# Legal Issues Related to Novel Influenza A H1N1

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**Coordinator**: Welcome and thank you for standing by. At this time all participants are in a listen only mode. During the question and answer session please press star 1 to ask a question. Today's conference is being recorded. If you have any objections you may disconnect at this time. Now I will turn the meeting over to Alycia Downs. You may begin.

**Alycia Downs**: Good afternoon and welcome to today's COCA conference call. Legal Issues Related to Novel Influenza A (H1N1). We are very excited to have Montrece Ransom, Joseph Foster, Priscilla Fox, Steven Gravely and Priscilla Keith present on this call.

We are using a PowerPoint presentation that you should be able to access from our Website. If you have not already downloaded the presentation please go to www.emergency.cdc.gov/coca. Click on conference call information summaries and slide sets.

The PowerPoint can be found under the call in number and passcode. There will be no continuing education credits available for this call. The material contained herein is for instructional use only and are 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 Montrece Ransom, Senior Public Health Analyst with the Public Health Law Program here at the Centers for Disease Control and Prevention.

**Montrece Ransom**: Thank you very much Alycia and welcome to all of you who are listening. On behalf of the Public Health Law Program, COCA and the American Bar Association, particularly the Health Law section, we appreciate you joining in for what we hope will be a very valuable and timely teleconference this afternoon. My job today is to introduce the speakers to you. And then we are going to hear from their perspective, issues related to legal preparedness for H1N1.

From the private sector, we will hear from Steve Gravely. Steve Gravely is the Healthcare Practice Group Leader at Troutman Sanders in Richmond, Virginia. He focuses his practice area on health law and disaster preparedness and has become a national expert with a number of publications on emergency preparedness and response.

We've also got Joseph Foster who represents the federal legal perspective. Joe earned his undergraduate degree from the University of Arizona and his law degree from Indiana University. He is a Senior Attorney with the CDC branch of the Office of the General Counsel.

His focus area is primarily infectious diseases and terrorism response and he leads that team. Next we will hear from Priscilla Fox. Priscilla Fox is going to offer the state perspective. She's a Deputy General Counsel with the Massachusetts Department of Public Health where she works in several areas including emergency preparedness, mutual aid and food regulation. She has been active in this area - presenting training programs for local health officials and related audiences throughout Massachusetts with regard to preparedness and legal preparedness.

And lastly we'll hear from Priscilla Keith. Ms. Keith is going to present the local perspective. She's the general counsel for the Health and Hospital Corporation of Marion County in Indianapolis, Indiana. She is also the Chair of the Public Health and Policy Interest Group in the American Bar Association. And she has previously worked as Assistant Counsel to Governor O'Bannon. And again Ms. Keith will be presenting to us the local perspective.

As of yesterday, June 8th, there were a total of 13,217 confirmed cases and 27 confirmed deaths resulting from H1N1. With cases confirmed in all 50 states and in Puerto Rico. The legal response has not been gaining as much attention in the media but it's critically important as we've learned with previous public health emergencies.

With that I'm going to go ahead and turn it over to our first speaker, Mr. Steven Gravely who is going to talk about some of the legal issues faced from his perspective.

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**Steven Gravely**: Thank you Montrece. Good afternoon everyone, co-presenters as well as all those who are on the call. It's my pleasure to be here today and I'd like to thank the CDC for bringing this conference together.

I really think it's critical that we use our time wisely in the next few months to try to inform public discussion as much as possible about the possibility of a larger event in the influenza arena, the communicable disease arena.

And I'm honored to be a part of this program. If you have my slide deck in front of you, you can go to the first slide. It says 'Introduction.' We have a lot of slides here so I'm going to fly because I have committed to end at 1:20 and I apologize in advance for going quickly.

But there's a lot of material to cover. And I'm primarily going to focus on the healthcare sector response and some of the legal issues that the healthcare sector faces. That's my role today. The Intro slide just gives you a quick snapshot of recent global public health emergencies that we have faced.

I think all of you on this call understand that H1N1 is not remote; it's not in a vacuum; it's not an isolated event. Most of us remember SARS and even though the U.S. escaped

relatively unscathed, Toronto was hit very, very hard and is actually still recovering from the effects of SARS which was a relatively contained disease.

But it did a tremendous amount of social and economic damage particularly to the healthcare system in Toronto. H5N1 of course has been stalking us for years and is, as you know, very deadly. The mortality rate fluctuates around 60%. Pretty darn high.

And, it just doesn't want to go away. And then of course H1N1. I think all of us who have been involved in this for any period of time were alarmed at how rapidly this diseased emerged and how rapidly this disease spread and how unlike many of our planning assumptions it did not start in Asia or the Pacific Rim.

We did not have a month or six weeks to get ready for it. It was in our neighborhood almost immediately. And even though this has died down from a media perspective, you know the H1N1 virus is not over. It's still spreading.

And, fortunately, it's been relatively mild. But you know, the bottom line is - as I say here, our luck's running out. When you put just these three events into context I think the threat is painfully clear. And the healthcare delivery system both - both the private sector which constitutes about 85% depending on your metric, but about 85% of the actual healthcare capacity - delivery capacity in our country.

But also the public sector. The healthcare delivery system is at the center of everyone's emergency preparedness and response framework. The healthcare delivery system is critical to an effective response. And that's why we are so concerned about, not only the threat, but also some of the issues.

You can go to the next slide now. The question is so what do we do about this. And there are lots of answers to that. You'll hear that people are doing a lot of things. What I want to talk to you about, again, is primarily some of the challenges for the healthcare sector.

And unfortunately there is still a bit of a mindset out there that "I'll just do the best I can. And the more I talk about this and plan for it, the strong plan I might create may actually be used against me after an event. And if I just hunker down and do the best I can, and let events unfold, then that's my safest bet."

That is a very, very persistent and perhaps even pervasive mindset among the healthcare delivery system in the U.S. And I don't demean that. I understand it. I've been in healthcare since 1977 in one capacity or the other.

I totally get that perspective. But the problem with that is it's just flat wrong. Just taking the first slide in this deck you can see that the threat of a global pandemic is imminently foreseeable. We have been warned over and over and over, since 2002, that this can happen.

It can happen quickly. It can come out of nowhere. And it can be very deadly. And so we are on notice. All of us are on notice that this is a threat and it can happen at any point. "I'll just do the best I can." I just don't think that's a viable strategy anymore from a risk management perspective. And we have seen in the wake of SARS and in the wake of Katrina, a host of litigation and emerging new tort issues for the lawyers on the phone.

A tort is simply a civil wrong. We've seen an emerging tort around this notion of negligent failure to prepare and negligent failure to respond. And - and I think that is something that we all have to reckon with and understand that planning is really an absolute - it's not really an option anymore.

It's a basic risk management response to the evidence that's actually on the table. Let's go to the next slide. One of the key areas that everyone is concerned about (and I'm going to actually skip right through to the next slide that says 'Altered Standards of Care: The Context').

One of the key things that healthcare providers are worried about is liability. What is their liability? If they change the way care is delivered, if they have to curtail services, if they have to modify their practices and they have to actually heaven forbid, ration certain resources?

We like to talk about ventilators but most hospitals have plenty of ventilators. What they don't have are respiratory therapists. But we have to begin to change the way we provide care whether we call that altered standards of care (which is somewhat provocative), or whether we call it providing care under altered circumstances or whatever, any of the other rubrics.

The fact is we're going to have to deal with this. Our healthcare delivery system today, under normal time, is very stressed and is really on a knife's edge. And this recession has been very tough on healthcare, particularly the private sector.

And so already strained hospitals, from a financial fiscal point of view, are even more under duress financially because of shifts in the payer mix and more uninsured. And so both from a volume and from a financial point of view our healthcare system is very stressed right now.

And any type of event - any type of significant event that you introduce into this system has the capacity to ripple out and create real disruptions in care. It doesn't have to be a pandemic. It doesn't even have to be a Katrina. It could be flash floods. It could be any number of things on the threat matrix.

All of those have the potential, and some might even say the inevitability, of creating disruptions in the delivery of care. And we saw some of that in the Trust for America's Health report, which if you haven't read I recommend to you.

It's very interesting reading. Even with the H1N1 being a mild strain, they did talk about how some portions of the healthcare delivery system in some parts of the country were

under water from a surge point of view because of the surge in the number of patients that presented for care.

So the bottom line is I think we have to plan now for how are we going to provide care in a scarce resource environment when we simply don't have enough staff, we certainly won't have enough staff but perhaps also enough equipment and supplies to do things the way that we do them now.

So if we go to the next slide. There are a lot of myths about altered standards of care. The one that I find the most pervasive and the most dangerous is when hospital folks say, "Hey, this is a government job. My local health department is going to do this. My state health department is going to do it, the CDC is going to do it, the President is going to do it, Homeland Security is going to do it. Somebody is going to give me the rules of engagement and tell me what to do and I'm just going to follow the playbook and then I'll be fine."

Well, the fact of the matter is that there is a lot of work being done at the local, state and federal levels of government on allocation algorithms. But the field is so vast that we can't possibly have algorithms for everything. And we can't possibly give a definitive playbook for how every facility in the country is supposed to allocate resources.

And you're going to hear about some really great work today that states are doing which is going to be very helpful. But there simply isn't enough time perhaps ever to come up with the definitive playbook that will give us all the rules that we need to follow.

And if you don't believe me, which you may not, turn to the next slide and you'll see essentially this concept stated by AHRQ in their 2006 guidance. This is now 2-1/2 years old - talks about providing care with scarce resources and mass casualty events.

And here you see very clearly they talk about the perfect world - where we can follow guidance and decisions from others and that's fine. But what I want you to focus on are

the next two caveats. Even with these tools, which in many cases we just don't have, but even with these tools it's the hospital that will have to take on the role of implementing them.

And then the second whammy is if there is no guidance, which in many cases there isn't today, it's incumbent on the hospital to have a plan or strategy for bringing together the appropriate personnel who can make the best decisions possible.

I can tell you that is no small feat. We're actually working with the Virginia Department of Health on one of the CDC competitive grants in the essential services category. We're working with Norfolk General Hospital which is a Coronary Care teaching hospital in Norfolk, Virginia. Many of you are probably familiar with it.

And we are implementing a portion of the critical resource planning guide that Virginia adopted that we were involved with, that we developed originally in '05 and updated in '08. We're actually implementing that on a pilot basis at Norfolk General.

And it has - it's a one year project and it has been extraordinarily fruitful, but extraordinarily complex. And my key learning from that at this point, halfway into it, is that this planning is very doable but it takes a lot of time.

And it's not something that you can really afford to put off until the event is already upon you. So let's move onto the next slide and talk about EMTALA. Now for those of you who don't know what EMTALA is, I have a slide here that gives you a quick summary.

It's an old federal law and basically it requires hospitals to screen and stabilize patients who present at the emergency department for care. And it has a long history. Most of you probably know why it was adopted and why its plan is enacted. And it's a very, very far reaching and comprehensive law. Those of you who are in the field know how much time your facilities spend on EMTALA compliance. It is a complaint driven process, but these complaints are extremely resource consumptive.

When the enforcement teams descend on your facility to investigate it, they do a very thorough job, and the penalties are really not the issue. It's really responding to the allegation and all the management time and money that it takes to respond. And then patients of course have a private right of action as well.

So there's a lot of EMTALA enforcement out there, as there should be. It's a very serious thing. When it comes to disasters a lot of folks think, "You know well yeah, I understand EMTALA but that's not going to be around. The Secretary is going to waive that in a disaster."

Well, the fact of the matter is that the Secretary does have waiver authority under the Social Security Act, however it is very limited waiver authority. And basically what the Secretary is allowed to do by statute is to waive the imposition of certain sanctions for failure to comply with specific provisions of the law.

So, it is not a wholesale set aside of the act, it is also not a suspension of EMTALA. EMTALA continues in full force and effect no matter what the disaster is. It's simply that the Secretary can waive sanctions for certain portions of EMTALA and we're going to touch on what those are.

But it's important that we burst that myth because it is a very dangerous myth for people to be laboring under. So in terms of facility responsibilities during a disaster, under EMTALA an ER is required to do a medical screening exam. This is different from triage.

This is an EMTALA term and it must be done on patients that present for care, and it must be done by a qualified medical person, someone who the facility has designated to do the job and someone who the facility has trained and who meets the minimum requirements.

So it's not just anyone. Section 1135 of the Social Security Act - this is one of the provisions that can be postponed under a waiver. And in fact the secretary has issued a lot of waivers since Katrina for all manner of natural disasters and others including - well, they actually didn't get this far with H1N1, but there are a lot of waivers that are all posted on the HHS Website if you want to go look at them.

And this is one of the sections that the waivers generally do impact. They allow the facility to postpone. You still have to do the MSE but you can postpone doing the MSE and that is not sanctionable. In terms of stabilization services and MSEs, the law says that you have to do this within the capabilities of your facility.

And that is really a facts and circumstances type of test. And there's been a lot of debate about this, not in the disaster context, but in the normal context because we all know that ERs routinely exceed their posted capacity on a daily basis.

EDs are in crisis. They have been for 20 years. And so what is an ED's capacity at any point in time is actually an open question right now. And that could become very critical in a disaster in terms of capacity.

You can see what that means for our planning efforts so I'm going to skip over that because I need to move on and I want to talk about HIPAA. You all know what HIPAA is. It's the basic federal privacy law. If you will skip to the flowchart. The Office of Civil Rights put out an emergency planning tool for HIPAA a few years ago.

And everyone said, "Oh, this is great. This is our definitive answer." Unfortunately, as we've worked with this we realized that it really doesn't answer some of the tough questions. It's certainly helpful but it leaves a lot of open questions for the healthcare provider, for the covered entity.

And so facilities still need to be doing HIPAA planning even with this OCR tool. So if you turn to the next slide. Again, a lot of folks had this misconception that the Secretary will simply waive HIPAA, but much like EMTALA that is not the case.

HIPAA will not be set aside. There will be waiver of sanctions for specific HIPAA violations. Go to the next slide. What does this mean for planning efforts? What it means is - and this is true for both HIPAA and EMTALA - in your planning you must assume that these laws are going to remain in effect because they are.

You should certainly be alert to the waivers that are issued and understand what - what flexibility they give you. But certainly understand that these laws remain in full force and effect. And then you should pre-plan for all the situations where protected health information might need to be shared with third parties.

And be sure that you have policies and procedures in place, and probably business associate agreements in place, to allow for that sharing to occur because that will not disappear.

Our next section is about staffing and HR. I'm pretty much out of time. I think someone else is going to talk about staffing. So, what I'm going to do is skip over that and I'm happy to take questions about it. I'm going to quickly wrap-up with the financial sustainability slide because I think this is an area that is overlooked to our peril.

So if you - right behind the financial sustainability slide there's a slide that says 'The Truth About Financial Sustainability.' There is a misconception that - among a lot of healthcare providers - that FEMA is going to cover everything, all of their expenses that they have in a disaster under the Stafford Act.

And again unfortunately that's just not true. Certainly FEMA will provide some coverage, and it can be very important reimbursement, but it does not cover many, many things.

And the most relevant one is that FEMA does not cover the provision of definitive medical care. The other important issue is that FEMA is a payer of last resort. You have to exhaust every other avenue of payment before you can make a claim under FEMA for what they do cover.

So financial officers, who are largely not engaged in emergency planning around the country in hospitals, need to be thinking about this. You need to bring them into your discussions if you're in charge of emergency planning.

And I have on the last slide a list of things that you all should be thinking about in terms of financial sustainability for your facility. And with that I'm going to take a breath and I'm going to turn it over to Joseph Foster.

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**Joseph Foster**: Okay. Thanks Steve. First I'll say thanks to Steve and the organizers of the teleconference. There are a myriad different authorities that could come into play in federal response to outbreaks such as H1N1.

I'm going to stick with about three just because these are the ones that have been the most material to the actions taken so far. The first is a determination of public health emergency under Section 319 of the Public Health Service Act.

The second is emergency use authorizations (EUAs) and then finally, I'll talk for a few minutes about the PREP Act or the Public Readiness of Emergency Preparedness Act. And hopefully you'll learn a little bit about what they are and what they do and maybe have a little better information about how they've been used in the current outbreak.

I point you to the first slide in my slide deck. There are a number of resources there, including citations and some Web sites where additional information can be had. So first up the public health emergency determination.

This is what Steve was referring to a minute ago when he talked about the Secretary waiving HIPAA and waiving EMTALA. The way that that's done is that the Secretary of HHS first has to issue a determination that a public health emergency exists under Section 319 of the Public Health Service Act.

And it's exactly what it sounds like. It's a determination that there's a public health emergency. Up until right after 2001 that really didn't do a whole lot in and of itself. It did provide potential access to additional appropriation, if Congress had appropriated that fund.

But since that time a number of statutes have been enacted that are triggered by a public health emergency declaration and you can see a list of those on the next slide. I don't plan to go into all of these. For each one of them there is a citation and you can look those up if you're interested in. But with respect to H1N1 specifically, the only one that's really come into play is the very last one, the one that would authorize the Secretary to issue a declaration justifying emergency use of either unapproved products or products that are approved but for unapproved uses.

And so that gets us into the next subject which is the emergency use authorization. I'll talk a little bit more about what that is and then give some examples of questions that have arisen with respect to the H1N1 outbreak and the authorizations that have been so far issued.

Effectively, an emergency use authorization is an authorization by the commissioner of the Food & Drug Administration to use unapproved products or to use approved products for unapproved uses in an emergency. These authorizations are generally made in response to a request.

The ones that I'm most familiar with have been in requests that have been made by CDC but that's not to say that state and local governments or private sector entities cannot also

request emergency use authorization if they felt that that was necessary to carry out whatever responsibilities they may have.

Authorizations can cover drugs, biological products or devices that are otherwise subject to FDA statutory and regulatory control. The authorization itself is predicated upon two steps.

First, there must be a determination by one of three Secretaries of one of three different types of emergency. One - the first would be a declaration or a determination by the Secretary of Homeland Security that there is or there is a potential for a domestic emergency.

The second would be a declaration or a determination by the Secretary of the Department of Defense that there's a military or a potential military emergency. And then the third is the declaration or determination of public health emergency that I was just describing under Section 319 of the PHS Act.

So that's step one. Step two requires a declaration by the Secretary of HHS that those circumstances justify an emergency use authorization. That declaration must include the particular agents that the emergency use is to be provided for as well as the product that will be subject to the emergency use authorization.

Now you've got two steps. You have first the determination of emergency and then you have a declaration of emergency justifying the authorization itself.

And then the final step would be for the commissioner of FDA to issue the emergency use authorization. Each authorization has to contain a certain level of information or certain amounts of information. That information includes the disease or the condition for which a product may be used to diagnose, prevent or treat; findings that the commissioner makes with respect to the known potential risks or benefits, the safety and

potential effectiveness; and the assessment of available scientific evidence with respect to that particular drug or health conduction.

There are a number of statutorily-required conditions, as well as discretionary conditions, that the commissioner of FDA could impose. It gets published in the federal register, and then terminates either when it's revoked or when the underlying Secretary's determination - declaration terminates, which is in one year, or if it's previously determined that the circumstances justifying the emergency use authorization ceases to exist.

And of course they could be renewed if that's necessary. With respect to the H1N1 outbreak, five authorizations have been issued so far. One for Tamiflu, one for Relenza, both of which are antivirals; two for diagnostics that are being used by federal, state and local agencies to diagnose and subtype H1N1. And then one for (N95) respirators.

Just to give you an idea of why Tamiflu might be necessary, why an emergency use authorization may be necessary for Tamiflu, which is an approved drug. That drug is approved for individuals who are older than one year - one year or older I should say - and for individuals who exhibit symptoms for two days or less. The authorization allows it to be distributed, disseminated, and administered to individuals who are less than one year, as well as individuals who maybe exhibiting symptoms greater than two days.

So that gives you an idea of how it works with respect to approved products. A few issues have arisen in the outbreak - one has to do with translation of the fact sheets that are a part of the authorization.

And just to give you an idea, there's an authorization that goes back to the requester to describe how the product can be used. But then there are also fact sheets and other materials that are developed and approved as part of the process that are to be provided to patients or potentially to healthcare providers to get them information about the particular products and the emergency use authorization.

So one question that came up was whether or not those fact sheets had to be translated for populations that might not understand English. And that's actually obviously a very good question.

If you look at the authorizations themselves you'll see that what they say is that additional information can be provided so long as it's consistent with the authorization, and it doesn't exceed the actual authorization.

FDA has indicated that translations would fall under this rubric. So if the state and local health departments translate the information provided in the fact sheet into whatever relevant languages maybe necessary, then that would fall within the scope of the emergency use authorization and would be authorized.

And they've gone an additional step to indicate that those products do not need to be separately approved by FDA. Another interesting issue that popped up had to do with use of state and local or private stockpiles. As you maybe aware, state and local governments have been separately stockpiling some products, antivirals mostly, I believe.

There have also been some private companies that have stockpiled antivirals for their own employees and potentially for communities. So the question was whether or not products from those stockpiles could be used in accordance with this - with the emergency use authorizations.

The language that you'll see in these authorizations describes using products consistent with the medical response or the public health response of what's called an authority having jurisdiction.

That generally refers to state and local government agencies that are charged with medical or public health responses at differing levels.

What the emergency use authorizations say is that so long as you're providing products in accordance with those plans or those requirements of the authorities having jurisdiction to respond to the outbreak response, then those products would be covered under the emergency use authorization.

And then one last issue that's come up has to do with expiring products. Mostly again dealing with antivirals. The way that CDC, the strategic national stockpile, works with respect to a lot of the products is they are available on a rotational basis.

So as products get closer to their expiration date, they're injected back into the consumer stream and potentially provided to individual consumers on an as-needed basis as the market demands.

That works the CDC's benefit and to the consumer's benefit because there is not just a cache of products that's in a stockpile somewhere that expires and is of no use anymore.

When the decision was made by CDC, after the outbreak began, to ship out 25% of each state's share - obviously the way the CDC does that is they provide the product that is due to expire first. Product that was approaching its expiration date was shipped first with the expectation that it would be used immediately, but the outbreak didn't unfold in a way that necessitated the immediate use of the product. So now product is out there that may be expiring and the EUAs don't necessarily speak to what to do with the product that may be expiring.

My understanding is the CDC and FDA are working through that issue now to decide how to deal with it and will issue guidance in the future.

But those are a few issues that came up with respect to the emergency use authorization.

Let's move on now to the PREP Act, the Public Readiness and Emergency Preparedness Act. It's authorized under Sections 319F-3 and F-4 (for the lawyers in the crowd) of the Public Health Service Act.

It basically does two things. First, it authorizes the secretary of HHS to issue a declaration to provide immunity for tort liability with the exception of willful misconduct.

It also authorizes an emergency fund in the United States Treasury for compensation for injuries to individuals who receive what are called covered countermeasures, that is, products that are covered under any particular declaration issued under the PREP Act.

What I'll do real quickly is I'll try to go through a number of different subjects here like who is protected, what products are covered, what losses are covered, what losses are not covered, and what about those who are injured, and then a few additional points for folks that might be of interest.

So before we get to those questions, just to give you a general idea of how it works, it's triggered by a Secretarial declaration. You can see that there's quite a common theme with all these different statutes. They all seem to be triggered by some sort of Secretarial declaration.

By statute, the declaration has to contain quite a bit of information. It's got to contain a determination of threat or credible risk; a recommendation for action such as manufacture, testing, use, or distribution of a particular countermeasure; the category of diseases, health conditions or health threats for which that particular countermeasure is to be used; the exact countermeasure to be covered; the effective time period of the declaration; the population that's to receive it or may receive it; and the geographic area in which the product is to be administered,, as well as any limitation upon the declaration or upon the act itself.

It also contains what are called additional qualified persons and I'll get to those in a moment, because that often comes up in conversations about the scope of the act and its protections.

So who is protected? By statute, the individuals that are protected are called covered persons and not just people. Obviously these are manufacturers, distributors, as well as what's called program planners, and other qualified persons that are defined in the statute. There are definitions we can get into a little bit further. One is, as I mentioned, "qualified persons," which includes licensed health professionals as well as other individuals who are authorized by state law to prescribe and administer or dispense countermeasures that are covered by the statute. It also includes a discretionary category. It's a category of persons that the Secretary is allowed to describe in each declaration. So if you look at the declarations that are in existence now, like, for example, with respect to antivirals, you'll see that the Secretary has included an entire category of individuals within this group that include folks who are involved in the distribution of countermeasures in accordance with the state and local plan to respond to the outbreak.

And this could include volunteers, contractors, and official agents of the entities that are involved in those types of activities. So that is a useful provision to provide - it adds protection to individuals who might not otherwise be explicitly covered by statute.

And then of course the statute also covers the United States and any official agents or employees of the United States or any of these other entities that I was previously describing: manufacturers, distributors and so forth.

What products are covered? These are statutorily defined products but generally they're - they are devices, drugs and biological products that are otherwise regulated by FDA. They also include products that are described in the emergency use authorization such as the ones we were just talking about a few minutes ago, the antivirals and so forth.

What types of loss are covered? What types of loss are covered by the statute? It covers any loss that has any causal relationship to any stage of development, distribution, and administration of a countermeasure. This includes death; physical, mental or emotional injury; fear of physical, mental or emotional injury; any sort of medical monitoring that might be necessary; as well as economic damages such as loss or damage to property including business operations.

The statute's coverage is intended to be very broad in terms of the products it covers, the people that it covers and the losses that are covered. That's not to say that it's absolute. There are certainly losses that are not covered. For example, it doesn't cover losses for willful misconduct. It doesn't cover losses for other than tort claims. So cases or claims for violations of civil rights or civil rights laws, the ADA, or labor laws would not be covered under the act.

Similarly claims where there's no causal relationship between the loss and the development, distribution, or administration of the covered countermeasure would not be covered. Claims that are outside the declaration, for example, claims outside the effective date or the geographic area described in the declaration, wouldn't be covered. Finally, claims that are filed in foreign courts would not be covered.

So the next question that's usually asked is, "Well, what about those people who are injured? The statute does also set up a compensation fund. That fund is established legally upon the issuance of a declaration. However it requires Congress to appropriate it.

And to my knowledge none of those funds have been appropriated yet. I guess we've been fortunate that we haven't had situations where there've been a number of claims that have been filed or situations where they're giving rise to those claims. But before any person could recover under the act that those funds would need to be appropriated.

Compensation made available under the statute for medical benefits, lost wages, or death benefits, and would be reduced by insurance or workers' compensation. (Go on to the next slide.)

With respect to H1N1, there are two declarations that are relevant. The first is for antivirals. There was already a previously existing antiviral declaration but it was made specifically with respect to treatment of or exposure to H5N1 and so it was recently amended so that it would cover exposure or treatment for H1N1. The second declaration that exists with respect to influenza covers diagnostics and respiratory devices.

There are a couple points I wanted to make to get back to that "program planner" definition - just to point out that in terms of program planners, it's not just state or local government. It also includes private sector employers or community groups that supervise or administer a program with respect to the administration.

I think you can see how that might be useful in terms of private sector entities that are involved in ensuring that products get administered to patients.

I also wanted to bring up the definition of administration. We often get asked, "So I'm a private sector entity. I'm involved in plans to distribute products but, you know, what's the scope of that? What exactly do you mean by administration? You know, suppose I have people who are standing in line outside my facility that are pushing and shoving, there are slip and fall injuries, would the statute cover that?"

If you look in the declaration, in a number of them, the antivirals one particularly comes to mind, that the term "administration" is defined in the declaration to include "public and private delivery, distribution, and dispensing activities relating to the physical administration of countermeasure to recipients, the management and operation of delivery systems, and the management and operation of dispensing and distribution locations."

This definition of administration is intended to be very broad and to cover any sort of liability that might occur as a result of operating those types of dispensing locations. So that's I guess about the end of what I have to say. I'm going to suggest that we put up the last slide. Take a look at the last slide, which again has the resources that I was referring to earlier and I think that covers it. Move on to the next speaker.

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**Priscilla Fox:** Okay. Thank you very much. This is Priscilla Fox. And I'm glad to be here. Thank you for inviting me. The first slide is just the title so please go to the next one, which is health information, privacy. And actually what I'm going to be talking about in this whole slide set is what we did, really the state attorneys in Massachusetts, when we were faced with the outbreak of H1N1; we faced a number of different legal issues and we're very involved.

And so this is really what we did on the ground day by day. The privacy issue was really of concern; obviously there's a balance between the public wants to know a lot about the cases that are arising and the individuals have privacy rights.

So our local health departments all around the state were asking the State Department of Public Health for guidance on how much they should disclose. And we realized that we needed some sort of written confidentiality policy which is actually still a work in progress.

Now, our state regulations allow disclosure of personal health information without the patient's consent when, and you can see the actually regulatory language is, "necessary for disease investigation, control, treatment and prevention purposes."

But what does that really mean? That's very broad. And so we had to figure out how to balance it. And in the case of Massachusetts, we said releasing the county is all right but we have two quite small counties with limited population so we said we should combine

those two. And we said it's not okay to release the town of residence. Some of our towns are very small.

Then there was the issue of age range versus specific age of the person diagnosed. These were confirmed cases that we were getting in the early days, back in late April, early May. At first we had a list on our Web site of every single case with the person's specific age and county and whether or not they were hospitalized and the date of onset.

Some concern began to be raised about putting specific age in there. The lawyers said really age range would be better and in fact that's what we've gone to now.

We no longer list each specific case, not really because we thought we shouldn't, but more because we had so many cases coming along and now we're up to the several many hundreds. And so what we're doing now is simply aggregate numbers by county and whether they were hospitalized.

But if you go to the next slide, we still need further work on this issue because we need to drill down a little bit deeper to figure out when disclosure really is necessary for these listed reasons. And we realized that that will vary based on the virulence of the disease, how it spreads. You know, to what extent do people need to know say that there's a very dangerous disease breaking out in their local school or their local grocery store?

And so what we want to do, and we're going to do this as part of our overall debriefing, which we hope will happen in the next several weeks, is get together a group of people, epidemiologists and lawyers and others who will hash all this out. And see if we can come up with some guidance on how we can really be a little more specific as to these criteria. What are some criteria for when disclosure is necessary?

Next issue I'm going to talk about is school closures. Now, in Massachusetts, local school officials typically have the authority to decide on closure. But we looked into this and

wrote a legal memo that State Department or local boards of health can order closure under a couple of circumstances.

And I want to note too that Massachusetts, like many New England states, has no county health system. Our local health is based by town and we have 351 cities and towns in Massachusetts. So you can imagine the challenge there getting consistent guidance out to all of these entities. With the larger cities, it's much easier. They really know what they're doing and they have a good amount of staff.

But we have some tiny towns in the central and western part of the state and their board of health may be part time. And so it's just very difficult.

If school officials failed to follow health officials' recommendations and we determined that failure to close a school presented a danger to public health then the local board of health or the State Department Health could order school closure.

As I said, that didn't happen. What actually happened in reality was that local authorities did make the decisions. And according to our state epidemiologist when I asked him what had happened, he sent me an email saying we prefer the local authorities to base it on the capacity of the school to operate at a particular level of absenteeism but in some cases they jumped the gun. In other words, closed maybe too early.

But then, he says, when it was apparent that disease was not severe; things changed. And the main issue later became the seven day out of school requirement with parents pushing back and providers providing notes, medical providers providing notes to try to get kids back early. So, as you can see, school closure is a difficult issue and I think if H1N1 comes back in the fall or really any other dangerous disease comes along, school closure is something we need to discuss more and develop maybe some more policies about.

And of course there's the issue of parents not wanting to stay home and lose work time especially if they don't have sick benefits at their work and a lot has been written about

that. And that didn't come up in Massachusetts specifically for us to work on but I think that remains obviously an issue.

Okay. The next slide. Basically we use recommendations. As I said, we urge them to base closure on their capacity to operate with a given level of absenteeism. We urged them to isolate and send home students and staff with influenza like illness. And they were to report higher than normal absenteeism to us at the state and then they had to submit a closure reporting form if they did close.

And as of last Thursday, June 4, there were 31 closures. I just checked it again now and I think it's slightly up but not much. Four schools now remain closed. This includes public, private, parochial schools and colleges, graduate schools and it also includes daycare. So it's hard to get a total number - it's hard to get a percentage because it includes so many different types of schools and daycares. But as I say, we still do have four schools closed.

This next slide, information for schools, shows an example of two documents that were on our Web site, still are, for schools. We have - we had a very good, still do again, have a very good and complete Web site for many different groups. Providers to general public; we have fact sheets translated into many different languages. That was something that worked very well for us.

Next slide. I'm going to the next issue, which is police enforcement. Again, we were looking ahead. What if this disease was so severe that we would need to issue specific isolation orders to keep people in their homes for example and what if they disobeyed? Do the police have the authority to enforce such orders?

Well in our state, statutes are quite old and archaic. They're very general. They give us a lot of general authority which we like but we do not have explicit statutory authority for police enforcement of health orders if the Governor has not declared an emergency, either a state of emergency or public health emergency. And that did not happen in Massachusetts.

So what were we going to tell police in the event that we needed to do isolation orders, which, again, we did not but we were getting ready just in case? So counsel for various agencies got together several times in meetings and we developed a written policy to guide the police.

And we laid out the authority of the State Department of Public Health as well as local boards of health and then we talked about the authority of the police including the community care taking function that they have. And I'll be glad to address that in more detail in the question period if people are wondering about what that is. And then also enforcement of health related orders.

And we concluded that based on, even though there's no explicit statutory authority, based on more general authority plus regulatory authority of the department and local boards of health that police in fact did have or do have the authority to enforce an isolation order if necessary.

Next slide. The next issue we confronted was the use of antivirals and this links a little bit into what Joseph Foster was saying about the state and local law that - state and local laws that apply to the use of SNS assets. So Massachusetts received a portion of it's strategic national stockpile assets from CDC. The state took over custody of those and in turn distributed them out to hospitals, clinics and other medical places.

So we looked at the law - how were we going to control the use of these assets? So we looked at our state law and we have a law in our state statutes that gives the Commissioner of Public Health the authority to determine that an emergency exists due to the shortage of a pharmaceutical and if he determines that, then the department has the authority to set rules and priorities for distribution of that pharmaceutical.

So we use that authority. The Commissioner issued a determination and an order for dispensing of the two antivirals, which required strict compliance with clinical guidelines

that we posted on our Web site. So the order then provided background and legal authority for the next step that we did. Next slide.

In the actual distribution, we crafted written agreements between the department and the recipients. Again you can see down there in the bottom it included hospitals, clinics, ambulatory care practices and EMS services.

Those written agreements had to be signed upon receipt of the assets and the receiving entity had to sign and agree that they would dispense only in compliance with our guidelines, and that a qualified person in the facility had to provide approval to a clinician desiring to prescribe or dispense the particular antiviral.

So the idea was to have a check system whereby a doctor wasn't just going to give out Tamiflu under his or her own idea that this patient might need it. We wanted to check to make sure that the clinical guidelines were being followed.

And then there was a record keeping component as well. And PPE (Personal Protective Equipment) again, that had to be used in compliance with the guidelines and monitored the usage and the PPE.

So the next issue, the next slide, we polished up our template orders. Again, as I mentioned, the Governor declared public health emergency did not happen for H1N1 in Massachusetts. But if it had, it would have given broad powers to the Commissioner of Public Health.

And so we wanted to make sure that these template orders were in good standing, in good order in case we needed to use them. So if necessary, we could have suspended hospital regulations, state hospital regulations governing things like bed capacity and staffing ratios and requirements for discharge planning.

We might have had to suspend a portion of the state patient's rights statute; for example, the right to confidentiality of all communications. Again, we're thinking about things in a much more serious situation. For example, you've probably all seen those pictures of 1918 with the cots in the gymnasiums.

In a very serious situation, we might have to do something like that. We might have to open alternate care sites, influenza specialty care units where beds might be very close together and so we might not be able - the hospital might not be able to guarantee the right to confidential communication. So again, this is just something we were getting ready for.

And then another example was if the Public Health Commissioner were to decide that it was necessary to close public transportation or close large gatherings, we've got a template order ready for that as well.

Next slide, pending legislation. We have had what is known as either the Emergency Powers Bill or the Pan Flu Bill pending in the state legislature for many years. It keeps getting re-filed session after session. It never has gotten very far. But it passed the Senate on April 28, which I think was clearly due to the urgency that the Senate felt the outbreak of H1N1.

It would provide expanded liability protection for volunteers including people in the Medical Reserve Corps and also MSAR, the Mass System for Advanced Registration, which is our state component of the federally funded ESAR-VIP, the Emergency System for Advanced Registration of Volunteer Health Professionals.

So that bill is now in the House and we at the department are working with House staff to hopefully move it forward.

The other thing I wanted to mention, I don't have a slide on this, but since Steve Gravely mentioned altered standards of care, we have also been working very much on that. We

actually sponsored a symposium on May 28 - a one-day meeting, which was very well attended and very well received at Harvard Medical School, where it took place.

It was sponsored by the Department of Public Health, by the Harvard School of Public Health and also by the Johns Hopkins Center for Public Health Preparedness. And people came from a variety of different states as well as a lot of people from Massachusetts.

Different states presented what they had done to date on this issue. We had breakout groups in the afternoon talking about gaps and the need for further progress. And so we're quite optimistic that progress will be made as a result of that.

In Massachusetts, we have an Altered Standards of Care Advisory Committee which was getting ready to submit some recommendations to the department towards the end of April, early May and then the flu outbreak hit and so their timetable has been set back. Many of the experts on our committee are actually clinicians who were very much involved in the response to the flu.

And so we're hoping that in the fairly near future, assuming the outbreak doesn't spike again, that those people will be able to meet their recommendations and then give them to us at the department. We're actually drilling down pretty deeply.

So we're looking at clinical guidelines, actually clinical protocols for the use of things like ventilators, staffing issues, use of other resources. Ventilators is the one that I think people are most familiar with because there's been a lot written about that but we want to expand much more broadly and talk about many other types of resources that could be in short supply, hospital space and also staff. So, as I say, that's a work in progress.

And I think I'll wind it up there and turn it over to the last speaker.

**Priscilla Keith**: Thanks Priscilla. I appreciate it and I'm going to go through my slides very quickly here so that I can give everyone on the call an opportunity to ask any questions that they may have with regards to this presentation. And I'd like to thank the hosts, CDC and the ABA for asking me to participate.

And before I get started, I'd like to give credit where credit is due with regard to the information on the authority of local boards of health and health offices. Much credit is given to the public health law bench book, for the Indiana courts and that was done in collaboration with the University of Louisville as well as the Public Health Law Program at CDC.

So much of the information regarding the Marion County Health Department's powers and ISDA from that bench book and it's a very, very good bench book.

I'd like to go ahead and just start on Slide 2, if I may with regard to the general powers. Our local board of health, being Marion County, possesses all the powers that are necessary to supervise the health and lives of persons and the geographic scope really here in Indianapolis is Marion County.

So it's very important I think first and foremost for any local health department is to understand exactly what your statutory authority is. Could you go to the next slide please?

In terms of itemized powers, we do have the right to go in and inspect - make inspections, sanitary inspections, and surveys of all public buildings and institutions as well as private property. Next slide.

In regards to communicable disease control, we have a stake in that and we have a responsibility to take any action that is authorized by statute or by our State Department of Health to control that. Next slide.

Disease continued. If you look at epidemics, we are empowered to forbid any public gatherings, the operations of school and churches when we think it's necessary to prevent and stop epidemics. And as I go through on my slides, you will come to understand that the Marion County Health Department did exactly that with regard to two school closings with H1N1.

And we also have the authority to quarantine and isolate individuals or in mass gatherings where we think it's appropriate. We also have the authority to abate any causative conditions with regard to those that may increase transmission or generate or promote any type of disease.

And very quickly as to the next slide, we must collect, record, and report vital statistics to ISDH, our State Department of Health. The local health officer has the authority to hire personnel.

With regard to the next slide, we have rulemaking authority, enforcement powers and that may also include quarantine and isolation. And when we do that, obviously the health department is represented by counsel.

And the next slide, these are just very, very basic. We are required to make annual reports, monthly reports to our board. The next slide, budget, financial assistance and service fees. And the next slide after that discusses the Marion County Health Department and how we are a division of the Health and Hospital Corporation of Marion County. That is in conjunction with Wishard Health Services.

So I think the Marion County Health Department and Wishard Health Services under the direction of health and hospital is one of maybe nine in the country that has that model.

I'd like to go forward in talking to you about the timeline and talk about the experience with MCHD. And it was quite an experience. I too, as Priscilla Fox has said, am looking forward to debriefing and looking at lessons learned with regard to that.

Of course, you know, H1N1 was first reported or the cases first developed in Mexico and those authorities contacted the CDC and the World Health Organization for assistance. And then as we went into April then deaths were reported with regard to H1N1.

The CDC then issued its first health advisory on April 25 and ISDH on April 26 went into action and I'm going into the next slide. On April 26 our Health Director, who is Dr. Caine, called us, and I believe this might have been on a Sunday, to tell us to start preparing for our H1N1 meeting on Monday, which we did.

And of course we had an array of healthcare providers. Epidemiology was represented, as well as legal. We had our staff operations, human resources, finance, public health nurses and we also invited our partners from public safety and the city of Indianapolis, your emergency response and also hospital personnel. Next slide.

We opened our Department of Operations Center on April 27 and we also established a citizen's call center that ran from 7:00 am and 7:00 pm. And we thought this was important to field questions that we were getting from our community with regard to H1N1.

Also important was that we had people who were bilingual, who were very fluent in Spanish to take those calls. And we also had those calls staffed by our public health nurses in order to answer any clinical questions that may have come up.

As you can see, Dr. Caine did brief our President and CEO and we also the day after that had our first confirmed case of H1N1 from a Notre Dame student. Next slide.

We felt it was important to establish a Scientific Advisory Committee, which held its first meeting on April 28 to talk about many of the clinical issues that were coming up as well as administrative issues. Most notably the question of N95 masks came up. How do you

protect your providers? There were questions from an administrative perspective in terms of FMLA, worker's comp. But mainly we dealt with the clinical issues.

Dr. Caine then briefed the Mayor of Indianapolis, Mayor Ballard, with regard to the status of H1N1. And we also felt it was important to hold a town hall meeting. Many of the people at the town hall meeting were healthcare providers, people from our business community, schools and community leaders.

I think we had over 300 people to attend and this is less than a 24-hour notice. So you can tell that many people were interested in where we were with H1N1 and what the status was, what MCHD was doing as well as the Indiana State Department of Health. And I'd like to also say that there was daily contact with our State Department of Health with regard to H1N1.

What was important (the next slide) is that we scheduled a conference call with our school superintendent to talk about H1N1 and the possibility of school closing. And that was serendipitous because the following day Dr. Caine received a phone call from our State Health Commissioner, Dr. Judy Monroe to say that we had two confirmed cases of H1N1.

Next slide. We then met with the school to inform them that we were closing the school based on the criteria that we had from CDC at the time.

And I want to echo Priscilla Fox's comment that some of the questions that came up and rightly so in terms of childcare issues that many parents would face when were we going to close the schools; obviously not in the middle of the day but at the end of the day. How long were the schools going to be closed? And that sort of information.

We sent, as Massachusetts had (Priscilla had it on her slide), an advisory to the parents as to why we were closing the school and a reentry form that the parents had to sign or their

healthcare provider signed in order for the child or the children to come back to school. And our initial timeline for school closing was seven days.

And if you remember, Dr. Caine, our local health, Public Health Director, had the authority to close the schools. And so having that statutory authority we went ahead and moved forward on that. There were two school closings at that time. Next slide.

Our Scientific Advisory Committee again met and then, on May 6, Dr. Caine reopened the schools. And this was based on our new information from the CDC, new guidance from the CDC, in terms of H1N1 and that they were really leaving it up to the local authorities and local and state health authorities as to when it would be necessary to close the schools.

And I might want to add that and in terms of our letters that went out there were also - they were in English as well as Spanish and the reentry letters were also in Spanish and English. Next slide.

As we worked through our timeline, it was important for us to keep the call center open but as time moved on and progressed, the questions were fewer and so we officially ceased operations on May 15. And I'd like to add that we continue to receive confirmation of H1N1 cases and we’re continuing to monitor the situation.

In terms of some of our achievements, with the local health department is vitally important that you integrate yourself into the community and establish those partnerships that will bear fruit in terms of a crisis. And that proved to be well thought out as we spoke to many of our business leaders, many of our partners and the schools.

We also worked with our community health centers and we continue to do that in terms of emergency preparedness. Next slide.

MCHD opened its Department of Operations Center consisting of 25 key internal staff. And sometimes it was probably more than that depending on our partners from outside. And our call center was from 7:00 am to 7:00 pm. We have 15 volunteers a day and they were bilingual.

And with the last slide, we had our Scientific Advisory Committee as well as just talking about our town hall community meeting. So I would probably venture to say we were well equipped with our statutory authority as to what we could and could not do. And it empowered us to move forth.

Our relationship with our State Department of Health was and continues to be very, very close and the daily contact proved to be one that allowed us to move forth. And also our key contacts again with outside partners as well as hospitals was one which bore fruit as well.

And so I think going away from this, it was a very good exercise and we continue to look forward as to how we can continue to improve that. So I think I will turn this back over to Alycia.

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**Alycia Downs**: All right. Great. Thank you so much to presenters for that awesome presentation. We can now open up the lines for the question and answer session. Again, the material contained here 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 to any questions you may have regarding a legal matter.

And we can now open up for questions and answers.

**Coordinator**: Thank you. If you would like to ask a question, please press star 1 and record your name. Once again star 1 and record your name to ask a question. One moment for the first questions to queue.

**Question**: Jonathan Haber, Marriott International.

Hi. Thank you very much to all the speakers. And I apologize. It was a long conference, so if this was discussed again I'll apologize ahead of time.

So I was wondering what you see your roles at any level of Government whether it's local all the way to even Federal for the education of the public in regards to the H1N1 virus? I see a lot of great resources being given (unintelligible) response and reaction to the event. But how about awareness education to (unintelligible)?

**Priscilla Fox**: Well I'll jump in. This is Priscilla from Massachusetts. Yes. I think it is key that the state and local but in our case particularly the state take the lead on advising and educating the public and actually we have attempted to do that. I think we've done quite a good job through our Web site.

If you go to our main mass.gov Web site and then to the DPH Web site we have a link right there to our flu materials and they go on in great detail. As I mentioned before, we had general information for the public and I'm just counting down here, I think it's been translated into about 15 different languages in addition to English.

We also, interestingly, have a study ongoing with support from CDC, financial support, and this is a study that we're doing right now looking into the best way to get messages out to the public.

And we have a couple of public meetings coming up in two different parts of our state towards the end of June where the participants, which will be community members, will

be given a scenario of all background information about pandemic flu, in general, and of course questions about H1N1 will be answered.

But this is more of a hypothetical situation where they'll be given hypothetical that a pan flu is breaking out. And then we want to ask some questions like, “Who do you trust? Who do you want to hear information from; Government officials, your own doctor, the Internet, the newspaper, radio, TV and so on?”

And we want to use the information that we gain from that - those exercises to further and better craft our messages as the pubic health department. So we take this very seriously. And I'll stop and let others respond as well.

**Priscilla Keith**: Hi. This is Priscilla Keith from the Marion County Health Department. I agree with Priscilla Fox in terms of the State Department of Health. And I'd also like to say because our health department plays such an integral role in terms of public health here in Indianapolis, we take it upon ourselves to really try to educate the public about communicable diseases and particularly now with H1N1.

And that is why our outreach to different partners proved to work very well in terms of getting that information out, answering questions. And so we worked with many members in the Hispanic and other non-English speaking communities. We worked with our faith based groups. We worked with hospitals, community health centers because our community health centers are probably sometimes the front line.

And we just partnered very well with our State Department of Health. So it is incumbent upon your local and state health departments to really try to educate and get that information out to your community.

**Question cont’d**: And your Chambers of Commerce can help you by having the employers talk to the employees.

**Priscilla Keith**: Right. Absolutely.

**Question cont'd**: Right.

**Priscilla Keith**: I think Dr. Caine's emphasis has been and continues to be to work with the Chamber of Commerce and work with many of our employers to get that information to their employees. And we did exactly that in terms of distributing information on the signs and symptoms of H1N1 and how you could and how people could utilize the preventive measures.

And one of the other things that we also did in terms of working with our Marion County Superior Courts in terms of getting information to them about the signs and symptoms and preventive measures because of the large amount of people who enter that building on a daily basis. And so I do agree. Thank you.

**Coordinator**: Thank you.

**Question**: Fred Peterson, Hospital Council of Western Pennsylvania.

**Coordinator**: It's open.

**Question cont'd**: Good afternoon. Thank you all for a very straightforward presentation. To me as a non-attorney, I found this very useful. A question for Mr. Steve Gravely please. When you're talking about HIPAA and I believe back to EMTALA, you were very careful to use the phrase 'waiver of sanctions' not 'the law.'

What does that mean to me as a hospital administrator sort of in the middle of an event? I understand that you're saying when the declaration occurs there is a waiver of sanctions that I don't necessarily have to follow the specific items that are waived during the specific period.

But what happens when that window closes? Do I then have to worry about personal injury attorneys, for instance, who might look back at that and that I would be subject to some afterthought about what actions we took?

**Steven Gravely**: Great question Fred. The short answer is yes.

**Question cont'd**: Thanks.

**Steven Gravely**: There are two slides in the deck, one for HIPAA, one for EMTALA that talk about practical implications. But you picked up on it and that is that the laws remain in effect and what are waived, and this is all the Secretary has the authority to waive, are the sanctions for certain provisions which effectively mean those provision are waived for the duration of the event.

And, you know, it does matter - it does matter what type of event it is under the Pandemic and All-Hazards Preparedness Act. The Secretary was given some greater discretion for the duration of waivers in public health emergencies than would necessarily be automatically in effect although the Secretary can always extend the waivers.

So you get to the same place. But I think the take away message for everyone is that the laws themselves are not set aside. They don't disappear. There's simply relief and that's important but it's just you have to - you have to enter it with a mindset that I'm still covered by this law. I still have to comply with it even though I may have some relief on a limited basis.

**Question cont'd**: And may I follow with a question?

**Steven Gravely**: Sure.

**Question cont'd**: It's my understanding, please tell me if I'm wrong, that the date of the declaration of - or the date of the declaration may sometimes be retroactive. In other

words, the event starts on Monday. It takes them until Wednesday for the Federal government to catch up. But that they can retroactivate these waivers back to the beginning of the event. But I'm not comfortable with that during those two days until I hear. I'm not being very articulate. But can you help me with that?

**Steven Gravely**: Well yeah. I'll defer to Joseph for more clarification, but that's a basic precept under both Federal and state law that say whether it's the President and Stafford Act or the Secretary under the Public Health Emergency Declaration and this would also be true for Governors under state disaster laws.

They can generally make those declarations effective as of a date in time and it will - it will routinely precede the date on which the declaration is issued. And now since 9-11 I must say that we've gotten much quicker about issuing declarations which is a really positive thing.

But you're right. There's always a lag time. Sometimes among the states, you'll have verbal declarations. You don't see that as much with the Federal government. But you will in the states have verbal declarations that are then followed by written ones.

But yeah, they are retroactive. Now, you know, the dilemma I think is whether or not in fact you will have a declaration. You know, the two days you talked about...

**Question cont'd**: Yeah.

**Steven Gravely**: ...is a zone of ambiguity if you're not sure there's going to be a declaration. Now as a practical matter, I think that the government, both state and Federal government, have been fairly proactive in terms of issuing declarations. And so that's - maybe that's not a huge practical concern but, you know, it's a valid point, Fred.

**Question cont'd**: Thank you very much. I appreciate it.

**Question**: Bob Dempsey, the law firm of Robert E. Dempsey. My question is in regards to drug stockpiles and in regards to the development of criteria for the distributions for Governmental authorities of critical medications. What provisions are there for a public review of said rules and then either an administrative or judicial action to either clarify or challenge those rules?

**Woman**: I apologize. I think Joe Foster could answer that question but he had a prior commitment and he just stepped out. I will be happy to forward your question to him though and he can follow up with you later.

**Question cont'd**: That'd be fine. Thank you.

**Woman**: Thank you.

((Crosstalk))

**Coordinator**: ...is open.

**Question**: Yeah. Good afternoon. I want to thank you so much for sharing your proactive approach with us. I have two questions. One is there a Web site that we can go to to review those declarations for disclosure of information?

**Steven Gravely**: You may be referring to the waivers for HIPAA.

**Question cont'd**: Yes.

**Steven Gravely**: Yeah. Those are all on the HHS Web site.

**Question cont'd**: And do they give you the timeframes?

**Steven Gravely**: Yeah. I believe - yeah they do. I mean they go all the way back to Katrina. I think they're all on the Web site and most recent ones would involve some of the Midwest flooding. But they do have an effective date and so they should be helpful to you.

**Question cont'd**: My second question is about disclosure of information like during an emergency or disaster time when family member may be looking for another family member, is there a waiver to be able to disclose that information without having the authorization of that patient at least so a family member may be looking for?

**Steven Gravely**: That's a great question. And that really goes to the whole issue of family reunification. And there are - there are some family reunification provisions under HIPAA that do give - that do give covered entities some flexibility in that area.

And I tell you what, Alycia, I don't know if we can do this or not. There are a lot of - sounds like there are a lot of HIPAA and EMTALA questions. And there - I've got a couple of white papers that I would be more than happy to post if there's a way to do that. I'm happy to share those with folks. We're out of time here but obviously this is an area where there's a lot of concern. So we can talk about this offline but if it's possible, I am more than happy to put those out for the benefit of those who are on the call.

**Alycia Downs**: Yes. That would be possible if you could send them to coca@cdc.gov.

**Man**: Yeah.

**Alycia Downs**: Thank you so much.

**Priscilla Fox**: If I could jump in - this is Priscilla Fox. On the last question about family reunification, that's something we're working on in Massachusetts. And we are working with our Emergency Management Agency which under the law as we understand it and compliant with HIPAA, if there's a mass casualty incident for example, hospitals may

release information about named individuals being at their facility or not. And some basic information such as their condition and their name to an entity such as our Emergency Management Agency that has disaster responsibilities.

So we're right now looking into that issue and hoping that what will result is a letter from the state agencies to the hospitals alerting them that that is possible and that that is something they can do in future emergencies. And this actually arose out of a train accident that occurred a number of years ago and some of the family members were worried about trying to find their loved ones. And so this came up in a very real context.

But yes, I mean the short answer is yes. It can be done but it does take some pre-planning.

**Steven Gravely**: Well and just to put an exclamation point on that, you're right. We had this happen with Virginia Tech and they can - they can share the information but a lot of healthcare facilities are reluctant to.

And so what we've done in Virginia is we've actually gone the MOU route through the Department of Health and we've had some memorandum of understanding put together that gives the hospital a little more comfort in sharing that information. Because even though they're allowed to, in many cases they are reluctant to because they're not sure that they have the legal authority. And during disaster they have trouble reaching their legal counsel to get an opinion.

**Priscilla Fox**: Right. Right. Very good point.

**Question cont'd**: And part of my question is, during disasters you have a sibling bringing in a younger sibling for healthcare most the time, when schools are closed. And the disclosure of information at that point, couple of months later, couple of years later, when that information is to be disclosed, who is going to be - that is going to be able to give authorization for that minor patient?

**Man**: Yeah. That's a very fact specific question and I hate to dodge it but I just don't know that we can give you an answer that would answer that in every case. Because as you know, these are so fact specific; I'm actually going to suggest we can't really answer that in a fair way given the time that we have available.

**Question cont'd**: Thank you.

**Question**: Kathleen Marr, Collier County Health Department.

**Coordinator**: Your line is open.

**Question cont'd**: Hi. Thank you. My question is for Priscilla Fox. You had discussed pending legislation in Massachusetts regarding volunteers. Could you please define what you mean by expanded liability protection for volunteers?

**Priscilla Fox**: Well, what we have now in Massachusetts is really a patchwork of protection depending on the role that the volunteer is playing and whether for example Good Samaritan coverage could apply in an urgent emergency like an auto accident but perhaps not in a pandemic that lasts longer.

The Federal Volunteer Protection Act of course applies in certain circumstances all over the country. But the legislation that we have pending would provide liability protection under the State Tort Claims Act to any volunteer who is order or requested by a state or local employee to assist during a circumstance of a declared disaster or emergency.

We heard a lot of concerns from specifically MRC volunteers who are community based and were worrying about liability protection for themselves if they were called upon to volunteer in an emergency.

Actually the way the bill is worded is a little broader than a declared emergency. It's fairly complicated but declared emergency is one area where the Tort Claims Act would kick in. There are a few others as well.

For example, on the local level if there's a public health incident that demands an urgent response and if the Commission of Public Health agrees that the MRCs should be activated to deal with that then also liability protection would kick in under the State Tort Claims Act.

So it's a little bit complicated. If you want more information about it I suggest you could perhaps email CDC and they'll send the message on to me and I can have a greater dialog with you.

**Question cont'd**: Thank you.

**Question**: Marianne Horn, Department of Public Health in Connecticut.

Yes, hi. My question is for Priscilla Fox. And absolutely that was a wonderful conference up in Boston last week. Just great. I have a question for you on the clinical guidelines that you issued from in Massachusetts for dissenting Tamiflu and Relenza and whether those differed from the guidelines issued from CDC and if so if there were any concerns on the part of providers over any differences?

**Priscilla Fox**: I believe they were the same as CDC's guidelines. I would have to double check with our state epidemiologist about that. I don't think that they differed and I also have not heard of any concern on the part of providers about that. But I can double check for you and I think I have your email so I'll get back to you on that.

**Question cont'd**: Okay. Great. And I had a second quick question. The fact that there was not a public health emergency declared for the H1N1 which would have triggered

broad powers to the Commissioner of Public Health, did that cause you any difficulties in terms of responding to H1N1?

**Priscilla Fox**: Actually it didn't. That's a really good question. I think if we had felt that we needed that authority in order to do what we had to do then we would have - I mean probably the way it would have worked I'm assuming is that the Commission of Health would have talked to the Governor and explained why we thought we needed it. But no, we were lucky. We were not - or I guess in a way the whole country was lucky in that we didn't need massive isolation orders or quarantines or closing public transportation, things like that. So, no. We thought we did everything necessary without that declaration.

**Question cont'd**: Okay. Thank you.

**Priscilla Fox**: Sure.

**Question**: Robert Ball, South Carolina Department of Health.

Thank you all for the conference especially Steve who I am asking a question for, because Joseph is gone. Steve since this influenza virus currently and others seem to mutate faster than we can get around to issuing EUAs and declarations, then it is possible these emergency authorizations can be written to specify a variety of novel strains at least until the CDC HHS data disprove otherwise.

For example, Tamiflu sensitivity versus resistance of that uncertainty and has the FDA approved Tamiflu for the use of this new strain. That was one barrier. Or must we continue case by casing each of these new viral strains (after developing the UA)?

**Steven Gravely**: Well that's an excellent question and it - I'm sorry Joseph isn't here. The law is pretty constraining in terms of that particular provision. And I don't want to speak for the department. I think the law was written with the assumption that we would be able to identify strains more easily.

So, you know, I would expect that - some of the lessons learned from this would be perhaps some amendments to the statute and hopefully for the next one we'll have a little more lead time Robert.

**Question cont'd**: Amen. Thank you.

**Question**: Donna Levin, Massachusetts DPA.

**Coordinator**: Your line is open.

**Question cont'd**: Okay. Thanks. My question was for Priscilla Keith actually. I'm just curious that I think it was April 29 you held this meeting and it seems as if it was a corporal meeting. It wasn't by phone and you had 300 leaders. I'm wondering since we handled calls like that and I think up to 800 I think by conference call and it was so early relatively speaking for the outbreak in the state. Was anybody concerned about brining everyone together in that way?

**Priscilla Keith**: Was it expressed that we were acting too early?

**Question cont'd**: No, I mean to bring 300 leaders all in, you know, one auditorium. I'm wondering about - whether anybody thought about the wisdom of - and I realize there was social distance in going on anywhere else in terms of transportation. But it was the beginning of, you know, some school closings and we didn't know that much about the disease so I just - I'm just curious because in thinking about possibly the next round as soon as the fall.

**Priscilla Keith**: Right. You know, I think when we had that, when we brought everybody together and asked them to come, the invitation was extended to say, "Number one, we're having this meeting. Number two, here's what we're going to discuss. You're encouraged to really be there."

And there were no - we didn't twist arms but obviously because it's a novel virus in terms of people understanding what H1N1 was all about, questions people had about the process. No we didn't - that was not the reaction that we had at that time.

And in fact, it created partnerships that we didn't have at the time. And, you know, going forward in terms of trying to distribute information or working with various entities. I think it proved worthwhile. I do understand your question now in terms of, you know, at the next round, you know, will we get that type of participation?

**Question cont'd**: I guess my question is, would you want to? I would say it sounds like it obviously worked out but you're going to want to build on those partnerships now and for a more severe round.

**Priscilla Keith**: Right.

**Question cont'd**: You'd probably want to do it differently, yeah.

**Priscilla Keith**: Well I think the partnership - many of those people are our partners and I - you know, just going forward we think of it as sort of novel and continue to be in communication with our partners. So it's - I won't say it's never really well, we're just going to contact you this one time and then that's it. We tend to operate a bit more fluidly. But I do understand your comment.

**Question cont'd**: Okay. Thanks.

**Question**: Mary Casey-Lockyer, Northwest Community Hospital.

**Coordinator**: Mary, your line is open.

**Question cont'd**: Thank you. This is a question for Mr. Steve Gravely. Can you expand on exactly what FEMA will and will not cover in a public health emergency?

**Steven Gravely**: Yeah, but it will take about four hours. You know, what I would do is that is - that is just an immensely complex topic. And basically FEMA has issued a lot of guidance that would be helpful to you.

I would just recommend that you go to the FEMA Web site and they updated their emergency care policy, emergency medical care policy in July of 2008 in response to many of the issues and problems that the had with Katrina and Rita, they did an update and they broadened coverage in many areas. In several others, they didn't.

But I would look at that. I would also look at FEMA's pandemic influenza plan, which you'll find on their Web site and it gives you a pretty good overview.

The four things that I think you have to remember about FEMA reimbursement. One is, as I said, the payer of last resort. And so - and they take that very seriously. There's a very well known case out of Hawaii involving Hurricane Aniki in which FEMA litigated all the way up through the circuit to the Supreme Court actually fighting with the state of Hawaii about reimbursement for Hurricane Aniki based on insurance coverage.

So they are the payer of last resort and that has profound implications for healthcare providers obviously. The other three - the other three points really relate to their pandemic influenza plan and policy, which specifically says they do not - they do not consider definitive medical care to be an eligible cost.

And how that gets - how that gets interpreted is still not clear. But they do not consider definitive medical care to be an eligible cost. They do not consider follow up care to be an eligible cost. And they do not consider loss of revenue to be an eligible cost.

So when we think about pandemic influenza and we think about hospitals possibly stopping services or shifting the way services are provided perhaps in response to public health requests for surge capacity and other things, those aren't going to be reimbursable under FEMA.

They may be reimbursable under insurance but they're not going to be reimbursable under FEMA. And then FEMA has also clarified that they will not pay for preparation costs for surge capacity. They will pay for other preparation costs.

So it's very complex. Can't really do it justice. But I think those two resources will help you and, you know, you can follow up with me offline through COCA if you have some more specific question.

**Question cont'd**: Thank you.

**Steven Gravely**: Yeah.

**Alycia Downs**: Erin, we can take one more question.

**Coordinator**: Yes ma'am.

**Question**: Greg Stern, Whatcom County Health Department in Bellingham, Washington.

**Coordinator**: ...is open.

**Question cont'd**: Hi. Thanks. This is a question for Priscilla Fox and this is a follow up on some of the accountability for the strategic national stockpile antivirals. You mentioned that you'd get an agreement with a facility to have qualified person assure that they were following the health department guidelines for use.

And we have a situation where we're using a pharmacy based distribution where physicians - we're trying to get physicians to agree to follow the guidelines and set an accountability trail. And you mentioned that you had record keeping and I'm just wondering how much information does the health department collect on that use and how much auditing would be done - kind of what's involved in stewardship for that - for that asset and did you run up against any obstacles with the HIPAA privacy rule?

**Priscilla Fox**: That's a very good question. Those are all very good questions. And I don't have the answers off the top of my head. I think I'll have to check with people in our SNS program and also our epidemiologist. I think the record keeping as I recall - what we were asking them to do was actually relatively minor. Track the doses that were given and so keep a record of that and any adverse events that may have happened to a patient after receiving a dose.

But as far as following up on whether the people actually complied with our guidance, whether the clinicians complied with that, I can get back to you on that. Again I would suggest that you email through CDC and they can contact me and I can double check that and get an answer for you on that.

**Question cont'd**: Okay. Thanks.

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**Alycia Downs**: I'd like to thank all of our presenters for providing our listeners with this information. I'd also like to thank all of our participants for joining us today. I'd also like to apologize if anyone had trouble getting into the call. I think our lines were overwhelmed due to the popularity of this topic. So again I would like to thank our presenters for those very timely and popular presentations.

Now if you did have a question and weren't able to ask one, please send an email to coca@cdc.gov. If you know the person whom you would like to receive your inquiry, please put it to their attention.

The recording of this call and the transcript will be posted to the COCA Web site emergency.cdc.gov/coca when they become available. Thanks again for participating and I hope everyone has a wonderful day. Thank you.

**Coordinator**: We thank you for your participation. The conference has now ended. You may disconnect at this time.

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