

Guidelines and Policies for Michigan Care Improvement Registry Influenza Vaccine Exchange Network

Introduction

The need for a centralized location where Michigan physicians, their staff, and Local Health Department (LHD) officials could share influenza vaccine inventory information was recognized after the influenza vaccine shortage of 2004-2005. In response, the Michigan Department of Community Health (MDCH) Division of Immunization and the Flu Advisory Board have developed an influenza vaccine exchange network on the Michigan Care Improvement Registry (MCIR).

The MCIR Influenza Vaccine Exchange Network (IVEN) can be used to:

- Post surplus or needed vaccine inventory
- Search for providers with surplus vaccine inventory or a vaccine need

Under Section 503(c)(3)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a health care entity may sell, purchase or trade (or offer to do the same with) influenza vaccine to alleviate a shortage if there is a reasonable basis to conclude that a shortage of influenza 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 vaccine under section 503(c)(3)(B)(iv) of the FD&C Act, may obtain influenza vaccine from other health care entities to the extent necessary to alleviate or prevent the shortage. Health care entities should keep in mind, however, that "emergency medical reasons" for redistributing influenza vaccine do not include "regular and systematic sales to licensed practitioners" (21 C.F.R. 203.3(m)). Such sales would include agreements that hospitals will resell influenza vaccine to doctors in pre-set amounts, even though those doctors neither received a communication from their distributors that their vaccine delivery will be delayed, nor have any other reason to believe that they will not receive the influenza vaccine they ordered on time.

When redistribution occurs, the hospital or health care entity that is redistributing influenza vaccine should document and maintain the following information:

- **vaccine brand name**
- **manufacturer and distributor**
- **lot number**
- **number of doses transferred**
- **recipient's name and address**

In any such redistribution, the influenza vaccine and its transfer must comply with the FDA's current good manufacturing requirements. Information on proper handling, storage, and shipping can be found at http://www.cdc.gov/nip/publications/vac_mgt_book.htm#flu

Please note that Vaccines for Children (VFC) influenza vaccine is NOT to be posted on IVEN. If you are a VFC provider who would like to re-allocate VFC influenza vaccine or are in need of additional VFC vaccine, please contact your local health department Immunization Program Coordinator.

Policies and Disclaimers

Disclaimer

The information in the MCIR Influenza Vaccine Exchange Network (IVEN) is made available as a public service. The inclusion of a physician, practice, or LHD does not constitute a recommendation or endorsement by the Michigan Department of Community Health. The Michigan Department of Community Health does not endorse the physicians, provider offices, LHDs, or vaccine manufacturers presented. It is the responsibility of the user to evaluate all information prior to use based on individual needs and standards.

About Postings

The Michigan Department of Community Health (MDCH) is not responsible for the availability of influenza vaccine or the content of the postings, nor do we endorse, warrant, or guarantee the inventory or information described or offered on the IVEN site.

As a condition for the use of IVEN the sale price of any influenza vaccine shall be no more than the original buyer's price. The consequence of price gouging, or other similar behavior, may constitute a "lack of good moral character", in violation of MCL 333.16221(b)(vi) and therefore may have consequences for a healthcare professional's license.

Liability Disclaimer

The Michigan Department of Community Health does not warrant or assume any legal liability or responsibility for the accuracy, completeness, or usefulness of any information or products disclosed on IVEN postings.

If vaccine is shipped, the shipper assumes liability for the shipped product. Pick-up is encouraged to avoid problems in transit.

By participating in the MI Influenza Exchange Network on MCIR you agree to abide by these guidelines, policies, and procedures.

Frequently Asked Questions (FAQ's)

Who will have access to IVEN on MCIR?

Anyone who has access to MCIR will be able to use IVEN.

What types of information will be posted on IVEN?

End-users of vaccine will have their contact information and their influenza vaccine posted on the IVEN section of the MCIR website.

How is vaccine requested?

To request influenza vaccine, IVEN users are directed to contact the individual who posted the surplus inventory *by phone*. The person who posted the surplus is under no obligation to provide vaccine if requested, however.

How much does vaccine cost?

It is required of all users of IVEN that the price of any excess influenza vaccine offered for sale is reasonable, *i.e.*, no more than the original buyer's price. Price gouging, or other such behavior, constitutes a "lack of good moral character" and is in violation of MCL 333.16221(b)(vi); consequences for a licensee are, therefore, possible.

How do I pay for / get paid for my vaccine?

The buyer and seller should make their own arrangements.

How is vaccine shipped?

We recommend that individuals locate a nearby practice from which to purchase vaccine to avoid problems in shipment. If that is not possible, links to instructions for proper storage and shipping of TIV and LAIV influenza vaccine, as well as a vaccine shipment inventory worksheet, and temperature logs are available on the MCIR IVEN Screen. Many of these resources were taken from the Alliance for Immunization in Michigan (AIM) Toolkit. **Appropriate shipping procedures are the responsibility of the shipper.**

Can I request vaccine from MDCH?

No. MDCH provides administrative support for IVEN and information on the handling and storage of influenza vaccine, but the accuracy of the information posted is entirely the responsibility of discussion board users.

Can I use IVEN for VFC vaccine?

No. **Vaccines for Children (VFC) influenza vaccine should not be posted on IVEN.** If you are a VFC provider who would like to re-allocate VFC influenza vaccine or are in need of additional VFC vaccine, please contact your local health department Immunization Program Coordinator.