The Impact of the National Drug Shortage on Emergency Care

Proceedings Report
April 2012
Disclaimer

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The Impact of the National Drug Shortage on Emergency Care

Executive Summary

Overview

Over the last six years, drug shortages of medications have nearly quadrupled from a peak of approximately 70 drugs in shortage during 2006 to a peak of 267 today. It is estimated that nearly 40% of drugs in shortage impact the delivery of emergency care (EC) by virtue of the shortage’s strong effect on the availability of sterile injectables widely used in the EC setting. Outside of EC, cardiovascular, oncology, anesthetic, analgesic, and anti-infective medications are routinely in short supply. The national drug shortage is so acute that at times the only way health care administrators have known a drug is in shortage is when it was missing from a manufacturer’s shipment.

The Impact of the Drug Shortage on Emergency Care was hosted by the Emergency Care Coordination Center (ECCC) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the United States Department of Health and Human Services (HHS). The meeting informally gathered input from private medical and pharmaceutical organizations on what they considered to be the factors and effects of the national drug shortage, and the coping strategies they have employed. These constituent views are enumerated below.

Factors

Stakeholders identified a variety of factors contributing to the national drug shortage, suggesting the problem has stemmed from a confluence of systemic issues within government and the private sector over the last several years. Private stakeholders believed contributing factors to the shortage include:

- FDA regulations that are strict beyond what is necessary for the agency to fulfill its mission of preventing product contamination.
- Economic factors that compel manufacturers to reduce or discontinue production of unprofitable drugs.
- Production capacities of brand name drugs that consist of only one or two manufacturing facilities, inherently limiting their supply.
- Several manufacturing facilities around the country that are out of commission, contributing to production delays and capacity issues.
Drug Enforcement Administration (DEA) regulations that are intended to prevent loss, theft, and misuse of raw materials are at times obstructive and delay the arrival of substances needed for medication production.

- Shortages of one drug that increase the demand on second- and third-tier substitution drugs, and that cause shortages for those drugs as well.
- Routine business decisions of manufacturers that have unintended effects on production, and create short-term shortages of individual medications.

**Effects**

Private stakeholders noted that the national drug shortage is creating safety issues as well as a financial cost to the health care system of the United States of an estimated $216 million a year. Stakeholders have seen the national drug shortage occurrences cause the following conditions:

- Patients who are dosed with alternate formulations of medications, especially in the EC setting, presenting safety and liability issues and the risk of adverse events.
- Physicians, nurses, and pharmacists who are diverted from patient care to handle issues related to a drug in shortage.
- Treatment delays and rationing.
- Expiry dates that are extended and run the risk of toxicity.
- Development of a "gray market" where drugs in shortage are available but may cost hundreds of times what they normally would.
- Volume buyers who are hoarding drugs.
- Increased risk of disease transmission as expired drugs are kept in stockpiles longer, increasing their chance of being mishandled.
- Smaller hospitals that are trying to prevent shortages in their own facilities by referring patients out to larger hospitals, exacerbating shortages in those larger facilities.
- Increased activity in the U.S. market by non-traditional drug distributors, especially foreign pharmacies.
- Unreliable resupply dates that increase the difficulty of predicting when drugs will arrive.
- The increased use of second and third line agents that are not as effective and for which the competent education and training of medical professionals in their use cannot be guaranteed.
- Medical professionals who are precluded from administering second- and third-tier substitution drugs by state scope of practice laws.

**Coping Strategies**

Private stakeholders identified a range of coping strategies that they have employed or would like to see employed in the United States government in an effort to stem the effect of the national drug shortage. The strategies identified by the private stakeholders are:
• Giving advanced notification of those drugs at imminent risk of shortage was noted as being an effective strategy.
• Extending expiry dates of drugs where possible.
• Utilizing alternative dosages.
• Import drugs where safe and appropriate.
• Increasing reimbursement from CMS to incentivize the production of essential medications.
• Addressing government silos that have developed through regulation as a means of improving and expediting drug approval processes.
• Expanding FDA authority to identify and promote critical medications and manufacturing processes.
• Having FDA work with manufacturers to assist capacity building.
• Creating industry standards for prepare for future shortages.
• Utilization of compounding pharmacies.

Conclusions

Government and private stakeholders both recognize the national drug shortage as an issue requiring immediate attention. The development of emergency care enterprise coping strategies in dealing with drug shortages will require the engagement of all areas of the emergency care community. The Emergency Care Coordination Center, in conjunction with the ASPR and ASTHO will work to convene the stakeholders in emergency care at a future meeting to be held in Washington, D.C., in July 2012.
The Impact of the National Drug Shortage on Emergency Care

Overview

Many medications are in critically short supply across the United States. Over the last six years, drug shortages across all categories of medications have nearly quadrupled, from a peak of 70 drugs identified as being in shortage in 2007 to a current peak of 267 drugs in shortage. Because of the shortage’s disproportionate impact on sterile injectables, a significant percentage of drugs in critical shortage are used in the emergency care (EC) setting.

The Emergency Care Coordination Center (ECCC) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the United States Department of Health and Human Services (HHS) hosted The Impact of the Drug Shortage on Emergency Care to respond to the increasing threat of shortages of medications available to emergency care providers. This meeting gathered stakeholders across the federal government and private sector with an interest in public health and the regulation, production, and use of emergency care drugs.

The Impact of the Drug Shortage on Emergency Care identified the scope of the shortage of emergency care drugs as part of a larger, longer term national drug shortage issue. The national drug shortage was recognized as not having stemmed from a single point or bottleneck, but rather from a confluence of systemic issues that have developed over the last several years related to both government and the private sector.

Opening Remarks and Welcome

Gregg Lord, MS, NREMT-P
Director, Emergency Care Coordination Center
Office of the Assistant Secretary for Preparedness and Response

Gregg Margolis, PhD, NREMT-P
Director, Division of Health Systems and Health Care Policy
Office of the Assistant Secretary for Preparedness and Response

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
Mr. Lord began the meeting by recognizing that stakeholders from both the federal government and private sector were in attendance. The issue of drug shortages causing patient care problems has been a priority of HHS since last year. Mr. Lord stated that the purpose of the meeting was not to develop consensus or forward official recommendations to the federal government, but rather to provide attendees with valuable information on the shortage. The meeting also was intended as a forum in which to listen to the issues organizations are having because of the shortage, and to hear about solutions that have been developed on the local level.

Dr. Margolis noted the meeting was organized quickly and reiterated that its purpose was to identify short term shortage mitigation and coping strategies while the shortage’s longer term causes were solved. Drug shortages have been a growing problem over the last several years to the point where the shortage has evolved into a preparedness and health security issue. Although media and public attention have focused on the shortage of chemotherapy drugs, the problem is becoming more acute in anesthesia and emergency care. Noticing the shortage’s growing profile in EC, the recent National Joint EMS Leadership Forum held in Baltimore had made the national drug shortage a top priority. Dr. Margolis added that the drug shortage is a complex issue with few obvious answers and a growing number of obvious victims. The shortage does, however, provide an example of how public policy has a direct affect on EMS and EC, and how it may be used as a tool to create solutions to national problems.

Assistant Secretary for Preparedness and Response Nicole Lurie, MD, MSPH, provided welcoming remarks, noting that the meeting was intended to spur conversation among stakeholders about the possible causes and solutions to the drug shortage but not to produce any definitive policies. Dr. Lurie noted that the scope of the drug shortage is such that 40% of the drugs on the FDA’s drug shortage list are commonly used medications. The shortage is the result of systemic issues within both the federal government and private sector, and these issues may take several years to solve.

Dr. Lurie also stated that the nationwide drug shortage has a direct affect on larger disaster response because these larger responses depend on the framework of an effective day-to-day EC system; an EC system that does not have access to routine drugs cannot be expected to function on a daily basis and thus will not function during a disaster response. Because ASPR is the federal entity tasked with handling a large portion of the nation’s disaster response needs, it remains committed to expanding its leadership role in EC and assisting where it able to develop a solution to the drug shortage.

Dr. Lurie presented an overview of ASPR’s initiatives to improve EC in the day-to-day environment. Within ASPR a significant lens has been placed on EMS, including expanding on the office’s EMS capacity. This expanded capacity has allowed ASPR to engage in EC activities across the federal spectrum, knitting together EMS components in order to leverage their accumulated value. ASPR is also seeking more contact with EMS groups in the community in an effort to better understand how the federal government may be of more use to the states, especially as each state has a different EMS framework. In a more direct role, ASPR’s Biomedical Advanced Research Development Authority (BARDA) has seen success with creating and producing medical countermeasures, although it has had challenges with packaging and distributing these countermeasures. Because crises build over time, participants were asked
to consider how communities and crisis standards of care planning may be implemented to compensate for future drug shortages.

Dr. Lurie took the opportunity to introduce Edward Gabriel, Deputy Principal Assistant Secretary of ASPR. Mr. Gabriel spoke briefly, noting that a similar drug shortage crisis occurred in the early 1980s and that lessons learned from that incident will be helpful in meeting the current national drug shortage crisis.

**Panel Discussion - The Impact of Drug Shortages in Emergency Care**

*Scott Matin, MBA, NREMT-P  
Vice President  
MONOC Mobile Health Services*

*Eric Lavonas, MD  
Associate Director, Rocky Mountain Poison and Drug Center  
Denver Health and Hospital Authority*

*Lee B. Smith, MD, JD, FACEP  
Medical Director  
West Virginia Office of EMS*

*Paul Hinchey, MD, MBA  
Medical Director  
Austin/Travis County EMS*

*Gary Ludwig, MS, EMT-P  
Deputy Fire Chief  
Memphis Fire Department*

Mr. Matin spoke on issues regarding flexibility within state and local regulations and the regulations’ contribution to the national drug shortage. State-level regulations affecting expiry dates and required formularies in ambulances often require months to change, presenting problems with providing alternatives for medications in shortage. States need to recognize they have a role in alleviating some affects of the drug shortage by expediting regulatory changes that allow for other medications to be used.

Dr. Lavonas gave his perspective on the drug shortage in his role as a practicing physician, noting that six months ago he was first made aware of a morphine shortage when a shipment from a manufacturer was found to have been missing the drug. His experience underscores the need to have a better early warning system in place to inform physicians of when drugs are about to fall into shortage.

Other issues encountered by Dr. Lavonas have the potential of directly affecting patient safety. Medications have been delivered in different concentrations due to packaging issues, and these
differing doses can be overlooked by nurses; this problem also occurs when drugs of one concentration have to be taken from one unit to another unit where a different concentration is the norm. Medications essential to preventing pregnancy complications are also being taken off of ambulances for use elsewhere. It is difficult for physicians to track medication usage and stock when these impromptu transfers occur.

A further problem lies in physicians being forced to use compounders and expired drugs against regulations, simply to maintain patients’ medically necessary courses of treatment. Small hospitals have also been using the “gray market” to meet patient care needs, receiving drugs from out-of-country sources without informing the FDA.

Dr. Smith shared his experience as an EC provider in West Virginia. EC drug shortages have reached a crisis level, and medications treating cardiac conditions, stroke, and seizures are being severely affected by the shortage, as are sedatives, analgesics, and drugs for high-risk obstetric patients. West Virginia is also experiencing issues similar to the rest of the nation involving lack of availability, access, rationing, and the use of alternatives medications that violate state scope of practice laws. As a result, the state has seen similar problems with differing dosages, medical errors, wastage, diversion, and theft. West Virginia could also benefit from federal guidance on extending expiry dates of shortage medications.

Dr. Smith noted that advanced notification of imminent shortages can give physicians time to change practices relating to how they stock, order and use alternate vendors. It may also be of value to develop a tightened timeline for correcting shortages once they are identified, as well as have the federal government engage in testing drug shelf life extensions. The development and dissemination of best practices to meet drug shortages in the clinical environment would also be helpful.

Dr. Hinchey shared his perspective as an EMS provider in Austin, Texas, saying that the acuity of the drug shortage is having an impact on his emergency medical technicians (EMTs). EMTs are experiencing increased difficulties handling patients who react as a result of their being unable to receive required medications. In addition to the shortages raising costs, these shortages are also beginning to affect the public’s trust in the city’s response capability. Austin’s EC reputation is also being affected as EMTs are forced to use different drugs almost on a daily basis, which at times has presented adverse affects.

Representing the Memphis Fire Department, Mr. Ludwig gave a perspective on the national drug shortage from the fire service, which he asserted as transporting 40% of EC patients. The problems the drug shortage presents to the fire service mirrors those problems of dedicated EMS services, such as using drugs past their expiry dates. Mr. Ludwig noted that the shortage has forced paramedics to break vials of drugs while in the field in order to reconstitute formulas, running a high risk of causing medical errors.
Panel Discussion - Coping and Mitigation Strategies within EMS and Emergency Care

Steven Krug, Eric Lavonas, Scott Matin, and Gary Ludwig discussed problems and mitigation strategies in the drug shortage environment. Dr. Krug stated that the drug shortage affects patient care outcomes because second- and third-tier drugs are not as effective. In addition, dosing patients with alternate medication formulations can be tremendously hazardous. Despite these risks, the drug shortage is so acute that these solutions have to be utilized even under semi-normal operating conditions. From the standpoint of patient safety, Mr. Matin noted that providers feel more comfortable paying two to three times more for a drug if they know the drug provides an expected strength and concentration.

Dr. Krug reiterated the advantage of an early notification of imminent shortages. He also suggested that the federal government may help alleviate shortages if it addresses the regulatory silos that have formed across disparate agencies over the years, which through their complexities have developed to actually impede interagency communications. Dr. Lavonas spoke of having success by working more closely with new and non-traditional suppliers, local hospitals, and compounding pharmacies.

General Discussion: Q&A and the Way Forward

Gregg Lord and Gregg Margolis led an open discussion about actions which may be taken to alleviate the national drug shortage.

Stakeholders representing nursing associations noted that local hospitals across the country have been keeping single dose vials of medications for the in-hospital environment, while allotting multi-dose vials to the ambulance crews; doing this means ambulance crews are less likely to need to improvise formulations during emergencies. As a mitigation measure, nurses have been using distraction behaviors where appropriate in place of medications, such as encouraging patients with motion sickness in ambulances to close their eyes and pace their breathing in the event zofran is not available for nausea. Hospitals are finding it useful to use a multidisciplinary approach when strategizing solutions because this approach gives a wider and more accurate sense of where in a facility certain medications are actually needed, and from where they may be removed.

Several suggestions were offered to the federal stakeholders as to how the federal government may be able to better assist states. Although many states have exemptions and provisions for other exceptional circumstances, they often do not have a rule to follow in the event of a shortage. Because state regulations determine many aspects of EC, from scope of practice to what drugs are required on ambulances, model legislation or guidance could be developed to help states determine exemptions and special provisions to build into their laws for drug shortage occurrences. Model legislation or guidance would be especially helpful for states, such as Maryland, which lack flexibility in shortage situations because it employs universal EC protocols for every ambulance within the state.
Participants also recommended that the federal government convene national forums on drug shortages to share best practices, develop solutions or toolkits, and vet models for states to follow. These forums would be inclusive of all aspects of emergency care. The federal government also was asked to find ways to better communicate drug shortage guidance to state regulatory agencies and boards because these entities are usually not familiar with the dynamics of drug shortages. Finally, Congress could look into taking legislative action by passing laws dictating what the scopes of practice for EMTs, nurses, and physicians are under a presidential emergency declaration.

**Closing Remarks**

Gregg Lord closed the meeting at 4:30 p.m., and stated that ASPR will be continuing to work with the stakeholders on identifying solutions to the national drug shortage.
APPENDIX A

The Impact of the National Drug Shortage on Emergency Care

April 16, 2012
Washington Court Hotel
Washington, D.C.

8:00 AM REGISTRATION

8:30 AM OPENING REMARKS
Gregg Lord, MS, NREMT-P
Director, Emergency Care Coordination Center
Office of the Assistant Secretary for Preparedness and Response

Gregg Margolis, PhD, NREMT-P
Director, Division of Health Systems and Health Care Policy
Office of the Assistant Secretary for Preparedness and Response

8:45 AM WELCOME
Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

9:00 AM FEDERAL EFFORTS TO REDUCE SHORTAGES
Sandra L. Kweder, MD
Deputy Director, Office of New Drugs
U.S. Food and Drug Administration

9:30 AM THE IMPACT OF DRUG SHORTAGES IN EMERGENCY CARE
Scott Matin, MBA, NREMT-P
Vice President
MONOC Mobile Health Services

Eric Lavonas, MD
Associate Director, Rocky Mountain Poison and Drug Center
Denver Health and Hospital Authority

Lee B. Smith, MD, JD, FACEP
Medical Director
West Virginia Office of EMS

Paul Hinchey, MD, MBA
Medical Director
Austin/Travis County EMS

Gary Ludwig, MS, EMT-P
Deputy Fire Chief
Memphis Fire Department

10:30 AM BREAK

10:45 AM HOSPITAL-BASED PHARMACY PERSPECTIVE ON DRUG SHORTAGES
Bona E. Benjamin, BS Pharm
Director, Medication-Use Quality Improvement
American Society of Health-System Pharmacists
OPEN DISCUSSION

11:15 AM

LUNCH

12:00 PM

ECONOMIC CAUSES OF DRUG SHORTAGES
Sherry Glied, PhD
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

1:00 PM

PHARMACEUTICAL INDUSTRY PERSPECTIVE ON EMERGENCY MEDICATIONS
Elina Srulevitch-Chin
Executive Director
Pfizer Worldwide Regulatory Strategy

1:30 PM

COPING AND MITIGATION STRATEGIES WITHIN EMS & EMERGENCY CARE
Steven E. Krug, MD
Head, Pediatric Emergency Medicine, Professor of Pediatrics
Children’s Memorial Hospital

Eric Lavonas, MD
Associate Director, Rocky Mountain Poison and Drug Center
Denver Health and Hospital Authority

Scott Matin, MBA, NREMT-P
Vice President
MONOC Mobile Health Services

Paul Hinchey, MD, MBA
Medical Director
Austin/Travis County EMS

Gary Ludwig, MS, EMT-P
Deputy Fire Chief
Memphis Fire Department

2:00 PM

PANEL Q & A

3:00 PM

BREAK

3:15 PM

GENERAL DISCUSSION: THE WAY FORWARD
Gregg Lord, MS, NREMT-P
Emergency Care Coordination Center

Gregg Margolis, PhD, NREMT-P
Division of Health Systems and Health Care Policy

4:30 PM

ADJOURN
Non-Federal Invited Guests

Tony Baker
International Association of Fire Chiefs

Stacey Barksdale Price
Bound Tree Medical

Bona Benjamin
American Society of Health-System Pharmacists

James Blumenstock
Association of State and Territorial Health Officials

Marie Diglio
Regional Emergency Medical Services Council of New York City

Valerie Donovan
United Healthcare

Anita Ducca
Healthcare Distribution Management Association

Susan Friedman
American Osteopathic Association

Dia Gainor
National Association of State EMS Officials

Tamar Haro
American Academy of Pediatrics

Paul Jarris
Association of State and Territorial Health Officials

Casey Korba
America's Health Insurance Plans

Steven E. Krug
Lurie Children's Hospital of Chicago

Barbara Lardy
America's Health Insurance Plans

Harry Larson
Bound Tree Medical

Eric Lavonas
Rocky Mountain Poison and Drug Center

Kate Leeson
Holland & Knight

John J. Lewin III
Johns Hopkins Medical Institutions

Greg Lynskey
Association of Air Medical Services

Brian Marlow
Johns Hopkins Medical Institutions

Scott Matin
Monmouth-Ocean Hospital Service Corporation

Kristin McDonald
American College of Surgeons

John Mitas
American Heart Association

Jeff Ranous
American Heart Association
Melinda Ray  
MMR Consulting

Harry Teter  
American Trauma Society

Aarron Reinert  
Lake Region EMS

Ron Thackery  
Emergency Medical Services Corporation

Don Rice  
Urgent Care Clinic of Lincoln

Lisa Tofil  
Holland & Knight

Teresa Ross

Barbara Tomar  
American College of Emergency Physicians

Gene Ryan

Jan Towers  
American Academy of Nurse Practitioners

Ellen Schenk

Richard Sherlock  
Association of Air Medical Services

Dominique Waller  
SRA International

David Slattery

Lee B. Smith  
West Virginia University

Jonathan Washko  
North Shore-LIJ Health System

Elina Srulevitch-Chin  
Pfizer

Ian Weston  
Children's National Medical Center

Scott Teper  
SRA International

Allison Wiley  
Healthcare Distribution Management Association
State, Territorial, & Municipal Invited Guests

Dale Adkerson  
Oklahoma DOH

Wally Ainsworth  
North Carolina DOH

Richard Alcorta  
Maryland Institute for Emergency Medical Services Systems

Maxie Bishop  
Texas DOH

Carrie Crawford  
State of Nebraska

Richard Fenlason  
Nevada DOH

John Freese  
FDNY, New York City

Regina Godette-Crawford  
North Carolina DOH

Angela Goodwin-Slater  
Dale City, Virginia

Karen Halupke  
New Jersey DOH

Chuck Happel  
State of Wisconsin

Paul Hinchey  
City of Austin, Texas

Frederick Hornby  
State of Wisconsin

Brian Hricik  
City of Alexandria, Virginia

Pat Irwin  
Nevada DOH

Douglas Isaacs  
FDNY, New York City

Steven Kersse  
Prince William County, Virginia

Jeff Leaming  
Ohio Department of Public Safety

Ray Lemke  
State of Wisconsin

Brian Litza  
State of Wisconsin

Gary Ludwig  
City of Memphis, Tennessee

Tom Mitchell  
North Carolina DOH

William Montminy  
Prince William County, Virginia

Keith Morrison  
Fairfax County, Virginia

Katherine O’Connor  
Westchester County, New York

Joseph Pataky  
FDNY, New York City

Amber Pitts  
State of Michigan

Jason Rhodes  
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<td>Chris Zervas</td>
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<td>Dale Adkerson</td>
<td>Oklahoma DOH</td>
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<td>Maxie Bishop</td>
<td>Texas DOH</td>
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<td>William Sugiyama</td>
<td>City of Oakland, California</td>
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Federal Observers

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DHHS/ASPR/OPEO/ECCC
Kevin Haninger
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David Boyd
Indian Health Service
RADM Clare Helminiak
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Tabinda Burney
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Joselito Ignacio
DHS

Patrick Byrne
DHHS
Steven Immergut
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Matthew Cogdell
DHHS/ASPR/OPEO/ECCC
Lisa Kaplowitz
DHHS

Kristen Coll
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Sandra L. Kweder
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Stephen Curren
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Drew Dawson
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Scott Douglas
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Nicole Lurie
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Edward Gabriel
DHHS/ASPR
Murray Malin
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Andrew Garrett
DHHS/ASPR/NDMS
Gregg Margolis
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Marc Gautreau
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Sherry Glied
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Sarah Goes
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APPENDIX C

About the Emergency Care Coordination Center (ECCC)

The Emergency Care Coordination Center is a strategic entity located within the Office of the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services (HHS) in fulfillment of Homeland Security Presidential Directive #21 and in response to the following 2006 Institute of Medicine Reports: Emergency Care for Children, Hospital-Based Emergency Care and Emergency Medical Services: At the Crossroads. ASPR recognizes that the successful delivery of daily emergency care is a necessary foundation for our nation’s emergency preparedness efforts. Public health and medical disaster readiness continue to be priorities for the U.S. government. Improving the resiliency, efficiency, effectiveness, and capacity of daily hospital emergency medical care delivery will strengthen the nation’s state of readiness for public health emergencies and disasters.