Immunization Laws

Laws help improve immunization rates

This section covers federal and state laws designed to ensure that people are protected against vaccine-preventable diseases.

Overview of this section:
Laws, Rules, and Regulations

Who to Call
Centers for Disease Control and Prevention
800-232-4636

Minnesota Immunization Program
For Minnesota specific issues (e.g. Minnesota school law)
800-657-3970
651-201-5503
This section provides an overview of specific laws, rules, and regulations that direct certain aspects of an immunization program.

The National Childhood Vaccine Injury Act / National Vaccine Injury Compensation Program
Section 2125 of the Public Health Service Act (42 U.S.C. Sec. 300aa-26)

In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA). NCVIA was enacted in response to growing lawsuits against vaccine manufacturers who subsequently chose to leave the vaccine manufacturing business. The intent of NCVIA was to establish a program for informing vaccinees of rare risks of adverse events following vaccination and create a no-fault program for compensation for vaccines routinely recommended to children. The no-fault program is intended to reduce vaccine manufacturers' liability when persons have experienced an adverse event after receiving a nationally recommended vaccine.

There are three components to NCVIA, each with its own requirements.
Under NCVIA health care providers are legally required to:
1. **Provide risk-benefit information**
   - Provide federal Vaccine Information Statements (VISs) to patients or their parents/guardians for each vaccination including each dose in a multi-dose series (see Screening and Assessing on page 53).

2. **Adverse event reporting**
   - Report adverse reactions to vaccines by submitting a Vaccine Adverse Events Reporting System (VAERS) report for certain adverse events following vaccination (see Vaccine Administration on page 147).

3. **National Vaccine Injury Compensation Program (VICP)**
   - Record required information about the vaccine(s) administered in the patient’s medical record (see Documenting Shots on page 181).

Vaccines covered by NCVIA include:
- All vaccines or toxoids routinely recommended by the ACIP for children and adolescents and either purchased privately or supplied through government programs (e.g., MnVFC), including:
  - Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, and TT)
  - *Haemophilus influenzae*, type b (Hib)
  - Hepatitis A (HepA)
  - Hepatitis B (HepB)
  - Human papillomavirus (HPV)
  - Influenza (TIV, LAIV)
  - Measles, mumps, rubella (MMR)
  - Meningococcal (MCV, MPSV)
  - Polio (OPV or IPV)
  - Pneumococcal conjugate (PCV)
  - Rotavirus (RV)
  - Varicella (VAR)
  - Any combination of the vaccines above
  - Additional vaccines may be added in the future

For more information, see the VICP website at www.hrsa.gov/vaccinecompensation.

Adults are also covered under VICP if they received any of the NCVIA-covered vaccines.
Vaccines for Children (VFC)
_Omnibus Budget Reconciliation Act of 1993_

VFC is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. All vaccines recommended by the ACIP and approved by CDC and HHS are covered under the VFC Program at no cost to the participating health care provider. You don’t have to be a Medicaid provider to participate in VFC. Any health care provider authorized to prescribe vaccines under state law can be a VFC provider.

Provider requirements of the law:
- Provide the vaccine only to eligible children
- Charge only the allowable fees, set by law, for administering VFC vaccine
- Waive any administration fee for VFC vaccine if a patient is unable to pay
- Not charge a patient for the cost of vaccine if they receive a VFC vaccine

For more information, see the federal VFC program website at www.cdc.gov/vaccines/programs/vfc/default.htm.

Minnesota Vaccines for Children (MnVFC)
_Minnesota Statutes, Section 256B.0625 (subd. 39)_

MnVFC is Minnesota’s version of the federal Vaccines for Children (VFC) program which works to make vaccine accessible and affordable for all children. It is run by the Immunization Program at the Minnesota Department of Health.

By Minnesota law, clinics must enroll in MnVFC if they administer vaccines to children who are in a Minnesota Health Care Program (MHCP) including Medical Assistance (MA), MinnesotaCare, or a Prepaid Medical Assistance Program (PMAP).

For more information, see the MnVFC website and the MnVFC Policy and Procedure Manual at www.health.state.mn.us/vfc.

Minnesota’s Child Care and School Immunization Law
_Minnesota Statutes, Section 121A.15 (elementary or secondary school) Minnesota Statutes, Section 135A.14 (post-secondary schools and colleges)_

Minnesota’s School Immunization Law states that in order for a student to enroll or remain enrolled in any licensed child care, elementary, secondary, post-secondary school or college in Minnesota the parent/guardian must file a statement with the child care or school administrator showing the student has received the recommended immunizations or has a legal exemption for medical or conscientious reasons.

For more information, see Provider’s Quick Reference on Minnesota’s Immunization Laws on page 133 and the MDH immunization laws website at www.health.state.mn.us/divs/idepc/immunize/laws/index.html.
Sharing Immunization Data in Minnesota

Minnesota Statutes, Chapter 144.3351

This Minnesota law allows health care providers, group purchasers of health care services, child care facilities, schools and colleges, public health agencies, community action agencies, and the commissioner of health to share immunization information without the consent of the individual who was vaccinated or their parent/guardian if the person requesting the information provides services on behalf of the patient.

Intent of the law:
- To facilitate meeting immunization requirements in order to enroll in child care facilities, schools, and colleges.
- To avoid under- or over-immunization by allowing easier access to information on vaccination histories.

Who may share immunization information?
- Elementary and secondary schools, child care facilities, colleges, public health agencies, community action agencies, the state commissioner of health, health care facilities, home care providers, physicians, surgeons, osteopaths, chiropractors, registered nurses, licensed practical nurses, midwives, optometrists, physical therapists, psychologists, social workers, mental health workers, dentists, pharmacists, and podiatrists.
  (Note: federal law supersedes state law in the case of schools sharing immunization information, see The Family Educational Rights and Privacy Act on page 210.)
- Group purchasers (a person or organization that purchases health care services on behalf of an identified group of persons) including: HMOs, self-funded health plans, health insurance companies, Community Integrated Service Networks.

Information that may be shared
- Patient's name, address, date of birth, gender, parent or guardian's name
- Date vaccine was received, vaccine type, lot number, and manufacturer
- Contraindication and/or adverse reaction to an immunization

How does this law apply to MIIC?
Because immunization records in MIIC are protected by the Minnesota Immunization Data Sharing Law, only people who can see them or use them are those who:
- Give immunizations, or
- Provide services on behalf of the patient.

Opting out of MIIC
By law an individual may decide at any time to opt out of MIIC. Requests to opt can be made either verbally or in writing to the MIIC regional coordinator. Anyone who decides to opt out may elect to participate at a later time. There is no penalty for opting out of MIIC.

For more information, see the MIIC website at www.health.state.mn.us/divs/idepc/immunize/registry/index.html.
Developing Immunization Materials

*Minnesota Statutes, Chapter 121A.15 (subd. 3a)*

This Minnesota law applies to any written information given to parents/guardians about immunization requirements, including exemption information for enrollment in child care or school. Specifically, the information about exemptions must be in the same font size and style and on the same page as the immunization requirements. Parents must also be given a copy of the Vaccine Information Statement (this is also required by federal law).

Signed Consent to Vaccinate

*Minnesota Statutes, Chapter 144.341*

No federal law requires signed consent for vaccination; however, Minnesota law requires parental consent for medical care of a minor, including vaccination. Minnesota’s law does not stipulate how to obtain consent, and many clinics ask for the patient’s/parent’s signature. Be familiar with your facility’s policy on consent and do it the same way every time.

Exceptions

*Minnesota Statutes, Chapter 144.341, 144.342, 144.343, 144.344*

Minors do not need parental consent if:

- They want to receive a hepatitis B vaccine. (The intent of this provision of the law is to give teens quick and easy access to the vaccine that prevents hepatitis B virus infection.)
- They are a minor living separate and apart from parents or legal guardian, whether with or without the consent of a parent or guardian and regardless of the duration of such separate residence, and who are managing personal financial affairs
- They have been married or have borne a child
- The risk to the minor’s life or health is of such a nature in the professional’s judgment that treatment should be given without delay and obtaining parental consent would result in delay or denial of treatment

Professional Responsibilities Defined by Minnesota Law

Some professions, such as physicians, nurses, and pharmacists, have specific responsibilities defined by state rules and regulations (also known as “practice acts”). The intent is to both make sure persons holding a professional license are competent to practice and to ensure the safety, health, and welfare of the public. See the table *Immunization Related Professional Responsibilities* on page 209. While it doesn’t include all immunization-related responsibilities, it may help you think about who is legally allowed to perform them.

More on the scope of practice by profession:

- MD, PA: Minnesota Board of Medical Practice
  www.bmp.state.mn.us
- APRN, RN, LPN: Minnesota Board of Nursing
  www.nursingboard.state.mn.us
- RPh: Minnesota Board of Pharmacy
  www.phcybrd.state.mn.us
- MA: Minnesota Society of Medical Assistants
  www.mnsma.org
Immunization Related Professional Responsibilities

<table>
<thead>
<tr>
<th>Profession</th>
<th>Authorize purchase of vaccines</th>
<th>Write prescriptions</th>
<th>Delegation of duties</th>
<th>Assess patient for needed vaccines</th>
<th>Screen for contraindications and precautions</th>
<th>Administer vaccine</th>
<th>Document vaccination</th>
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</tbody>
</table>

¹ MD, PA, APRN, and RN are allowed within their established practice acts to delegate duties/responsibilities to qualified and trained staff as appropriate.

² Pharmacists can assess and administer influenza vaccine for persons age 10 years and older and assess and administer other vaccines to persons age 18 years and older under an MD’s order.

³ Can perform if delegated by a MD, PA, APRN, or RN.

Immunizations Required for Immigrants and Refugees

Section 212(a)(1) of the Immigration and Nationality Act

All refugees and immigrants applying to change their immigration status (commonly referred to as their green cards) must show proof of age-appropriate immunizations. The information on the U.S. Citizenship and Immigration Services (USCIS) form I-693 may be completed by any public or private provider and then must be signed by a designated U.S. civil surgeon. USCIS allows physicians affiliated with public health departments to act as civil surgeons when signing the I-693 for refugees who did not arrive in the U.S. with a Class A condition (e.g., active or infectious tuberculosis, leprosy).

For more information, see CDC’s Immigrant and Refugee Health website at www.cdc.gov/immigrantrefugeehealth/index.html.
Laws, Rules, and Regulations

HIPAA

*Health Insurance Portability and Accountability Act (HIPAA) of 1996*

*Code of Federal Regulations, 45 CFR 164.502*

*Minnesota Statutes, 121A.15, 144.3341, and 245A and Minnesota Rules Parts 4604 and 9502-9503*

HIPAA governs the use and disclosure of protected health information (PHI) and allows providers to share immunization data with child care and schools. It applies to health plans, health care clearinghouses, and health care providers that transmit certain health-claims information electronically. These entities must obtain written authorization from the individual in order to use and disclose PHI – unless the disclosure is to the individual themselves – for treatment, payment, health care operations, or the disclosure falls under one of the specified exceptions. One of the exceptions permits a covered entity to disclose PHI to a public health authority that is authorized by law, “to collect or receive such information for the purposes of preventing or controlling disease. . . and public health interventions.”

The Minnesota Department of Health believes that under HIPAA rules, a school or licensed child care provider is considered a “public health authority” for the purpose of enforcement of the School Immunization Law. Therefore, since Minnesota schools and child care providers are responsible for documentation and enforcement of the School Immunization Law, which is a public health matter, providers can share immunization data to schools and child care providers without patient authorization.

For more information, see the HIPAA and Immunization website at [www.health.state.mn.us/divs/idepc/immunize/hipaa.html](http://www.health.state.mn.us/divs/idepc/immunize/hipaa.html) or the U.S. Department of Health and Human Services Health Information Privacy website at [www.hhs.gov/ocr/privacy/](http://www.hhs.gov/ocr/privacy/).

The Family Educational Rights and Privacy Act

*Code of Federal Regulations, 34 CFR Part 99*

The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of student education records. FERPA does not allow schools to share immunization or other health data with anyone outside the school without patient or parent/guardian consent, this includes health care providers. This federal law overrides the Minnesota law that allows schools, health care providers, and selected others to share immunization data, see *Sharing Immunization Data in Minnesota* on page 207. If a health care provider is seeking immunization data on a patient from the school, they must get consent from the patient or their parent/guardian.

Bloodborne Pathogens and Needlestick Prevention


Minnesota Statutes, Section 182.6555

Federal and state OSHA regulations require needle-shielding syringes or needle-free injectors with engineered injury protection to eliminate or minimize employee exposure to blood borne pathogens. These regulations require all clinical settings to use safer injection devices for parenteral vaccination when such devices are appropriate, commercially available, and effective to achieve the intended clinical purpose.

The rules also require that providers keep records documenting the incidence of injuries caused by medical sharps (except in workplaces with 10 or fewer employees), and that non-managerial employees be involved in the evaluation and selection of safer devices to reduce the risk of such injuries. A variety of such devices are available and all providers should use them.

While the use of gloves is not required when administering injections, it is recommended for protection against bloodborne pathogens. For more information on the use of gloves, see Vaccine Administration, Practice needle safety and infection control on page 152 or OSHA’s website at: www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21010#Gloves.