641—4.4 (136A) Iowa maternal prenatal screening program (IMPSP). This program provides comprehensive maternal prenatal screening services for the state.

4.4(1) *Maternal screening policy.* It shall be the policy of the state of Iowa that all pregnant women are offered maternal prenatal screening. The Iowa maternal prenatal screening program provides a risk assessment for open neural tube defects, ventral wall defects, Down syndrome, and Trisomy 18.

a. If a patient desires this screening test, her health care provider shall direct that a specimen be drawn and submitted to the SHL.

b. As new technologies and tests become available, the center shall follow protocols developed by the department with regard to the addition of disorders to or the deletion of disorders from the screening program.

4.4(2) *Maternal screening procedure.*

a. Collection of specimens. A serum or clotted blood specimen shall be collected from the patient within the appropriate gestational range indicated by the requested screen.

b. Processing of specimens. The SHL shall test specimens within three working days of receipt.

c. Reporting of abnormal results. Abnormal screen results shall be reported within 24 hours to the consulting physician or the physician's designee who shall then notify the primary health care provider. On the next working day, this initial report shall be followed by a written report to the primary health care provider.

4.4(3) *Consulting physician responsibility.* A consulting physician shall be designated by the center in collaboration with the SHL to provide interpretation of screen results and consultation to the submitting health care provider. This physician shall provide consultation for abnormal screen results, assist with questions about management of identified cases, provide education and assist with quality assurance measures. The screening program, with assistance from the consulting physician, shall:

a. In collaboration with the SHL, submit a proposed budget and narrative justification for the upcoming fiscal year to the center by January 31 of each year, and

b. Submit a written annual report of the previous calendar year to the center by July 1 of each year. The report shall include:

(1) Number of women screened,
(2) Number of repeat screens,
(3) Number of abnormal results by disorder,
(4) Number of rejected specimens,
(5) Results of quality assurance testing, and
(6) Screening and educational activity details.

4.4(4) *SHL responsibility.* The SHL shall:

a. Contract with a courier service to provide transportation and delivery of maternal prenatal serum specimens.

b. Contact all entities submitting specimens to inform them of the courier's schedule.

c. Test specimens within three working days of receipt.

d. Distribute specimen collection kits and other materials to health care provider offices and drawing facilities as required.

e. Inform the submitting health care provider or drawing facility of an unacceptable specimen and request another specimen.

f. Provide educational materials concerning specimen collection procedures.

g. Have available for review a written quality assurance program covering all aspects of its screening activity.

h. Act as a fiscal agent for program charges encompassing the analytical, technical, administrative, educational and follow-up costs for the screening program.

4.4(5) *IMPSP fee determination.* The department shall annually review and determine the fee to be charged for all activities associated with the IMPSP. The review and determination of the fee shall be completed at least one month prior to the beginning of the fiscal year.

4.4(6) *Sharing of information and confidentiality.* Reports, records, and other information collected by or provided to the IMPSP relating to a patient's maternal prenatal screening results and follow-up information are confidential records pursuant to Iowa Code section 22.7.

a. Personnel of the program shall maintain the confidentiality of all information and records used in the review and analysis of maternal serum screening and follow-up, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. The program shall not release confidential information except to the following persons and entities, under the following conditions:

(1) The patient for whom the report is made.

(2) A primary health care provider or submitting laboratory.

(3) A representative of a state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency will be subject to confidentiality regulations which are the same as or more stringent than those in the state of Iowa.

(4) A researcher, upon documentation of patient consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department and the state board of health.

4.4(7) *Retention, use and disposition of residual maternal prenatal screening specimens.*

a. A maternal serum screening specimen collection consists of laboratory tubes with maternal serum and associated information about the patient, health care provider, or drawing laboratory.

(1) The residual serum specimens shall be held for a specified period of time in a locked area at the SHL in accordance with SHL policy and procedures.

(2) Reserved.

b. Research use.

(1) Investigators shall submit proposals to use residual serum specimens to the center. Any intent to utilize information associated with the requested specimens as part of the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board, the congenital and inherited disorders advisory committee, and the department.

(3) Personally identifiable residual specimens or records shall not be disclosed without documentation of informed patient consent obtained by the researcher.

(4) Research on anonymized or identifiable residual specimens shall be allowed in instances where research would further maternal prenatal screening activities or general medical knowledge for existing public health surveillance activities.

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