**Section 450.1310 Protocol for Conducting Health Screening**

a) Any entity that performs health screening shall establish a protocol for health screening activities that is *approved by a physician licensed to practice medicine in all its branches.* (Section 2-120(a) of the Act)

b) The protocol for conducting the health screening shall:

1) Indicate the tests to be conducted;

2) Indicate the way in which results shall be reported to the test subject, including any available oral counseling and health professional referral program;

3) Indicate how confidentiality will be maintained with provisions that allow testing personnel, test subject, and test subject's representative access to the test results;

4) Include a written quality control program to ensure accurate and precise test values as set by the physician signing the protocol and a description of the steps to be taken if the control values fall outside acceptable limits as set by the physician in the written quality control program;

5) Include the step-by-step instructions for the following:

A) Specimen collection, handling, transport, storage and disposal;

B) Patient preparation;

C) Type and volume of specimen needed and the established rejection criteria;

D) Proper specimen identification;

E) Proper reagent use, such as labeling, proper lot number usage, expiration dates, and storage requirements; and

F) Instrument operation and calibration in accordance with the manufacturer's instructions;

6) Include directions for the use of one reference material and one calibrator or two reference materials with different concentrations once each 24 hour period in which the analyzer is used;

7) Include a description of the training required of all staff conducting specific health screening tests;

8) Include a copy of educational materials for each individual screening test given to each test subject;

9) Be available to all health screening personnel at the test site;

10) Be sent to the Department at least 30 days prior to the initial testing date if more than one health screening event is conducted by that entity in a calendar year. These protocols shall be effective for one year. An existing protocol may be renewed by submitting to the Department a letter from the physician who signed the protocol specifying that no changes have been made in the protocol and that the protocol will be used for health screenings over the next year. This letter shall be submitted within 30 days prior to the expiration of the existing protocol;

11) Be signed, dated, and approved by a physician licensed to practice medicine in all its branches no earlier than three months prior to submission date;

12) Include a copy of the document to be given to each test subject which discloses the purpose and limitations of each individual screening test to be conducted;

13) Include copies of any forms used in the course of conducting health screening activities;

14) Indicate how documentation and quality control items are traceable to each individual analyte and instruments used in the health screening process and how records shall be maintained; and

15) Indicate how records of test subject results and documentation of quality control items shall be maintained for two years.

(Source: Amended at 44 Ill. Reg. 20004, effective December 9, 2020)