

CHAPTER 4615
DEPARTMENT OF HEALTH
MATERNAL AND INFANT HEALTH

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4615.0200 [Repealed, 11 SR 1887]

TESTS OF INFANTS FOR INBORN METABOLIC DEFECTS

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

4615.0400 DEFINITIONS.

Subpart 1. **Scope.** For the purpose of this rule, the following terms have the meanings given them.

Subp. 2. **Attending physician.** "Attending physician" means the physician who is identified on the specimen card as the physician submitting the specimen.

Subp. 3. **Newborn infant.** "Newborn infant" means a child from birth through the first five days of life.

Subp. 4. **Positive screening results.** "Positive screening results" means that laboratory tests clearly indicate that the child has a high risk for developing one or more of the diseases covered by parts 4615.0300 to 4615.0700.

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried blood from the newborn infant collected on a specimen card.

Subp. 8. **Specimen card.** "Specimen card" means a filter paper card provided by the Minnesota Department of Health and used to collect the specimen.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

A. Inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices.

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the phenylketonuria test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

C. Record on a permanent record the date the specimen is collected.

D. Send the specimen card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection.

E. If the newborn infant is transferred to a second health care facility before the specimen is collected, the responsible party shall inform the second facility of this fact and may delegate to it the responsibility for collecting and transmitting the specimen.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 276; 17 SR 1758*

4615.0600 DUTIES OF DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

4615.0700 DUTIES OF ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. Report, in writing, results of diagnostic evaluation of all instances of positive newborn screening results of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN 55440-9441.

B. However, if the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

METABOLIC DEFECT TESTING, TREATMENT, AND REGISTRY**4615.0750 PURPOSE AND SCOPE.**

The purpose and scope of parts 4615.0750 to 4615.0760 is to describe the responsibilities of the Minnesota Department of Health to assure that persons diagnosed as having hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: (1) have access to approved laboratory treatment control tests when available; (2) have necessary financial assistance for treatment of diagnosed cases when indicated; and (3) be included in a registry of cases for the purpose of coordinating follow-up services.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 2290; 17 SR 1758*

4615.0755 DEFINITIONS.

Subpart 1. **Scope.** For the purpose of parts 4615.0750 to 4615.0760 the following terms have the meaning given them.

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

Subp. 3. **Follow-up services.** "Follow-up services" means assisting the patient in accessing appropriate treatment and other services.

Subp. 4. [Repealed, 17 SR 1758]

Subp. 5. **Patient.** "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia or the person's parents or legal guardian.

Subp. 6. **Physician.** "Physician" means the medical doctor licensed under Minnesota Statutes, chapter 147, who is supervising the ongoing treatment of the patient. The patient may identify more than one such physician.

Subp. 7. [Repealed, 17 SR 1758]

Subp. 8. **Registry.** "Registry" means a permanent record maintained by the department on each patient diagnosed by a physician and reported to the department as having hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 9. **Treatment control test.** "Treatment control test" means a laboratory test to monitor medical treatment in diagnosed patients to assist in the medical management of the patient's metabolic disease.

Subp. 10. **Treatment control test specimen.** "Treatment control test specimen" means a specimen of blood or other body fluid collected from a patient.

Subp. 11. **Treatment control test specimen kit.** "Treatment control test specimen kit" means a kit containing suitable containers and other materials provided by the department and used to collect and transport a treatment control test specimen.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 2290; 17 SR 1758*

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

Subpart 1. **Treatment control test specimen kits.** The department shall develop and make available treatment control test specimen kits to physicians and patients as medically indicated to effectively monitor treatment, and provide the treatment control test specimen kit and the laboratory evaluation of the treatment control test specimen at no cost to the patient.

Subp. 2. **Reporting of test results.** The department shall report the laboratory results of the treatment control tests to the physician or patient submitting the treatment control test specimen. If the treatment control test specimen is submitted directly by the patient, the patient shall identify a physician who shall receive a copy of the laboratory results.

Subp. 3. **Assistance in obtaining treatment.** The department shall make arrangements for the medically indicated treatment of the metabolic defect in diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia when the patient is uninsured or is unable to pay the cost of treatment because of a lack of available income. The arrangements include referral to appropriate agencies which have financial resources to pay for medically indicated treatment such as private health insurance companies, medical assistance, Minnesota-Care, and Services for Children with Handicaps.

Subp. 4. **Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia reported to the department. The registry shall be updated not more often than annually by direct contact with the patient to determine their address and their need for medical treatment services, educational materials, and counseling related to their metabolic disease. The registry shall include the following minimum data on each patient:

- A. name of patient;
- B. gender;
- C. date of birth;
- D. place of birth;
- E. parents' names;
- F. current address of patient;
- G. diagnosis;
- H. name and address of physician; and
- I. other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall treat all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 2290; 17 SR 1758; L 1995 c 234 art 8 s 56*

REPORTING OF MATERNAL DEATHS

4615.0800 PROCEDURES FOR REPORTING OF MATERNAL DEATHS.

Any death associated with pregnancy, including abortion and extrauterine pregnancy, or the puerperium for a period of three months postpartum, whether or not it is the actual cause of death, shall be reported by mail within three days after death to the

Minnesota Department of Health, Section of Maternal and Child Health, by the attending physician and by the hospital where the death occurred.

Statutory Authority: *MS s 144.05; 144.12*

EARLY AND PERIODIC HEALTH AND DEVELOPMENTAL SCREENING PROGRAMS

4615.0900 PURPOSE AND SCOPE.

The purpose and scope of parts 4615.0900 to 4615.2000 is to establish minimum standards and procedures for MDH approved nurse administered local provision of comprehensive health screening of children.

Parts 4615.0900 to 4615.2000 apply to those organizations seeking MDH approval in order to qualify for reimbursement by third parties for which such reimbursement requires MDH approval; and constitutes standards for the nurse-supervised EPSDT programs as prescribed in Department of Human Services parts 9505.1500 to 9505.1690 and early childhood screening program as prescribed in Department of Children, Families, and Learning parts 3530.3000 to 3530.4310.

Statutory Authority: *MS s 144.06; 144.07; 144.12 subd 1*

History: *L 1984 c 654 art 5 s 58; 1Sp1985 c 12 art 6 s 27; L 1995 1Sp3 art 16 s 13*

4615.1000 DEFINITIONS.

Subpart 1. **Scope.** For the purposes of parts 4615.0900 to 4615.2000 the following terms have the meanings given them.

Subp. 2. **Applicant.** "Applicant" means a local organization, such as but not limited to a community health agency, hospital, voluntary nonprofit group or school, which is seeking approval and has submitted for approval a completed plan for an early and periodic screening (EPS) program.

Subp. 3. **Application.** "Application" means a written request for MDH program approval in a format as specified by the MDH. This format shall require submission of the information required by parts 4615.1400 to 4615.1600.

Subp. 4. **Approved program.** "Approved program" means a screening program which offers regularly scheduled comprehensive health screening for children from birth through 20 years of age, in accordance with the standards contained in parts 4615.1100 to 4615.1300, and which has been approved by MDH.

Subp. 5. **Children.** "Children" means those individuals from birth through 20 years of age.

Subp. 6. **Diagnosis.** "Diagnosis" means the systematic classification of the nature or the cause of physical or mental disease or abnormality through the combined use of health history, physical, developmental and psychological assessments, and laboratory tests and X-rays.

Subp. 7. **Early.** "Early" means the entrance of a child to the health care system at his/her youngest possible age.

Subp. 8. **EPS.** "EPS" means early and periodic screening.

Subp. 9. **EPSDT invoice.** "EPSDT invoice" means a report which when completed by approved programs and submitted to MDH provides a summary of results of screening for each child and contains data which can be used for MDH and local program analysis and evaluation pursuant to part 4615.2000, subpart 5.

Subp. 10. **EPS trained nurse.** "EPS trained nurse" means the nurse who is trained to perform the screening assessments and tests in an approved program inasmuch as the nurse meets the qualifications as contained in part 4615.1200, subpart 1, item B.

Subp. 11. **MDH.** "MDH" means the Minnesota Department of Health.

Subp. 12. **Periodic.** "Periodic" means health screening occurring at predetermined intervals.

Subp. 13. **Periodicity schedule.** "Periodicity schedule" means the schedule set out in part 4615.1100, subpart 4, and which specifies the frequency and age ranges at which the specified screening assessments and tests are to be administered to a child.

Subp. 14. **Physician integration plan.** "Physician integration plan" means the option whereby an MDH approved program seeks to extend its services by substituting a physician-administered health history, physical examination and laboratory services, and immunizations for the nurse administered health history, physical assessment, and laboratory services.

Subp. 15. **Early childhood screening program.** "Early childhood screening program" means the health and developmental screening program under the auspices of the Department of Children, Families, and Learning, whereby children are screened once before they enter kindergarten, pursuant to Minnesota Statutes, section 123.701 et seq.

Subp. 16. **Screening.** "Screening" means the use of those simple and quick procedures as outlined in part 4615.1100, subpart 3 to sort out apparently well children from those in need of more definitive study of possible physical or developmental problems.

Subp. 17. **Sliding fee scale.** "Sliding fee scale" means a predetermined schedule which identifies the amount to be paid by the parent(s) or guardian(s) toward the cost of screening. The sliding fee scale is developed by the applicant or approved program and is based on such factors as average incomes for the region, individual family income, and the number of persons in the family.

Subp. 18. **Third-party reimbursement.** "Third-party reimbursement" means payment to approved programs, by sources other than the child, or his/her parent(s) or guardian(s) and which is applied to the cost of screening. The sources of this reimbursement may include title XIX (medical assistance), other federal, state, or local moneys, insurance benefits, or in kind contributions converted into dollar equivalency.

Subp. 19. **Title XIX (medical assistance).** "Title XIX (medical assistance)" means the program authorized under the Social Security Act, title XIX, United States Code, title 42, sections 1901 to 1910, and rules promulgated thereunder, to provide medical care for individuals whose resources do not enable them to purchase such care.

Subp. 20. **Tracking.** "Tracking" means documenting the results of diagnosis and treatment resulting from the screening of a child. This data also may be used to evaluate the type and appropriateness of referrals.

Subp. 21. **Treatment.** "Treatment" means medical, dental, nursing, preventive, rehabilitative, or other relevant services to prevent, correct, or ameliorate disease or disability detected by diagnostic services for a qualified professional.

Statutory Authority: *MS s 144.06; 144.07; 144.12 subd 1*

History: *1Sp1985 c 12 art 6 s 27; 17 SR 1279; L 1995 1Sp3 art 16 s 13*

4615.1100 MINIMUM STANDARDS TO QUALIFY FOR MDH APPROVAL.

Subpart 1. **Components required.** Applicants seeking MDH program approval shall develop a screening program containing the components in subparts 2 to 7.

Subp. 2. **Outreach.** An outreach component shall include a demonstrated ability to stimulate or encourage participation in the screening program.

Information about a screening program may be disseminated by a variety of methods such as the following: person-to-person communication; and public information outreach such as, but not limited to, planned meetings with groups, contacts with agencies such as schools or Head Start, in order to obtain assistance with regard to their specific child populations, distribution of pamphlets, use of the mass media.

Outreach efforts shall be coordinated with the outreach function of local welfare departments in relation to children under the title XIX (medical assistance) program and with local school districts in relation to children under the early childhood screening program.

Subp. 3. **Screening.** A screening component shall include a demonstrable ability to provide at least the following assessments and tests which must be available at the frequency and age ranges as specified in the periodicity schedule found in subpart 4:

A. A health history assessment which shall include at least an individual review of past and present health status including perinatal, psychosocial, and family health.

B. An immunization assessment which shall include a review of the immunization status of the child in relation to the following immunizations: diphtheria, pertussis, tetanus, polio, measles, mumps, rubella. It is recommended that approved programs provide immunizations on site.

C. A nutrition status assessment which shall include at least a review of the child's food intake for a 24-hour period preceding screening.

D. A physical growth assessment which shall include measurement of the child's height, weight, and head circumference and comparison with the ranges considered normal for children of that age.

E. An unclothed physical assessment which shall include pulse, respiration, blood pressure, head, eyes, ears, nose, pharynx, neck, chest, heart, lungs, genitals, abdomen, spine, extremities, joints, muscle tone, skin, and neurologic reaction.

F. A dental inspection which shall include inspection of the child's mouth for any evident oral or dental abnormalities.

G. Developmental screening tests which shall assess the child's development in the areas of fine and gross motor skills, speech and language, social-emotional behavior, and self-help skills. In order to assess these developmental areas, MDH recommends the use of the Denver Prescreening Developmental Questionnaire (PDQ) and the Denver Developmental Screening Test (DDST) with its manual or an acceptable alternative meeting the criteria below. Alternative tests shall be approved as substitutes for the Denver Developmental Screening Test (DDST) provided the following criteria in subitems (1) and (2) are fulfilled:

(1) An applicant considering substitution for the Denver Prescreening Developmental Questionnaire (PDQ) and the Denver Developmental Screening Test (DDST) shall submit a narrative which describes the alternative test in the following areas: content and construction of the test, norms, administration, scoring and interpretation, validity, and reliability.

(2) In order to secure approval of an alternative test, such a test must be standardized and able to provide at a minimum: written procedures for administration and scoring; evidence of validated norms for age range being tested; the same information regarding the child's development as would be provided through the use of the Denver Developmental Screening Test (DDST).

H. A hearing assessment shall include procedures which test for deviations from the normal range of auditory acuity.

MDH approved programs must use the puretone audiometric screening procedure. A Verbal Auditory Screening for Children (VASC) hearing procedure as described in the 1977 edition of "Fortunate Fours: Preschool Medical Survey of Vision and Hearing" may be used for four-year-old children.

I. A vision assessment shall include procedures which test for eye health deviations, including the normal range of visual acuity and muscle balance in the child. Approved programs must:

(1) Observe and examine the child's pupils and light following reflex, presence or absence of nystagmus, muscle balance, and an inspection of the eyes;

(2) Muscle balance screening procedures include at least observation, cover test, Hirschberg Test. The Worth 4-Dot may be used for children age five or over who are cooperative;

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(3) Test for visual acuity. A test, as appropriate for the child's age, such as the Screening Test for Young Children and Retardates (STYCAR), the Snellen E Cube, the Snellen E Chart, and the Plus Lenses shall be used.

J. Laboratory tests. The following tests shall be administered according to the periodicity schedule found in subpart 4: urine and bacteriuria (Bililabstix and Cultura Assay) test for bacteria and other abnormal substances in the urine; anemia (Microhematocrit, Hemoglobin) tests; a blood lead test for increased lead absorption and for lead poisoning in children whose history indicates the possibility of exposure to undue levels of lead in the environment or atmosphere; a sickle cell test shall be administered only with the consent of the parent(s), or guardian(s), or the child, if he/she is over 18 years, and only to those children at risk for the sickle cell trait or disease.

Subp. 4. **Periodic schedule.** The assessment and tests listed above shall be available on the following periodic schedule.

INTERVALS (1)	MONTHS					YEARS					
	6-7	8-11	12-15	16-19	20-35	3-4	5-7	8-10	11-13	14-17	18-21
History	X	X	X	X	X	X	X	X	X	X	X
Health	X	X	X	X	X	X	X	X	X	X	X
Perinatal	X	◀	◀	◀	◀	◀					
Psychosocial	X	X	X	X	X	X	X	X	X	X	X
Nutrition	X	X	X	X	X	X	X	X	X	X	X
Immunization Review	X	X	X	X	◀	◀	X	◀	◀	X	◀
Developmental											
DDST	X	X	◀	◀	◀	X					
PDQ			X	X	X						
Assessment											
Height	X	X	X	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X	X	X	X
OFC	X	X	X	X	X	◀	◀				
Physical Inspection	X	X	X	X	X	X	X	X	X	X	X
Oral Inspection	X	X	X	X	X	X	X	X	X	X	X
Blood Pressure						X	X	X	X	X	X
Tests											
Hearing	X	◀	X	X	X	X	X	X	X	X	X
Vision	X	◀	X	◀	X	X	X	X	X	X	X
Urine (BiliLabstix)						X	◀	◀	◀	◀	◀
*Bacteriuria (females)						X	◀	X	◀	◀	◀
Microhematocrit or Hgb.	X	◀	X	◀	X	X	◀	◀	◀	X	◀
Blood Lead (Only if history positive)			X	◀	X	X					
Sickle Cell (Upon parental request)	X	◀	◀	◀	◀	◀	◀	◀	◀	◀	◀

(1) The period, birth to six months, is not addressed in the program based upon the assumption that nearly all children of this age interval are receiving ongoing physical care.

Procedure to be completed if not done at the previous visit; or on the first visit.

* The local agency may wish to consult with the local medical society regarding use of this procedure.

Subp. 5. **Education.** An interpretation and parent education component shall include discussions aimed at sharing with the family and child information collected during screening. These discussions must incorporate guidance regarding sound health

practices, normal growth and development, and the clarification of any concerns on the part of the child or family. A copy of the screening results shall be given to the parents.

Subp. 6. **Referrals.** A referral component shall include an organized system of arranging for children with problems identified through screening to be seen by an appropriate resource for evaluation, diagnosis, or treatment. Arrangements shall be made to establish all children who have been screened with ongoing health care services. Whenever a child identifies a personal physician, that person shall be notified of the referral.

Subp. 7. **Follow-up.** A follow-up component shall include an organized system for securing information on children who are referred to another resource for evaluation, diagnosis, and treatment. Follow-up efforts are to assure that the required services were made available and to evaluate the effectiveness of the screening program.

A follow-up plan shall consist of at least the following:

A. Written and formal arrangements with other agencies such as the local social services agencies, Head Start, Developmental Achievement Centers, community action councils, public health nursing services, and school services to define and coordinate each agency's responsibilities with respect to follow-up.

B. A description of activities such as personal contact with the child, family, or referral resource. At least two attempts shall be made to contact parent(s) or provider(s) concerning diagnosis and treatment results.

C. A written identification of nursing personnel who shall have supervisory responsibility for follow-up.

Statutory Authority: *MS s 123.702*

History: *1Sp1985 c 12 art 6 s 27; L 1994 c 631 s 31*

4615.1200 PERSONNEL FOR EPS SCREENING OF CHILDREN.

Subpart 1. **Qualifications and/or responsibilities of the screening personnel.** An individual may perform one or more of the functions in the screening program provided that the appropriate qualifications are met. The use of volunteers is encouraged in the screening program, providing they meet the qualifications as defined in subparts 2 to 6.

Subp. 2. **Coordinator.** EPS clinic coordinator shall have the responsibility for coordination and management of the local screening program. These responsibilities include management as well as specific organization of activity in the clinics.

Subp. 3. **Nurse.** EPS trained nurse shall meet all of the following criteria: be currently licensed as a professional nurse by the Minnesota Board of Nursing, have successfully completed EPS training seminars provided by MDH, or have participated in equivalent training programs designated by MDH, demonstrate ability to satisfactorily perform to an EPS consultant designated by MDH, those child assessments as required in part 4615.1100, subpart 3, items A to J.

Subp. 4. **Laboratory Assistant.** EPS laboratory assistant shall be a lab technician or an assistant who can document training in performing the specific tests used in the screening session under the supervision of the EPS nurse.

Subp. 5. **Vision and hearing technician.** EPS vision and hearing technician shall have documentation of the successful completion of a course in vision and hearing screening offered by MDH and demonstrate ability to satisfactorily perform the vision and hearing screening as required in part 4615.1100, subpart 3, items H and I; and if the VASC is used, have documentation of the completion of training to perform the Verbal Auditory Screening of Children (VASC).

Subp. 6. **Clinic assistant.** EPS clinic assistant shall:

A. Be able to document the completion of training in the administration of the developmental tests selected for use in the screening program. Such training may be provided by the EPS nurse or consultant who has documented training in develop-

mental testing from institutions such as, but not limited to, area mental health centers, or community colleges and schools.

B. Have experience in working with children either through paid employment or volunteer activity.

Statutory Authority: *MS s 123.702*

4615.1300 REQUIREMENTS OF THE PHYSICAL FACILITY.

The physical facility shall meet the following requirements:

A. as appropriate, areas shall be provided for screening procedures, waiting, and play areas;

B. physical privacy shall be maintained for interviewing and physical assessment; and

C. equipment needed for the assessments and tests shall be available to the program and maintained in serviceable and reliable condition so as to ensure the integrity of the tests specified in part 4615.1100, subpart 3, items A to J.

Statutory Authority: *MS s 123.702*

4615.1400 INTENT TO ESTABLISH EPS PROGRAM.

Local organizations shall notify MDH in writing of their intent to establish an EPS program and to apply for MDH program approval in accordance with the standards specified in these rules. The sections of the application addressing statement of need and evaluation and fiscal management shall be considered for purposes of program planning at state and local level and, if necessary, for provision of technical consultation by MDH. The section of the application relating to the methods of accomplishing program components, and personnel shall be applicable to the approval process as defined in part 4615.1700.

Statutory Authority: *MS s 144.11; 144.12*

4615.1500 APPLICATION INSTRUCTIONS.

Upon receipt of the letter of intent, MDH shall transmit application instructions to the applicant.

Statutory Authority: *MS s 144.11; 144.12*

4615.1600 SUBMISSION OF APPLICATION.

The applicant shall submit the completed application to MDH and to the MDH district nursing consultant for the district in which the applicant is located. The application shall include at least the following information:

A. A statement of need for EPS. The applicant shall provide a general statement of the extent of the need for this kind of preventive health service in the community to be served and includes information on the following:

(1) the geographic area of the proposed program;

(2) the age range and numbers of children to be served in each age group. An applicant may elect to serve only one age group of children;

(3) the estimate of the number of title XIX (medical assistance) eligible children identified in each age group;

(4) the identification of all the school districts within the geographic area of the proposed program;

(5) the identification of other child and adolescent health screening programs in the area and specification of how the proposed program will coordinate with these programs;

(6) the identification of existing and ongoing health services in the community to prevent duplication of services and care, and how this proposed program will coordinate and utilize the existing network.

B. A description of the method of accomplishing each of the program components: outreach, screening and interpretation, education, referral, and follow-up.

C. Outline the number and type of personnel necessary to implement each component and the plans for training personnel.

D. Outline the methods, other than those specified in this rule, by which the applicant will evaluate its own program. Such methods may include parent surveys, and/or analysis of the use of referral resources, and numbers of children screened.

E. Fiscal Management - include the following:

(1) the method for determining unit cost;

(2) the plan for implementing a sliding fee scale and for collecting third-party reimbursements and a copy of the sliding fee scale except where prohibited by Laws of Minnesota 1977, chapter 437, the Preschool Screening Act;

(3) the copy of the authorization from the duly constituted authority (such as county commissioners, city councils) to charge fees for services, except as prohibited by Laws of Minnesota 1977, chapter 437, the Preschool Screening Act.

Statutory Authority: *MS s 144.11; 144.12*

4615.1700 REVIEW AND DISPOSITION OF APPLICATION.

Subpart 1. **Process.** There shall be a two-stage approval process.

Subp. 2. **First stage of approval.** With regard to the first stage of approval: upon receipt, the application shall be reviewed by MDH staff in order to determine that it contains the information specified in part 4615.1600, items A to E. The MDH staff shall make arrangements for the local EPS personnel to be trained in EPS seminars. An initial screening session shall be scheduled by the applicant. An EPS consultant, as designated by MDH will be assigned to the applicant for on-site consultation to assist the applicant to develop adequate skills. A subsequent consultation may be provided as necessary.

Subp. 3. **Provisional approval.** Upon completion of application, training, the initial screening session, and a satisfactory EPS consultant report, the commissioner of health shall grant provisional approval to the applicant prior to any other screening of children by the applicant. Provisional approval by MDH shall constitute approval for purposes of other governmental agencies and their provision of third-party reimbursement. In the event that MDH staff intends to recommend to the commissioner of health a denial of provisional approval, the staff shall notify the applicant in writing of the conditions necessary to gain approval. Technical assistance and consultation shall be offered by MDH to the applicant. If following the offer of consultation and with reconsideration MDH staff intends to recommend to the commissioner of health denial of provisional approval, the staff shall notify the applicant at least 35 days prior to the submission of the recommendation to the commissioner of health. If the applicant contests the proposed staff recommendation to deny provisional approval, it shall request in writing a hearing within 30 days of receipt of the proposed staff recommendation or otherwise it shall be deemed to concur with the staff recommendation. This hearing shall be conducted in accordance with the Minnesota Administrative Procedure Act, Minnesota Statutes, chapter 14, and the rules of the Office of Administrative Hearings.

Subp. 4. **Final stage of approval.** With regard to the final stage of approval: a second visit shall be made by the EPS consultant within the first six months of the programs' operation to evaluate the screening program and staff performance to assure implementation and fulfillment of the program components as specified in parts 4615.1100 to 4615.1300. The MDH staff shall make a final staff review of the screening program. This review consists of the EPS consultant's evaluation of the ability of program personnel to adequately perform the screening procedures as outlined in the rule, the MDH district nursing consultant's evaluation of the overall program administration and a review of the application in accordance with standards as specified in parts 4615.1100 to 4615.1300.

If the commissioner of health concurs with staff comments and recommendation, the commissioner shall notify the applicant within 30 days of final approval. Such approval by MDH shall constitute approval for purposes of other governmental agencies and their provision of third-party reimbursement.

If not in substantial compliance: the conditions necessary to gain approval shall be stated in writing by MDH staff to the applicant. Technical assistance and consultation shall be offered by MDH staff to the applicant. If following the offer of consultation and reconsideration, MDH staff intends to recommend to the commissioner of health a denial of final approval, the staff shall notify the applicant in writing of the reasons therefor at least 35 days prior to the submission of the recommendation to the commissioner of health. If the applicant contests the proposed staff recommendation to deny approval, it shall request in writing a hearing, within 30 days of the receipt of the proposed staff recommendation, or otherwise it shall be deemed to concur with the staff recommendation. This hearing shall be conducted in accordance with the Minnesota Administrative Procedure Act, Minnesota Statutes, chapter 14, and the rules of the Office of Administrative Hearings.

Statutory Authority: *MS s 144.11; 144.12*

4615.1800 ANNUAL REAPPROVAL.

An approved program shall be reviewed annually by the MDH staff to determine if approval status shall continue. Reapproval shall be based on the program's continued compliance with the standards specified in parts 4615.1100 to 4615.1300. The commissioner of health shall notify the program within 30 days after receipt of the staff recommendation of reapproval. In the event that MDH staff intends to recommend to the commissioner of health a denial of reapproval, the staff shall notify the program in writing of the conditions necessary to gain reapproval. Technical assistance and consultation shall be offered by MDH to the program. If following the offer of consultation and with reconsideration, MDH staff intends to recommend to the commissioner of health denial of reapproval, the staff shall notify the program at least 35 days prior to the submission of the recommendation to the commissioner of health. If the program contests the proposed staff recommendation to deny reapproval, it shall request in writing a hearing within 30 days of receipt of the proposed staff recommendation or otherwise it shall be deemed to concur with the staff recommendation. This hearing shall be conducted in accordance with the Minnesota Administrative Procedure Act, Minnesota Statutes, chapter 14, and the rules of the Office of Administrative Hearings.

Statutory Authority: *MS s 144.11; 144.12*

4615.1900 SERVICES FOR APPLICANTS AND PROGRAMS.

The MDH shall provide technical assistance and consultation for the planning, implementing, and administering of EPS programs and those programs seeking approval. The MDH shall survey and evaluate approved programs on a periodic basis to assure compliance with the standards contained in parts 4615.0300 to 4615.2000. The MDH shall provide in-service EPS training seminars for local staff based upon the needs as determined jointly by approved programs and MDH staff. This training shall address at least the following areas: administration of EPS; pediatric nursing skills in relation to the specific screening assessments and tests of children.

Statutory Authority: *MS s 123.703*

4615.2000 APPROVED PROGRAM RESPONSIBILITIES.

Subpart 1. **Standards.** Approved programs shall provide EPS service in accordance with or exceeding the standards contained in parts 4615.0300 to 4615.2000.

Subp. 2. **Referrals.** Approved programs shall refer children to an appropriate resource for evaluation, diagnosis, and treatment. Whenever a child identifies a personal physician that person shall be provided a copy of the screening results with the approval of the parent/guardian or emancipated child.

Subp. 3. **Personnel training.** Approved programs shall assure that EPS personnel obtain continuing education in order to maintain or improve clinical skills. This training may be provided by MDH or the University of Minnesota, School of Public Health. The content shall relate to child ambulatory health care, screening principles, and clinical skills.

Subp. 4. **Coordination.** Approved programs shall coordinate the EPS program with schools or other community child health programs and health care providers.

Subp. 5. **Evaluations.** Approved programs shall participate in evaluation of their programs and submit evaluation data as requested by MDH. This data includes at least an EPSDT invoice and forms for tracking diagnosis and treatment results. Data provided to MDH by approved programs may be summarized and the child's identity shall remain anonymous.

Subp. 6. **Approved program option.** Approved programs may include the physician integration plan, provided such a plan meets or exceeds the standards contained in parts 4615.0300 to 4615.2000. If this plan is included, the health history, physical examination, and the laboratory tests shall be performed on the child, under a physician's supervision. This examination shall be performed within the previous six months if the child is under the age of two, within 12 months if the child is two years or older, or 60 days after the provision of the other EPS screening tests (vision, hearing, and developmental). There shall be a mutual exchange of information to assure that each provider has the complete health and developmental profile of the child.

Statutory Authority: *MS s 123.702*

MATERNAL AND CHILD NUTRITION ACT OF 1975

4615.2100 PURPOSE.

Parts 4615.2100 to 4615.3300 are promulgated to establish procedures and criteria for those local organizations which seek funds from the Minnesota Department of Health in order to distribute nutritional supplements to mothers and children under parts 4615.2100 to 4615.3300.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.2200 DEFINITIONS.

Subpart 1. **Scope.** For the purposes of the maternal and child nutrition program, the terms in this part are defined as follows.

Subp. 2. **Act.** "Act" means the Maternal and Child Nutrition Act of 1975 (Laws of Minnesota 1975, chapter 346).

Subp. 3. **Administrative costs.** "Administrative costs" means all costs directly attributable to program operations, except expenditures for food.

Subp. 4. **Affirmative action program.** "Affirmative action program" is a program that meets state and federal laws which prohibit discrimination in employment, public service, and public assistance.

Subp. 5. **Agency.** "Agency" means any local health agency as defined in the act (Laws of Minnesota 1975, chapter 346, section 1, subdivision 2).

Subp. 6. **Applicant.** "Applicant" means those local health agencies who have submitted program applications to the commissioner of health in accordance to parts 4615.2100 to 4615.3300.

Subp. 7. **Birth weight.** "Birth weight" means weight of an infant determined within two hours of birth, or as soon thereafter as is practicable.

Subp. 8. [Repealed by amendment, L 1977, c 305 s 39]

Subp. 9. **Children.** "Children" means persons at least one year of age but less than four years of age.

Subp. 10. **Competent professionals.** "Competent professionals" means physician and/or registered nurses duly licensed by the state of Minnesota, or public health nutritionists, registered dietitians, or persons designated and supervised by one of the above as being competent to evaluate nutritional risk.

Subp. 11. **Certification process.** "Certification process" means the method by which the grantee designates certified individuals in accordance with the criteria specified in part 4615.2700 dealing with certification.

Subp. 12. **Certified individuals.** "Certified individuals" means those persons who have been certified by the grantee as eligible to receive supplemental food and services pursuant to the program.

Subp. 13. **Grantee.** "Grantee" means those agencies who have contracted with the commissioner of health to participate in the program.

Subp. 14. **Infants.** "Infants" means persons under one year of age.

Subp. 15. **Lactating woman.** "Lactating woman" means any breast-feeding individual who presents competent evidence of having been delivered of a surviving child within the 12 months immediately preceding the filing of an application for nutritional supplements.

Subp. 16. **Low birth weight.** "Low birth weight" means a birth weight less than 2,500 grams.

Subp. 17. **Low income.** "Low income" means a gross annual income at or below the following: \$4,652 for a single person, \$6,083 for a family of two, \$7,515 for a family of three, \$8,947 for a family of four, \$10,378 for a family of five, \$11,810 for a family of six, \$12,078 for a family of seven, \$12,346 for a family of eight, \$12,615 for a family of nine, \$12,883 for a family of ten.

Subp. 18. **Nutritional risk.** "Nutritional risk" means in addition to those items specified in the act (Laws of Minnesota 1975, chapter 346, section 1, subdivision 7), a condition in which an individual's health has, or may become, compromised due to an inadequate consumption of necessary nutrients as can be demonstrated under the criteria specified under part 4615.2700, item D, subitem (1).

Subp. 19. **Pregnant women.** "Pregnant women" means persons determined by licensed physician, midwife, or appropriately trained registered nurse to have one or more fetuses in utero.

Subp. 20. **Program.** "Program" means the program specified in the act.

Subp. 21. **Program area.** "Program area" means the geographic boundaries determined by the agency and approved by the commissioner of health, within which the distribution of benefits under this program and under parts 4615.2100 to 4615.3300 shall be administered.

Subp. 22. **Public assistance.** "Public assistance" means any form of federal, state, or local aid wherein qualification is based upon financial need of the recipient.

Subp. 23. **Responsible official.** "Responsible official" means the person designated by the local health agency as being accountable to the department for carrying out the provisions of the act and of parts 4615.2100 to 4615.3300.

Subp. 24. **Supplemental food.** "Supplemental food" means any food authorized to be made available under part 4615.2800, subpart 3, item A.

Subp. 25. **Vendor.** "Vendor" means any retailer who has entered into a written contract with a grantee to provide food to certified individuals pursuant to parts 4615.2100 to 4615.3300.

Subp. 26. **Voucher.** "Voucher" means the coupon issued by the grantee to the certified individuals and/or their parents or guardians for purchase of specified supplemental foods from a vendor.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.2300 CONTRACTS BETWEEN THE COMMISSIONER OF HEALTH AND GRANTEES.

The commissioner of health will make funds available only to those grantee agencies with which it has entered into a written contract. The commissioner of health will provide funds, technical assistance, and consultation to grantees to enable them to establish and implement a certification process to determine individuals eligible for supplemental food vouchers in accordance with the act and parts 4615.2100 to 4615.3300. The commissioner of health and the grantee shall enter into a contract that shall specify at least the following: the local grantee will operate pursuant to the act and parts 4615.2100 to 4615.3300 and the grantee shall have an affirmative action program as defined in part 4615.2200, subpart 4.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.2400 CONDITIONS FOR ENTERING A FUNDING CONTRACT WITH THE COMMISSIONER OF HEALTH.

Subpart 1. **Conditions.** Subparts 2 to 5 list the conditions for entering a funding contract with the commissioner of health.

Subp. 2. **Applications accepted.** The commissioner of health will accept applications from agencies seeking to become grantees. The commissioner of health may execute a contract only with those agencies which submit an acceptable application as specified in subpart 3 and upon consideration of the criteria as specified in subpart 4.

Subp. 3. **Application content.** The applications for contract shall be submitted in triplicate. The commissioner of health may request the submission of additional information consistent with the provisions of the act and parts 4615.2100 to 4615.3300, as well as information necessary to clarify matters already contained in the application. Such information shall be for the sole purpose of enabling the commissioner of health to fairly, adequately, and completely evaluate the application to determine whether a grant should be awarded. The commissioner of health may refuse to award a grant for failure of the applicant to submit the requested information. The application shall contain at least the following information:

- A. the name, address, and telephone number of the applying agency;
 - B. the name of the person who will be designated the responsible official for supervising local program operations;
 - C. the title and number of all persons, including clerical or nonprofessionals, who are employed by the agency and will be working with the program;
 - D. the title and number of all members of the staff who will examine and/or interview persons in order to designate certified individuals for the program;
 - E. the geographic boundaries of the proposed program area;
 - F. an estimate of the total population living within the proposed program area and the basis upon which that estimate is made;
 - G. an estimate of the low-income population living within the proposed program area and the basis upon which that estimate is made;
 - H. an estimate of the number of pregnant or lactating women, infants, or children which the grantee expects to serve monthly under the program and the basis upon which that estimate is made;
 - I. an estimate of the monthly cost of purchasing supplemental foods for potential participants as based on current retail prices and a description of the basis on which that estimate was determined;
 - J. an estimate of the monthly administrative costs for the program by the general type of expenditure with a brief justification for each such budgeted expenditure;
 - K. a proposed plan for establishing and implementing a certification process;
- and

L. a statement that the information furnished in the application is true and accurate to the best knowledge of the responsible official who signs it.

Subp. 4. **Criteria also considered.** In addition to information provided in the application, the commissioner of health will consider the following criteria in determining whether it will contract with an applicant:

A. the absence of any similar supplementary feeding program serving the clientele within the proposed program area of the applying agency;

B. the ability of the applicant to meet program requirements for individual certification, recordkeeping, reporting, nutrition education, and all the other requirements of the act and parts 4615.2100 to 4615.3300; and

C. the severity of nutritional risk and other health problems which affect residents of the proposed program area as demonstrated by the commissioner of health data ranking counties based on percent of women receiving prenatal care, percent of premature births, perinatal death rate, percent of mothers less than 20 years old, percent of illegitimacy, percent of family income below \$6,000, and fertility rate.

Subp. 5. **Notification.** Each applicant will be notified in writing by the commissioner of health as to the action taken on its application for contract and the reason for such action. Such notification shall specify the amount of funds which the commissioner of health will make available to the grantee and any contingencies upon the application.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.2500 GRANTEE TO DESIGNATE CERTIFIED INDIVIDUALS.

Each grantee is responsible for identifying persons who may be designated as certified individuals. Each grantee shall inform these persons of program benefits and procedures to be followed in order to be designated as certified individuals. The grantee shall designate only competent professionals to certify individuals.

Statutory Authority: *MS s 145.894*

4615.2600 CERTIFICATION PROCESS.

Each grantee shall be responsible for establishing and implementing a certification process and for documenting the fulfillment of criteria by which each certified individual was determined as certified by a competent individual. No person shall be certified for more than six months. Any person desirous of continuing in the program shall be recertified in accordance with parts 4615.2100 to 4615.3300 relating to any certification.

Statutory Authority: *MS s 145.894*

4615.2700 DESIGNATION OF PREGNANT WOMEN OR CHILDREN AS CERTIFIED INDIVIDUALS.

Each grantee may designate pregnant or lactating women, infants, and children as certified individuals provided such individuals meet all of the following requirements:

A. they are not receiving a similar supplement under any federal, state, or local program;

B. they reside in an area served by the grantee;

C. they are eligible for, or a recipient of, any form of public assistance authorized by law or they are determined by the grantee to be at low income, as can be verified by a statement provided by the commissioner of health which each individual applying for certification must sign, to purchase necessary supplemental foods; and

D. they are determined by the grantee to be at nutritional risk as defined by any one or more of the following criteria:

(1) nutritional anemia as found by blood analysis, either hemoglobin or hematocrit, showing results which are lower than those indicated on the following list:

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	Age	gm/100 ml
Hemoglobin	6-23 months	10.0
	2-4 years	11.0
	nonpregnant	12.0
	pregnant	11.0
	Age	Packed Cell Volume in Percent
Hematocrit	up to 2 years	33
	2-4 years	34
	nonpregnant	36
	pregnant	33

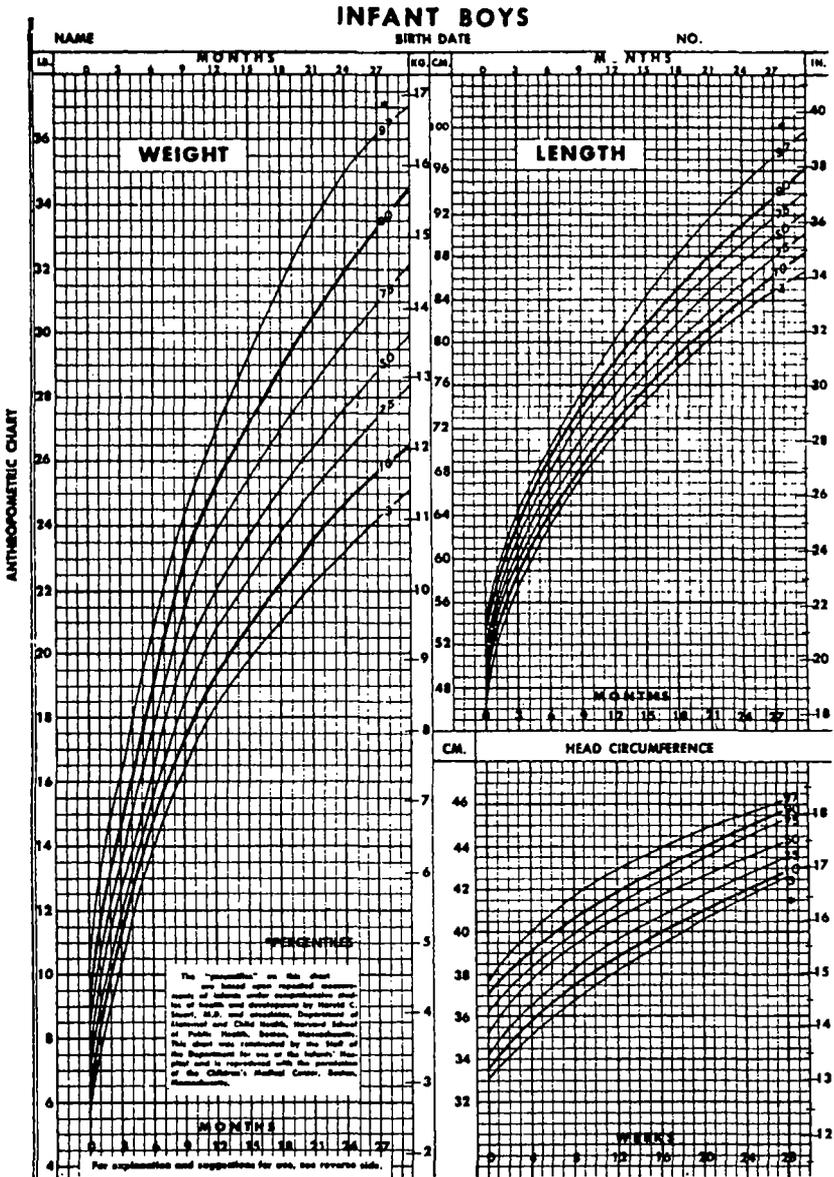
(2) inadequate diet as demonstrated on a food intake record form provided by the commissioner of health, and which indicates the diet contains less than the specified amounts of the following nutrients and calories:

	0-6 Months	6 Months to 1 Year	1-3 Years	3-4 Years	Pregnant Woman	Lactating Woman
Protein	2.2 gm/kg	2.0 gm/kg	23 g	30 g	76 g	66 g
Iron	10 mg	15 mg	10 mg	10 mg	18 mg	18 mg
Calcium	360 mg	540 mg	800 mg	800 mg	1,200 mg	1,200 mg
Vitamin A	1,400 IU	2,000 IU	2,000 IU	2,500 IU	5,000 IU	6,000 IU
Vitamin C	35 mg	35 mg	40 mg	40 mg	60 mg	80 mg
Calories	117/kg	108/kg	1,300	1,800	2,400	2,600

(3) inadequate pattern of growth in infants and children as demonstrated when heights and weights plotted on the following growth grids show height and/or weight to be two or more standard deviations below the mean:

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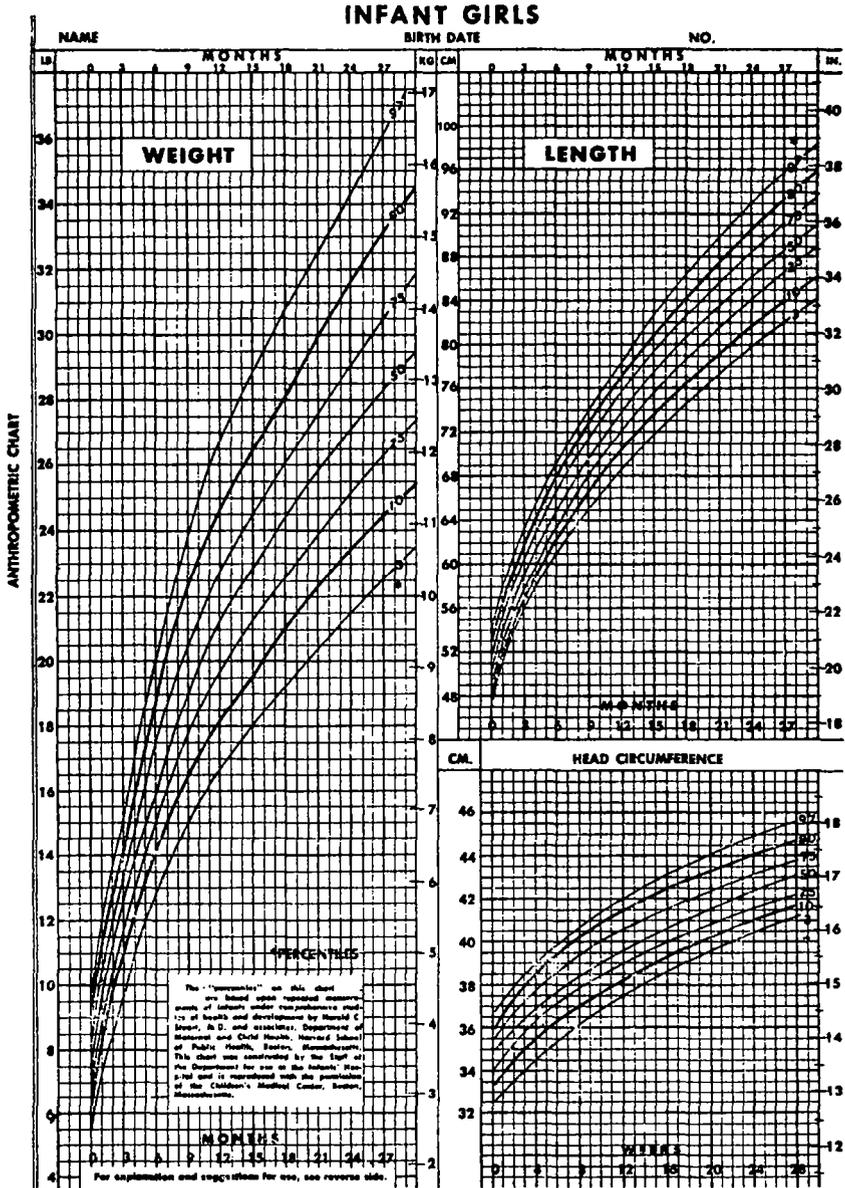
MATERNAL AND INFANT HEALTH 4615.2700



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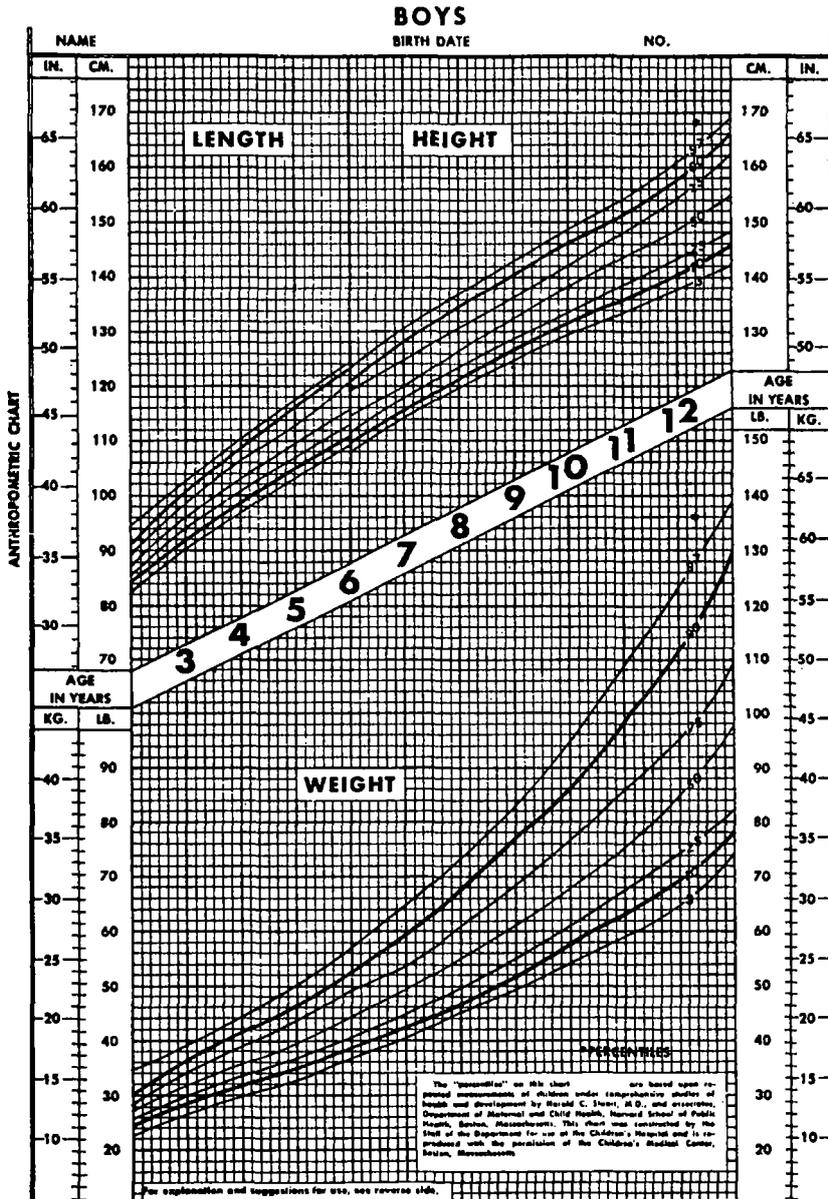
4615.2700 MATERNAL AND INFANT HEALTH

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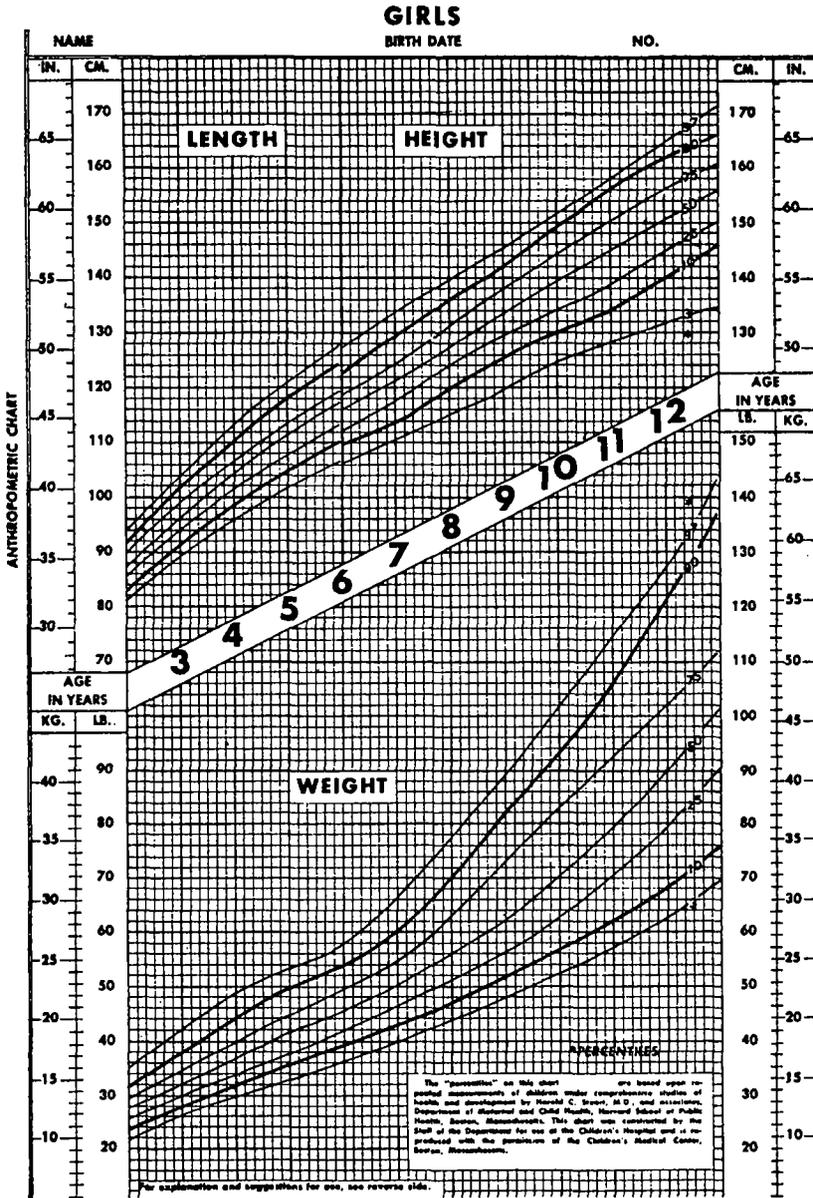


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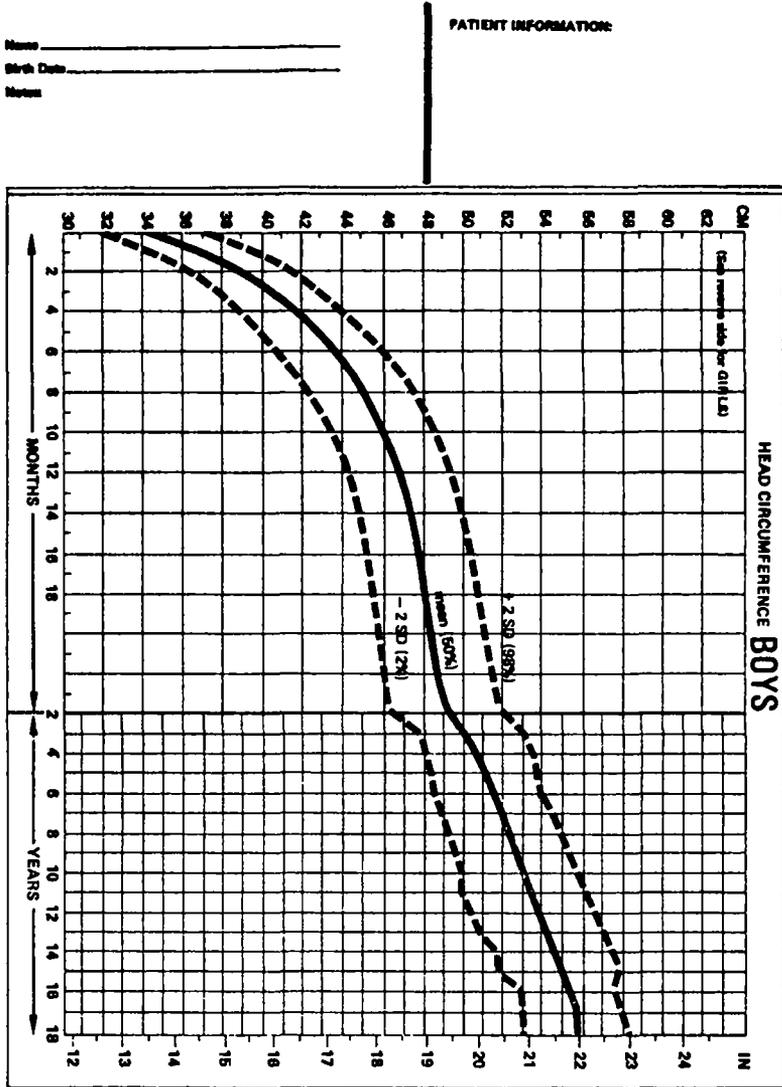


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(4) inappropriate preconception weight as demonstrated by a preconception weight ten percent or more below weight for height as shown on the following chart:

Height Barefoot	Weight
4' 9"	92
4' 10"	94
4' 11"	96
5' 0"	99
5' 1"	102
5' 2"	105
5' 3"	108
5' 4"	111
5' 5"	114
5' 6"	118
5' 7"	122
5' 8"	126
5' 9"	130
5' 10"	134
5' 11"	138
6' 0"	142

(5) inappropriate preconception weight as demonstrated by a preconception weight 20 percent or more above the weight for height as shown on the following chart:

Height Barefoot	Weight
4' 9"	119
4' 10"	122
4' 11"	125
5' 0"	128
5' 1"	131
5' 2"	134
5' 3"	138
5' 4"	142
5' 5"	146
5' 6"	150
5' 7"	154
5' 8"	158
5' 9"	163
5' 10"	168
5' 11"	173
6' 0"	178

(6) inappropriate weight gain during pregnancy as demonstrated by a weight gain of seven pounds or more per month or a weight gain of less than two pounds per month after the first trimester;

(7) medical history or finding suggesting nutritional need as shown by a competent professional by one of the following conditions:

(a) intrauterine growth retardation or difficulty with previous pregnancy that could be nutritionally related such as, but not limited to, five or more pregnancies, two or more spontaneous abortions, less than one year since last delivery, or a neonatal death that may have nutritional cause;

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(b) pregnant or lactating patient 17 years of age or under and/or her infant;

(c) premature or low birth weight infant or an infant having a sibling with a history showing failure to thrive.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.2800 GRANTEE PROVISION OF SUPPLEMENTAL FOODS.

Subpart 1. **Procedure.** Subparts 2 to 5 list the procedures by which grantee is to provide supplemental foods to certified individuals.

Subp. 2. **Vouchers.** The commissioner of health shall provide vouchers to the grantee and the grantee shall provide secure storage of the vouchers until they are issued. The grantee shall issue vouchers to certified individuals on the basis of individual need, but in no case shall exceed the maximum quantity stated in subpart 3. Upon presentation of vouchers provided by the program grantee, certified individuals may obtain supplemental foods from a vendor. Each voucher shall state the specified food and the maximum quantity of that food that can be provided by the vendor.

Subp. 3. **Maximum quantities through vouchers.** Maximum quantities that will be provided for certified individuals through the vouchers are indicated for each food as follows. Substitutions are not allowed.

A. For infants:

Foods	Unit	Maximum Number of Units per Month
Iron fortified infant formula	13 fluid oz can of concentrated liquid, or dry or ready-to-use form in an amount to provide 26 ounces of single strength formula	31
Infant Cereal	8 oz package	3
Juice, single strength or frozen, concentrated fruit juices in 12 ounce cans, at the same rate or in an equivalent volume in other can sizes	46 fluid oz can	2 or 15 four ounce cans of infant juice

B. For children and pregnant and lactating women:

Foods	Unit	Maximum Number of Units per Month
Whole, skim, or lowfat fluid	fluid quart or evaporated or	31 or 28 units plus one pound

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milk	nonfat dry milk in equivalent amount	cheese or 25 units units plus two pounds of cheese
Eggs	dozen	2 1/2
Cereals	8 ounce package	4
Juice, single strength or frozen, concentrated fruit juices in 12 ounce cans at the same rate or in an equivalent volume in other can sizes	46 fluid ounce can	6

Subp. 4. **Specifications of supplemental foods available through voucher.** The kinds and specifications of supplemental foods to be made available through voucher are as follows:

A. For infants:

(1) iron fortified infant formula with at least ten milligrams of iron per liter of formula at standard dilution (which supplies 67 kilocalories per 100 milliliters; i.e., 20 kilocalories per fluid ounce);

(2) infant cereal which contains a minimum of 28 milligrams of iron per 100 grams of dry cereal; and

(3) fruit juice which contains at least 30 milligrams of vitamin C per 100 milliliters.

B. For children and pregnant or lactating women:

(1) whole fluid milk fortified with 400 International Units of vitamin D per quart, or evaporated milk fortified with 400 International Units of vitamin D per reconstituted quart; or skim or lowfat milk fortified with 400 International Units of vitamin A per reconstituted quart, or cheese (Swiss, cheddar, or pasteurized process American). Children with milk allergies may continue to receive special formulas provided there is a written request from a physician;

(2) cereal (hot or cold) which contains a minimum of 15 milligrams of iron per 100 grams of dry cereal which is not presweetened;

(3) fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters;

(4) eggs.

Subp. 5. **Contract with local vendor.** Each grantee shall enter into a written contract with local vendors serving the project area. The contract shall require the vendor to agree that:

A. the vouchers will be redeemed only for those foods and quantities specified on the voucher;

B. the price charged for each item on the voucher will be the same price charged to all purchasers of those items on the days vouchers are redeemed;

C. the vendor shall send a monthly statement showing cost of redemption to the grantee; and

D. the grantee shall pay the vendor monthly upon submission of statement.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.2900 NUTRITION INFORMATION AND COUNSELING.

Each grantee shall provide nutrition information and counseling to certified individuals and/or parents or guardians. The grantee shall develop a written plan showing how nutrition information and counseling will be provided. This plan will include an implementation schedule showing the dates by which objectives will be prepared and when the methods are to be put into operation.

Statutory Authority: *MS s 145.894*

4615.3000 RECORDS AND REPORTS.

Subpart 1. General. Grantees shall maintain full and complete records concerning operation. All such records shall be retained indefinitely unless state archives approves their destruction. The commissioner of health has the right to review and inspect all records at its discretion.

Subp. 2. Contract records. Each grantee shall keep a record of all contracts entered into with local vendors.

Subp. 3. Financial records. Each grantee shall keep complete and accurate records of all funds received and disbursed for the program. All financial disbursement records shall be summarized and submitted in report form monthly to the commissioner of health on forms supplied by the board.

Subp. 4. Food records and reports. Each grantee shall keep a record of the food issued each month to each certified individual. A monthly summary shall be submitted to the commissioner of health on forms supplied by the commissioner of health.

Subp. 5. Medical records. The grantee shall record height, weight, and infant head circumference at each certification visit. If hematocrit and/or hemoglobin tests are a routine of the agency, these should also be recorded.

Subp. 6. Nutrition information and counseling records. Each grantee shall report quarterly on progress made toward accomplishment of objectives stated in their nutrition information and counseling plan.

Subp. 7. Voucher records. Vouchers must be accounted for from point of receipt from the commissioner of health. A record shall be kept of vouchers issued to certified individuals. Any voucher not intended to be redeemed shall immediately be marked "VOID."

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.3100 FAIR HEARING PROCEDURE.

Each grantee shall have an established hearing procedure in accordance with the Minnesota Administrative Procedure Act, Minnesota Statutes, chapter 14, under which a person or his or her parent or guardian can appeal a decision made by the grantee respecting the refusal of the grantee to designate the person as a certified individual.

Statutory Authority: *MS s 145.894*

4615.3200 PAYMENTS TO GRANTEEES.

The commissioner of health shall advance funds to grantees based on the number of certified individuals. This advance of funds shall be made quarterly and is to cover food and allowed administration costs. The dollar amount allowed per participant shall be based on current prices of the supplemental foods. The grantee shall be responsible for costs incurred in excess of the program budget.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

4615.3300 GRANTEE DISQUALIFICATION.

Any grantee may be disqualified from participation if it fails to comply with the provisions of this act, parts 4615.2100 to 4615.3300, and/or its contract with the commissioner of health. If, in accordance with the Minnesota Administrative Procedure Act, Minnesota Statutes, chapter 14, it is determined that any part of the money received by the grantee was through grantee negligence or fraud misused, the grantee shall, on demand of the commissioner of health, pay the commissioner of health a sum equal to the amount of the money misused or diverted. If, in accordance with the Minnesota Administrative Procedure Act, the commissioner of health determines that any part of the money received by the grantee, or vouchers redeemed with program funds, were lost as a result of thefts, embezzlements, or unexplained causes, the grantee shall, on demand of the commissioner of health, pay to the commissioner of health a sum equal to the amount of money or the value of the vouchers so lost.

Statutory Authority: *MS s 145.894*

History: *L 1977 c 305 s 39*

TERMINATION OF PREGNANCY**4615.3400 DEFINITIONS.**

Subpart 1. **Scope.** The applicable definitions to these rules printed herein from MHD 342 (7 MCAR Section 1.342) are as follows.

Subp. 2. **Abortion.** The term "abortion" is not used in these regulations, since it also applies to spontaneous early terminations of pregnancy. These rules do not apply to spontaneous abortions.

Subp. 3. **Ambulatory facility.** "Ambulatory facility" shall mean any institution, place or building, or part thereof, including hospital outpatient services, devoted primarily to, as determined by the department, the maintenance and operation of facilities for the performance of procedures designed to terminate a pregnancy on an outpatient basis irrespective of whether the entire structure is devoted primarily to this purpose.

Subp. 4. **Termination of pregnancy.** "Termination of pregnancy," "pregnancy termination," or "termination procedure," shall mean administering to a woman any medicine, drug, substance, or thing whatever, or the employment upon her of any instrument or other means whatever, with intent to induce or procure miscarriage of such a woman.

Statutory Authority: *MS s 145.413*

4615.3500 INTERNAL RECORDS OF THE AMBULATORY FACILITY.

The pregnancy termination facility shall keep a signed consent form of each patient undergoing a pregnancy termination procedure.

Statutory Authority: *MS s 145.413*

4615.3600 REPORTS TO THE COMMISSIONER OF HEALTH.

Subpart 1. **Statistical reports.** Each ambulatory facility shall submit a written compilation of statistical data quarterly to the commissioner of health on such forms and in such manner as the commissioner may prescribe.

Subp. 2. **Reporting terminations.** An ambulatory facility shall report all pregnancy terminations performed by its staff as follows:

A. By the tenth of each month all pregnancy terminations performed in the ambulatory facility during the preceding month shall be reported on forms prescribed by the commissioner which shall include but not be limited to the following items:

- (1) patient's city, county and state of residency;
- (2) census tract for city of Minneapolis and city of Saint Paul;

- (3) patient or chart number;
- (4) age;
- (5) race;
- (6) marital status;
- (7) number of living children;
- (8) facility name;
- (9) facility address;
- (10) number of previous induced pregnancy terminations patient;
- (11) estimate of gestational age;
- (12) date of pregnancy termination;
- (13) type of termination procedure;

B. All surgery-related or anesthesia-related complications which result in morbidity or death of a patient shall be reported in writing to the commissioner within 15 days from the notification to the ambulatory facility of the morbidity or death of the patient.

C. The commissioner shall ensure and maintain confidentiality of all individual pregnancy termination records.

Statutory Authority: *MS s 145.413*