

Summary of Relevant Legal Issues

EXECUTIVE ORDER

On October 28, 2009, Governor Paterson issued Executive Order number 29 declaring a state disaster emergency and suspending certain provisions of state law to provide additional personnel and flexibility to local governments as they work to implement the statewide 2009 H1N1 influenza vaccination campaign. Among other things, the Executive Order allows an expanded number of trained health care personnel to legally administer flu vaccine in state and local health department sponsored flu vaccine programs or Points of Dispensing (PODs). Physician assistants, specialist assistants, dentists, dental hygienists who have been issued a special anesthesia/analgesia certificate, pharmacists without a certificate authorizing them to administer vaccinations, podiatrists, midwives, and advanced emergency medical technicians have been authorized to immunize people at these vaccine programs for 2009 H1N1 and seasonal influenza provided they first receive training approved by the Commissioner of Health, in consultation with the Commissioner of Education. The Executive Order also authorizes school-based health centers to vaccinate adults at the centers and allows hospitals to operate part-time immunization clinics on school campuses. A copy of the executive order is available at

http://www.nyhealth.gov/press/releases/2009/docs/executive_order_29.pdf.

The Public Readiness and Emergency Preparedness Act

The federal Public Readiness and Emergency Preparedness (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 related to the 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. This immunity extends to entities and individuals involved in the development, manufacturing, testing, distribution, administration, and use of such countermeasures. On June 15, 2009, the Secretary of Health and Human Services (HHS) issued a declaration extending the PREP Act’s liability protections to 2009 H1N1 influenza vaccine. Other 2009 H1N1-related declarations have also been issued (e.g., antivirals, influenza diagnostics, and certain respiratory protection and support devices) and can be found at the following website: <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>.

Immunity from tort liability means there is no legal tort claim that can be pursued in court, whether state or federal. Tort claims precluded by the PREP Act declaration for 2009 H1N1 vaccine include all claims (except for willful misconduct) under federal or state law 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; fear of such injury; or property damage or loss, including business interruption loss. 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 appears to include “slip and fall” types of claims, not just injuries arising from receiving the vaccine.

The PREP Act provides immunity to “covered persons,” which includes a “program planner.” Under the Act, a program planner means a State or local government, including an Indian Tribe; a person employed by the State or local government; or other person (such as a private sector employer or community group) who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance, or provides a facility to administer or use a covered countermeasure, in accordance with the Secretary’s declaration. Public health departments and schools administering 2009 H1N1 school-based vaccination clinic programs likely would be covered by the Act’s protections as “program planners.”

Immunity under the declaration for H1N1 vaccine is also extended to “qualified persons,” which includes:

1. a licensed health professional or other individual who is authorized to prescribe, administer, or dispense covered countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or
2. any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the vaccine, and their officials, agents, employees, contractors, and volunteers. The “Authority Having Jurisdiction” is the public agency or entity or its delegate with legal responsibility and authority to respond to the incident.

Immunity from liability is not available for death or serious physical injury caused by willful misconduct. The PREP Act also does not extend immunity to acts that occur outside the scope of the declaration or for violations of laws that are not tort claims, such as civil rights or labor laws.

The PREP Act also authorized a “Covered Countermeasures Process Fund” to provide compensation to eligible individuals who suffer specified injuries from administration or use of a countermeasure pursuant to the declaration. Any requests for compensation must be filed within one year of administration or use of the countermeasure. Requests would go to the Health Resources Services Administration (HRSA) Preparedness Countermeasures Injury Compensation Program (<http://www.hrsa.gov/countermeasurescomp/default.htm>). Compensation may be

available for medical benefits, lost wages, and death benefits to eligible individuals for specified injuries. Any compensation will be reduced by public or private insurance or worker's compensation available to the injured individual.

Local Government Immunity, Defense, and Indemnification

If there is a declared disaster emergency, New York State Executive Law § 26 provides that a chief executive or any elected or appointed county, city, town, or village official shall not be held responsible for acts or omissions of municipal employees, disaster preparedness forces, or civil defense forces performing disaster assistance. Depending on individual facts and circumstances, local executives, officers, and employees may also be able to raise a common law defense of governmental immunity. Under the doctrine of governmental immunity, public officers and employees may be immune from liability for injuries caused by discretionary actions, *i.e.* those acts that involve the exercise of reasoned judgment.

New York State Public Officers Law § 18 may provide defense and indemnification for officers and employees of public entities acting within the scope of their public employment duties. Public entities include (i) counties, cities, towns, villages, and any other political subdivisions or civil divisions of the state; (ii) a school district, board of cooperative educational services, or any other governmental entity or combination or association of governmental entities operating a public school, college, community college, or university; (iii) a public improvement or special district; (iv) a public authority, commission, agency, or public benefit corporation; or (v) any other separate corporate instrumentality or unity of government. The term "employee" includes any commissioner, member of a public board or commission, trustee, director, officer, employee, or volunteer expressly authorized to participate in a publicly sponsored volunteer program.

The provisions of Public Officers Law § 18 apply *only* to a public entity whose governing body has agreed by the adoption of local law, bylaw, resolution, rule, or regulation to confer the benefits of this section upon its employees and to be held liable for the costs incurred under these provisions. Unless otherwise provided by law, any duty to indemnify shall not arise where the injury or damage resulted from intentional wrongdoing or recklessness on the part of the employee.

Each county should individually assess the applicability of any available insurance coverage.

Family Educational Rights and Privacy Act (FERPA)

FERPA is the federal law, administered by the U.S. Department of Education, which protects the privacy of student education records, including health records, maintained by educational agencies and institutions. The law applies to all educational agencies

and institutions that receive funds under a program administered by the U.S. Department of Education. FERPA generally prohibits the disclosure, without prior written consent, of education records or personally identifiable information (PII) from education records to outside entities, although there are a number of exceptions to the requirement of prior written consent. (See: <http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html>).

The applicability of FERPA will vary based on who is conducting the school-located vaccination clinic as outlined below:

- If a public health department, or an entity acting on its behalf (e.g., a commercial community vaccinator with whom the public health department contracted), conducts the clinic and maintains the student's records, FERPA does not apply to the vaccination records because they are maintained by the public health department.
- If a school, school district, or an entity acting on its behalf (e.g., a commercial community vaccinator with whom the school or district contracted), conducts the clinic and maintains the student's records, FERPA applies to the vaccination records because they are maintained by the school or school district.
- If an entity, other than the public health department or the school/school district, conducts the clinic (e.g., a commercial community vaccinator not under a contract with the school or the public health department) and maintains the student's records, then FERPA does not apply to the vaccination records because they are not maintained by an educational institution or agency or a party acting for an educational institution or agency.

FERPA Applicability During 2009 H1N1 Activities

Under the FERPA regulations at 34 Code of Federal Regulations (C.F.R.) Part 99, many disclosures of PII from education records of students require signed and dated parental consent. However, when a student turns 18 years of age or attends an institution of postsecondary education, the signed and dated consent must be obtained from the student per 34 C.F.R. 99.3 (definition of "Eligible student") and 99.5. The FERPA regulations provide that the prior written consent must specify the records to be disclosed, the purpose of the disclosure, and the party or class of parties to whom the disclosure may be made per 34 C.F.R. 99.30. For example, in the absence of a health or safety emergency, a signed and dated consent is generally needed for a school to release PII from education records to public health authorities (e.g., for entry into an H1N1 immunization registry) or to the child's health care provider (e.g., for inclusion in the child's health care record).

Certain disclosures may be made without prior written consent per 34 C.F.R. 99.31. For example, a disclosure may be made without prior written consent to other school officials within the educational agency or institution whom the agency or institution has determined to have legitimate educational interests (e.g., school officials may be

informed that a student has the H1N1 virus and has been advised to stay at home; the disclosure is needed so that school officials can monitor whether that student nevertheless attends school or a school-related activity) per 34 C.F.R. 99.31(a)(1).

In addition, under 34 CFR 99.31(a)(10) and 99.36, an educational agency or institution may disclose without prior written consent PII from an education record to appropriate parties in connection with an emergency, if knowledge of the information is necessary to protect the health or safety of the student or other individuals. In making a determination

about whether the sharing of H1N1 information is appropriate under this provision, an educational agency or institution may take into account the totality of the circumstances pertaining to a threat to the health of a student or other individuals per 34 CFR 99.36(c). These circumstances may include, but are not limited to, the occurrence of H1N1 at the educational agency or institution, together with public health guidance about the threat posed by H1N1 and the Secretary of Health and Human Services' declaration of a public health emergency. If the educational agency or institution determines that there is an articulable and significant threat to the health or safety of a student or other individuals, it may disclose information from education records to any person whose knowledge of the information is necessary to protect the health of the student or other individuals. Id. If, in these circumstances, based on the information available at the time of the determination, there is a rational basis for the determination, the Department of Education will not substitute its judgment for that of the educational agency or institution in evaluating the circumstances and making its determination. Id. When an educational agency or institution discloses PII from an education record under the health or safety emergency exception, it must record both the articulable and significant threat to the health or safety of a student or other individuals that formed the basis for the disclosure and the parties to whom the educational agency or institution disclosed the information per 34 CFR 99.32(a) (5).

Examples of the types of situations in which the health or safety emergency exception to the general requirement of prior written consent may apply include the nonconsensual disclosure of PII from education records to a doctor if there is a student who suddenly becomes ill at school, needs emergency care, and the student's parents cannot be reached or to public health authorities, if a number of students at a school with H1N1 report severe illness to the school, and public health authorities seek to contact the students in order to investigate the virulence of the outbreak.

Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule requires entities covered by HIPAA to protect individuals' health records and other identifiable health information (known as "protected health information") by requiring appropriate safeguards to protect privacy and by setting limits and conditions on the uses and disclosures of such information without the individual's authorization. Covered entities may use or disclose protected health information only as the Privacy Rule specifically permits or requires, or if the individual who is the subject

of the information (or the individual's personal representative, such as the parent of a minor) signs a HIPAA-compliant authorization form. Additionally, HIPAA gives individuals rights to their protected health information, and requires covered entities to provide individuals with a Notice of Privacy Practices and train their workforce members, including volunteers, so that they understand privacy policies and procedures.

Entities subject to HIPAA (known as "covered entities") include: health plans, health care clearinghouses, and health care providers who electronically engage in certain

transactions with a health plan. Entities may determine whether they are covered by HIPAA by accessing the Department of Health and Human Services web tool at: <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/CoveredEntitycharts.pdf>

A health care provider, such as a physician practice, a hospital, or a public health department that provides health care, services, or supplies, covered by HIPAA, must comply with its current HIPAA policies and procedures for the use and disclosure of protected health information in its operation of a H1N1 vaccination clinic.

The HIPAA Privacy Rule permits covered entities to use or disclose an individual's protected health information without a signed HIPAA authorization for certain purposes as specified in the Rule. Generally, covered entities must limit their uses and disclosures of protected health information to the minimum necessary for the particular purposes.

Uses and disclosures permitted without the individual's authorization include uses and disclosures for:

- Treatment, payment, and health care operations: Covered entities may share patient information with others for treatment purposes. Treatment purposes include the provision, coordination, or management of health care and related services for an individual. For example, a covered entity may share an individual's immunization records with the individual's private physician for treatment purposes.
- Public health activities: Covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability, or for the conduct of public health surveillance, public health investigations, and public health interventions. For example, a covered entity may share an individual's immunization records with an immunization registry operated by a public health department. Additional information on public health activities may be found on OCR's website

(<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/publichealth/index.html>) and on CDC's web pages on Public Health and HIPAA Guidance (<http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm>).

If the use or disclosure of protected health information is not for treatment or public health activities or is not otherwise permitted under the HIPAA Privacy Rule, covered entities may use or disclose protected health information with the individual's (or his or her personal representative's) written authorization on a HIPAA-compliant authorization form. A HIPAA-compliant authorization may not be combined with a consent for treatment form. If an authorization is needed, covered entities may use their existing HIPAA-compliant authorization forms for the sharing of 2009 H1N1 vaccination information.

In most cases, the HIPAA Privacy Rule does not apply to elementary or secondary schools because the schools either: (1) are not HIPAA covered entities; or (2) are HIPAA covered entities, but maintain health information on students only in records that are by definition "education records" under FERPA and, therefore, are not subject to the HIPAA Privacy Rule. If a person or entity acting on behalf of a school subject to FERPA, such as a school nurse who provides services to students under contract with or otherwise under the direct control of the school, maintains student health records, these records are education records under FERPA, just as they would be if the school maintained the records directly.

However, FERPA only protects records that are held by schools or educational agencies that receive funding from the federal Department of Education. Most private schools at the elementary and secondary school levels typically do not receive funding from the U.S. Department of Education, are not subject to FERPA, and may be subject to the HIPAA Privacy Rule if they are covered entities. Additional information on the intersection of HIPAA and FERPA can be found at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf>

The above summary does not include all of the applicable requirements. The HIPAA Privacy Rule, at 45 CFR Parts 160 and 164, and the OCR website at <http://www.hhs.gov/ocr/privacy/> should be consulted.