641—4.3(136A) Iowa maternal prenatal screening program (IMPSP). This program provides comprehensive maternal prenatal screening services for the state.

4.3(1) *Maternal screening.* The IMPSP provides a risk assessment for certain congenital or inherited conditions and disorders of a newborn. The department will identify the minimum conditions included in the assessment on the department's website.

a. If a patient desires this screening test, the health care provider shall direct that a specimen be drawn and submitted to the SHL or a laboratory with the capacity to provide screening for the minimum type of prenatal screening services.

b. As new technologies and tests become available, the department will develop and follow protocols for the addition or deletion of conditions and disorders from the screening program.

4.3(2) *Maternal screening procedure.*

a. *Specimen collection.* A serum or clotted blood specimen shall be collected from the patient within the appropriate gestational range indicated by the requested screen.

b. *Specimen processing.* The SHL will test specimens within three working days of receipt.

c. *Reporting 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.

4.3(3) *Consulting physician responsibility.* A consulting physician shall be designated by the department 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 department by January 31 of each year, and

b. Submit a written annual report of the previous calendar year's activity to the department by July 1 of each year. The report will include:

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

4.3(4) *SHL responsibility.* The SHL will:

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

b. Contact all entities submitting specimens to recommend use of the courier service to transport specimens to the SHL.

c. Test specimens within seven 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 to health care provider offices.

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.

4.3(5) *IMPSP fee determination.* The department will annually review and determine the fee to be charged for all activities associated with the IMPSP. The review and determination of the fee will be completed at least one month prior to the beginning of the fiscal year.

4.3(6) *Information sharing 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 that are the same as or more stringent than those in the state of Iowa.

c. Maternal prenatal information shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

4.3(7) *Retention, use and disposition of residual maternal prenatal screening specimens.* 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.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]