



SECTION VI: IMMUNIZATION

VI1. The local health department shall offer immunization services to the public.

References: Omnibus Reconciliation Act of 1993, section 1928 and Part IV- Immunizations, Sec. 13631

2003 Vaccines for Children (VFC) Operations Manual

PA 368 of 1978, 333.9203

1.1 The LHD shall offer vaccine to the public for protection in case of an epidemic or threatened epidemic of a disease as ordered by the director.

This indicator may be met by:

- a. The LHD shows evidence of public health preparedness for vaccine preventable disease outbreaks including, but not limited to, pandemic influenza, smallpox, and SARS.

Documentation Required:

- Demonstrate that your public health preparedness plans includes a section on vaccine preventable disease outbreaks.

Evaluation Question:

- How does the LHD show ability to respond to a vaccine preventable disease outbreak?

1.2 LHD conducts free periodic immunization clinics for children residing in its jurisdiction.

This indicator may be met by:

- a. The LHD advertises immunization clinic hours within the community.



- b. The LHD screens for VFC eligibility when making immunization appointments for children.
- c. The LHD does not charge eligible clients for VFC vaccine.
- d. The LHD is a VFC provider.

Documentation Required:

- Documentation of all walk-in and appointment based clinic hours showing availability to meet the public demand
- Review of LHD VFC profile
- Review of protocol for charging and billing private vaccine

Evaluation Questions:

- How does the LHD screen for VFC eligibility?
- How are clinic hours publicized?

- 1.3** The local health department shall utilize an immunization policy and procedure manual that includes but is not limited to, the *Standards for Pediatric and Adolescent Immunization Practice* and *Standards for Adult Immunization Practice* to assure that all children, adolescents, and adults are appropriately vaccinated according to the Recommended Schedule.

This indicator may be met by:

- a. Scheduled appointments, if applicable, should be timely and not cause delays in vaccination.
- b. Strategies to assure children and adults within the community are vaccinated
- c. Vaccinations are coordinated with other healthcare services being provided at the health department.
- d. Barriers to vaccination should be defined and minimized at the local health department.



- e. Fee schedules should not exceed the maximum set through the federal VFC program.
- f. Administration fees should be waived for individuals who do not have the ability to pay for vaccines.
- g. Clients cannot be charged for the cost of vaccines purchased using federal or state funds.
- h. Immunization educational / promotional materials should be available in waiting rooms at each clinic site.
- i. Publicly purchased vaccine should only be used for eligible children and adults according to guidelines distributed by the Immunization Division.
- j. Proper counseling of persons receiving vaccines should be performed explaining immunization risks and benefits including the distribution of the VIS.
- k. Only true contraindications should be used when vaccinating individuals.
- l. All required fields for vaccination must be properly documented.
- m. The Immunization Manual should be available in each immunization clinic showing current standing orders and emergency treatment orders for vaccination.
- n. Show evidence of patient-oriented and community-based approaches to increase immunization levels within the health jurisdiction, (e.g., use of community data/demographics, client surveys, foreign language materials as appropriate for community, etc.).
- o. An orientation guide that ensures immunization staff has been properly trained and updated on immunization practices
- p. Clients seeking healthcare services at a local health department should be assessed at every encounter to determine which vaccines are indicated.
- q. Local health department staff should simultaneously administer as many indicated vaccine doses as possible.



Documentation Required:

- Review scheduled appointments if applicable and determine delay in scheduling of clients.
- Review fee schedule.
- Review immunization educational / promotional materials in waiting rooms at site.
- Review LHD immunization screening tool.
- Review LHD pamphlets explaining immunization risk benefits including VIS.
- Review current guide to contraindications used within the clinic.
- Review 10 charts from each clinic site to assure all needed immunization documentation is correct.
- One complete Immunization Manual available (standing orders and emergency treatment orders) at each immunization clinic site.
- Show evidence of patient-oriented and community-based approaches (e.g., use of community data/demographics, client surveys, foreign language materials as appropriate for community, etc.)
- Review PHN immunization orientation plan to assure immunization staff have been properly trained.
- See evidence of any staff training regarding current immunization practices/standards during past year.

Evaluation Questions:

- Notification posted to let clients know that immunization fees can be waived?
 Yes No
- Do LHD programs screen and refer clients to the immunization



clinic or private provider?

Yes No

- Does the LHD have a referral system if problems arise after a client receives vaccine?

Yes No

- Do local health department clinics only follow true contraindications (i.e., Guide to Contraindications to Vaccinations – September 2003 or most current if updated by CDC)?

Yes No

- Does the clinic administer all needed vaccines simultaneously?

Yes No

- Does the clinic co-schedule immunization appointments in conjunction with appointments for other child health services?

Yes No

- Are vaccines handled appropriately in the clinic setting (between main storage and administration)?

Yes No

- 1.4** The local health department shows evidence that the LHD recalls children not up to date for vaccines to promote age-appropriate immunizations.

This indicator may be met by:

- a. Maintains on file the number of reminder or recall notices sent monthly and details which methods were used (cards, letters, phone calls, other methods of outreach).
- b. Maintains on file documentation of collaboration with private providers to promote/implement a recall system.



Documentation Required:

- The local health department shows evidence that the LHD recalls children not up to date for vaccines to promote age-appropriate immunizations.
- Review three client records that have that have been tracked through that system.
- Documentation of a system to work with private providers to promote reminder/recall activities.

Evaluation Questions:

- Documentation of the number of reminder or recall notices sent monthly and details which methods were used (cards, letters, phone calls, other methods of outreach).

Yes No

- Maintains on file documentation of collaboration with private providers to promote/implement a recall system.

Yes No



VI2. The local health department shall be an active participant and user of the Michigan Childhood Immunization Registry (MCIR).

Administrative Rule 325.164 (4.2)

Reference: Public Act 368 of 1978

CPBC Provision

Public Act 540 of 1996

Administrative Rule 325.163, § 5

Administrative Rule 333.2433 (2b, 2d)

2.1 The local health department shall sustain an immunization level in the MCIR of at least 70% or an improvement of at least 15 percentage points for the last three years for children who are 19 through 35 months of age for four (4) doses of DTaP vaccine; three (3) doses of polio vaccine; one (1) dose of MMR vaccine; three (3) doses of Hib vaccine (or complete series); three (3) doses of hepatitis B vaccine; and one (1) dose of varicella vaccine (or documented immunity).

This indicator may be met by:

- a. Provide MCIR county profile reports for all counties within the jurisdiction which show completion rates at or above 70% or show an increase of 15 percentage points or more for the past 3 years for the 4:3:1:3:3:1 series and review profile report at the time of the accreditation review.

Documentation Required:

- Report using the MCIR, the number and percent of children who have received four (4) doses of DTaP vaccine; three (3) doses of polio vaccine; one (1) dose of MMR vaccine; three (3) doses of Hib vaccine (or complete series); three (3) doses of hepatitis B vaccine; and one (1) dose of varicella vaccine (or documented immunity), (4:3:1:3:3:1 series) at the time of the accreditation review.



- Written protocol included in the Immunization Manual to maintain an immunization level of 70% or more for the 4:3:1:3:3:1 series in the MCIR for children aged 19 through 35 months
- Written strategy within the Immunization Manual to identify immunization pockets of need within the jurisdiction

Evaluation Questions:

- Has the local health department reached at least a seventy percent (70%) level for children 19 through 35 months of age within the local health department's jurisdiction as recorded in the MCIR? Those children assessed shall have received four (4) doses of DTaP vaccine; three (3) doses of polio vaccine; one (1) dose of MMR vaccine; three (3) doses of Hib vaccine (or complete series); three (3) doses of hepatitis B vaccine; and one (1) dose of varicella vaccine (or documented immunity) 4:3:1:3:3:1 series.

Yes No

OR

- Did the MCIR county profile reports show an increase of at least 15% for the 4:3:1:3:3:1 series since the last accreditation visit?

Yes No

- Did the health department have MCIR county profile reports for all counties within their jurisdiction?

Yes No

- 2.2** The local health department shall submit immunization data to the MCIR according to the statutory time lines.

This indicator may be met by:

- a. There is evidence that 75% of the immunization data submitted to the MCIR and administered by the local health department is submitted within 72 hours. **Reference: Administrative Rule 325.163, § 5**



Documentation Required:

- MCIR reports for 90 consecutive days prior to the review showing at least 75% of the MCIR data entered within 72 hours

Evaluation Question:

- Were 75% of immunizations administered entered into MCIR within 72 hours?

Yes No

- 2.3** Local Health Department will provide written notice to individuals receiving a vaccination that the immunization data will be added to the registry. This is commonly done using the Michigan version of the Vaccine Information Statement (VIS).

This indicator may be met by:

- a. The LHDs use VIS forms that include MCIR language.

Documentation Required:

- None

Evaluation Question:

- Does the LHD use the version of the VIS that contains the MCIR statement allowing for an individual to opt out of the MCIR?

Yes No



VI3. The LHD shall comply with federal requirements in the VFC Operations Manual.

References: Immunization Program Operations Manual (IPOM), 2.1, 2.2

Omnibus Reconciliation Act of 1993, section 1928 and Part IV-Immunizations, Sec. 13631

2003 Vaccines for Children (VFC) Operations Manual

3.1 The local health department shall assure adequate storage and handling of vaccines that it administers and distributes. (Immunization Program Operations Manual, 2.1 AND Omnibus Reconciliation Act of 1993)

This indicator may be met by:

- a. The local health department has appropriate equipment and monitoring devices to safely store vaccine at each of its clinic sites.
- b. The local health department can demonstrate that all staff responsible for storage and handling of vaccines are familiar with and have access to the most current CDC storage and handling guidelines and other guidelines, information and policies related to storage and handling that are provided by MDCH.
- c. The local health department has procedures in place to assure appropriate storage of vaccines and demonstrates these procedures.
- d. The local health department uses appropriate storage and handling methods in the ordering of vaccines and the transport of vaccines to off-site clinics and to other providers.

Documentation Required:

- Plug guards or other mechanisms to prevent unwanted disconnection from the power supply for each refrigerator and freezer used to store vaccine and a 'DO NOT DISCONNECT' warning which is visible at the outlet and circuit breaker used for each unit
- Vaccine orders by the local health department for the past 3 years



- Vaccine orders by private providers since the last accreditation review
- Written policies and procedures for the safe storage of vaccines at each LHD clinic site where vaccine is stored and these policies and procedures readily available to all staff involved in vaccine storage and handling
- Written emergency procedure within the Immunization Manual for responding to vaccine storage problems that is easily accessible to all staff responsible for handling vaccines
- A file containing the name and location of an adequate back-up storage site and the written agreement updated annually stating that the site will serve as back-up for vaccine storage
- The past 90 days of temperatures logs, monitored and recorded twice daily for each of the units used to store vaccine. All monitoring devices should be calibrated with a certified thermometer on a weekly basis and documented as such on the temperature logs.
- Written policy within the Immunization Manual requiring the use of coolers and appropriate coolant when transporting vaccine
- CDC Vaccine Management Guide available to all staff
- Check of sensaphone/alarm, check current status/settings, and visually check that sensaphone is plugged into phone line and power supply with battery backup or that the alarm system is operational.

Evaluation Questions:

- Does the local health department have adequate equipment to store varicella vaccine at all of its clinical sites where vaccine is routinely administered?

Yes No



- Does the local health department have adequate equipment to store refrigerated vaccines at its own facilities' clinical sites?
 Yes No

- Does each refrigerator/freezer have a thermometer, recording thermometer, and, for each unit used in the routine storage of vaccines which exceed \$1,000 in total value per unit, an alarm system in place and operational?
 Yes No

- Is there evidence that the vaccine storage and handling procedures have been reviewed at least annually?
 Yes No

- Is there evidence that the emergency procedure has been reviewed since the last accreditation?
 Yes No

- Does the local health department routinely order vaccine more than once each month?
 Yes No

- Does the local health department have vaccine storage and handling written procedures and staff training plans on file that is consistent with the most recent CDC storage and handling guidelines?
 Yes No

- Does the local health department have the current CDC Vaccine Management Guide in view and at all vaccine storage sites?
 Yes No

- Inspection of vaccine storage equipment and vaccines demonstrates that the local health department complies with CDC storage and handling guidelines.



Yes No

- Is there documentation that the temperatures are monitored twice per day and calibrated at least once per week in all vaccine storage units?

Yes No

- Are all temperature monitoring devices calibrated with a certified thermometer at least weekly?

Yes No

- Are thermometers reconciled if the reviewer's thermometer does not match the LHD certified thermometer?

Yes No

- There are no accident reports attributable to negligence on the part of the LHD filed, without satisfactory resolution of the problem, for any of its sites since its last accreditation review. All vaccine loss reports within the health jurisdiction must be reported according to MDCH procedures.

Yes No

- The local health department monitors vaccine orders from private providers to assure proper transport of the vaccine and the ordering of reasonable amounts of vaccine for the practice.

Yes No

- Do a sample of provider vaccine ordering patterns show consistency with provider profiles?

Yes No

- Coolers and coolants are in place and operational for transport of vaccines.

Yes No



- Is the vaccine monitoring system functional and a review of the settings of the system shows the ability to notify personnel in case of a vaccine management emergency.

Yes No

3.2 The local health department shall assure that all requirements for participation in vaccine programs (including VFC and other vaccine distribution programs) are met. **Reference: Vaccines for Children Operations Guidelines, IPOM 2.2**

This indicator may be met by:

- a. The local health department sends the Michigan Department of Community Health a VFC provider enrollment form and profile form for the agency for each participating health care provider, including each community/migrant/rural health center in its jurisdiction, no later than February 15 of each year.
- b. The local health department estimates their annual vaccine needs for all participating providers in the vaccine programs on the provider profile form.
- c. The local health department completes the Michigan Department of Community Health vaccine dose reporting forms and vaccine inventory forms and collects these forms from all participating health care providers participating in the vaccine distribution programs. On a monthly basis the local health department sends summarized data for the agency.
- d. The local health department will adhere to ACIP recommendations published in the *MMWR*, ACIP/VFC resolutions, and guidelines to contraindications for pediatric and adult immunizations.
- e. The local health department maintains on file a sample of written informational material provided to private providers regarding requirements for the VFC Programs during the enrollment process.
- f. The local health department will perform VFC site visits to VFC providers in its jurisdiction, according to minimum and maximum standards formulated by MDCH.



- g. The local health department documents and reports to MDCH appropriate follow-up to corrective action plans (CPAs) resulting from VFC site visits.
- h. The local health department assesses each child's eligibility for the VFC Program.

Documentation Required:

- Documentation of VFC site visits completed for the past 3 years beginning in 2005 with all CPAs addressed. LHDs will visit at least 20 VFC providers' sites each year and jurisdictions with 20 or fewer providers should visit at least 80% of their sites each year. The city of Detroit is expected to visit 100% of their providers annually using Provider Service Representatives (PSRs).
- Written protocols or procedures in the Immunization Manual used to assure each child's eligibility for the VFC Programs
- Documentation that biologic reports and doses administered reports submitted by the 15th of each month
- Copies of the VFC provider enrollment form and provider profile form for the agency and for each participating health care provider, including each community/migrant/rural health center, in its jurisdiction submitted by February 15th of each year
- Documentation of the methodology used to estimate vaccine needs for the jurisdiction
- ACIP recommendations published in the *MMWR*, ACIP/VFC resolutions, and guidelines to contraindications for pediatric and adult immunizations are included in the standing orders, and are current.
- Evidence of standing orders for immunizations reviewed and signed annually
- Procedures for assessing client eligibility for all vaccine programs
- Review provider enrollment packet for the VFC program.



- LHD billing shows that VFC eligible children are not billed more than the maximum amount allowed by Centers for Medicare & Medicaid Services CMS.
- The LHD ensures that 25% of VFC providers have an AFIX visit.
- Review of 10 immunization records from prior clinic at each site

Evaluation Questions:

- The LHD completes the MDCH vaccine dose reporting forms and vaccine inventory forms and collects these forms from all participating health care providers. Biologic reports and doses administered reports are reported on schedule 75% of the time (9 out of 12 months).

Yes No

- Does the local health department have a procedure to assess for eligibility for vaccine programs?

Yes No

- Current standing orders reviewed and signed by the medical director annually and accessible within each immunization clinic?

Yes No

- The local health department documents VFC site visits to private provider offices for the purpose of determining private provider compliance with relevant vaccine program requirements. The number of visits will be consistent with the Michigan Department of Community Health VFC Program guidelines. All site visits and CPAs are complete and accurate.

Yes No

- The LHD is assessing 100% of clients for VFC eligibility and vaccine programs?

Yes No



- Is the LHD profile consistent with the amount of vaccine ordered?

Yes

No



VI4. The local health department complies with vaccine safety recommendations.

Reference: VAERS: PL 99-660, The National Childhood Vaccine Injury Act of 1986

Federal Register (42 USC § 300aa-25, 42 USC§ 300aa-26)

4.1 The local health department vaccine programs conform to VAERS program requirements.

This indicator may be met by:

a. The LHD maintains on file written VAERS policies, procedures, and reports complying with program requirements.

Documentation Required:

- VAERS written policy
- Review VAERS reports filed in the last three years.

Evaluation Question:

- Is there proper documentation on all VAERS reports that have been submitted?

Yes No

4.2 The local health department provides the appropriate Vaccine Information Statement (VIS) to every client or parent/guardian prior to administering vaccines and provides supplies of these statements to all private providers.

This indicator may be met by:

a. The LHD distributes VIS to all clients receiving vaccine at the clinic.

b. There is a protocol to distribute and update Vaccine Information Statements (VIS) to private providers.



Documentation Required:

- All VIS dates are current.

Evaluation Questions:

- All local health departments' vaccine administration records indicate the revision date of Vaccine Information Statement.

Yes No

- Is the LHD using the most current VIS for all vaccines?

Yes No

- VIS are given to every patient with every vaccination.

Yes No



VI5. The local health department uses the combined MCIR and School Immunization Record-keeping System (SIRS) (MCIR/SIRS) web-based program to track immunization levels of childcare center enrollees and school children.

Reference: PH code 333.9208, 9209, 9211, 9212, 9215, 9221

5.1 The local health department uses the MCIR/SIRS reporting web-based program to assure complete and accurate school entrants and sixth grade children data has been submitted by December 15 and March 15 of each school year.

This indicator may be met by:

- a. The local health department will assure complete and accurate school immunization data for all schools in the jurisdiction have been reported December 15 and March 15 of each year to MDCH.

Documentation Required:

- Written procedures that detail the methods for reviewing school immunization data
- Review of IP-100 and IP-101 forms or data within the MCIR/SIRS system
- Documentation showing timely submission of complete and accurate school data by December 15 and March 15 of each year

Evaluation Questions:

- The local health department has evidence of follow-up mechanisms for non-compliant schools and school entrants.

Yes

No



- The LHD submits accurate data by December 15 and March 15 of each year to MDCH using the SIRS/MCIR web application.

Yes No

- 5.2** The local health department will assure complete and accurate child care reporting for child care center immunization data by February 1 each year to MDCH.

Reference: PH code 333.9208

This indicator may be met by:

- a. The local health department will assure complete and accurate child care immunization data has been reported by February 1st of each year to MDCH.

Documentation Required:

- Written procedures, which detail the methods for reviewing child care immunization data
- Review of IP-100 and IP-101 forms or data within the MCIR/SIRS system
- Documentation showing timely submission of complete and accurate child care data by February 1 of each year

Evaluation Questions:

- The local health department has evidence of follow-up mechanisms for non-compliant child care centers and enrollees.

Yes No

- The LHD submits accurate data by February 1st of each year to MDCH using the MCIR/SIRS web application.

Yes No



VI6. Develop a comprehensive immunization plan to assure full immunization of all citizens living in the program area.

Reference: PA 333.2433 (1)

WIC Policy Memorandum #2001

CDC Program Operations Manual

6.1 The local health department uses the IAP mechanism to improve immunization rates, assure convenient, accessible clinic hours, coordinate immunization services, provide educational and technical services, and develop private and public partnerships.

This indicator may be met by:

- a. The LHD submits semi annual Immunization Action Plan (IAP) reports on April 15th and October 15th of each year.
- b. The LHD submits an annual IAP plan by December 31st of each year.
- c. At least one representative from each local health department will attend the IAP meetings held twice a year.

Documentation Required:

- IAP reports submitted for the last 3 years
- IAP plan submitted for the last 3 years (starting in 2003)

Evaluation Questions:

- Did at least one representative from each local health department attend each of the bi-annual IAP meetings?

Yes

No



- Did the LHD submit all IAP reports in the last 3 years by April 15th and October 15th?

Yes No

- Did the LHD submit an annual IAP plan on or before December 31st of each for the last 3 years?

Yes No

6.2 The local health department shall coordinate WIC and immunization services.

**Reference: USDA Memorandum (WIC Policy Memorandum #2001),
Immunization Screening and Referral in WIC**

This indicator may be met by:

- a. The local health department shows evidence of coordination of WIC and immunization services in an effort to increase the immunization levels of children seen in WIC clinics.

Documentation Required:

- Review WIC written procedures and see evidence of plan in process.

Evaluation Questions:

- Does the local health department actively use the WIC/MCIR report to help track and follow-up on children attending WIC clinics with incomplete immunization records?

Yes No

- Do the WIC and Immunization programs coordinate services in order to assure all children have complete immunization records?

Yes No



- Does the WIC clinic staff assess every child using the MCIR for complete immunization records?
 Yes No

- Does the WIC clinic staff vaccinate on site or refer to an immunization clinic if a child is found incomplete for one or more immunizations at every visit?
 Yes No