

## SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT’S RESPONSE

### Rules And Regulations Relating To Testing Newborn Infants For Detection Of Causes Of Cognitive Disabilities And Selected Genetic Conditions (now titled Newborn Bloodspot Screening Rule)

#### 10-144 CMR, Chapter 283

The Department of Health and Human Services, Maine CDC held a public hearing on June 20, 2018 on the proposed rule, 10-144 CMR, Ch. 283. Representatives from Maine CDC, including staff from the Newborn Bloodspot Screening Program (NBSP), facilitated the public hearing. On May 30, 2018, a notice of agency rulemaking was published in five major newspapers; announced on the Secretary of State website; and sent to stakeholders, electronically or by mail. Also on this date, the proposed rule and notice of rulemaking were uploaded to the Maine CDC Rules website. Comments were accepted through June 30, 2018.

Commenter ID #	Name	Date	Representing	Format
1	Liz Pujolas, on behalf of Carolyn D. Jones	6/29/18	Biogen	Written
2	Jaimie Vickery, on behalf of Kenneth Hobby Jill Jarecki, PhD Mary Schroth, M.D., and Richard Rubenstein, Esq	6/29/18	Cure SMA	Written

Commenters 1 – 2 are identified in Table 1 above. Commenters presented written comments during the comment period. Comments have been summarized below, followed by the Department’s response that explains whether the changes were made based on the comment(s). If the changes were not made as a result of comment, then the reason why the Department did not make changes is explained. Changes made following public comments and review by Office of the Attorney General for form and legality are contained in the adopted rule.

- Comment:** Commenters 1 and 2 requested that spinal muscular atrophy (SMA) be added to the list of conditions included in the rule. Commenter 1 and 2 stated that the Secretary of the US Department of Health and Human Services (HHS) is reviewing the recommendation by the US HHS Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) that SMA be added to the Recommended Uniform Screening Panel (RUSP). Commenters suggested that adding SMA to Maine’s screening panel could provide more treatment options for newborns with SMA and mitigate negative outcomes of the disease. Commenter 2 suggested that, since Maine contracts with Massachusetts to perform these screenings and Massachusetts currently screens for SMA, adding SMA to Maine’s panel should not present any significant logistical challenges.

**Response:** At this time, Maine CDC’s Joint Advisory Committee for the Maine Newborn Screening Program (JAC) is currently reviewing SMA as one of four conditions for inclusion in Maine’s list of conditions required for NBS screening. Prior to implementing a new required screening test, the JAC considers the HHS recommendation that disorders be chosen, based on evidence that supports the potential benefit of screening and the capacity to provide screening and effective treatments. The Department has determined that adding SMA to Maine’s screening panel requires additional time to allow for program infrastructure assessment and development. As a result, this recommended change will not be implemented for this rulemaking. The Department refers the commenters to Section 8 of the rule, to explain the Department’s process in determining whether new conditions are added. The Department made no change to the rule based on these comments.

#### LIST OF CHANGES IN RESPONSE TO AAG REVIEW:

Based on the fact that no changes were made as a result of public comment, the following changes were made for clarity or in response to AAG review for form and legality:

##### Throughout Rule:

- Corrected minor grammatical errors;
- Changed health care provider to “healthcare provider”;
- Consistently used the term “Residual Filter Paper Specimen”;

##### Section 2 Definitions:

- Removed reference to 22 MRS §2150(F)in Section 2(A);

- Moved the definition of “Principal birthing attendant” from Section 2(A)(2) to Section 2(A)(8) to be consistent with alphabetical order and changed “principal attendant” to “primary”. The statement “This may be a midwife or other adult attendant” was removed
- In Section 2(A)(9), added “specimen” to “Residual filter paper” definition;

### **Section 3 Responsibility for Specimen Collection....**

- In Section 3(B), removed proposed language referring to parental refusal requirements in Section 9;

### **Section 4 Responsibility for Newborn Bloodspot Specimen Collection from Infants....**

- In Section 4(A) and 4(C), changed “authorized” to “qualified”;
- In Section 4(A), removed the word “other” to describe “principal birthing attendant”;
- In Section 4(D), removed proposed language referring to parental refusal requirements in Section 9;
- Due to removal of proposed 4(D) language, Section 4(D) became the new Section (C) (Section 4.3 in the former rule);
- Removed the proposed language “the governing statute and” in Section 4(D)(4).

### **Section 11 Advisory Committee**

- In the title of the section, added “Joint” before Advisory and added “(JAC)” after “Committee”;
- In Section 11(A), changed the proposed “must” back to the original “shall”;
- Added a Section 11(B) that clarified that committee meetings are public, held twice per year and are advertised on the Maine CDC website. A link is provided;

### **Section 12 Filter Paper Storage and Use**

- In the title of the rule, added “Residual” to describe “filter” and added “specimen” after “paper”;
- Removed language from Section 12(E), which was Section 12.6 in the former rule, and replaced with “Information obtained during the testing process becomes the property of the Department and may be used in compliance with confidentiality laws, for program evaluation or research by the Department or Department-approved scientific researchers to improve the health of mothers and children.” ;
- Added Section 12(F) as new language that states: “Newborn blood specimens obtained during the testing process becomes the property of the Department and may be used in compliance with confidentiality laws, for program evaluation or research by the Department or Department-approved scientific researchers to improve the health of mothers and children, unless the person or his/her legal authorized representative: 1. Specifically prohibits such use in writing on a form provided by the Department; or 2. Requests destruction of the residual filter paper specimen under Section 13.
- Due to the new Section 12(F) language, the originally proposed Section 12(F) language is now Section 12(G);
- Amended 12(G) language (originally proposed as Section 12(F)) by updating terminology, clarifying the Department’s process for removing personally identifiable information, removed the originally proposed language of Section 12(F)(2) about letters of support and replaced it with: “Prior to release of any NBS specimens, the external agency receiving the specimens will sign an appropriate Confidentiality and Use Agreement which will specify that the released sample and any information obtained with or derived from, it may only be used for the specifically approved study.”

### **Section 13 Filter Paper Destruction**

- Amended the title of this section to: “Residual Filter Paper Specimen Destruction”;
- Changed the title of the form from “Request for Destruction of Newborn Filter Paper Specimen Form” to “Request for Destruction of Residual Filter Paper Specimen Form”;
- In Section 13(B), added “residual” to “filter paper specimens”;

### **Section 14 Fees**

- Removed proposed Section 14(A) formerly Section 13.1 language and replaced with: Hospitals and healthcare providers must use the filter paper approved by the Department for NBS specimen collection.