Vaccine Redistribution

Under Section 503(c)(3)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a health care entity may redistribute or trade (or offer to do the same with) Influenza A (H1N1) 2009 Monovalent Vaccine to alleviate a shortage if there is a reasonable basis to conclude that a shortage of Influenza A (H1N1) 2009 Monovalent Vaccine exists or will actually occur. A "shortage" includes a temporary shortage arising from delays in or interruptions of regular distribution schedules. Health care entities that experience a shortage or have a reasonable basis to conclude that they will experience a shortage, which would constitute an "emergency medical reason" for redistributing Influenza A (H1N1) 2009 Monovalent Vaccine under section 503(c)(3)(B)(iv) of the FD&C Act, may obtain Influenza A (H1N1) 2009 Monovalent Vaccine from other health care entities to the extent necessary to alleviate or prevent the shortage.

Providers are encouraged to contact their local health departments if they find that they are unable to use the vaccine allocated to them. Local health departments may have knowledge of other vaccine providers in their area who are in need of vaccine and thus may be able to facilitate vaccine redistribution.

What are the restrictions for vaccine redistribution?

Vaccine providers may NOT redistribute the following:

- Partially used multi-dose vials.
- Syringes, which have been drawn up from multi-dose vials.

Vaccine providers may not redistribute vaccine to providers who do not have a H1N1 PIN #.

How do I transport the vaccine?

Appropriate cold-chain management must be followed to ensure the integrity of the vaccine. For more information on proper handling, storage, and shipping of vaccine, visit the Centers for Disease Control and Prevention website: www2a.cdc.gov/vaccines/ed/shtoolkit/.

What are the recordkeeping requirements?

When redistribution occurs, the vaccine provider that is redistributing H1N1influenza vaccine should document and maintain, at a minimum, the following information: vaccine brand name, manufacturer, distributor, lot number, number of doses transferred, and the recipient’s name and address.

What are the reporting requirements?

All vaccine redistribution **MUST** be reported to the NYSDOH using a Zoomerang survey: http://www.zoomerang.com/Survey/?p=WEB229T486T6ZP

The redistributing vaccine provider MUST report the following items on the survey noted above.

- Redistributing vaccine provider name, address, and H1N1 PIN#.
- County in which the redistributing and receiving vaccine providers practice.
- Receiving vaccine provider name, address, and H1N1 PIN#.
- Number of doses being transferred.
- Manufacturer and type of vaccine being transferred.
- National Drug Code (NDC) of vaccine being transferred.
- Lot Number of vaccine being transferred.
- Date of transfer.
- Process used to transfer vaccine (i.e. commercial shipper, personal vehicle, pick-up, etc.)
- If applicable, whether ancillary supplies were also redistributed {NOTE: Ancillary supplies (e.g., syringes for multi-dose vials), if required for vaccine administration, should be redistributed in conjunction with the vaccine}.

Please note: It is the responsibility of the **redistributing** vaccine provider to ensure that these steps are followed.