho.org/Programs/Preparedness/Coping-With-Drug-Shortages/Orange-County-California-Drug-Shortage-Advisory/. Accessed 1/22/2013.
- Utah Department of Health, Division of Family Health and Preparedness, “Utah EMS Medication Shortage Procedure: For Emergency Medication Use Up to Six Months Beyond Labeled Expiration Date” Available at www.health.utah.gov/ems/rulereg/medication_shortage_policy.pdf. Accessed 1/17/2013.

Medication Substitutions

Maryland

- Maryland Institute for Emergency Medical Services Systems, “Emergent Addition of Diazepam for Active Seizure Management.” May 18, 2012. Available at www.miemss.org/home/LinkClick.aspx?fileticket=Q3isM33odnc%3D&tabid=36. Accessed 1/14/2013.
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Massachusetts

- The Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health, Office of Emergency Medical Services, “Advisory: Immediate Change to Paramedic-Level Ambulance Required Medication List to Make Morphine Optional.” Nov. 15, 2011. Available at www.astho.org/Programs/Preparedness/Coping-With-Drug-Shortages/Massachusetts-Ambulance-Advisory-Fentanyl-and-Morphine/. Accessed 1/17/2013.
- The Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health, Office of Emergency Medical Services, “Memo: Drug Supply Shortages: D50, Furosemide, and Substitutions in Temporary Shortages.” Aug. 10, 2010. Available at www.astho.org/Programs/Preparedness/Coping-With-Drug-Shortages/Massachusetts-D50-and-Furosemide-Shortage-Memo/. Accessed 1/17/2013.
- The Commonwealth of Massachusetts, Executive Office of Health and Human Services, Department of Public Health, Office of Emergency Medical Services, “Memo: Shortage of Diazepam/Lorazepam and Magnesium Sulfate.” Sept. 1, 2011. Available at www.astho.org/Programs/Preparedness/Coping-With-Drug-Shortages/Massachusetts-Diazepam-Lorazepam-and-Magnesium-Sulfate-Shortages-Advisory/. Accessed 1/17/2013.
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New Jersey

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Ohio

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Other

- Commonwealth of Virginia, "Drug Kit Statute 18VAC110-20-500." Sept. 2, 2009. Available at <http://leg1.state.va.us/cgi-bin/legp504.exe?000+reg+18VAC110-20-500>. Accessed 1/17/2013.

Additional Resources

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Appendix B: EMS Systems

Coping Strategies for Drug Shortages

Strategy	Advantages	Disadvantages	Considerations
Utilization of expired medications	<ul style="list-style-type: none"> • Dosing consistency • Immediate availability • Reduces unnecessary waste • Data supporting efficacy 	<ul style="list-style-type: none"> • Regulatory noncompliance issues, including misbranding and adulteration • Public perception and mistrust • Fear of potential liability • Impracticality of testing for efficacy of expired medication • Potential variable storage conditions that may impact efficacy of expired medications, especially in environments external to hospital pharmacies 	<ul style="list-style-type: none"> • Inventory management practices should be examined and refined to minimize the amount of expired drugs on hand. • Determine the regulatory requirements of and level of enforcement discretion being exercised by your jurisdiction's professional board and federal regulatory agencies. • Establish clear documented institutional guidance and authority governing this practice. • Contact the drug manufacturer to learn more about the stability characteristics as a means to make a more informed decision on a drug-by-drug basis. • Maintain patient record documentation including a reference to a clinical assessment determination of medical necessity and that patient benefit clearly outweighed known theoretical risk(s).
Utilization of Compounded Medications	<ul style="list-style-type: none"> • Immediate availability • Addresses medical needs of certain special populations 	<ul style="list-style-type: none"> • Increased expense • Shorter shelf life (possible waste) • Not widely or readily available to all (geographic and regional limitations) • Potential for human error (possible impact on patient safety, thus increasing liability) • State-based restriction 	<ul style="list-style-type: none"> • Contact the compounding company to identify testing procedures, product effectiveness, manufacturing practice, and safe utilization. • Contact your state board of pharmacy to identify regulations, best practices, and use of compounded drugs, as well as legal ramifications.

Appendix B: EMS Systems

Coping Strategies for Drug Shortages

Strategy	Advantages	Disadvantages	Considerations
Conservation: Including Tiered Utilization (Priority Given to Select Patients with Medical Necessity)	<ul style="list-style-type: none"> Conservation of a scarce resource Life-threatening situations treated first Treatment with the same drug 	<ul style="list-style-type: none"> Possible perceptions of inequity Need for strong ethical framework Sub-optimal treatment Fear of increased exposure to liability and potential litigation 	<ul style="list-style-type: none"> Exercise extreme caution in establishing an ethical framework, including consideration of legal ramifications and liability.
Substitution: Utilization of a Different Drug from the Same Class or a Different Drug from a Different Class	<ul style="list-style-type: none"> Allows for timely treatment, no delay in foregoing drug administration May reduce the potential for inappropriate hoarding of preferred medication in limited supply 	<ul style="list-style-type: none"> Provider lack of familiarity of and/or professional competence with alternative drugs leading to possible medication errors Increased possibility for jeopardizing patient safety Imperative need for additional clinician education and training that carries extra cost and commitment Burden of increased procurement costs and storage space Increased liability Limited options for special needs patient populations 	<ul style="list-style-type: none"> Consider and become familiar with specific laws and guidelines governing drug substitution. Implement additional training protocol to increase practitioner knowledge and comfort ability and reduce error potential when utilizing substitution. Consider financial strategies for mitigation of increased cost in procurement of drugs that may be utilized.
Sparing: Using Multi-Dose Vials of Medications on Multiple Patients	<ul style="list-style-type: none"> Readily available drug of choice Decreases costs Reduces product waste 	<ul style="list-style-type: none"> Potential for product contamination Potential for dosing errors Potential for diversion Establishing guidelines and improved practices for proper vial storage after opening Maintaining increased documentation requirements 	<ul style="list-style-type: none"> Patient safety and the safety of the provider should be of the highest concern. Utilizing proper sterile technique and implementing safe practice protocol for administration are essential. 100% assurance of sterility is impossible.