



MAY 5, 2009

HEALTH ADVISORY

Antiviral Adverse Events Reporting

In response to the potential increase in antiviral use for treatment and prophylaxis of people affected by the current novel H1N1 influenza virus strain, the U.S. Centers for Disease Control and Prevention (CDC) will be working with the Food and Drug Administration (FDA) to evaluate adverse events associated with the use of antivirals. The North Dakota Department of Health encourages providers to report these adverse events through the regular FDA reporting mechanism.

Severe adverse events associated with the administration of antiviral medications used to prevent or treat influenza (e.g., those resulting in hospitalization or death) should be reported to MedWatch, the (FDA) Safety Information and Adverse Event Reporting Program, by calling 1.800.FDA.1088, by facsimile at 1.800.FDA.0178, or via the internet by sending Report Form 3500 (available at www.fda.gov/medwatch/safety/3500.pdf).

Unlike vaccine adverse events, adverse events associated with antivirals do not need to be reported to the North Dakota Department of Health (NDDoH).

For further information about influenza antiviral medications, including contraindications and adverse events, visit: www.cdc.gov/flu/professionals/antivirals/side-effects.htm or www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm.

For any questions or concerns about this issue, please contact the North Dakota Department of Health Division of Disease Control at 701.328.2378 or toll-free at 800.472.2180.

Categories of Health Alert messages:

- *Health Alert conveys the highest level of importance; warrants immediate action or attention.*
- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
- *Health Update provides updated information regarding an incident or situation; no immediate action necessary.*
- *Health Information provides general information that is not necessarily considered to be of an emergent nature.*

This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, and hospital public information officers.