

Amend Statement of Basis and Purpose # 2) to strike paragraph 2 and 3 and insert after paragraph 1.

In response to stakeholder feedback, the Department has retained and clarified current rule language concerning quality control and education in Sections 5. Section 5: 1) clarifies existing rule language, 2) provides continuity of these rules across initial newborn screening and second newborn screening, and 3) clarifies which rulemaking body is promulgating the rules.

GET BOH SUPPORT OF THIS AMENDMENT PRIOR TO ED ADOPTING:

Amendment Statement of Basis and Purpose # 2) paragraph 4, last sentence add “additional”.

The Department will monitor this; if a need arises to establish **ADDITIONAL** standards in rule, the Department will assess whether the standards need to apply to initial and second screening, which lends itself to Executive Director rulemaking, or Board of Health rulemaking for second screening.

Amend rule text to add at line 590:

SECTION 5: QUALITY CONTROL AND EDUCATION (PROMULGATED BY THE EXECUTIVE DIRECTOR)

5.1 The laboratory shall have available for review a written quality assurance ~~program~~ plan covering ~~all aspects of~~ testing and reporting INITIAL AND second NEWBORN SCREENING specimens.

5.1.1 THE WRITTEN QUALITY ASSURANCE PLAN WILL INCLUDE MONITORING THE POSITIVE PREDICTIVE VALUE OF TESTING.

5.1.1.1 THE POSITIVE PREDICTIVE VALUE OF TESTING SHALL BE COMMUNICATED BY THE DEPARTMENT TO IMPROVE THE QUALITY OF INITIAL AND SECOND NEWBORN SCREENING

5.1.2 THE WRITTEN QUALITY ASSURANCE PLAN WILL INCLUDE COLLECTING DATA ON NEWBORNS WITH A SCREEN NEGATIVE RESULT WHO ARE LATER DETERMINED TO HAVE A DIAGNOSED CONDITION WHICH WAS IDENTIFIABLE THROUGH SCREENING.

5.2 The laboratory shall make available educational materials and training concerning INITIAL AND SECOND NEWBORN SCREENING specimen collection to all submitting agencies.

5.2.1 THE LABORATORY SHALL COLLECT AND ANALYZE QUALITY INDICATORS TO MONITOR AND INFORM THE NEWBORN SCREENING PROCESS INCLUDING COLLECTION AND TRANSIT OF INITIAL NEWBORN SCREENING SPECIMENS AND UNSATISFACTORY INITIAL

NEWBORN SCREENING SPECIMENS. THE DATA WILL BE USED TO IMPLEMENT QUALITY IMPROVEMENT ACTIVITIES.

5.2.1.1 QUALITY INDICATORS AND PERFORMANCE DATA SHALL BE COMMUNICATED BY THE DEPARTMENT TO IMPROVE THE QUALITY OF INITIAL AND SECOND NEWBORN SCREENING.