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DATE: September 28, 2009

TO: Wisconsin Local Health Departments
Wisconsin Tribal Health Directors

FROM: Seth Foldy, MD, MPH, FAAFP
State Health Officer and Administrator
Wisconsin Division of Public Health

RE: Federal and State Liability Protection – H1N1 Vaccinations

This correspondence confirms that both federal and state liability protections are in place to cover Wisconsin local health departments, and federally recognized American Indian tribes or bands located in Wisconsin during activities to provide the H1N1 vaccine. These protections are designed to support and expedite your ongoing efforts to assure patient safety and protect the health and safety of your communities during this public health emergency.

These protections apply to the medical advisor signing the standing orders, and to recruited staff and volunteers (both licensed and unlicensed assistance personnel) with Wisconsin local and tribal health departments. Protections also apply to entities that provide equipment, materials, facilities, labor or services on a paid or free basis. To allay concerns about liability protection during H1N1 vaccination efforts, health officers and directors are urged to share and discuss this memo, along with the tables titled Federal Liability Protection and State Liability Protection, with their city and/or county executives, corporation or tribal counsel, and medical advisors. Please note that this is meant only as a general overview of the legal protections in place. Each law has its own conditions that must be met so you will need further consultation and advice from your counsel as to those specifics.

The authority for liability protection is anchored in federal and state statutes that include:

1. The Public Readiness and Emergency Preparedness Act, 42 USC 247d-6c. This is also known as the PREP Act.
2. The Federal Volunteer Protection Act, 42 USC 14501, et seq.
3. Wis. Stat. § 250.042 (4)
4. Wis. Stat. §§ 166.03(8) and 166.03(10)
5. Wis. Stat. § 251.07, that specifically covers volunteer medical advisors.

The legal protections vary between immunity (exemption from civil liability) and indemnification (generally this Department's assumption of responsibility to pay damages). We anticipate that the PREP Act will provide the best liability protection during your mass

vaccination activities. The Secretary of the U. S. Department of Health and Human Services has issued the necessary declaration to invoke the Act's immunity protections for the use and administration of the H1N1 vaccines. Unless misconduct is involved, the Act will provide tort immunity to you, your staff and agents as you plan and operate the mass vaccination clinics, and to qualified providers who dispense and administer the vaccination.

Wisconsin law also provides specific protections to:

- A broad array of health care volunteers who work under the authority of the local health officer or tribal health director;
- Persons and organizations that provide equipment, materials, facilities, labor or services, on a paid or free basis during a public health emergency;
- Employees and registered volunteers of state or local emergency management units who work under the direction of emergency management authorities;

Finally, to assure both patient safety and the coverage of liability protections, regulated health care professionals will be expected to uphold the provisions of their state licenses or certifications as issued by the Wisconsin Department of Regulation and Licensing or other certifying bodies.

In the coming days, the Department will issue a standing medical order for the administration of H1N1 live attenuated and inactivated vaccines and a companion procedure to assure safe supervision and delegation of that medical order by local health departments and American Indian tribal clinics.

The Department stands ready to assist you in any way possible. We congratulate you for your excellent leadership and service to the people of your community and the people of Wisconsin.

Thank you.

cc Karen Timberlake, Secretary, Wisconsin Department of Health Services
Bureau of Community Health Promotion and Control staff
Bureau Directors and Regional Office Directors and staff
Office of Tribal Affairs