

Federal Public Health Emergency Law: Implications for State and Local Preparedness

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Coordinator: Welcome and thank you for standing by. At this time all participants are on a listen-only mode until the question and answer session of today's conference. At that time you may press star 1 if you'd like to ask a question. Today's call is being recorded. If you have any objections please disconnect at this time. I would now like to turn the call over to your first speaker, Ms. Alycia Downs. M'am you may begin.

Alycia Downs: Good afternoon and welcome to today's COCA conference call – "Federal Public Health Emergency Law Implications for State and Local Preparedness." This is a facilitated teleconference sponsored by CDC's Public Health Law Program and the Coordinating Office for Terrorism Preparedness and Emergency Response.

We are very excited to have Susan Sherman, Kim Dammers, Diane Donley, and Jennifer Ray present on this call. We are using a PowerPoint presentation that you should be able to access from our Web site. If you have not already downloaded the presentation please go to emergency.cdc.gov/coca. Click on Conference Call Information, Summaries, and Slide Sets.

The PowerPoint can be found under the call in number and pass code. And just as a clarification this call will not include an update of the ongoing swine influenza investigation. This was a previously scheduled call but does contain timely information that has implications for the current situation.

Additionally, the material contained herein is for instructional use only and is not intended as a substitute for professional, legal, or other advice.

Always seek the advice of an attorney or other qualified professional with any questions you may have regarding a legal matter. I will now turn the call over to Brian Kamoie, Deputy Assistant Secretary for Preparedness and Response and Director of the Office of Policy, Strategic Planning, and Communications at the U.S. Department of Health and Human Services.

Brian Kamoie: Thank you very much Alycia, and welcome all for what I know is an exciting and very valuable and timely conference this afternoon. I'm pleased to be able to be with you to open this and introduce our speakers and then, unfortunately, given the current influenza outbreak I'll have to drop off the call.

As Alycia mentioned, I'm responsible for policy matters related to preparedness and response to the Department of Health and Human Services and in that capacity work with CDC very closely, other divisions of the department, and the interagency on the policy issues that arise in preparedness and response and it will be no surprise to you that public health legal emergency preparedness forms a core foundation of those policy questions.

And although I know Alycia mentioned this is not about an update of the current activities related to the influenza outbreak, I can tell you that core legal preparedness questions and policy questions around use of the public health emergency authorities, emergency use authorization, and the PREP Act - the Public Readiness and Emergency Preparedness Act- for example, have been critical thus far in the earliest days of our response to this event.

And so legal preparedness is critical to the department and to our nation. I want to acknowledge before introducing all of the speakers Susan Sherman

from our Office of General Counsel and her leadership and in being the brain child for this event and those who work closely on these issues know that Susan is our lawyer, if you will, here as ASPR very ably assisted by Jennifer Ray who you'll also hear from.

And so we appreciate their legal advice very much and we also appreciate their leadership in making sure these kinds of educational opportunities are available to you all. And then I'd also like to comment CDC's Coordinating Office for Terrorism Preparedness and Emergency Response and the Public Health Law Program specifically for sponsoring the call.

Finally I want to tell you about three Web sites that - or three very practical tools that you might be able to use to assess powers surrounding social distancing should those become necessary for you to review. Those are on the CDC Web site at www.cdc.gov/phlp for public health law program.

Those tools include pandemic influenza legal preparedness tools, case studies on strengthening coordination between public health and law enforcement during an influenza pandemic, a guide for developing a memorandum of understanding for multi-sector response, and a pan flu preparedness legal checklist for healthcare providers.

So I commend those resources to your attention. And now I'm going to introduce your speakers this afternoon. First off, Kim Dammers is an Assistant to the United States Attorney in the northern district of Georgia which includes Atlanta and the CDC. She is a member of the Terrorism, Violent Crimes and Organized Crimes section of the United States Attorney's office and is currently on a 12-month detail to CDC. She has a BS in microbiology from Cornell and did her graduate work in microbiology at Rutgers University.

Her law degree is from Georgia State University College of Law and she is the co-author of “Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations.” She is also an adjunct Professor of Law at Emory University School of Law which makes her uniquely qualified to teach you about the legal emergency powers.

Diane Donley is not only in the FEMA Office of Chief Counsel but is my friend and colleague. She works at FEMA in numerous response, recovery and logistical issues and the event of Presidentially declared disasters or emergencies. She has been deployed to a number of disasters, including Hurricane Katrina, where she and I worked together; the World Trade Center; the Pentagon; and the loss of the space shuttle Columbia.

And she previously served on one of two national response teams who are at the ready all the time. She has a Bachelor’s degree from Wellesley College, a Master’s degree in Urban and Regional Planning and a law degree from Catholic University of America. She co-authored a chapter on the national response plan for a book on homeland security and has written articles on transportation planning and water quality management.

Jennifer Ray who has a law degree and a certificate of advanced study in health law from the University of Pittsburgh in 2004. Her MPH is from Boston University in public health law in 2001 and her Bachelor’s from Pennsylvania State University in 1999. She is a senior attorney serving the Public Health Division of the Office of General Counsel here at HHS and currently serves as a legal advisor to the department’s emergency preparedness activities in our office.

And again, I can't tell you how much we and the Assistant Secretary for Preparedness and Response Division appreciate her wise counsel. She has been an attorney with HHS since 2004.

Last but certainly not least, Susan Sherman who earned her undergraduate degree from Vassar College and her law degree from the George Washington University National Law Center. She earned her Master's of public - oh, I'm sorry - Master of Health Science Degree from the Johns Hopkins Bloomberg School of Public Health and she is a senior attorney serving the Public Health Division and in the headquarters of the Office of General Counsel here at HHS.

And Susan leads the team, includes Jennifer, that provides legal advice to our office in preparedness and response and she coordinates legal advice on these issues across the eight divisions and ten regions of the department's Office of General Counsel. She has been an attorney with HHS since 1990.

So I want to thank you all. I want to thank our speakers, again the CDC programs who sponsored this and with that Diane I will turn it over to you. Thank you.

Diane Donley: Good afternoon. I'm Diane Donley. As you've heard, I'm in FEMA's Office of Chief Counsel. I've been here about nine years - starting on my tenth. If you'll start with Slide - my Slide 4 it says "History" up at the top. I wanted to give you a little bit of background about the Stafford Act and the authorities that FEMA operates under when it goes to assist state and local governments when there's been a Federally declared disaster.

This all began roughly in 1950 when the first public law was passed creating a Federal disaster relief program. And in 1988 the Robert T. Stafford Disaster

Relief and Emergency Assistance Program was - Assistance Act was passed. The next notable thing from our perspective in 2002 the Homeland Security Act. Previously FEMA was an independent agency and it became a part of the 22 agencies that make up the Homeland Security Department.

And then in 2006 the post Katrina Emergency Management Reform Act. There are number of changes in FEMA's authority that occurred in 2006. That statute was passed October 4, 2006, in response to many of the perceptions about what happened during Hurricane Katrina. Please go to Slide 5. The primary disaster relief legal authorities are, as I've mentioned, the Stafford Act, the Homeland Security Act, and the Executive Order 12148 which has been amended many times.

That executive order was during the Carter administration. And then Title 44 of the Code of Federal Regulations, in particular part 206. Slide 6 please, has "The Stafford Act" up at the top. The Stafford Act authorizes the president to issue a major disaster or an emergency declaration to states when states have requested assistance from the Federal government in stating that they have declared a state of emergency and are overwhelmed - their resources are overwhelmed.

This declaration triggers our statutory authority and access by FEMA to something called the disaster relief fund which is a special appropriation from Congress. It has several billion dollars in it so that it's readily available to immediately get money to states and local governments when they need aid for emergency services and assistance for restoration of services.

The Stafford Act also authorizes FEMA to coordinate the administration of all the disaster relief. Next slide please - Slide 7. "Primary Mission" is at the top of the slide. The mission of the agency as amended by the Post Katrina

Emergency Reform Act is to reduce the loss of life and property and protect the nation from all hazards.

The specific activities include working with state, local, and tribal governments, emergency response providers, other Federal agencies, and the private sector to build a system of emergency management. Slide 8 is the next slide. It has “Major Disaster” up at the top. It’s a very important slide because it is actually the definition of what is a major disaster.

And the first three words “any natural catastrophe” have been interpreted to mean that it would be possible if the situation called for it that there could be a Stafford Act declaration during a pandemic influenza outbreak. What happens when there’s - and then let’s go to the next slide first and then I’ll discuss a little bit about declarations.

The next slide is Slide 9 and has “Emergency” up at the top. It says any - this is another very important point - any occasion or instance for which in the determination of the President federal assistance is needed to supplement state and local efforts and capabilities to save lives, to protect property and public health and safety. And the most important part is to lessen or avert the threat of a catastrophe in any part of the United States.

And in FEMA’s view this provision to “lessen or avert the threat of a catastrophe” would probably be the first stage in a situation with a - any kind of pandemic flu where there would be a request from the state that felt it was becoming overwhelmed with people going to hospitals and they needed additional assistance and they would send a request to our regional office and ask for an emergency declaration.

Emergency declarations are capped at this time at \$5 million, however, FEMA regularly seeks additional - FEMA can notify Congress and then go above that cap of \$5 million and FEMA regularly does that. So on Slide 10 which says “Request for a Declaration” up at the top it explains the governor must execute the state’s emergency plan - state in writing that the situation is of such severity and magnitude that effective response is beyond the capabilities of the state in order to get a declaration.

On the next slide It states that the declaration made by the President specifies the types of assistance authorized which I’m going to get to shortly. If you’ll go to Slide 11 - the “Declaration for Primary federal Responsibility.” It is possible for the President to issue an emergency declaration if the emergency involves a Federal primary responsibility.

And that’s an interesting question -- whether the President might or might not consider a health event to fall within a federal primary responsibility because I think what you’ll hear from the HHS persons -- the staff persons who are going to be speaking -- that health issues are really a joint state and federal responsibility and not primarily a federal responsibility.

So it would be possible, however, to issue an emergency declaration -- and the President has done that -- if the emergency involves a subject area for which under the Constitution or laws of the United States the United States exercises exclusive or preeminent responsibility. And the Murrah building I’ve listed here - the Murrah building in 1995, the Pentagon attack in 2001, the space shuttle Columbia explosion - those are three examples of when the President, without receiving a request from a state, declared an emergency.

If you’ll switch to Slide 12 that’s “Disaster Assistance.” There are three primary types of disaster assistance. Under the Stafford Act one is called

Public Assistance and there FEMA is assisting states and local governments and certain types of private non-profits with emergency work that is immediate repairs -- to shore up a building, for example -- and permanent work to do repairs on a building if it's damaged by a flood or earthquake or some other natural catastrophe like that.

Individual Assistance is a separate program. Currently the maximum that an individual can receive is \$30,300 but the concept is to give a person who has just immediately lost everything a leg up. They can get some money right away to assist them with lodging, getting some clothes for themselves, making sure they have enough to eat, and that sometimes is done with emergency assistance where we work very closely with the Red Cross.

And this assistance called Individual Assistance comes right after - say within five days to the person if they've - after they've received just immediate assistance with their needs.

Hazard Mitigation is a separate program where a state can receive between 7 and 15% of the total amount of money for the state in the particular disaster can be set aside for hazard mitigation. Hazard Mitigation is doing things for example to build a town hall higher off the ground so that it would not be a subject to floods and there can be hazard mitigation monies to assist with that. We've done a great deal of that with Hurricane Katrina. Next slide provides more details about public assistance and that's on Slide 13.

Emergency work - I've listed the sites for it both in - both for in a major disaster as well as an emergency. It provides debris removal, search and rescue, evacuations. Debris removal in the beginning of a disaster is in any kind of natural disaster - so important to get the roads clear. It also provides

medical care, mass care, shelter, food, water. We put up tents or modular units for town halls and we provide technical advice to state and local governments.

Emergency work is generally a 75% federal share and a 25% state share although the federal share can be increased by the President. Next slide - Slide 14 "Public Assistance: Permanent Work." As I indicated this is repair and restoration of damaged facilities provided through grants and they're written up on project worksheets - again 75%.

Next slide please - Slide 15. It says "Public Assistance" at the top. The delivery of emergency work by direct federal assistance. Here the governor is certifying that the state can't perform or contract for the performance of the requested emergency work and thus FEMA either arranges to do the work itself through contractors or mission assigns another Federal agency to perform the emergency work.

For example, in Hurricane Katrina the Department of Health and Human Services was mission assigned by FEMA to take on the health issues in Hurricane Katrina which were enormous. So Health and Human Services, HHS, then worked with a number of support agencies to organize federal assistance to the state. The state remains responsible for the applicable non-federal cost share and the federal agency does get reimbursed by FEMA when it's acting under the Stafford Act rather than its own statutory authority.

There's a section of the Post Katrina Emergency Management Reform Act which has caused a lot of confusion for people. It's called accelerated federal assistance. The concept was it needed to be added to the statute because there was a feeling during Katrina that the federal government could have done things and didn't do them quickly enough when they knew there was a need.

And thus after there's either a major disaster or an emergency declared, the federal government can go in and carry out activities that it is clear the state would need to have done even if the state has not specifically requested. Now in that instance the federal government is to notify the state that it is planning to do that as soon as practicable.

So if you think about the situation where somebody's on top of a roof in a flooding situation and a federal person is nearby and can save the person, the federal person does not have to go get permission from the state to save one of its citizens. Next slide please. Slide 16 "Mission Assignments, Direct Federal Assistance & PSMAs." PSMAs are pre-scripted mission assignments.

Mission assignments are what I was talking about just a moment ago and it's the concept that we can direct other federal agencies to assist us in disasters which we have done regularly with the Department of Health and Human Services. They're an important partner with FEMA in responding to disasters. Direct federal assistance merely means either FEMA will do the work or FEMA will issue a mission assignment with a cost share because there are other kinds of mission assignments.

There are mission assignments that are federal operational mission assignments and they are covered 100% by the federal government. And also there's a technical assistance mission assignment and that's also covered 100% by the federal government. Pre-scripted mission assignments are draft mission assignment. FEMA has worked very closely with a number of federal agencies to create draft mission assignments from our experience in the field.

There are over 200 now. They're drafts but both FEMA and the agencies have already determined that this is - this particular approach, for example, the details of sending a team from HHS to go to a state to assist them are spelled

out, such as, how many people are going and what needs they have. Slide 17 - "Appropriations." The funding for disaster assistance under the Stafford Act, as I indicated, is from the disaster relief fund and the appropriation says for necessary expenses in carrying out Titles IV and V of the Stafford Act.

And that money is used for carrying out major disasters and emergencies under the Stafford Act. Next slide - Slide 18. One of the issues that came up again during Katrina was the concept that federal law enforcement officials were preventing essential service providers from entering disaster sites when they were working to repair services.

I'm not aware that that happened but I'm not saying that it didn't happen. Thus there's this new provision in the law that basically says any essential service provider may enter a disaster site. Finally I wanted to mention in Slide 19 the "Authority to Assist the Private Sector." The Stafford Act is not really designed to assist the private sector. It's designed to assist state, tribal and local governments and individuals.

However, in certain situations when it is of direct benefit to the federal government it is possible that the federal government can assist the private sector. The example I like to give is when there's a tank farm and the federal government has purchased fuel from the tank farm for a several month period and the guards for the tank farm have fled, the federal government could go and guard the tank farm to protect the fuel that it had purchased.

This is an indirect benefit to the private sector because their tank farm is being protected but it's not a direct benefit to the private sector. It's a direct benefit to the federal government. That's all I have. I'm ready to turn it over to the next speaker. Thank you very much.

Susan Sherman: Hi. This is Susan Sherman. Good afternoon. We'll start in right now. The Slide 21 here that's just our introduction. I'm Susan Sherman. With me is Jennifer Ray. We're going to talk to you about HHS public health emergency authorities. If you go to Slide 22 you'll see here are our topics.

We're going to give you a very brief overview of HHS authorities for emergency response and reference when appropriate the authorities of our Assistant Secretary for Preparedness and Response who, as (Brian) explained to you, is our primary client here at HHS for the two of us.

And then we're going to briefly touch upon authorities related to three areas of public health emergency response - the deployment of personnel, public health emergency declarations, and issues related to medical countermeasure distribution. If you'll turn to the next slide which is 23 there are our main statutory authorities that we'll be referencing.

Primarily our authorities flow from the Public Health Service Act that was enacted back in 1944 and has been amended frequently since then. And that's the statute that we'll reference by and large. When appropriate we'll also tell you about some of the federal Food, Drug, and Cosmetic Act authorities that are relevant to emergency response as well as Social Security Act authorities. And we'll also be mentioning the Stafford Act that Diane just described to you and the National Emergencies Act when appropriate.

If you go to the next slide you'll see this is our list of legislation that affected HHS emergency preparedness authorities since 2001. We just use this slide to show there's really been a lot of legislative activity in this area and when we describe our authorities to you, even though we're mentioning the Public Health Service Act, by and large that Act has been amended by these other

pieces of legislation like the Smallpox Emergency Personnel Protection Act, the BioShield Act, the most recent Pandemic and All-Hazards Preparedness Act.

We don't tend to refer to them because they all amended our primary authorities I just spoke about. But we're certainly giving you, you know, the latest version and we may reference those statutes as well as needed. I'm going to turn the podium over to Jennifer who's going to speak about HHS authorities, personnel deployments, and public health emergency declarations.

Jennifer Ray: Good afternoon. I'm going to start with Slide 25 that's entitled "HHS Authorities." When the Pandemic and All-Hazards Preparedness Act or PAHPA was passed in 2006 it amended the Public Health Service Act to designate the HHS Secretary as the lead for all Federal public health and medical response to public health emergencies and incidents covered by the national response framework.

PAHPA also amended the Public Health Service Act to establish the position of the Assistant Secretary for Preparedness and Response or the ASPR. The HHS ASPR serves as the Secretary's principle advisor on matters related to Federal public health and medical preparedness and response for public health emergencies.

As many of you know on the phone, HHS is the lead at the federal level for ESF 8, or Emergency Support Function 8, which is the public health and medical services annex of the national response framework. HHS is also the lead for the biological incident annex of the national response framework as well as a supporting agency for ESF 6, Mass Care, Housing, and Human Services.

Moving onto the next slide. In terms of HHS' authorities to assist states, Section 311 of the Public Health Service Act provides the Secretary with authority to extend temporary assistance to states or localities in meeting health emergencies at the request of states or local authorities. And this can include utilizing HHS personnel, equipment, medical supplies and other resources when states are overwhelmed.

The Secretary can provide assistance under this section even in the absence of a formal declaration of a public health emergency which I'm going to talk about a little bit more later in my presentation. While Section 311 provides HHS with broad authority to render assistance to states, HHS would also need to have funding and resources to respond to particular events.

Often when HHS assists states when they are overwhelmed during a large emergency HHS is responding under a mission assignment from FEMA, like Diane just spoke about, which provides money to HHS to carry out those activities. Moving on to the next slide 27 - "Deployment of Personnel." I wanted to shift gears a little bit and talk about some of the legal issues that arise when HHS - or when healthcare personnel are deployed and to mention briefly some specific personnel assets that are either part of HHS or that HHS has played a role in coordinating or developing.

Many of you out there may be very familiar with some of the groups I'm going to talk about so please bear with me while I provide just a brief overview for folks that may not be quite as familiar. This Slide 27 outlines how HHS personnel that are deployed may be utilized in the field. One category is to provide medical surge and this can be - have something to do with sheltering and patient collection sites, in operating federal medical stations which can deliver some non-acute hospital bed surge capacity, to back-fill healthcare facilities and mobile medical units.

We assist with patient evacuation if we need to evacuate hospitals or facilities that are in the path of a storm. We staff our HHS incident response coordination team in the field and we serve as liaisons to other types of response teams in the field at different levels of government. We have human services teams in the field that operate under ESF 6 that do case management type activities.

And then finally we have teams of course doing public health assessments, FDA inspectors, those types of perhaps more routine public health type assessments. Moving onto Slide 28 - "Federal Employees." When healthcare personnel are being deployed, particularly across state lines, two of the biggest legal issues that arise are licensing and liability concerns.

Worker's comp coverage is also a third issue that can be a concern as well. These three issues are fairly straightforward when we're talking about federal employees. Federal employees are covered by the Federal Tort Claims Act or the FTCA which means that covered employees are not personally liable for negligent acts committed within the scope of their federal employment.

This means if they are sued for negligence while they are carrying out their federal mission they would be removed from the lawsuit and it would become a lawsuit against the federal government. In terms of worker's comp coverage federal employees are covered by the Federal Employee Compensation Act which is worker's comp coverage for federal civilian employees who are injured or killed while in the performance of their duties.

And then finally in terms of licensing for positions requiring a state license, Office of Personnel Management regulations and federal job descriptions generally require an employee to be licensed in "a" state. This means that

federal healthcare workers can carry out their federal duties in any state to which they're deployed.

And again, this is because that individual is a federal employee who is carrying out federal duties. It does not matter whether they're on federal land or property or not. And the federal government determines what qualifications are necessary for particular position, would be responsible for verifying credentials and their other qualifications.

Moving onto next Slide 29. When healthcare professionals are deployed across state lines and not federally - state to state or through some other mechanism, licensing and liability issues become a lot more complicated as laws addressing licensing reciprocity and liability protection differ from state to state.

In terms of liability many states do have provisions that provide for some type of liability protection for healthcare providers but, you know, we kind of refer to it as a patchwork of protection. And what particular protections apply and the scope of those protections may differ from state to state. I'm just going to talk very generally about some of the protections that could apply.

As they mentioned at the beginning of the call if you had any specific questions please do consult your state attorneys or other attorneys for your organization about specific advice on these issues. One potential way for folks to have liability is in EMAC - the Emergency Management Assistance Compact. That is a compact that all states are signatories to and it's a mechanism for states to exchange resources, including personnel from one state to another.

There is an immunity provision in there that will apply. However, it is limited to state officers and employees who are exchanged under EMAC. So that could be a fairly significant limitation and in terms of exchanging folks who are from the private sector, if a state doesn't have the ability to make those individuals some type of temporary state officer or employee or agent of the state.

EMAC also does have a licensing reciprocity provision so folks that are exchanged under that would be able to practice in the state to which they would be exchanged to. All state governors have emergency powers that kick in when they've declared an emergency or a disaster or a public health emergency. It probably differs from state to state what the event would be called but those emergency powers allow them basically to make or amend or rescind temporarily orders, rules, and regulations necessary to carry out the state's emergency function.

In some states they may interpret that power or the powers may specifically provide the ability for the state to extend some type of liability protection to healthcare workers who are responding including those from out of state and to also provide some type of license reciprocity. Also when a governor declares an emergency or a disaster or other type of event some states have some statutory provisions in their emergency laws that would extend some type of immunity or indemnify healthcare volunteers.

Again, there might be specific provisions that would also extend license reciprocity to folks from out of state. State Good Samaritan statutes may offer some liability protection to healthcare workers; however, these really differ very widely state to state in terms of the type of people they cover, you know, whether it's just emergency workers, healthcare professionals, or the general public, whether they just apply at the scene of an accident.

So you'd really have to check to see what a particular state's Good Samaritan statute looks like. Some states have Volunteer Protection Acts that could potentially provide some protection. There's also a Federal Volunteer Protection Act that could provide some liability protection to folks who are volunteering with a non-profit organization or a government entity.

And finally there's a law called - a model law that was drafted called the Uniform Emergency Volunteer Health Practitioners Act which does address liability and licensing. It's my understanding thus far seven states have adopted this model Act. As more states adopt it that might be also a solution to address liability concerns as well as licensing.

Finally in terms of licensing I mentioned above some ways that reciprocity might be offered. Also certain professions have some specific compacts like the Nurse Licensure Compact that some states may be members to. And then finally it's my understanding that the Red Cross has negotiated reciprocal license agreements with each state in providing the basic first aide that they provide. And that might be a mechanism if folks are volunteering with the Red Cross and want to cross state lines.

So moving onto Slide 30 I'm going to shift gears now to some specific types of personnel groups that HHS has or some other types of groups. The "Commissioned Corps" - Slide 30. HHS authorities establish a regular Commissioned Corps and a Reserve Commission Corps for duty in the time of emergency.

This is one of the uniformed services that's led by the Surgeon General. The President may also use the Commissioned Corps in war or an emergency proclaimed by the President. Moving onto Slide 31 - the "National Disaster

Medical System” or the NDMS. That is a coordinated effort of the Department of Homeland Security, the Department of Defense, the Veterans Administration, and HHS in collaboration with states and public and private entities.

NDMS teams can be deployed to provide health services, health related social services, other appropriate human services -- this can include veterinary teams, mortuary teams, and other teams -- to respond to the needs of victims of a public health emergency and be present where and when the Secretary determines location is at risk of a public health emergency.

Activation and deployment of the NDMS does not require a formal public health emergency declaration though. NDMS members are intermittent employees of the public health service so this means that when they are activated they are federal employees and so they would have FTCA tort liability coverage, they'd have the FECA workers' comp coverage.

And the statute also gives them USERRA coverage. If you're not familiar USERRA, it is the Uniform Services Employment and Re-Employment Rights Act which provides protections to the reserve components of our uniformed services so individuals who are deployed don't lose their jobs. Our NDMS members when they're activated would also have certain protections under that law.

And finally, again because they're federal employees, they would only need to be licensed in “a” state to be carrying out their activities. Moving onto Slide 32 - the “Medical Reserve Corps.” The MRC is comprised of practicing and retired physicians, nurses and other folk's not necessarily healthcare providers and are formed mainly at the local level, sometimes at the state level, to

address their community's ongoing health - public health needs as well as to assist those communities during a large scale emergency.

During a public health emergency the Secretary has authority to activate and deploy willing members of the Corps to areas of need with the concurrence of state, local, or tribal officials. HHS is very sensitive to the fact that they don't want to deploy people who are needed in their own communities for response. MRC members may also be activated as intermittent employees of the public health service like the NDMS members.

And just like the NDMS members when they are hired by HHS, they would have FTCA coverage, worker's comp coverage, and also the USERRA coverage that I just was talking about in terms of the NDMS and they would only need to be licensed in one state. The Secretary can also deploy select members of the MRC without hiring them and have authority to pay their travel and transportation expenses.

But when we don't hire them or when MRC members are operating just at the local level or state to state they are subject to the laws of the state in which they're activities are undertaken. Moving onto Slide 33 - the "Emergency System for Advanced Registration of Volunteer Health Professionals." It's kind of a mouthful - ESAR-VHP.

In 2002 HHS was instructed to develop a system for advanced registration of healthcare providers for the purposes of verifying credentials, hospital privileges, licenses, et cetera. And that's when the ESAR-VHP program was developed. What ESAR-VHP is a national system of state based programs that include recruitment, advanced registration, licensure and credential verification, assignment of standardized credential levels, and mobilization of volunteers.

Again, these are state systems so inclusion in an ESAR-VHP network does not constitute federal employment although folks that are registered in ESAR-VHP systems could potentially be utilized by HHS if we were to exercise our temporary hiring authorities to hire certain volunteer healthcare professionals on a temporary basis. But generally speaking they are not federal employees and because they are not federal employees they're not going to qualify for FTCA coverage or FECA coverage and if they want to cross state lines they're going to need some kind of mechanism that will allow a license reciprocity.

So moving onto Slide 34 in public health emergency declarations. This is a pretty timely topic as most of you are probably aware. Over the weekend the Secretary of HHS declared a public health emergency in response to the swine flu outbreak. It's being reported as a U.S. public health emergency but this was indeed - it was the Acting Secretary of HHS that declared this public health emergency and that was under Section 319 of the Public Health Service Act.

Section 319 authorizes the Secretary to declare a public health emergency if she determines after consulting with such public health officials as may be necessary that a disease or disorder presents a public health emergency or a public health emergency including significant outbreaks of infectious disease or bioterrorist attacks otherwise exist.

This is a very broad definition and it gives HHS broad discretion to determine that a particular event constitutes a public health emergency. Public health emergency declarations last for 90 days or they can be terminated earlier if the Secretary determines the emergency no longer exists. They can also be

renewed by the Secretary for additional 90 day periods of the emergency continues to exist.

Moving on to Slide 35. When the Secretary has declared a public health emergency, Section 319 of the Public Health Service Act authorizes the Secretary to take certain actions. This includes accessing a public health emergency fund when funds are available. Right now there is no money in that fund so currently when the Secretary declared a public health emergency, you know, for the swine flu that did not provide any funding.

This is quite different from the Stafford Act declarations that Diane spoke about during her part of the presentation that do have funding attached to them. Also when the Secretary declares a public health emergency, consistent with his other authorities he can make grants and provide awards for expenses and enter into contracts, conduct and support investigations. We can extend deadlines and waive some sanctions related to submission of data reports that are required under HHS laws.

And then moving on to Slide 36, most importantly when the Secretary has declared a PHE he or she can take various steps under various HHS laws that would require that public health emergency declaration to be in place first. In prior emergencies -- such as the recent flooding in North Dakota and Minnesota, recent Hurricanes Gustav and Ike -- the key reason the Secretary declared a public health emergency was to be able to waive or modify certain Medicare, Medicaid, and CHIP requirements under Section 1135 of the Social Security Act.

I'm going to talk a little bit more in detail about those 1135 waivers in a minute. In this current event for the swine flu a public health emergency was necessary so that the Secretary could make a different declaration that

justified emergency use of investigational products. Susan is going to talk more about this emergency use authorization or EUA authority during her part of the presentation.

Finally there are some other flexibilities that a public health emergency declaration can provide to HHS -- in terms of things like temporary hiring authorities, certain grant requirement flexibilities -- but it's really the 1135 authority and the EUA authority that can often drive this determination to make a public health emergency declaration.

Moving on to Slide 37. As I mentioned I just want to talk a little bit more about 1135 waiver since this is such an important basis for declaring a public health emergency. As I noted this waiver authority can be used to waive or modify certain Medicare, Medicaid and CHIP requirements applicable to healthcare providers.

Section 1135 lists types of requirements that can be waived or modified. Specific waivers or modifications that are granted under section 1135 can be helpful to assist states in providing surge capacity. So, for instance, the types of things that can be waived are conditions of participation, and certification requirements.

How this has come up in practice before is for example, if folks are being evacuated from hospitals and they need to be placed in critical access hospitals which will require critical access hospitals to exceed their bed limits. This is one reason that someone may - a hospital may need a waiver under Section 1135 of the Social Security Act.

There are some certain HIPAA sanctions that can be waived but just to be very clear this is not a waiver of the HIPAA privacy rule in its entirety. It

addresses some very minor things like posting names of people in hospital directories.

HIPAA itself has certain exceptions built into the rules for sharing information for treatment purposes and other public health purposes that can be helpful and does not depend on 1135 waiver. Finally there is a waiver for a requirement that healthcare providers hold licenses in the state in which they provide services but this is only for the purposes of Medicare, Medicaid, and CHIP reimbursement.

Neither a public health emergency declaration nor an 1135 waiver waives licensing for healthcare providers across the United States or in the states in which they're issued. Moving on to the next Slide 38. If the Secretary wants to invoke Section 1135 of the Social Security Act both an HHS Secretarial declaration of a public health emergency and a Presidential declaration under the Stafford Act or the National Emergencies Act must be in place in order for that authority to be triggered.

The 1135 waiver applies only in the emergency area during the emergency period and the emergency area is the geographic area covered by those two triggering declarations. The emergency period ends whenever the Presidential declaration ends or the public health emergency declaration ends or, if specifically invoked in the 1135 waiver document, 60 days from the date the waiver is published.

In past events the 1135 has expired when the public health emergency declaration has expired which is after 90 days unless that is renewed. Moving on to Slide 39. Despite the termination period I just mentioned, the waiver of HIPAA sanctions, and non-pandemic related waivers of sanctions under

EMTALA are limited to a 72 hour period beginning upon implementation of a hospital disaster protocol.

HIPAA and EMTALA waivers are not effective for actions that discriminate among individuals on the basis of payment source or ability to pay. When a public health emergency does involve pandemic infectious disease waivers of EMTALA, sanctions could extend through the duration of the public health emergency.

And then finally moving onto Slide 40 I just wanted to talk a little bit about the request process. Unlike Stafford Act declarations that ordinarily require formal requests by state governors Diane discussed during her part of the presentation, there is no statutory requirement that a government or other entity make a formal request for a PHE declaration or an 1135 waiver.

In practice governors may want to make a formal request or the state may want to make a request in some way to HHS for such a waiver. Generally when state officials believe that a public health emergency declaration and/or 1135 waivers are needed they usually work with their HHS Regional Emergency Coordinator and regional CMS officials to discuss their request.

When the Secretary of HHS issues an 1135 waiver it's kind of a blanket document that lists all the types of things that could be waived but then what happens is that hospitals and other entities have to work with their HHS Regional CMS officials who will then facilitate CMS' granting of specific waiver requests under that 1135 waiver on a case-by-case basis.

And I'm going to turn it back over to Susan. Thank you.

Susan Sherman: Thank you. I'm going to talk about the deployment of medical countermeasures now starting with Slide 41 entitled "Strategic National Stockpile." This is the statutory authority under the Public Health Service Act for the Secretary of HHS to maintain a stockpile of drugs, vaccines, biological products, medical devices, and other supplies.

Basically it's maintained down at the CDC, the Assistant Secretary of Preparedness and Response, HHS is involved in making decisions about what needs to be in there as is DHS. And the thing I wanted to point out about this slide, is the thing that we focus on, is it is to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations.

That language was considered quite a bit and we believe that the stockpile can be deployed for a variety of situations in order to provide the emergency health security of the United States including, for example, a foreign deployment to control an outbreak of an infectious disease abroad if we think it's going to help lessen the spread or provide for our emergency health security.

Now if you go to the next slide, Slide 42 those are the - the first two bullets are the statutory provisions for deployment and as you can see the Secretary of Homeland Security can ask us to deploy or the Secretary of HHS has the ability to deploy stockpile contents for an actual or a potential public health emergency or another situation in which its necessary to protect public health and safety.

And so like some of the authorities Jennifer mentioned, although it references a public health emergency this is not one of the ones where the Secretary needs to make a formal declaration. Even though a formal declaration can be

done fairly quickly, there are a lot of actions that can be taken without that and this is one of them in which we don't need to take that step. We can deploy the stockpile even in advance of an actual public health emergency.

You can see it's for a potential public health emergency as well. And then I had already mentioned that this can be largely domestic but foreign deployments are not precluded when they provide for the emergency health security of the United States. Now one of the authorities I want to talk about in regard to using medical countermeasures is the emergency use authority. As Jennifer mentioned, one of the reasons the Acting Secretary declared a public health emergency on Sunday was so that we could be able to issue some emergency use authorizations of a couple of products that are needed in this particular emergency.

And basically that authority was added by the Project BioShield Act in 2004. If you look at Slide 43 here the statutory authority says that the Secretary can authorize use of an unapproved new product, unlicensed biological product, or unapproved/not cleared medical devices to respond to an emergency involving a chemical, biological, radiological, or nuclear agent.

He has to make a determination that there is a serious or life-threatening disease or condition, that it's reasonable to believe that the product may be effective, that the known and potential risks outweigh - no, I'm sorry - the known and potential benefits outweigh the potential risks, and that there is no adequate approved available alternative. And it applies to both unapproved products and products that are approved but not for the particular use that we need them for.

And this was enacted back in 2004 with the idea that, you know, there might be some kind of chemical, biological, radiological or nuclear attack or some

development, even a natural development such as the one we're seeing now with swine flu, where the best product we have is something that's not approved by FDA yet but we have sufficient evidence to believe that it's effective and that the benefits outweigh the risk and we don't have alternatives.

And so we didn't want to hold things up that we would have to go through a formal FDA approval process which can be quite lengthy if we had something we thought could help save people's lives or provide for their healthcare. So how does an EUA get issued? If you go to the next slide - the process there's one of three declarations that can actually trigger an emergency use authorization.

This is all step one but it has three alternatives. The Homeland Security Secretary can decide that there's an actual or a significant potential for domestic emergency involving a heightened risk of attack with a specified chemical, biological, radiological, or nuclear agent. And that was actually done last October to support an emergency use authorization of some anthrax countermeasures that are being - can be pre-placed by the U.S. Postal Service in homes in cities that are working on the city readiness initiative.

And so there is an EUA in place for that that was begun with a DHS declaration. A second alternative to start off the process is a declaration by the Secretary of Defense of an actual or significant potential for military emergency involving a heightened risk to U.S. military forces. And that actually took place the first EUA ever issued was for the military, again for anthrax countermeasures.

And that EUA actually was terminated. Once they were able to use the products after they got FDA approval for them the EUA was no longer

necessary. The third alternative and the one that we're operating under now is that the Secretary can declare a formal public health emergency under Section 319 of the Public Health Service Act as Jennifer just described to you. When that declaration is being made to support an EUA he or she also has to find that the public health emergency actually or potentially affects national security and involves a specified chemical, biological, radiological, or nuclear agent.

So you'll find that language in the public health emergency declaration that was signed on Sunday and it is posted to the HHS Web site so you can take a look at it. So once that declaration is made there is a second step and this comes under the Federal Food, Drug, and Cosmetic Act Section 564. The Secretary then declares that the emergency justifies the emergency use authorization.

So there is a second declaration and that specifies again the chemical, biological, radiological, or nuclear agent and the product that we think would be useful. It's different than the public health emergency we just described to you. It's a second step and it's different from a prep act declaration that I'll describe to you in a moment.

So we do have a variety of declarations for specific purposes. The main one is usually the public health emergency declaration you just heard about but when we need an EUA there is a second determination that needs to be made. And you'll see a couple of those were signed. For this current outbreak there was one to enable emergency use of an in-vitro diagnostic tool for this particular virus strand because such a thing didn't exist until the virus was identified - or wasn't able to be made.

And then for some of the anti-virals that are in the stockpile and can be made available to states and localities an emergency use authorization was needed to enable folks to give those products to children because they're not previously approved by FDA for children under certain ages depending on the product. It's for Tamiflu and Relenza and so the FDA and CDC worked very hard and very quickly to prepare and assess the risks and the benefits and whether or not there would be an emergency use authorization for that.

So once the declaration was made they were working concurrently and they were able to actually issue the emergency use authorization. What that actually - how that actually happens is that the Food and Drug Commissioner issues it. CDC requested the authorizations and so the Food and Drug Commissioner basically wrote a letter to the CDC authorizing the emergency use of these particular products.

And in that written authorization what the Commissioner does is he, you know, basically identifies the disease or conditions for which the product may be used to diagnose, prevent, or treat and reiterates the findings regarding the known and potential risks and benefits, the safety, the potential effectiveness, and assessment of available scientific evidence.

So they have to look at all of those things before deciding it's okay for folks to go forward and use the product for this emergency use. The FDA Commissioner under the statute can also impose some required conditions as practicable in the emergency that are aimed at protecting the public health. There's also a variety of additional conditions the Commissioner can impose at his discretion, also aimed at protecting the public health during the emergency use of this product.

Now all of these documents do get published in the Federal register. We haven't had a chance to do that yet since some of these were signed just the other day but they will be posted in the Federal register and made publicly available. As you go to the next slide, "EUA Duration." Basically the Secretary's declaration in justifying and emergency lasts for a year or when the circumstances justifying the authorization cease to exist.

So it can be shorter but it can also be longer. It can be renewed. The FDA authorizations basically last as long as the Secretary's declaration but it can be revoked if we find - the FDA Commissioner finds that the criteria for the authorization simply aren't being met, are no longer met, the EUA can be revoked. But again, like other authorities were described it can be renewed as needed as the emergency continues.

So that's the EUA authority. But I did also want to talk to you about the Public Readiness and Emergency Preparedness Act beginning on Slide 47 here. That's an authority we got in the end of 2006 and this authority again is aimed at medical countermeasure development and distributions.

It authorizes the Secretary of HHS to issue a declaration that provides liability immunity from tort liability immunity, except for willful misconduct, for claims related to death, physical, mental, emotional injury, illness, disability. You can see there on the bullet quite a wide variety of things; it's fairly broadly written.

It does have to be causally related to the development, distribution, administration and use of covered countermeasures, which I'll talk about in a moment, and the claims have to be against covered persons. And these are terms from the statute. Again, I'll give you a little bit more information on that in a moment.

So, it's fairly broad in what it covers. It is aimed at medical countermeasure development. This is not the ability for the HHS Secretary to broadly waive liability immunity for all health care in an emergency. It is for this medical countermeasure development and distribution when we're responding to that kind of an emergency.

Now, at the bottom of the slide, the PREP Act also has authorized an emergency fund in the U.S. Treasury for compensation, so there is a compensation program, if people are injured by the medical countermeasures that we've been distributing. There's currently not funding in that, but the statutory authority is there for whenever Congress puts money into it, a compensation program that can accompany one of these declarations.

In the next slide, there is a statutory definition for what we mean when we say covered countermeasures, of what can be covered by the PREP Act, basically, a pandemic or epidemic product or a security countermeasure which is drawn from other parts of our statutory authorities. And, basically, it's drugs, biological products, devices that are approved, things that are necessary to protect public health.

They have to be either, and this is important to remember about the PREP Act, it is limited to drugs that are either approved, licensed or cleared by the FDA. It can be approved drugs and devices, but - and it also includes EUAs and investigational drugs and investigational devices.

So, if something's basically not meeting FDA requirements under one of those mechanisms, it's not going to get PREP Act coverage and so we're very careful to look at that and make sure the products being recommended are going to come under one of those things if it is issued as a PREP Act

declaration. And, in fact, some of these emergency use authorities are aimed at making sure that happens.

So, in the next slide, you'll see who are the covered persons. Well, it's really the entire chain. It starts with, and all of these terms are defined further in the statute, it's the manufacturers, it's anyone in the distribution chain, program planners, which is a term used in the statute, but it specifically includes states, local governments, tribes and then broadly covers others who supervise or administer countermeasure programs. So, it could, in fact, apply to the private sector when they're behaving the way state or local government would be, whether supervising or administering these distribution programs.

It also covers qualified persons and that's basically aimed at the healthcare providers who are actually administering the countermeasure to the population in need. And it's defined as licensed healthcare professionals who are licensed in their state to prescribe medication. But it also gives the Secretary the opportunity to identify others who can be authorized to do so. So, in fact, it's not limited to people who are licensed under state law to prescribe healthcare countermeasures to the population.

We can, for example, say we think other folks are, in the declaration, we can identify other folks who are able to do this and extend liability immunity to them.

This is not a replacement for state licensing authority. We're not saying they are licensed under the state, but we're saying we're extending liability immunity to them.

And the declarations that have been written, there actually is language talking about other qualified persons and we've characterized it in a way that includes

anyone operating under the authority having jurisdiction in your area to respond is covered. So, if your area has identified volunteers, groups of people in the private sector, the Lions Club, whoever they may be, who are part of your formal emergency response and are responding following the declaration of an emergency, if it's a countermeasure for which we've offered a PREP Act declaration, we would consider those folks to be qualified persons and be eligible for this coverage.

It also, of course, covers the United States and officials, agents and employees of all of the folks covered - covered persons.

So what does the declaration look like? How do we issue it? If you go to the next slide, basically, the statute requires the Secretary to consider the desirability of encouraging design, development, clinical testing, investigation, manufacturing labeling, it goes on to all those other things, anything that's relevant to creating a countermeasure. He or she has to determine that a disease, health condition or threat to health constitutes a public health emergency or a credible risk of a future health emergency.

And that last phrase has enabled us to issue PREP Act declarations in advance of an actual emergency. We don't need to wait around and that's one of the reasons it's valuable to distinguish this from a public health emergency declaration.

We actually issued PREP Act declarations to provide liability immunity for a variety of countermeasures that are actually listed on our penultimate slide that it's aimed at making sure that people are able to build programs, that manufacturers will step forward and start creating the countermeasures knowing they have this protection or states and local groups will get together and plan, knowing that they can - that the PREP Act declaration is in place

We also specifically recommend the manufacturing, testing, development, distribution and use of the countermeasure and then specifically say liability is in effect for these activities.

If you look at the declaration, those are the findings we have to make, the declaration itself, the statute specifies things that need to be said in a declaration, specifically the category of diseases or health conditions for which we're telling folks they should be aimed toward the administration needs for the countermeasure.

There is an effective time period stated in each declaration, who's supposed to get it, the patient population, and if there's a geographic limitation for administration and use. So far, the declarations have not had one but, basically, made them nationwide- but there can be a geographic limitation.

Any limitations on distribution which can be specified by the declaration, we haven't made any of those except for one which I'll discuss in a moment. And then, as I previously mentioned, additional qualified persons the Secretary wants to identify, who could receive liability immunity under the PREP Act, prescribing or distributing or dispensing the countermeasure.

On the next slide, you'll see there are limitations; it's not an open-ended liability protection scheme. The statutory exceptions that I mentioned earlier are willful misconduct that the statute specifically excludes willful misconduct, it also defines that term. If you go to the statutory authority, you'll see that it is defined at a very high threshold.

So, it's not meant to open the door to lots of tort liability claims that we're trying to preclude, but there is an exception in the statute. You can't basically

be intentionally, willfully, knowingly harming people; knowingly you're giving them a product that outweighs the benefit, that sort of thing. But, there's a high bar.

Of course, it's not going to cover countermeasures that are used and administered outside the conditions stated in the declaration, so the declarations do have to be read carefully to make sure that you're following what the Secretary recommended in the declaration. For example, it's not written to cover anytime anyone goes to a doctor and gets one of the medications listed. We are covering the public health emergency type deployment.

Of course, it doesn't cover claims not causally related to countermeasure administration, it's not going to, you know, you're not going to be able to claim, folks who were defendants, you won't be able to claim tort liability immunity. It won't cover claims filed in foreign jurisdictions, obviously, because it's a U.S. law, but that has come up. I mean, if people file in the United States or under U.S. law, we think the tort - the PREP Act liability immunity protections that pertain, but it's not going to be helpful for claims in foreign jurisdictions of course.

It doesn't cover other claims other than tort liability. I've been careful to focus on that. I have received questions about discrimination claims and that sort of thing. It's really not aimed at that.

And then, there is, in the current declarations, a limitation about countermeasures that are obtained through non-voluntary means. That is aimed at trying to discourage government officials from seizing private stockpiles and so there is that limitation on distribution that's written into the

current declaration. It's not part of the statute. It is under the authority of limitations on distribution.

If you go to the next slide, you'll see there is a listing of the current declarations in place. There's been several for pandemic influenza, vaccines, antiviral and, the one on the bottom slide, diagnostic respiratory protection devices and support devices. There's also one issued for smallpox countermeasures, acute radiation countermeasures, botulin and toxin countermeasures and anthrax, as I had mentioned earlier.

One of the actions we took just recently was to amend the antiviral declaration and make sure it covers the current strains that are out there. All of these things are published on the Federal Register, you can see. We will be publishing an amendment to the antiviral one shortly.

So, that is it. I'm turning over the podium to Kim Dammers who is going to talk to you about quarantine and isolation.

Kim Dammers: Hi, this is Kim Dammers and I am a Department of Justice employee who is on detail to CDC for a year. And, while here, I am working with the Public Health Law program, as well as the general counsel.

I will be discussing quarantine and isolation law, the basics of quarantine and isolation law on a federal level.

The first slide, Slide 56, however, is social distancing measures. And Brian referred to the Public Health Law Program website that has a lot - several different templates and tools for use in designing state social distancing laws and I would encourage you all to take a look at that. That can be found at the Public Health Law Program's Website at the CDC.

The reason we started with public distancing measures is because isolation and quarantine really does not work unless it's also in concert with at least some non-pharmaceutical interventions. And during this swine flu outbreak, you can see that, right now, the recommendations that CDC is issuing deals with non-pharmaceutical intervention, to wash your hands, cover your mouth, those kinds of things.

Sort of a step up from that are the kinds of interventions that Mexico is undertaking, closing schools, closing daycares, large public gatherings, encouraging people to stay home even if they're not sick, telecommuting. CDC has a strong telecommuting policy for the very reason that there may be an outbreak where we need to access our work not from our offices but from our homes.

What we encourage states to do is think about these things in advance, obviously. And one of the - what you're seeing here, these are not federal measures. The federal measures generally tend to be more in the lines of isolation and guarantee and, as Diane said, in fact, state measures, public health, are both state and federal issues equally.

Slide 57 discusses the difference between isolation and guarantee. Isolation isolates the sick person from the rest of the population where as quarantine separates those who have been likely exposed to an infectious disease from the rest of the population. We use those terms interchangeably. The objectives and the goals of quarantine is, obviously, to reduce the transmission of disease.

So when a quarantine or an isolation is being designed and implemented, the factors that drive the amount or the degree of separation relate to the

communicability of the disease, how long before exposure and onset of the disease. How is the disease transmitted? Diseases that are airborne require perhaps a greater quarantine because they are easier to transmit between people.

The separation that is required between the sick individuals and exposed individuals and the rest of the population. The options for treatment; we're always looking for the least restrictive means of isolating someone or quarantining a population and the options for quarantining away from a hospital so that there is conditional release.

If someone is isolated or quarantined, we can release them to their home with the agreement that, under the orders, that they stay in their home, that they don't go to work. They interact only with immediate family members. Then, if they violate those regulations or those orders, additional measures can be undertaken.

In Slide 59, there is the federal quarantine and isolation to be a quarantinable disease. The disease has to have been listed in Executive Order 13295 or 13375. Those diseases are listed here, cholera, diphtheria, most recently, SARS was added, as was pandemic influenza.

And, when I say pandemic influenza, the proper term is actually slightly broader than this under the Executive Order, such that pandemic influenza, as designated, would clearly fall under the Executive Order but so would a virus that has the potential of causing a pandemic. An influenza virus that has the potential of causing a pandemic. So that, for instance, the World Health Organization with swine flu, has designated this outbreak as the potential of causing a worldwide pandemic.

The federal regulations regarding quarantine and isolation generally fall into two parts. Part 70 is the interstate quarantine, the domestic quarantine of people moving from one state to the other.

And Part 71, is international; it's for those travelers who were seeking entry into the United States And those international travelers may be leaving the United States for other parts of the world with the idea that the, especially with air travel, people come back into the United States.

What's different in a federal quarantine or isolation order for many states is that a court order is not necessary; they're self-executing upon the signature of the director of the CDC or his or her designee, such that the court is not involved in this process until there is a violation of that order.

Instead, it is based on the reasonable belief of the director that the individual poses a public health threat and has a communicable disease or has been exposed to a communicable disease listed in the executive order.

In Slide 60, the constitutional requirements and the groundwork and framework for the constitutional requirements of federal isolation and quarantine, are somewhat different than the state. The federal isolation and quarantine orders derive primarily or exclusively from the commerce clause, the ability of the United States to regulate commerce on its borders and between the states.

Whereas state quarantine powers generally derive from the state police powers, the 10th Amendment powers, that partially explains why the federal order can be self-executing regardless of whether it's a state or federal quarantine order, the same sort of personal liberty rights are implemented or implicated.

For instance, there's a 5th Amendment due process cause, there must be procedural process built into the order and the challenge to an order, such that, while the isolation may be fair, the process by which the person is isolated is also fair. Things that are included in that are the concepts of right to notice, right to counsel at certain stages of the hearing, right to a hearing itself on request and a reasonable belief that there needs to be a detention. Those are the federal requirements.

States can raise those requirements. For instance, many states have a threshold above reasonable belief that is usually clear and convincing if it is above reasonable belief. The state can go above the federal constitution. The federal constitution requires at least a reasonable belief for the detention of an individual.

The current quarantine and isolation regulations in Parts 70 and 71, are somewhat vague. In November 2005, the federal government issued proposed new regulations; those were never made final. With the change of administration and gathering the comments, they have yet to be published final.

Congress, at the end of the last term, passed the TB Elimination Act, which requires the federal quarantine and isolation regulations to issue before or no later than the middle of June 2009. Whether, in fact, those will be published final during that time, is unclear. The proposed regulations extend beyond and provide much more specific due process than do the existing isolation and quarantine regulations. The value of that is that it provides notice to people. Due process has to be written into the regulations as they existed

With the proposed regulations, some due process is spelled out specifically and it gives those people who may be subject to a quarantine or isolation a sense of notice about what will likely to happen to them. The proposed regulations add definition; but it has the same disease list. In other words, it's the same list under the executive orders. It requires the same interstate nexus.

The disease must be at a qualifying stage, however, such that if it's not symptomatic, if it's pre-communicable, but likely to cause a public health emergency or become communicable, that would qualify. There's something in the proposed regulations called provisional quarantine. That language may or may not exist in the final regulation, but the concept is the same. It's actually a due process.

After three days, there is a review by the director of the CDC as to whether quarantine should be continued; that review is on paper, that's called a medical reassessment.

The medical reassessment, the director of the CDC examines the entire file, all the evidence for which the quarantine was based, the isolation was based. Then the director of CDC issues a decision to either extend the quarantine, continue the quarantine, dismiss the quarantine, or a third choice to modify the quarantine, for instance, allowing conditional release for the individual to return home.

If, in fact, the quarantine is continued or modified such that liberty is still restricted, the individual has a right to request a medical review. A medical review allows the individual to present the factual basis and to challenge the factual basis for the quarantine. That is done through a medical representative so that the patient has a medical representative. If the medical representative -

if the patient is unable to afford a medical representative, one would be appointed to them if they request one.

The difference between the reassessment at the three day stage by the director and the medical review, is the reassessment is mandatory and automatic. The medical review is an option if the patient has made a request to seek a medical review. This has not been implemented; there has been no quarantine extended beyond three days - the federal government issued quarantine orders that provide this right.

To date, every quarantine that the federal government has issued since the idea of a medical review has been instituted has been rescinded before three days and that's often because in those states that have had this issue, the state generally steps in and does a quarantine order and the federal government will then dissolve its quarantine of the person. So, we've never had to get to the federal review stage.

The medical review stage requires some thought about where that's going to happen. In other words, will we fly out a medical reviewer and a medical representative for the person who represents the person as well as the person who reviews in an oral hearing, to the patient or will we have a video conference? Those kinds of things in a large scale quarantine would be dramatic.

The kinds of quarantines we have seen to date have been revolving around tuberculosis, so it's single patient quarantines. The issues there are easier because it's just one patient, everyone gets on a plane and goes out to that patient fairly easily.

If we talked about a large-scale isolation or quarantine, then the procedural and logistical issues would be certainly forefront.

After the, and I'm on Slide 62, after the medical review, and so there's a reassessment, there's a medical review. After the medical review, the individual in quarantine is able to bring a habeas petition if he or she so desires to federal court. At this point, the right to counsel attaches. Before that, there was the right to a medical representative, now there's a right to counsel.

Before a habeas petition can be brought, however, and can be heard by a court, administrative remedies have to be exhausted, that's a federal habeas law, so that the patient cannot, as it stands now, jump ahead. He or she cannot first file a habeas petition; instead, they have to go through the three-step process.

Part of what the proposed regulations have are compelled medical exam for screening purposes, which are also part of the regulations. So that at airports, for instance, screening can be done on arrivals; every traveler who comes in can be screened. If they're being screened, non-invasive screening methods can be used according to the proposed regulations.

So, those include, asking questions, doing a survey. They include looking at the person, a visual. And also, thermal scanning, if there are thermo scanners available, which is a device to take a temperature of an individual through a camera basically. Hong Kong has been using those in all of their airports since 2005 for most international arrivals.

And, if you've seen them recently in the newspapers you can see photographs where they have pictures of a thermo scanner. That is a non-invasive

technique to take someone's temperature. That's all that is allowed under the regulations for screening unless there's some indication that the person is ill.

And if there is an indication that the person is, in fact, ill, they report having a fever, if they have been to an area where there is a high prevalence of illness and they don't look well, then an order can be drafted to compel a medical exam that would allow a determination.

And, I think most states have a similar process for compelled medical examination. The legal readiness aspect, as we've talked about, centers around the hearings and process of service on Slide 64. There has to be a system to recognize a large number of hearings, maybe requiring a mass quarantine or isolation event.

For those people who recall a summer or two ago, the government in Texas took custody of children who were allegedly neglected and, I think there were 400 children who were effectively seized, and if you can recall the photographs of the lawyers looping around the outside of the Texas courthouses because each one of those children had to have representation, that's what advanced planning, hopefully, will avoid. But, there's no doubt, logistically a mass quarantine raises several challenges.

One of those challenges is how to have these hearings, whether you have them in person or you have telephonically. Many states allow telephonic hearings or video hearings. In the federal system, it's a little bit less prevalent and, in fact, the 11th Circuit, which is the district that I practice in, has - there is a case that disallows videoconferences, except in the most amazing circumstances, such that, as it stands now, I could not, with great certainty, tell you that we could have a videoconference here in the 11th Circuit.

I think, however, if it is a public health emergency, that judges would clearly understand that it is far safer to have a videoconference.

For those people under house quarantine, however, people who are confined to their homes, it's really kind of unclear how it's going - how they're going to get representation first of all and then, how they would appear. It would probably be telephonic as opposed to video.

Part of this, and every court in the United States, every federal court and I'm sure every state court, has plans to address what would happen in a situation of a pandemic flu because the personnel of the court may be unwilling to appear in a courtroom. And, I can tell you, the first time that there is a courtroom deputy who wishes not to appear in the same room as an ill person, you will have a judge who wants to do something different than have this person be in their courtroom.

I have appeared several times with patients, with defendants, criminal defendants who have tuberculosis, who are not being charged criminally because of their tuberculosis. They're being charged criminally for something else, but they happen to have active TB. And it is somewhat disconcerting to be in a courtroom with a person with a mask, where there has to be an announcement beforehand that this person has infectious TB. Those are the kinds of things that have to be discussed and thought about when there is a mass quarantine or isolation, documentation, affidavits. We have to be careful, each case is individually discussed, each case is individually determined.

So while there may be forms, the state has the same sorts of forms for quarantine. In fact, there has to be an articulation as to why an individual, the particular individual in front of you, needs to be quarantined. And we have to

be very careful that we maintain that even in situations where there are a lot of people being quarantined at one particular time or one planeload of people.

The place where, federally, I think most of the legal challenges will occur in a large scale quarantine or isolation, are the kinds of cases about business disruption, about temporary restraining orders to travel, people who wanted to be put in the status quo ante of where they were before there was an order saying that they can't travel by plane, for instance.

They will be seeking injunctions against the implementation of an order if, for instance, on a state level, if a state were to close and cancel every concert, the concert promoter could very well bring a challenge that can end up in federal court on diversity of course.

The procedures for instituting treatment, on Slide 65, the legal proceedings can be rigorous, but they can also be rigorous to keep somebody in isolation or quarantine, even when the evidence is fairly clear that this is the right result. For instance, in New York in 2004, in a case called *Best v. Bellevue Hospital*, a non-infectious TB patient was confined when he sought to leave the hospital and refused to cooperate with treatment. The court used a clear and convincing standard and it used that standard, but applied it to mental commitments, so it used it in an analogous way to mental commitments.

Federally, the standard is lower to remind you again. But this is a non-infectious TB patient as opposed to an infectious TB patient, which could make all the difference. In that case, Mr. Best, the person in quarantine, filed the suit against the health department and the hospital.

And the questions that the court asked were, was he a danger to himself and the community, which is a very standard mental commitment question. And

did he have an adequate right to a hearing? That's the procedural due process aspect of this. So that, even though the commitment was right, there had to be enough process built in so that it was a fair proceeding and the result you could be sure was a fair one.

In the end, the hospital and the State of New York prevailed, but it took four hearings, seven state hearings, and it took judicial orders both on a state and administrative level and over two years. This is a costly proceeding for the State of New York.

Slide 67, sets forth the basic obligations to those people who are being quarantined or isolated including food, medical care, safety and sanitary needs.. There is a duty that the government, whether it's state, local or federal, has to isolate that person from others. In other words, the isolated individual, the person who is sick, cannot even be in the same room with the quarantined individual who may turn out to be sick, because of exposure.

So, when you're talking about a planeload of people, when travelers come off, those people who look ill, need to be taken to a location where they can be examined and interviewed separately, even from the people they're traveling with, their traveling companions, if the traveling companions themselves do not display symptoms of illness.

There has to be availability of medical treatment, obviously. Accommodations have to be comfortable, there has to be protection from known threats and, in a perfect world, there are religious and dietary considerations that must be considered and, to some extent, to the extent that they are constitutional, provided. This is, in fact, for those who are in Minnesota, there was a "New York Times" article about the struggles that Minnesota has been having with the large number of people from many different cultures and all of those

cultures have to be respected. And, if we are talking about a planeload of people, those are the kinds of things that must be considered.

On Slide 69, your state and local jurisdictional issues regarding the protection of people, and this is just sort of a reminder that the police powers, including public health powers, are reserved to the states under the 10th Amendment. And those are the powers that the states rely on when they institute a quarantine or isolation. But, even in those cases, federal and international jurisdiction issues may arise, clearly, not just constitutional issues.

Federal constitutional issues include under quarantine, a recognition that, as quarantine laws stand today notwithstanding the proposed rules for November 2005, they really were enacted to reflect a time that is long past. And that is a time when most people came to the United States through overseas - through a boat, through boat and marine transport. And that is just not the case in this part. So they are not designed to protect infectious people bound for other countries leaving the United States expressly.

There may, however, be an implied power to be able to do this. And that is under, again, the concept that when someone leaves the United States, they generally come back into it. And that planes, the crews for sure are coming in and out of the United States, so that air crews or people who travel both inside and outside the United States on a regular basis.

And that concludes the quarantine and isolation.

We lost our moderator, who is picking up the question and answer session.

Coordinator: If you would like to ask a question, please press star 1. Please make sure you unmute your phone and record your name clearly when prompted your name is required so that I may introduce your question.

And we'll just take a few moments to take any questions.

Your line is open.

Question: Yes, can you hear me?

Kim Dammers: Yes.

Question cont'd: I have a question. I am a faculty member in a nurse practitioner program and I'm also an MBMS medical team member. And as (unintelligible) nurses vary widely in terms of their scope from state to state and in terms of educating people for preparation for the use of these roles on federal teams, what scope of practice one would be expected to appear to in the event of widely varying scopes from state to state? Of course, someone can't practice beyond that which they have been trained, but is there some federal level scope of practice which one could refer to?

Jennifer Ray: This is Jennifer. Can you hear me?

Question cont'd: Yes.

Jennifer Ray: Hi It's my understanding that the MBMS description kind of lie out for each position what's within that scope of practice. So it would be for federal positions that would be up to the federal government to decide what an individual is qualified to do. So, what their scope of practice would be. And,

as I said, it is my understanding that position descriptions would sort have fit into that kind of information.

Question cont'd: Oh, okay. I found it to be a little bit, to be frank, a little bit vague and I'm sure that's for specific reasons. So, that's fine, I didn't know if there were other documents or other acts that we could refer to.

Jennifer Ray: I don't think there's any specific acts at a federal level that would lie that out in great detail. I would just recommend that you speak with your MBMS commanders or the MBMS staff if you have specific questions about scope of practice for a particular position.

Question cont'd: Okay, thank you very much.

Coordinator: Our next question. Your line is open.

Question: Hi. I just wanted to know, I'm a respiratory therapist. I just wanted to know the best way to protect our staff. Are (unintelligible) masks recommended? Are alcohol-based sanitizers helpful? Do they actually work? And do our patients need to be in negative pressure rooms?

Susan Sherman: This is Susan. I'm afraid, we're just lawyers and we really...

Question cont'd: Oh, sorry.

Susan Sherman: ...and we really don't have those answers for you. But I know CDC, specifically if you're talking about some of the current situations, CDC is working hard to post guidance on its new Website about these sorts of issues and, so, really the public health professionals and the medical staff would be the best place to go to for that kind of information. And, if you don't find the

sorts of information you're looking for on the CDC Website, certainly, you can submit the question and we'll make sure it gets routed to the right people.

Jennifer Ray: Yeah, absolutely. Send that question to COCA@cdc.gov. That address is C-O-C-A@cdc.gov. And if you have any, or if anyone on the phone has any clinical questions, please send your questions to that email address. Thank you.

Question cont'd: Thank you.

Coordinator: Our next question. Your line is open.

Question: Yes, thank you for that incredible presentation. It was so deep with information.

My question has to do with other federal authorities that might be able to declare public emergencies other than the ones that we covered today. Specifically, I was wondering about the EPA because I understand they were asked to consider declaring a public health emergency in a particular area. And whether or not, that creates any obligations on the part of, well, Health and Human Services for instance.

Susan Sherman: Hi, this is Susan. That's a very interesting question. I mean, certainly, the ones we told you about are the ones that fall under our Secretary's authority. We are aware of the EPA's secretary's authority to declare a public health emergency and I think the discussions have been ongoing between the two departments about how things have been carried out if that kind of declaration is made and what our, I don't know if you'd call them obligations, but certainly, the agencies work together on that sort of thing.

Question cont'd: Thank you.

Coordinator: Our next question. Your line is open.

Question: Yes. I think I heard, but may have heard wrong, one of you folks mentioned that the PREP Act declaration, one of them I imagine is the one relating to Tamiflu, Relenza has been amended to essentially address the swine flu situation.

Susan Sherman: Yes, this is Susan. That's correct, we have drafted an amendment and the Acting Secretary signed it, I believe, Sunday afternoon. That should be posted fairly shortly on the Web, if it hasn't been already.

Question cont'd: I cheated and I looked and I did not see it. Is there any way of knowing when it will be posted or exactly where?

Susan Sherman: Well, I think it will be posted - actually, I'm sorry, I don't know exactly. I know that the public emergency declaration is available from a link right when you go to HHS.gov. I think there'll be links to lead you to the other documents as they're posted. There's a short delay in getting them up on the Web because they have to be given to our Web team and be posted in accordance with section 508 and other things. But they're fairly quick and we are expecting it to go up I would think sometime today.

Question cont'd: If there's a delay of a day or two, is it possible to get it directly from one of you folks or some other source?

Susan Sherman: With all due respect, we're really not going to be able to meet hundreds of requests for sending out documents. It would be really helpful if people would be able to just check the Website.

Question cont'd: Okay, thanks.

Coordinator: Our next question. Your line is open.

Question: Thank you. Thank you for the presentation.

I have a question about the HHS Public Health Emergency Fund. It was mentioned earlier that there were currently no funds available. I was just wondering as to the source of these funds and why there weren't funds available and if there would be in the near future, if funds were available considering our current climate?

Jennifer Ray: The current health emergency funds would have appropriations that Congress would appropriate. And currently, Congress hasn't appropriated any funds to that particular account and that's why I said that there wasn't any money in it that's available. So, it is a fund that is out there, but Congress would have to appropriate money into that account for us to be able to tap into it when the Secretary has declared a public health emergency.

Coordinator: Our next question. Your line is open.

Question: Is this document available for sharing with our state and local partners?

Jennifer Ray: Do you mean the slides?

Question cont'd: The slides, the PowerPoint presentation.

Jennifer Ray: Yes, they're on the CDC Website; they're public.

Question cont'd: Okay, great. Thank you very much.

Susan Sherman: You should be able to go to the Public Health Law program website on CDC and be able to get them

Question cont'd: Okay, thank you.

Coordinator: Our next question. Your line is open.

Question: Yes, thank you. I have a point of information and a question.

Point of information is just simply that the best case was against the City of New York, not the State of New York. It's just a little New York City parochialism coming out.

But, my question, and I'm looking at Slide 62, with regard to the right to counsel as I understand it, the proposed regulations would have the right to counsel attach and I'm wondering if there is the ability - how meaningful the right to counsel is? Does a person have the right to assistance of counsel in preparing a habeas corpus petition or is it the right attaches after the petition has been filed?

Kim Dammers: The right would attach after the petition files because there's no other way to know they're going to file one in advance. So, as it stands, in any federal habeas proceeding, it does not take very much to trigger a habeas petition. The petition itself is not a threshold particularly. If you get any of the words right, you get a habeas hearing or at least you get a habeas consideration in this case because we're dealing with quarantine, the courts may or not be on notice that a habeas petition might be filed by someone.

Once they receive the habeas petition, the right of counsel would attach and then become an adversarial proceeding. And it would be provided enough time to gather all the information and to present the evidence, including making a legal argument.

At that point, there will have been a factual determination through the medical review that the facts support quarantine. So, the habeas petition is likely to focus solely on an unconstitutional taking of my body.

And you were right, I'm sorry, I apologize about New York City versus New York State. And, I'm from New Jersey, I should have known that.

Question cont'd: Right. And just to follow-up, is there a financial means clause for providing a lawyer and just how meaningful a right is it if a person is isolated and whether it's easy or not, may be difficult?

Kim Dammers: There is an indigent test. Because you're now, you've changed from HHS public health system to a straight legal system to the judiciary branch. It would be the same test as for any provision of attorney that is indigency, which is simply a financial affidavit in the federal court. There's no real testing of that, it's a sworn statement that you're unable to afford an attorney.

There is an issue when the person's isolated. You have to find a lawyer who is willing to take on a client who is isolated depending on what the disease is. If it's TB, it's fairly easy; if it's smallpox, you know, it could be a little more difficult. And so the question is, how do you provide meaningful counsel?

And you can provide meaningful counsel through a telephone conversation, even if the person's in a terrific isolation facility or, what's more likely, is a

lawyer will take protective measures to visit with her client. So, I don't think that, in and of itself, is a bar, but it is clearly a consideration.

Question cont'd: Thank you.

Kim Dammers: Thank you.

Coordinator: Our next question and your line is open.

Question: Hello, good afternoon. Thank you very much, this is a wonderful presentation.

In looking at isolation and quarantine, I'm also wondering, however, about community containment measures, such as sheltering in places normally used for radiologic events. Are the laws that would apply to that very different because it is a community containment measure, but it's not actually isolation and quarantine? Are the legal regulations different for that or would it fall under the same?

Kim Dammers: You know, most social measures and sort of non-pharmaceutical interventions are going to be carried out at the state level because the federal government would be very unlikely to step in, for instance, in closing schools, although it may have the authority to do so. But, for the most part, these are going to be state, because the state interests are so great in controlling within its own borders.

So, unless, for some reason, the federal government made the decision and determination that the state was inadequate, the state's response was inadequate, which does give it the right to act intrastate, the regulations are not expressed and it would simply fall under the fact that the state was not implementing an adequate response.

Question cont'd: Thank you.

Kim Dammers: Thank you.

Coordinator: Your line is open. Yes, your line is open.

Question cont'd: Yes, thank you. Actually, I'm glad (Wilfredo Lopez) is on the call. My question is a little bit related. For people who are confined to their homes for isolation, you seem to be mentioning that they would have a right to contest that.

And, I'm wondering if that is as much of a right or do they have an actual right to a trial-type hearing do you think because, if you're told to stay home, it's non-custodial and I believe that New York City during the SARS outbreak a number of years ago, provided for a telephone appeal of people in that situation. And in Massachusetts where I work at the Department of Public Health, that's what we have done as well.

We have assumed if someone is confined to their home, it's certainly not as egregious as being confined to a hospital or jail or anything like that. So, we have kind of assumed that a telephonic appeal in the first instance would be sufficient and I'm wondering about your thoughts on that.

Kim Dammers: I do not disagree at all. I mean I think, first of all, it's a lesser deprivation of a liberty right. But, it's clearly still a deprivation when you tell someone they can't leave their home, they can't go to work, that would certainly fall under a right that is able to be raised in a habeas petition.

The actual mechanism of a telephonic appeal is probably, and I don't know how it's set up, I can't make this about Massachusetts or New York, but I can say that as a concept, there's nothing wrong with that concept at all. And it's just unclear, even federally, versus one person who is told to stay home versus 400 people who are told to stay home.

So, as the number of people who are under order increases, safeguarding their rights becomes more difficult, but there are also other ways to do it such as telephonic interviews. And it would just make total sense.

Question cont'd: Okay, thank you. And I also want to thank you for the presentation. It was very helpful.

Kim Dammers: Well, thank you very much.

Coordinator: Our next question. Your line is open.

Question: Yes, sir. Earlier in the presentation, there was, under the Stafford Act there was mention of the declaration of an emergency and a direct declaration of a major disaster. Is there not an intermediate, just a disaster?

Diane Donley: This is Diane Donley. No, there is not. There is a major disaster declaration and an emergency declaration and there is not an intermediate step. Many people talk about disaster declarations, but it's the actual legal term is a major disaster declaration or an emergency declaration.

Question cont'd: Alright. Thank you.

Coordinator: Our next question. Your line is open.

Please check your mute button.

Question: Hello. Can you hear me now?

Coordinator: Yes.

Question cont'd: Question for Kim. At the end of your very thorough talk, Kim, there's mention of international health regulations. And we had a question how that might apply to the current swine flu situations. We have someone leaving our Minneapolis airport who has the current mild case of swine flu and the federal quarantine officer is aware of that and the person's getting on a non-stop for Tokyo. Do, the IHRs impose some requirement on our government to restrain that person or give some forewarning to Japanese authorities?

Kim Dammers: Let me say this. Because it is a fast-moving flu situation with swine flu and as much as we like to think that the lawyers are integral to it, we know things a lot later than everybody else. So, we won't discuss a particular. But IHRs are, while we are a signatory to it and while we have raised the reservation regarding federalism issues because the United States, unlike almost every other country, has dual sovereignty, states rights and federal rights.

Given all that, they are non-binding, although we have a treaty, a contractual obligation but they are non-binding. And so they won't be - the measures under the IHR will not be implemented until there is a declaration or an announcement such by the Secretary. I think there's where it's got to come from, if it does come, it's from the secretary or HHS. As to respecting and implement IHRs, so, at this point, there are considerations, they're out there, we're familiar with them and they're being discussed.

Is that fair enough?

Question cont'd: Okay. It tells me where you are and where you're not.

Coordinator: Our next question. Your line is open.

Question: Good afternoon and thank you very much for the presentation.

It's my understanding with respect to the swine influenza outbreak that there's no current FDA approved dosage for the antivirals for children under one year of age and is there a need for an emergency use authorization in that regard?

Susan Sherman: Yes, that's what the emergency use authorization, or one of them, was issued for. The FDA commissioner issued it in the early hours of Monday morning.

Question cont'd: Early hours of Monday morning. Okay. Thank you.

Susan Sherman: And we're trying to get information out about that quickly. I know CDC and FDA are working on talking points and, hopefully, we'll have information out to people about it as soon as we can.

Question cont'd: Okay. But I can find this on the HHS Website?

Susan Sherman: You should be able to. I'm sorry, I haven't looked myself to see what's been posted but I know they're working quickly to get things up there. And, of course, the EUA, itself, will be published in the Federal Register and will be publically available.

Question cont'd: Okay. Thank you.

Jennifer Ray: And, if we can take one more question.

Coordinator: Our next question. Your line is open.

Question: Thank you very much. It's (Larry Hearn). I've got a question about seafarers going out to ships. A hundred and twenty-five thousand ships currently around the world have practically no influenza medication as determined over a couple of years' research. And seafarers, when they leave the United States going out to foreign flagships (unintelligible) U.S. flagships are technically limited to 30-day supplies of medications.

And I was wondering if there's any means by which individuals and/or companies might obtain freedom from restrictions as to limitations, particularly those individuals going out on six-month articles and, indeed, 12-month articles and can they obtain freedom from seizure, also freedom of passage and retention both exiting and re-entering the U.S.?

And then the other question I had regarding mandatory compliance with IHRs, I believe you answered somewhat that question are shipping companies now compelled or is it strictly voluntary to abide by IHRs prior to declaration by the Secretary?

Susan Sherman: This is Susan, I believe I'm speaking for all of us, I'm not sure. It's the first question, I have to admit that's not something that necessarily falls in our authorities. But if you don't mind submitting that question, we will try and find someone who can respond to that.

You've sort of hit on an areas that we're not terribly familiar with. The IHR in question, Kim, you may want to respond to that.

Kim Dammers: I think my response to that would be the same as to the previous caller in question, is that, at this point, until there is an announcement that we are following particular rules regarding that, then, we are not in fact doing anything other than what we would normally do under our regulations.

Question cont'd: Okay, I see. That does indeed mean that IHR does not necessarily apply.

Kim Dammers: Let me add this caveat though. If a particular provision of IHR is applying now, it would continue to apply. At this point, there's nothing different, as far as I know. Now, we've been on this call for two and a half hours, so something could have happened. This is really very quickly moving which is why this doesn't constitute legal advice as we keep telling you for that very reason.

Question cont'd: And for non-seafarers, the general public, entering and exiting the borders of the U.S. with more than 30 days' supply per FDA restrictions a few months ago, at least, but seeking to retain and carry and enjoy free passage with more than 30 days of prescribed antibiotics or antivirals for example, are those restrictions, how might they go about researching those restrictions.

Susan Sherman: Well, none of us actual advise on FDA issues, we can refer that to our colleagues who do work with FDA and are knowledgeable about FDA law and see if we can get something back to you.

Question cont'd: So, that would be the COCA email address?

Susan Sherman: Yes.

Alycia Downs: I would really like to thank all of our presenters for providing our listeners with this information. I think it was a real informative presentation and very timely.

And, again, if we were unable to answer your question or if you have a follow-up, please send that email to COCA@cdc.gov. That is C-O-C-A@cdc.gov. And we'll work with the CDC public health law and the presenters will try to get responses to your inquiries, but please be patient as we are very much immersed in the current situation.

The recording of this call and the transcript will be posted to the COCA Website, when they become available at [Emergency.cdc.gov/COCA](https://www.cdc.gov/emergency/coca).

Thank you again for participating and have a wonderful day.

Coordinator: That concludes today's conference call. Thank you for your participation. You may disconnect at this time.

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