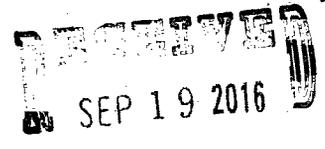


Administrative Procedures – Final Proposed Rule Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the “Rule on Rulemaking” adopted by the Office of the Secretary of State, this final proposed filing will be considered complete upon the submission and acceptance of the following components to the Office of the Secretary of State and to the Legislative Committee on Administrative Rules:

- Final Proposed Rule Coversheet
- Adopting Page
- Economic Impact Statement
- Public Input Statement
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)
- Copy of ICAR acceptance e-mail
- A copy of comments received during the Public Notice and Comment Period.
- Responsiveness Summary (detailing agency’s decisions to reject or adopt suggested changes received as public comment).



BY:

All forms submitted to the Office of the Secretary of State, requiring a signature shall be hand signed original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted, no later than 3:30 pm on the last scheduled day of the work week.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Rule Title: Newborn Screening Program Rule

Paul Dragan Pa, on 9-16-16
(signature) (date)

Printed Name and Title:
Hal Cohen
Secretary, Agency of Human Services

RECEIVED BY: _____

- Final Proposed Rule Coversheet
- Adopting Page
- Economic Impact Statement
- Public Input Statement
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)
- ICAR Approval received by E-mail.
- Copy of Comments
- Responsiveness Summary

1. TITLE OF RULE FILING:

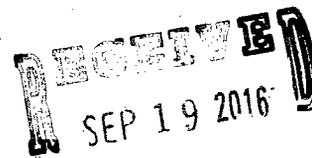
Newborn Screening Program Rule

2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE

16P-040

3. ADOPTING AGENCY:

Department of Health



4. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: Lillian Colasurdo

Agency: Department of Health

Mailing Address: 108 Cherry Street, Burlington, VT 05402

Telephone: 802 951 - 0107 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

Web URL (WHERE THE RULE WILL BE POSTED):

http://healthvermont.gov/regs/index.aspx

5. SECONDARY CONTACT PERSON:

(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: David Englander

Agency: Department of Health

Mailing Address: 108 Cherry Street, Burlington, VT 05402

Telephone: 802 863 - 7280 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

6. RECORDS EXEMPTION INCLUDED WITHIN RULE:

(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

7. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

3 VSA §801(b)(11), 3 VSA § 3003; 18 VSA §§102, 115; and 5087.

8. THE FILING HAS NOT CHANGED SINCE THE FILING OF THE PROPOSED RULE.
9. THE AGENCY HAS NOT INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
10. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
11. THE AGENCY HAS INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
12. THE AGENCY HAS INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.
13. **CONCISE SUMMARY (150 WORDS OR LESS):**
Act 152 (2016) amended 18 V.S.A. § 115 to require that the Department promulgate rules requiring the screening for congenital heart defects (CCHD) on every newborn in the state. This proposed rule change adds this language to current screenings. The overall purpose of this rule is to provide standards for screening for certain diseases in newborn children.
14. **EXPLANATION OF WHY THE RULE IS NECESSARY:**
The rule change is necessary to mandate the screening for CCHD in newborns. The rule is necessary to help with early identification and prevent severe disability and/or death by assuring timely initiation of treatment services.
15. **LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:**
Health care providers, newborn infants and their parents or guardians.
16. **BRIEF SUMMARY OF ECONOMIC IMPACT(150 WORDS OR LESS):**
No impact is expected. Providers are already screening nearly 100% of newborns in the state and the Department added CCHD to the list of recommended screenings during the last rulemaking.
17. A HEARING WAS NOT HELD.
18. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date:

Time: AM

Street Address:

Zip Code:

19. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

8/18/2016

20. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Newborn Screening

Dried bloodspot testing

CCHD

Congenital heart defect

Critical congenital heart disease

Pulse oximetry

Run Spell Check

208 HURRICANE LANE, SUITE 103
WILLISTON, VERMONT 05495



OFFICE OF THE SECRETARY
TEL: (802) 871-3009
FAX: (802) 871-3001

HAL COHEN, SECRETARY
PAUL DRAGON, DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Jim Condos, Secretary of State
FROM: Hal Cohen, Secretary *HC*
DATE: January 8, 2016
SUBJECT: Signatory for Purposes of Authorizing Administrative Rules

I hereby designate Deputy Secretary of Human Services Paul Dragon as signatory authority to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedure Act, 3 V.S.A. § 801 et seq.

A large, handwritten signature in black ink, appearing to read "Hal Cohen", with a long horizontal line extending to the right.

Administrative Procedures – Adopting Page

Instructions:

This form must be completed for each filing made during the rulemaking process:

- Proposed Rule Filing
- Final Proposed Filing
- Adopted Rule Filing
- Emergency Rule Filing

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:

Newborn Screening Program Rule

2. ADOPTING AGENCY:

Department of Health

3. AGENCY REFERENCE NUMBER, IF ANY:

16P040

4. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

- **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
- **NEW RULE** - A rule that did not previously exist even under a different name.
- **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

This filing is **AN AMENDMENT OF AN EXISTING RULE** .

5. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND LAST DATE OF ADOPTION FOR THE EXISTING RULE*):

Newborn Screening Program Regulations, May 1, 2016 Secretary of State Rule Log #16-008

Run Spell Check

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES

To: Louise Corliss, SOS
Chris Winters, SOS
Charlene Dindo, LCAR
ICAR Members

Date: July 12, 2016

Proposed Rule: Newborn Screening Program Rule
(Agency of Human Services/Dept of Health)

The following official action was taken at the July 11, 2016 meeting of ICAR.

Present: Chair Michael Clasen, Diane Bothfeld, Steve Knudson, Clare O'Shaughnessy, Dirk Anderson, John Kessler and David Englander for Allan Sullivan

Absent: Jenn Duggan – voted electronically
Scott Bascom

Abstain: David Englander

The Committee has no objection to the proposed rule being filed with the Secretary of State.

The Committee approves the rule with the following recommendations.

1. Economic Impact Statement #3: Correct spelling of "potential".

The Committee opposes filing of the proposed rule.

cc: Lillian Colasurdo

Administrative Procedures – Public Input Statement

Instructions:

In completing the public input statement, an agency describes what it did do, or will do to maximize the involvement of the public in the development of the rule. This form must be completed for the following filings made during the rulemaking process:

- Proposed Rule Filing
- Final Proposed Filing
- Adopted Rule Filing
- Emergency Rule Filing

1. TITLE OF RULE FILING:

Newborn Screening Rule

2. ADOPTING AGENCY:

Department of Health

3. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

The Department published the rule in newspapers of record and posted the rule on its website:

http://www.healthvermont.gov/admin/public_comment.aspx

No hearing was held as the changes incorporated by this proposed rule revision are mandated by the Legislature and CCHD was added through the public rule-making process, without opposition, during the previous rule revision.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

Health care providers, American Heart Association.

Run Spell Check

Administrative Procedures – Economic Impact Statement

Instructions:

In completing the economic impact statement, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule. This form must be completed for the following filings made during the rulemaking process:

- Proposed Rule Filing
- Final Proposed Filing
- Adopted Rule Filing
- Emergency Rule Filing

Rules affecting or regulating public education and public schools must include cost implications to local school districts and taxpayers in the impact statement (see 3 V.S.A. § 832b for details).

The economic impact statement also contains a section relating to the impact of the rule on greenhouse gases. Agencies are required to explain how the rule has been crafted to reduce the extent to which greenhouse gases are emitted (see 3 V.S.A. § 838(c)(4) for details).

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I conclude that this rule is the most appropriate method of achieving the regulatory purpose. In support of this conclusion I have attached all findings required by 3 V.S.A. §§ 832a, 832b, and 838(c) for the filing of the rule entitled:

Rule Title: Newborn Screening Rule

Paul Dragon FR, on 9-6-16
(signature) (date)

Printed Name and Title:

Hal Cohen
Secretary, Agency of Human Services

BE AS SPECIFIC AS POSSIBLE IN THE COMPLETION OF THIS FORM, GIVING FULL INFORMATION ON YOUR ASSUMPTIONS, DATABASES, AND ATTEMPTS TO GATHER OTHER INFORMATION ON THE NATURE OF THE COSTS AND BENEFITS INVOLVED. COSTS AND BENEFITS CAN INCLUDE ANY TANGIBLE OR INTANGIBLE ENTITIES OR FORCES WHICH WILL MAKE AN IMPACT ON LIFE WITHOUT THIS RULE.

1. TITLE OF RULE FILING:

Newborn Screening Program Rule

2. ADOPTING AGENCY:

Department of Health

3. CATEGORY OF AFFECTED PARTIES:

LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

Health care providers for newborn infants, newborn infants, parents or guardians of newborn infants. Newborn screening provides significant potential economic benefits and health care cost savings by allowing for earlier diagnosis and intervention for certain serious disorders.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS:

No impact.

5. COMPARISON:

COMPARE THE ECONOMIC IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

No impact is expected. Providers are already screening nearly 100% of newborns in the state and the Department added CCHD to the list of recommended screenings during the last rulemaking.

6. FLEXIBILITY STATEMENT:

COMPARE THE BURDEN IMPOSED ON SMALL BUSINESS BY COMPLIANCE WITH THE RULE TO THE BURDEN WHICH WOULD BE IMPOSED BY ALTERNATIVES CONSIDERED IN 3 V.S.A. § 832a:

No impact.

7. GREENHOUSE GAS IMPACT: *EXPLAIN HOW THE RULE WAS CRAFTED TO*

REDUCE THE EXTENT TO WHICH GREENHOUSE GASES ARE EMITTED, EITHER DIRECTLY OR INDIRECTLY, FROM THE FOLLOWING SECTORS OF ACTIVITIES:

A. TRANSPORTATION —

IMPACTS BASED ON THE TRANSPORTATION OF PEOPLE OR PRODUCTS (e.g., “THE RULE HAS PROVISIONS FOR CONFERENCE CALLS INSTEAD OF TRAVEL TO MEETINGS” OR “LOCAL PRODUCTS ARE PREFERENTIALLY PURCHASED TO REDUCE SHIPPING DISTANCE.”):

No impact.

B. LAND USE AND DEVELOPMENT —

IMPACTS BASED ON LAND USE AND DEVELOPMENT, FORESTRY, AGRICULTURE ETC. (e.g., “THE RULE WILL RESULT IN ENHANCED, HIGHER DENSITY DOWNTOWN DEVELOPMENT.” OR “THE RULE MAINTAINS OPEN SPACE, FORESTED LAND AND /OR AGRICULTURAL LAND.”):

No impact.

C. BUILDING INFRASTRUCTURE —

IMPACTS BASED ON THE HEATING, COOLING AND ELECTRICITY CONSUMPTION NEEDS (e.g., “THE RULE PROMOTES WEATHERIZATION TO REDUCE BUILDING HEATING AND COOLING DEMANDS.” OR “THE PURCHASE AND USE OF EFFICIENT ENERGY STAR APPLIANCES IS REQUIRED TO REDUCE ELECTRICITY CONSUMPTION.”):

No impact.

D. WASTE GENERATION / REDUCTION —

IMPACTS BASED ON THE GENERATION OF WASTE OR THE REDUCTION, REUSE, AND RECYCLING OPPORTUNITIES AVAILABLE (e.g., “THE RULE WILL RESULT IN REUSE OF PACKING MATERIALS.” OR “AS A RESULT OF THE RULE, FOOD AND OTHER ORGANIC WASTE WILL BE COMPOSTED OR DIVERTED TO A ‘METHANE TO ENERGY PROJECT’.”):

No impact.

E. OTHER —

IMPACTS BASED ON OTHER CRITERIA NOT PREVIOUSLY LISTED:

No impact.

Run Spell Check

Public Comment Responsiveness Summary Newborn Screening Rule

The Vermont Department of Health (“Department”) held a public comment period on the Newborn Screening Rule from July 22, 2016 through August 18, 2016.

The following is summary of comments received from the public and the Department’s response to each comment. Comments of a similar or consistent nature have been consolidated and responded to accordingly.

- 1. Comment:** The Department received several comments requesting that the use of pulse oximetry screening for critical congenital heart disease (CCHD) be required in section 4.2.2. Some commenters suggested language employed by Pennsylvania.

Response: Act 152 (2016) states, “On or before January 1, 2017, the Commissioner of Health shall adopt rules pursuant to 3 V.S.A. chapter 25 requiring the screening for a congenital heart defect on every newborn in the State, unless a critical congenital heart defect was detected prenatally. Screening tests for critical congenital heart defects may include pulse oximetry or other methodologies that reflect the standard of care.” The Department has adopted the exact language from Act 152 in order to harmonize the current rule with the new statutory requirements for mandatory screening. Additionally, the Department does not see any additional benefit to mandating a specific diagnostic test, particularly one that is already considered to be the standard of care. It is useful to note that Vermont’s Newborn Screening Program reports that 100% of live births, whose parents did not specifically refuse, were screened in 2015. Mandating a particular type of diagnostic screening tool interferes with the medical profession’s ability to set the standard of care for practice.