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TO: **Iowa Department of Public Health**

FROM: **Heather Adams, Assistant Attorney General**

DATE: **October 28, 2009**

RE: **Public Readiness and Emergency Preparedness (PREP) Act for H1N1 Vaccination and Emergency Use Authorizations (EUAs) for H1N1 Countermeasures**

You have asked me to outline the relevant provisions of the PREP Act and recent EUAs as they relate to distribution and administration of the H1N1 vaccines and antivirals.

PREP ACT

The Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity from lawsuits to persons who manufacture, distribute, and administer covered vaccines. The PREP Act grants broad immunity protections to all persons in the H1N1 vaccine distribution chain; from those who manufacture the vaccine to the person who administers the vaccine.

In addition, the PREP Act grants immunity to healthcare providers who prescribe, administer, and dispense countermeasures -- including antivirals -- which are provided as part of an emergency response and either approved by the FDA or authorized under an Emergency Use Authorization (EUA).

I have included below a "frequently asked questions" document published by the United States Department of Health and Human Services which addresses many issues related to the PREP Act and H1N1 vaccine administration. In addition, I have added Iowa-specific information where relevant, and have addressed some additional questions which have arisen in this state. I have noted my additions as "IA AAG Addition" and in different font below.

Q1:	**What is the PREP Act?**
A1:	The Public Readiness and Emergency Preparedness Act or PREP Act is a federal law that authorizes the Secretary of Health and Human Services to issue a declaration to provide tort liability immunity (except for willful misconduct) to individuals and organizations involved in the development, manufacture, distribution, administration and use of countermeasures against pandemics, epidemics and diseases and health threats caused by chemical, biological, radiological, or nuclear agents of terrorism.
Q2:	**How does the PREP Act work?**
A2:	On June 15, 2009, Secretary of Health and Human Services Kathleen Sebelius extended the PREP Act declaration for pandemic vaccines to H1N1 vaccines, and amended the declaration to add provisions that can help H1N1vaccination campaigns. IA AAG addition: The purpose for issuing a PREP Act declaration is to provide immunity from tort liability; a PREP Act declaration is different and independent from other emergency or disaster declarations. The PREP Act also creates an emergency fund in the US Treasury to provide compensation for any injuries which are caused by administration of H1N1 vaccines. Other H1N1-Related Declarations: Iowa Public Health Disaster Declaration. In Iowa, Governor Culver issued a proclamation of disaster emergency and public health disaster related to the H1N1 outbreak on May 2, 2009. This proclamation has expired and the state of Iowa is not currently operating under a Governor-declared disaster proclamation. Federal Public Health Emergency. The Secretary of the US Department of Health and Human Services issued a public health emergency for H1N1 on April 26, 2009, which was renewed on July 24, 2009. This declaration authorizes the Food and Drug Administration (FDA) to issue emergency use authorizations (EUAs) for H1N1 countermeasures. In response to this declaration, the FDA has authorized emergency use of five medical products requested by the CDC, including the antiviral products Relenza and Tamiflu; certain types/models of N95 respirators; rRT-PCR Swine Flu Panel diagnostic test; and rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA) diagnostic test. Presidential Emergency Declaration. President Obama issued a National Emergency Declaration on October 23, 2009. This declaration authorizes the United States Department of Health and Human Services to waive certain regulatory requirements for healthcare facilities, including regulations related to Medicare, Medicaid, EMTALA, and HIPAA. Iowa facilities should submit requests for waivers or questions about whether they are eligible for waivers to the Iowa Department of Inspections and Appeals, Mary Spracklin, Bureau Chief, (515) 281-0286; email Mary.Spracklin@dia.iowa.gov.

Q3:	**What is tort liability immunity?**
A3:	Tort liability immunity means that no legal tort claim related to activities described in the declaration that can be pursued in State or U.S. Federal court. The declaration provides legal liability protections for individuals or entities that are involved in the distribution and administration of H1N1 vaccine.
Q4:	**Who is immune from tort liability under H1N1 vaccine declaration?**
A4:	The H1N1 vaccine declaration provides tort liability immunity to a group named "program planners." Program planners include State and local governments, Tribes, other entities that supervise or administer a vaccination program, establish requirements, provide policy guidance, supply technical or scientific advice or assistance, or provide a facility to administer the vaccine. Program planners can include private sector individuals and organizations, community groups, schools, or businesses. Government program planners only have tort liability immunity when the vaccines are provided to them voluntarily, such as when Federal Government provides vaccines from Federal stockpiles, or when the vaccines are donated or sold. The H1N1 vaccine declaration also provides tort liability immunity to a group named "qualified persons." Qualified persons include healthcare professionals or others authorized under State law to prescribe, administer, and dispense vaccines. IA AAG Addition: Under Iowa law, the following licensed/certified healthcare professionals are authorized to administer vaccines and hence would be considered "qualified persons" under the declaration: physicians; nurses, including LPNs, RNs, and ARNPs; physician assistants; EMT-paramedics and paramedic specialists (authorized to administer influenza vaccine only via written protocol from medical director); and pharmacists (authorized to administer influenza vaccine via prescription order or to adults via written protocol). The declaration also provides tort liability immunity to individuals or organizations that assist public officials with vaccination programs, even if they are not licensed healthcare professionals. Qualified persons also include individuals or organizations (including their officials, agents, employees, contractors and volunteers) that are part of the public health and medical emergency response of the "Authority Having Jurisdiction" for prescribing, administering, delivering, distributing, or dispensing the vaccine following a declaration of emergency issued by a federal, regional, State, or local official. The "Authority Having Jurisdiction" is the public agency or entity or its delegate with legal responsibility and authority to respond to the incident. These qualified persons can include any public or private person, entity, or organization – such as local businesses, community groups and volunteer groups -- and their officials, agents, employees, contractors and volunteers, assisting in carrying out vaccine programs under agreements, plans, protocols, procedures, policies or other arrangements with any State, local or other public agency or its delegate that has legal responsibility and authority for

	public health and medical response. The Acting HHS Secretary's April 26 declaration of nationwide public health emergency caused by H1N1, which was renewed by the HHS Secretary on July 24, can be used by "Authorities Having Jurisdiction" to begin their public health and medical response. The H1N1 vaccine declaration also provides tort liability immunity to the United States, to vaccine manufacturers, and vaccine distributors. Officials, agents, and employees of program planners, qualified persons, the United States, manufacturers, and distributors are also immune from tort liability.
Q5:	**Which vaccines are covered under the H1N1 vaccine declaration?**
A5:	All of the H1N1 vaccine procured by the Department of Health and Human Services and distributed to the states is covered by the declaration. Vaccines are covered only when they are administered and used as 1) licensed or approved by the Food and Drug Administration (FDA); 2) authorized for investigational use by the FDA; or 3) authorized under an Emergency Use Authorization (EUA) by the FDA. On September 15, 2008, the FDA approved four vaccines against H1N1 that are covered by the declaration.
Q6:	**What tort claims are prevented by the H1N1 vaccine declaration?**
A6:	The declaration prevents tort liability claims under U.S. Federal law and State law (except for willful misconduct) for losses caused by, arising out of, relating to, or resulting from administration or use by any individual of the vaccine, including any claim with a causal relationship to any stage of development, distribution, dispensing, prescribing, administration or use of the vaccine. Types of loss include death; physical, mental, or emotional injury, illness, disability or condition; fear of physical, mental, or emotional injury illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption. In addition, by defining "administration" to include "delivery, distribution, and dispensing activities… and management and operation of distribution and dispensing locations" the H1N1 vaccine declaration clarifies that "slip and fall" types of claims are also covered, not just injuries and illnesses arising from actually receiving the vaccine.
Q7:	**What types of claims are not prevented by the H1N1 vaccine declaration?**
A7:	The declaration does not prevent claims for willful misconduct. Willful misconduct is a term used in the PREP Act, and is beyond any standard of negligence or recklessness. Willful misconduct does not include acts or omissions by program planners and qualified persons who act consistently with the declarations, as long as they notify HHS

	or a State or local health authority within seven days of discovering any serious physical injury or death from the administration or use of the countermeasure. The declaration also does not prevent other types of claims, such as claims for negligence in providing medical care unrelated to vaccine administration and use, claims brought under foreign law, or claims for civil rights or labor law violations.
Q8:	**What compensation is available for vaccine injuries?**
A8:	The U.S. Department of Health and Human Services is establishing a Countermeasures Injury Compensation Program for H1N1 vaccines. Under this program, compensation may be available to eligible individuals who suffer serious physical injuries or death from administration of the vaccine under the declarations. Eligibility, and the types of injuries for which compensation may be available, will be defined by regulations. Compensation can include medical benefits, lost wages and death benefits.
Q9:	**Where can I go for more information?**
A9:	For a copy of the PREP Act declaration for H1N1 vaccines, please go to: http://edocket.access.gpo.gov/2009/E9-14948.htm. For more information about PREP Act liability protections, please go to http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html. For more information about PREP Act Countermeasure Injury Compensation Program, please go to http://www.hrsa.gov/countermeasurescomp/default.htm. For more information about the H1N1 vaccines approved by FDA, please go to http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm
Q10:	IA AAG addition: **Is HIPAA waived by the PREP act declaration?**
A10:	No, the provisions of HIPAA are unaffected by the PREP Act declaration. However, the recently issued Presidential Declaration of National Emergency authorizes the U.S. Department of Health and Human Services to waive sanctions and penalties arising from non-compliance with certain with HIPAA privacy provisions. Iowa facilities with questions about waiving HIPAA provisions should contact the Iowa Department of Inspections and Appeals, Mary Spracklin, Bureau Chief, (515) 281-0286; email Mary.Spracklin@dia.iowa.gov. In addition, regardless of whether a Presidential declaration is in place, the HIPAA privacy rule authorizes disclosure of patient information without authorization for treatment purposes and authorizes disclosures of patient

information without authorization to public health authorities, including state and local public health agencies. For example, HIPAA allows covered entities to share patient information without authorization with the Iowa Department of Public Health and local public health departments for public health activities, including preventing and controlling H1N1. (45 C.F.R. 164.512(b)(1)(i)).

EMERGENCY USE AUTHORIZATIONS

I have included below a "frequently asked questions" document published by the Food and Drug Administration which addresses many issues related to EUAs and H1N1 countermeasures. In addition, I have added Iowa-specific information where relevant, and have addressed some additional questions which have arisen in this state. I have noted my additions as "IA AAG Addition" in different font below:

Q1:	**What is an emergency use authorization?**
A1:	An Emergency Use Authorization (EUA) may be issued by the Food and Drug Administration (FDA) to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents. Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), amended by the Project BioShield Act of 2004, permits authorization of such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.
Q2:	**What is required before the FDA may issue an EUA?**
A2:	The Act requires that, before an emergency use may be authorized, the Secretary of the Department of Health and Human Services (HHS) must declare an emergency justifying the emergency use, based on one of the following grounds: 1. The Secretary of the Department of Homeland Security determines that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or 2. The Secretary of the Department of Defense determines that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

3. The HHS Secretary determines that there is a public health emergency under the Public Health Service Act (PHS Act) that affects, or has a significant potential to affect, national security, and involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Q3: On what basis may the FDA issue an EUA?

A3: Once the HHS Secretary has declared an emergency justifying the emergency use, the FDA Commissioner may authorize an emergency use only if, after consultation with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) (to the extent feasible and appropriate given the circumstances of the emergency), he determines that certain statutory criteria have been met. Specifically, the Commissioner must conclude, as follows:

1. That the agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;
2. That, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing—
   (a) The serious or life threatening disease or condition, or
   (b) A serious or life-threatening disease or condition caused by a product authorized under section 564, or approved, cleared, or licensed under the Act or PHS Act, for diagnosing, treating, or preventing the disease or condition referred to in paragraph (1) and caused by the agent specified in the declaration of emergency;
3. That the known and potential benefits of the product outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life threatening disease or condition that is the subject of the declaration; and
4. That there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life threatening disease or condition.

An EUA may remain in effect for the duration (one year) of the declaration justifying the emergency use unless revoked. Both the declaration of an emergency and EUAs issued under that declaration may be renewed if justified after a year. The law requires the FDA

to publish notice of each EUA in the Federal Register, each termination or revocation of an authorization, and an explanation of the reasons for the action.

Q4: Are there any limits on the use of an EUA product?

A4: For unapproved products, the law requires the FDA Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an EUA that the Commissioner finds necessary or appropriate to protect the public health, and permits the Commissioner to establish other conditions that he finds necessary or

appropriate to protect the public health. Such conditions may include a requirement to disseminate information to health care providers or authorized dispensers and prospective patients and other consumers regarding the EUA, the product's significant known and potential benefits and risks and the extent to which such benefits and risks are unknown; available alternatives and their benefits and risks; and, for prospective patients and consumers, the option to accept or refuse the product and any consequences of refusal. Other conditions may include adverse event reporting and monitoring, data collection and analysis, and recordkeeping and records access.

For unapproved uses of approved products, certain of these conditions and other conditions may be required in an EUA.

Use of a product under an authorization must be consistent with any conditions imposed on the EUA.

Q5: What is the PREP Act?

A5: **The PREP Act and EUAs**

The PREP Act authorizes the Secretary of the Department of Health and Human Services ("Secretary") to issue a declaration ("PREP Act declaration") that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or

resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from tort liability, and is different from, and not dependent on, other emergency declarations. The PREP Act also authorizes an emergency fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the Secretary's declaration. While no funds have been appropriated for this purpose, if funds are appropriated, compensation may then be available for medical benefits, lost wages and death benefits to individuals for specified injuries.

For more information on the PREP Act visit HHS: Public Readiness and Emergency Preparedness Act Questions and Answers.

Q6: What happens if the unapproved drugs or approved drugs for unapproved uses are distributed outside the scope of, or inconsistent with, the conditions of the EUA once it has been issued?

A6: If the FDA issues an EUA to allow for the lawful distribution or dispensing of products for emergency use under certain circumstances and states do not distribute or dispense the

countermeasures in accordance with the scope and conditions of the EUA, liability protections afforded by the PREP Act may be affected.

Q7: Are there EUAs currently in effect?

A7: **2009 H1N1 Countermeasures**

Yes. In response to the Secretary's declaration of public health emergency involving swine influenza A virus (novel H1N1 flu virus) on April 26, 2009, the FDA has authorized emergency use of important medical products under certain circumstances. FDA has issued EUAs on the 5 medical products CDC requested; FDA-issued EUAs allow for the emergency use of antiviral products (Relenza, Tamiflu), certain types/models of N95 respirators, rRT-PCR Swine Flu Panel diagnostic test, and rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA) diagnostic test.

For other medical products also currently FDA-authorized for use under EUAs (requested by non-CDC entities) in response to novel H1N1 flu (swine flu), please visit the FDA 2009 H1N1 Virus site and scroll down to the section entitled **FDA Regulated Products**.

Q8: Why are EUAs needed to distribute novel H1N1 flu countermeasures?

A8: While Tamiflu and Relenza have been previously approved by the FDA, certain aspects of the distribution and use of these products are not covered by their approved applications. An EUA allows these drugs to be legally distributed for the unapproved uses for which they are being authorized.

FDA has authorized emergency use of certain types/models of disposable N95 respirators by the general public during this declared emergency. These respirators may help to keep out germs that may be present in the air you breathe. Please see the N95 Respirators: EUA Summary Fact Sheet for additional information.

The rRT-PCR Swine Flu Panel and the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) diagnostic tests have not been approved or cleared by the FDA. An EUA allows these unapproved diagnostic kits to be legally distributed and used for the authorized purposes.

Q9: Will the EUAs cover novel H1N1 flu countermeasures not supplied by the Strategic National Stockpile?

A9: In addition to the countermeasures supplied by the Strategic National Stockpile, Tamiflu and Relenza that are supplied via state and local governments are also covered by the EUAs, if the terms and conditions of the EUAs are met.

IA AAG Addition: The IDPH has obtained the following additional guidance from the FDA regarding the use of Tamiflu and Relenza by private providers:

	The EUAs for Relenza and Tamiflu are not limited to Tamiflu and Relenza held in the Strategic National Stockpile. However, the EUAs are limited to Tamiflu and Relenza distributed under the authority of the Centers for Disease Control and Prevention (CDC) and/or the appropriate local state and local public health authorities, and impose conditions on CDC and the state and local public health authorities for doing so. To the extent that private entities are part of state and local emergency response plans for distributing drugs in an emergency in compliance with the terms and conditions contained in the EUAs, they would be covered by the EUAs. However, private entities simply distributing product outside of the emergency response plans of the [state and local public health departments] would not be within the scope of the EUAs. The EUA is justified by the Department of Health and Human Services declaration, so the state does not have to issue its own declaration in order to use an EUA within its response plans. That said, a doctor prescribing within the patient-doctor relationship would be acting under the state's practice of medicine laws. (email of 9/25/2009 from EUA.OCET@fda.hhs.gov)
Q10:	**Will the recipient and health care provider fact sheets be available in multiple language translations?**
A10:	**Fact Sheets** Currently, the EUAs do not include translated versions of fact sheets.
Q11:	**Will states be distributing their own state-developed fact sheets for novel H1N1 flu countermeasures deployed from the Strategic National Stockpile for use under an EUA?**
A11:	For the use of a countermeasure to be under an EUA, fact sheets as specifically authorized by the EUA will be distributed.
Q12:	**Will Project Areas need to plan to include information required under section 503(b)(2) of the Act on the label of the dispensed Tamiflu and Relenza?**
A12:	**Labels** No. The EUAs will permit that not all of the information required under section 503(b)(2) of the Act would appear on the label of the distributed Tamiflu and Relenza.
Q13:	**Where do I go to find information on adverse events (side effects) of the different novel H1N1 flu countermeasures?**
A13:	**Adverse Events** For information on recognizing adverse events (side effects) related with use of each medical countermeasure, please refer to the respective EUA Fact Sheets for that product. (Tamiflu, Relenza, N95)

Q14:	**How do I report adverse events from using Tamiflu, Relenza and N95 respirators?**
A14:	Health care professionals and consumers may report serious adverse events (side effects) with the use of these products or product quality problems to the FDA's MedWatch Adverse Event Reporting program: • Online: FDA's MedWatch Adverse Event Reporting program • Regular Mail: use postage-paid FDA form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 • Fax: (800) FDA-0178 • Phone: (800) FDA-1088