



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

Office of General Counsel
Second Floor

Telephone (617) 624-5220

Fax (617) 624-5234

MEMORANDUM

To: Mary Clark, Director, Emergency Preparedness Bureau

From: Priscilla Fox
Deputy General Counsel

Cc: Donna Levin, General Counsel

Date: August 11, 2009

Re: Liability Protections for People Involved in H1N1 Vaccination Campaign

We have received questions from people and entities outside the Department, particularly from local health authorities, regarding what liability protection is available for people who will be involved in the H1N1 vaccination campaign this fall. Although we cannot provide legal advice to these groups, we can summarize the law as we understand it. This memo provides such a summary.

State Law

M.G.L. c. 112, § 12C provides that “No physician or nurse administering immunization or other protective programs under public health programs shall be liable in a civil suit for damages as a result of any act or omission on his part in carrying out his duties.” This statute provides complete immunity from liability for **physicians and nurses** who work in **government-funded** public health programs. However, it does not protect physicians and nurses who administer immunizations that are not part of a government program.

Federal Law

The federal Public Readiness and Emergency Preparedness Act, known as the PREP Act, was enacted in 2006. The operative provisions are found at 42 U.S.C. § 247d–6d. After an appropriate declaration is made by the Secretary of the U.S. Department of Health and Human Services (see below), the Act provides immunity from tort liability under state and federal law

for various categories of people and entities (“covered persons”) involved in various acts with respect to necessary medications, which are known as countermeasures.

The following covered persons and acts are protected:

- The United States
- Pharmaceutical manufacturers
- Pharmaceutical distributors (e.g. repackagers, common carriers, and retail pharmacies)
- “Program planners” (e.g. state and local governments and their employees, and businesses involved in planning for dispensing countermeasures). Program planners include people who establish program requirements; provide policy guidance; supply technical or scientific advice or assistance; or provide a facility for use in the program.
- “Qualified persons” who are authorized to prescribe, administer, or dispense the particular countermeasure under state law. These are licensed health care providers or any other individuals who are authorized to take these actions under state law.

Effective June 15, 2009, the Secretary of HHS published a PREP Act declaration covering vaccines for H1N1 flu. This declaration lasts until March 31, 2013. This means that people and entities in the categories above have immunity from liability for claims of negligence or gross negligence arising out of their participation in the H1N1 vaccination program. Willful misconduct (intentional wrongdoing) is not covered.

The immunity provided by the PREP Act is very broad. Under the terms of the Act, a covered person is immune from liability “with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d–6d (a)(1).

There is only one circumstance in which this broad immunity does not apply: when government authorities seize the countermeasure from the private sector. Under the terms of the HHS declaration (rather than under the Act itself), the immunity is only in effect for governmental program planners “to the extent they obtain covered countermeasures through voluntary means of distribution, such as (1) donation; (2) commercial sale; (3) deployment of covered countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained covered countermeasures from state, local, or private stockpiles.” In other words, if the state were to seize the vaccine from private stockpiles under emergency legal authority, there would be no immunity from liability under federal law if people were harmed through negligence in the course of the vaccination campaign.