

BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 37.51.102, 37.51.306,) PROPOSED AMENDMENT AND
37.95.102, 37.95.140, 37.95.160,) REPEAL
37.95.184, and the repeal of ARM)
37.51.307 pertaining to revisions in)
immunization requirements for)
attendance in child care facilities and)
in foster homes)

TO: All Concerned Persons

1. On December 4, 2017, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, at Helena, Montana, to consider the proposed amendment and repeal of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on November 24, 2017, to advise us of the nature of the accommodation that you need. Please contact Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.51.102 YOUTH FOSTER HOMES: DEFINITIONS The following definitions apply to youth foster home licensing rules:

(1) "ACIP" means the Advisory Committee on Immunization Practices of the U.S. Public Health Service.

(1) remains the same, but is renumbered (2).

(3) "DT vaccine" means a vaccine containing a combination of diphtheria and tetanus toxoids for pediatric use.

(4) "DTP vaccine" means a vaccine containing diphtheria and tetanus toxoids and pertussis (whooping cough) vaccine combined, including a vaccine referred to as DTaP, diphtheria, tetanus toxoid, and acellular pertussis vaccine combined.

(2) through (4) remain the same, but are renumbered (5) through (7).

(8) "MMR vaccine" means a live virus vaccine containing a combination of measles, mumps, and rubella vaccine.

(9) "PCV vaccine" means a vaccine containing pneumococcal conjugate vaccine.

(5) through (7) remain the same, but are renumbered (10) through (12).

(13) "Td vaccine" means a booster vaccine containing a combination of tetanus and diphtheria toxoids.

(14) "Tdap vaccine" means a booster vaccine containing a combination tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine.

AUTH: 52-1-103, 52-2-111, 52-2-601, 52-2-621, 52-2-622, MCA

IMP: 52-1-103, 52-2-102, 52-2-111, 52-2-112, 52-2-113, 52-2-115, 52-2-601, 52-2-603, 52-2-621, 52-2-622, MCA

37.51.306 YOUTH FOSTER HOMES: PRESCHOOL AGE CHILD IMMUNIZATION REQUIREMENTS (1) All children residing in the foster home other than the foster child under five years of age shall be immunized against measles, rubella, mumps, poliomyelitis, diphtheria, pertussis, tetanus, varicella, hepatitis B, pneumococcal, and Haemophilus influenza type B according to the following schedule:

Total Immunizations Required, By Age

<u>Age</u>	<u>Number Doses - Vaccine Type</u>
under 2 months old	no vaccinations required
by 3 months of age	1 dose of polio vaccine 1 dose of DTP vaccine 1 dose of Hib vaccine <u>1 dose of Hep B vaccine</u> <u>1 dose of PCV vaccine</u>
by 5 months of age	2 doses of polio vaccine 2 doses of DTP vaccine 2 doses of Hib vaccine <u>2 doses of Hep B vaccine</u> <u>2 doses of PCV vaccine</u>
by 7 months of age	2 doses of polio vaccine 3 doses of DTP vaccine *2 or 3 doses of Hib vaccine <u>2 doses of Hep B vaccine</u> <u>3 doses of PCV vaccine</u>
by 16 months of age	2 doses of polio vaccine 3 doses of DTP vaccine <u>1 dose of varicella vaccine</u> 1 dose of MMR vaccine, administered ne

	earlier than 12 months of age *1 3 or 4 doses of Hib vaccine given after 12 or 15 months of age <u>2 doses of Hep B vaccine</u> <u>*4 doses of PCV vaccine</u>
by 19 months of age	1 dose of varicella vaccine 3 doses of polio vaccine 4 doses of DTP vaccine 1 dose of <u>MMR vaccine</u> , administered no earlier than 12 months of age *1 3 or 4 doses of Hib vaccine given after 12 or 15 months of age <u>3 doses of Hep B vaccine</u> <u>*4 doses of PCV vaccine</u>
<u>By 6 years of age</u>	<u>3 doses of polio vaccine, one given after the 4th birthday</u> <u>4 doses of DTP vaccine, one given after the 4th birthday</u> <u>2 doses of varicella vaccine</u> <u>2 doses of MMR vaccine</u> <u>3 doses of Hep B vaccine</u>
<u>By 11 years of age</u>	<u>3 doses of polio vaccine, one given after the 4th birthday</u> <u>1 dose of Tdap vaccine</u> <u>2 doses of varicella vaccine</u> <u>2 doses of MMR vaccine</u> <u>3 doses of Hep B vaccine</u>

(*) varies depending on vaccine type used or the ACIP catch-up schedule.

~~(2) If the child is at least 12 months old but less than 60 months of age and has not received any Hib vaccine, the child must receive a dose.~~

~~(3) Documentation of each required vaccination must include the date of birth and the month, day, and year of each vaccination.~~

~~(4) (2) Hib and PCV vaccines is are not required or recommended for children five years of age and older.~~

~~(5) (3) Doses of MMR and varicella vaccines, to be acceptable under this rule, must be given no earlier than 12 months of age. A child who received a dose prior to 12 months of age must be revaccinated; however, vaccine doses given up to four days before the minimum interval or age are counted as valid. Live vaccines not administered at the same visit must be separated by at least four weeks.~~

~~(4) Vaccines immunizing against diphtheria, pertussis, and tetanus must be administered as follows:~~

(a) a child less than seven years of age must be administered four or more doses of DTP or DTaP vaccine, at least one dose of which must be given after the fourth birthday;

(b) DT vaccine administered to a child less than seven years of age is acceptable for purposes of this rule only if accompanied by a medical exemption meeting the requirements of ARM 37.114.715 that exempt the child from pertussis vaccination; and

(c) a child seven years old or older who has not completed the requirement in (1) must receive additional doses of Tdap vaccine or Td vaccine to become current in accordance with the ACIP schedule.

(5) Immunization history may be recorded on the certificate of immunization form (HES-101) provided by the department or on a physician- or clinic-provided immunization record, which must include:

(a) the name of the physician or clinic;

(b) the name and birth date of the child; and

(c) the date and type of immunization.

(6) The immunization information is to be kept on file in both the foster home and the licensing file.

(7) A child residing in the foster home other than the foster child is not required to have any immunizations which are medically contraindicated. A written and signed statement from a physician that an immunization otherwise required by (1) of this rule is medically contraindicated will exempt a child from those immunization requirements as deemed necessary by the physician. It is preferred, but not mandatory, that a physician's medical exemption be recorded on HES-101, and medical exemption documentation must include:

(a) which specific immunization is contraindicated;

(b) the period of time during which the immunization is contraindicated;

(c) the reasons for the medical contraindication; and

(d) when deemed necessary by a physician, the results of immunity testing.

The tests must indicate serological evidence of immunity and must be performed by a CLIA approved lab.

AUTH: 52-1-103, 52-2-111, 52-2-601, 52-2-621, 52-2-622, MCA

IMP: 52-1-103, 52-2-111, 52-2-601, 52-2-621, 52-2-622, 52-2-735, MCA

37.95.102 DEFINITIONS (1) "ACIP" means the Advisory Committee on Immunization Practices of the U.S. Public Health Service.

(1) through (15) remain the same, but are renumbered (2) through (16).

(17) "Hep B vaccine" means a vaccine containing Hepatitis B vaccine.

(16) through (25) remain the same, but are renumbered (18) through (27).

(28) "PCV vaccine" means a vaccine containing pneumococcal conjugate vaccine.

(26) through (53) remain the same, but are renumbered (29) through (56).

AUTH: 52-2-704, 53-4-212, 53-4-503, MCA

IMP: 52-2-702, 52-2-703, 52-2-704, 52-2-713, 52-2-723, 52-2-725, 52-2-731, 52-2-735, 52-2-736, 53-2-201, 53-4-211, 53-4-212, 53-4-601, 53-4-611, 53-4-612, MCA

37.95.140 IMMUNIZATION (1) Before a child ~~under the age of five~~ may attend a Montana day care facility, that facility must be provided with the documentation required by ~~(4)~~ (5) that the child has been immunized as required for the child's age group against measles, rubella, mumps, poliomyelitis, diphtheria, pertussis (whooping cough), tetanus, varicella, hepatitis B, pneumococcal, and Haemophilus influenza type B, unless the child qualifies for conditional attendance in accordance with ~~(9)~~ (7):

<u>Age at Entry</u>	<u>Number of Doses-Vaccine Type</u>
under 2 months old	no vaccinations required
by 3 months of age	1 dose of polio vaccine 1 dose of DTP vaccine 1 dose of Hib vaccine <u>1 dose of Hep B vaccine</u> <u>1 dose of PCV vaccine</u>
by 5 months of age	2 doses of polio vaccine 2 doses of DTP vaccine 2 doses of Hib vaccine <u>2 doses of Hep B vaccine</u> <u>2 doses of PCV vaccine</u>
by 7 months of age	2 doses of polio vaccine 3 doses of DTP vaccine *2 or 3 doses of Hib vaccine <u>2 doses of Hep B vaccine</u> <u>3 doses of PCV vaccine</u>
by 16 months of age	2 doses of polio vaccine 3 doses of DTP vaccine <u>1 dose of varicella vaccine</u> 1 dose of MMR vaccine administered no earlier than 12 months of age *4 <u>3 or 4 doses</u> of Hib vaccine given after 12 or 15 months of age <u>2 doses of Hep B vaccine</u> <u>*4 doses of PCV vaccine</u>
by 19 months of age	1 dose of varicella vaccine 3 doses of polio vaccine 4 doses of DTP vaccine 1 dose of MMR vaccine administered no earlier than 12 months of age

*4 3 or 4 doses of Hib vaccine given after 12 or 15 months of age
3 doses of Hep B vaccine
*4 doses of PCV vaccine

By 6 years of age

3 doses of polio vaccine, one given after the 4th birthday
4 doses of DTP vaccine, one given after the 4th birthday
2 doses of varicella vaccine
2 doses of MMR vaccine
3 doses of Hep B vaccine

By 11 years of age

3 doses of polio vaccine, one given after the 4th birthday
1 dose of Tdap vaccine
2 doses of varicella vaccine
2 doses of MMR vaccine
3 doses of Hep B vaccine

(*) varies depending on vaccine type used or the ACIP catch up schedule.

~~(2) If the child is at least 12 months old but not less than 60 months of age and has not received any Hib vaccine, the child must receive a dose prior to entry. Hib and PCV vaccines are not required or recommended for children five years of age and older.~~

~~(3) DT vaccine administered to a child less than seven years of age is acceptable for purposes of this rule only if accompanied by a medical exemption meeting the requirements of ARM 37.114.715 that exempts the child from pertussis vaccination. Doses of MMR and varicella vaccines, to be acceptable under this rule, must be given no earlier than 12 months of age and a child who received a dose prior to 12 months of age must be revaccinated; however, vaccine doses given up to four days before the minimum interval or age are counted as valid. Live vaccines not administered at the same visit must be separated by at least four weeks.~~

~~(4) Before a child between the ages of five and 12 may attend a day care facility providing care to school aged children, that facility must be provided with documentation required by (5) that the child has been immunized as required for the child's age group against measles, rubella, mumps, poliomyelitis, diphtheria, pertussis (whooping cough), tetanus, and Haemophiles influenza type B, unless the child qualifies for conditional attendance in accordance with (9).~~

Vaccine
Polio

Dosages Required by Age

~~Each child must receive at least three doses of polio vaccine, one of which is administered after age four.~~

DTP or DTaP

Each child must receive at least four doses of DTP or DTaP (diphtheria, tetanus and pertussis) vaccines by age four and one dose of DTaP after age four but before age seven, unless a licensed health care provider has issued a medical exemption for the pertussis portion of the DTP or DTaP vaccine. If a medical exemption has been issued for pertussis, the child must receive at least four doses of DT vaccine or a combination of four doses of DT, DTP, and DTaP vaccines before age four and one dose of the DT vaccine after age four but before age seven.

Because neither DTP nor DTaP vaccines are recommended or required for a child older than age seven, a child in the day care age seven or older who has not received the four doses of DTaP or DTP vaccinations described above must receive a Td vaccine (tetanus and diphtheria vaccine intended for persons seven years of age or older) as soon as possible and must then receive sufficient additional Td doses to reach a minimum of three doses of any combination of DTP, DTaP, DT, or Td.

Td

Each child in the day care must receive a Td tetanus diphtheria vaccine intended for children younger than seven years of age booster shot unless the child has had a DTP, DTaP, DT, or Td shot within the previous five years or the child received a Td shot at seven years of age or older.

Vaccines immunizing against diphtheria, pertussis, and tetanus must be administered as follows:

(a) a child less than seven years of age must be administered four or more doses of DTP or DTaP vaccine, at least one dose of which must be given after the fourth birthday;

(b) DT vaccine administered to a child less than seven years of age is acceptable for purposes of this rule only if accompanied by a medical exemption meeting the requirements of ARM 37.114.715 that exempt the child from pertussis vaccination; and

(c) a child seven years old or older who has not completed the requirement in (1) must receive additional doses of Tdap vaccine or Td vaccine to become current in accordance with the ACIP schedule.

(5) Documentation of immunization status for purposes of this rule consists of a completed Montana certificate of immunization form (HPS-101), including the date

of birth, the name of each vaccine provided, and the month, day and year of each vaccination.

Immunization history must be recorded on the Montana certificate of immunization form (HES-101) provided by the department or on a physician- or clinic-provided immunization record, which must include:

(a) the name of the physician or clinic;

(b) the name and birth date of the child; and

(c) the date and type of immunization.

(6) remains the same.

~~(7) Hib vaccine is not required or recommended for children five years of age and older.~~

~~(8) Doses of MMR vaccine, to be acceptable under this rule, must be given no earlier than 12 months of age and a child who received a dose prior to 12 months of age must be revaccinated, before attending a day care facility.~~

~~(9) (7) A child may initially conditionally attend a day care facility if:~~

~~(a) remains the same.~~

~~(b) a form prescribed by the department documenting the child's conditional immunization status is on file at the day care facility and is attached to the department's Montana certificate of immunization (HPES-101); and~~

~~(c) remains the same.~~

~~(10) remains the same, but is renumbered (8).~~

~~(11) (9) The day care facility must maintain a written record of immunization status of each staff member, enrolled child, and each child of a staff member who resides at the day care facility. The facility must make those records available during normal working hours to representatives of the department or the local health authority.~~

~~(12) A child seeking to attend a day care facility is not required to have any immunizations which are medically contraindicated. A written and signed statement from a physician that an immunization is medically contraindicated will exempt a person from the applicable immunization requirements of this rule.~~

~~(13) (10) A child under five years of age seeking to attend a day care facility is not required to be immunized against Haemophilus influenza type B if the parent or guardian of the child objects thereto in a signed, written statement indicating that the proposed immunization interferes with the free exercise of the religious beliefs of the person signing the statement. A claim of exemption on religious grounds must be notarized and maintained on an Affidavit of Exemption on Religious Grounds form (HES-113) provided by the department.~~

~~(14) The department adopts and incorporates by reference ARM 37.114.715, which sets the requirements for a medical exemption from vaccination. A copy of ARM 37.114.715 may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, P.O. Box 202951, Helena, MT 59620-2951.~~

(11) A child is not required to have any immunizations which are medically contraindicated. A written and signed statement from a physician that an immunization otherwise required by (1) of this rule is medically contraindicated will exempt a child from those immunization requirements as deemed necessary by the

physician. It is preferred, but not mandatory, that a physician's medical exemption be recorded on HES-101, and medical exemption documentation must include:

- (a) which specific immunization is contraindicated;
- (b) the period of time during which the immunization is contraindicated;
- (c) the reasons for the medical contraindication; and
- (d) when deemed necessary by a physician, the results of immunity testing.

The tests must indicate serological evidence of immunity and must be performed by a CLIA approved lab.

AUTH: 52-2-704, 52-2-735, MCA

IMP: 52-2-704, 52-2-735, MCA

37.95.160 DAY CARE FACILITIES: STAFF RECORDS (1) The provider shall maintain records regarding each care-giver which include:

- (a) through (c) remain the same.
- (d) immunization records that establish compliance with

~~ARM 37.95.140~~ 37.95.184.

- (2) remains the same.

AUTH: 52-2-704, MCA

IMP: 52-2-704, 52-2-723, 52-2-732, MCA

37.95.184 DAY CARE FACILITIES: HEALTH HABITS (1) remains the same.

- (2) Every employee, volunteer, or resident at a day care facility must:

- (a) and (b) remain the same.

(c) provide documentation of complete measles, mumps, and rubella immunizations and a tetanus and diphtheria booster within the ten years prior to commencing work, volunteering, or residing at the day care facility at least one dose of Tdap vaccine, and for all adults born in 1957 or after, one dose of MMR vaccine unless they have a medical contraindication to the vaccines or laboratory evidence of immunity to each of the three diseases.

- (3) remains the same.

AUTH: 52-2-704, MCA

IMP: 52-2-704, 52-2-723, 52-2-731, MCA

- 4. The department proposes to repeal the following rule:

37.51.307 YOUTH FOSTER HOMES: SCHOOL AGED CHILD IMMUNIZATION REQUIREMENTS found on page 37-11538 of the Administrative Rules of Montana.

AUTH: 52-1-103, 52-2-111, 52-2-601, 52-2-621, 52-2-622, MCA

IMP: 20-5-403, 52-1-103, 52-2-111, 52-2-601, 52-2-621, 52-2-622, MCA

- 5. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services, Montana Immunization Program (department), is proposing amendments to ARM 37.51.102, 37.51.306, 37.95.102, 37.95.140, 37.95.160, and 37.95.184. The department is also proposing the repeal of ARM 37.51.307. The following describes the purpose and necessity of the proposed rule amendments and repeal.

ARM 37.51.102 and ARM 37.95.102

The proposed addition of several definitions to these rules is necessary to provide explanation of acronyms used in subsequent immunization-related rules, but that are not defined in statute. The addition of these definitions is also consistent with the department's statutory obligations under the administrative procedures act for providing clear and understandable rules.

Developed by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, and others, the acronyms are intended to provide a uniform approach to vaccine references. Uniform vaccine references allow health care providers to quickly and accurately interpret immunization histories. The proposed definitions allow a reader to connect a vaccine acronym and a disease that the rules require a child residing in a youth foster home to be immunized against.

ARM 37.51.306 and ARM 37.95.140

The proposed amendments to these rules are necessary to accomplish two purposes: 1) to bring immunization standards for children residing in youth foster homes or attending Montana day care facilities in line with current ACIP recommendations; and 2) to provide for a standardized method of record keeping for the immunization histories of those children.

Based upon disease epidemiology and burden, vaccine efficacy and effectiveness, vaccine safety, economic analyses and implementation, ACIP develops uniform guidance on the use of vaccines for effective control of vaccine-preventable diseases in the civilian population of the United States. ACIP routinely updates specific recommendations, and revises the general recommendations on immunization every three to five years. However, the department's most recent revision of these rules is from 2006. Inconsistency between the two can lead to confusion for parents and healthcare providers who vaccinate patients, and reduce the efficacy of efforts to prevent vaccine-preventable diseases.

Standardized methods of immunization record keeping are necessary because consistent and accurate records prevent duplicate immunizations and reduce inconveniences such as rescheduled appointments due to the unavailability of accurate immunization histories. This revision is also necessary so that records of immunizations administered under the rule remain consistent with advancements in medical records technology.

ARM 37.95.160

The proposed amendment to this rule is necessary to correct an erroneous cross-reference. ARM 37.95.184 sets forth the substantive immunization or evidence of immunity requirements for staff members at a day care facility, whereas ARM 37.95.140 is a more general requirement that documentation be kept of the immunization status of staff members, enrolled children, and children of staff members who reside at the day care facility. Because ARM 37.95.160 solely pertains to staff member records and not enrolled children or children of staff members, the cross-reference to ARM 37.95.184 is more appropriate.

ARM 37.95.184

The proposed amendment to this rule is necessary to bring immunization standards for staff members at Montana day care facilities in line with current ACIP recommendations, and to provide for exceptions where vaccination is medically contraindicated or where there is evidence of immunity to each of the three listed diseases. Inconsistency between the rules and ACIP recommendations can lead to unnecessary immunization and conflict with prevailing medical standards of care.

ARM 37.51.307

The department proposes the repeal of this rule because the proposed amendments to ARM 37.51.306 collapse an unnecessary distinction in the rules between preschool aged and school aged children. As amended, proposed ARM 37.51.306 will reflect proper immunization requirements for both groups, and provides for consistency with the department's statutory obligations under the administrative procedures act for periodic rule review and for providing clear and understandable rules.

FISCAL IMPACT

The rule change may affect all parents of children attending a licensed child care facility. The children may be required to have a doctor's visit and update their vaccination status. The fiscal impact to these parents should be minimal due to the fact that vaccines are considered to be preventative care and covered fully under insurance. Additionally, the federally funded Vaccines for Children (VFC) program is in place to provide vaccines without cost to those who would normally not be vaccinated due to inability to pay.

6. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., December 12, 2017.

7. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

8. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 6 above or may be made by completing a request form at any rules hearing held by the department.

9. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

10. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment and repeal of the above-referenced rules will not significantly and directly impact small businesses.

11. Section 53-6-196, MCA, requires that the department, when adopting by rule proposed changes in the delivery of services funded with Medicaid monies, make a determination of whether the principal reasons and rationale for the rule can be assessed by performance-based measures and, if the requirement is applicable, the method of such measurement. The statute provides that the requirement is not applicable if the rule is for the implementation of rate increases or of federal law.

The department has determined that the proposed program changes presented in this notice are not appropriate for performance-based measurement and therefore are not subject to the performance-based measures requirement of 53-6-196, MCA.

12. The department intends to make these rules effective June 1, 2018.

/s/ Nicholas Domitrovich
Nicholas Domitrovich
Rule Reviewer

/s/ Shannon McDonald for
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State October 30, 2017.