Congenital and Inherited Disorders Advisory Committee
Minutes
July 29, 2022
12:00 p.m. to 2:00 p.m.
Zoom and conference call

Minutes
Video recording of the meeting is available at

Members Present	Members Absent	Others Present
Carol Cross	Jennifer Nutt	Kimberly Noble Piper - IDPH
Jeneane Moody	Jona Conklin	Carol Johnson
Anya Prince	Andrea Greiner	Jaclyn Kotlarek
Dan Rowley	Tom Scholz	Jason Picconi
Kelly Schulte	Nate Noble	Sarah Feddersen
Adam Brown	Stacy Frelund	Emily Phillips
Wade Aldous/Mike Pentella	Amy Calhoun	Miranda McAuliffe
Paul Romitti	Barbara Pappas	Michelle Bargren
Francis Degnin	Hannah Bombei	Diane Recker
Carrie Bernat	Kimberly VonAhsen	Hari Patel
Jeremy Penn		Natalie Dennler
Amanda Devereaux		Kayla Blankenship
Shane Austerman		Tate Kappell
		Jacob Ginter
		Melody Hobert-Mellecker
		Georgianne Younger
		Meghan Kofod
		Zheni Shen
		John Bernat
		Christina Trout
		Jon Washburn

Topics	Discussion/Action
Call to Order	▪ Penn called the meeting to order at 12:07 pm. ▪ Roll call attendance was taken. There is a quorum of members present.
Announcements	Piper shared an update about the DHHS alignment, including the draft functional org chart and CCID place in the new DHHS structure. There will be a DHHS alignment presentation for stakeholders on Monday, August 1 at 9:00 am. Zoom information: **Join Zoom Meeting** https://us02web.zoom.us/j/83011274215?pwd=UzRpakkvSU1Oc1ZTZTNlTjFkcXZ2dz09 **Meeting ID:** 830 1127 4215 **Passcode:** 817235 One tap mobile +13126266799,,83011274215#,,,,*817235# US (Chicago) +16468769923,,83011274215#,,,,*817235# US (New York) **Dial by your location** +1 312 626 6799 US (Chicago) +1 646 876 9923 US (New York) +1 646 931 3860 US

	+1 301 715 8592 US (Washington DC) +1 669 900 6833 US (San Jose) +1 253 215 8782 US (Tacoma) +1 346 248 7799 US (Houston) +1 386 347 5053 US +1 564 217 2000 US +1 669 444 9171 US **Meeting ID:** 830 1127 4215 **Passcode:** 817235 Find your local number: https://us02web.zoom.us/u/kdqjZRrd5c
Update on Notice of Intent to Amend (NoIA)Iowa Administrative Code 641.4	Piper stated the former NoIA 641.4 was rescinded in order to address some questions & concerns the proposed revisions raised, and in order the proposed revisions are consistent with policy revisions coming through the DHHS alignment process. A new NoIA for 641.4 was noticed this week, and all the proposed revisions relate to the new SF2345 requirements for CIDAC responsibility for management of the newborn screening panel and the authority given to the SHL to set the NBS fee.
CIDAC Sub-committee for the Management of the Iowa Newborn Screening Panel	Penn presented the proposed charge, structure and function of the proposed Subcommittee for the Management of the Newborn Screening Panel. Penn noted that the plan for reviewing the efficacy of the newborn screening panel may fall to two separate subcommittees to assure a timely review moving forward. Presentation materials are available attached to these minutes. After discussion, Degnin moved to approve the establishment of the Subcommittee as presented by Penn. Rowley 2nd. Roll-call vote = motion passed by a vote of 11 ayes and 1 nay.
Update newborn screening for Pompe, MPS I and X-ALD	Update from SHL/STFU on screening for Pompe, MPS1, and X-ALD. Tate Kappell from SHL - SHL has the instruments required for testing all three of these disorders. The Pompe assay is close to validation and SHL will be testing for Pompe for South Dakota on September 1, 2022. For MPS1- SHL is close to being able to begin validation testing for MPS 1 because it comes in a kit with the other LSDs. XALD will take a little more time –SHL is moving forward with assay development and validation, but it's hard to set a timeline for that due to other variables; under perfect conditions we hope to complete the XALD assay validation within 6-8 months. This gives SHL some time to build some contingency plans, IT infrastructure, etc. Carol Johnson for STFU – Medical consultants have been identified for all three conditions. Dr. John Bernat will be the medical consultant for Pompe and MPS1 and Dr. Dimah Saade will be the medical consultant for X-ALD. STFU is very close for having their protocols done for Pompe and MPS1. They have an outline of a template for XALD. Carol mentions that the IDPH/INSP submitted a grant proposal to CDC for support to implement screening for these three conditions, and expect to hear about that any day now.
Public Comment	Public Comments were presented from Carol Johnson, Shane Austerman, Amanda Devereaux, and Carol Cross. Comments can be found in the recording of this meeting available here, starting at the minute mark 1:42.
Adjournment	Meeting adjourned at 1:50 pm. Next CIDAC meeting is October 28, 2022 from 12:00 pm to 2:00 pm via Zoom.

IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADMINISTRATION

FINANCE
- Accounting Services
  - Purchasing, Payments, and Receipts
  - Collection Services
- Budget and Planning
- Public Health Finance Office

GENERAL BUSINESS SERVICES

HUMAN RESOURCES
- Human Services Delivery and Payroll

INFORMATION TECHNOLOGY
- Human Services Information Technology
  - Enterprise Systems
  - Enterprise Infrastructure Services
  - Enterprise Data and Business Intelligence
  - Project Management
  - Architecture and IT Strategy
  - Application Development
- Public Health Information Technology

COMPLIANCE

ADMINISTRATIVE RULES AND APPEALS

ALIGNMENT IMPLEMENTATION OFFICE

AUDIT

CONTRACTS AND DATA
- Contracts and Procurement
  - Service Contracting and Grant Management
  - Program Support
  - Information Technology Contracting, Management, and Systems
- Data Sharing and Privacy

MEDICAL CANNABIDIOL

PROFESSIONAL LICENSING AND REGULATION
- Board of Medicine
- Board of Nursing
- Board of Pharmacy
- Professional Licensure
- Dental Board

STRATEGIC OPERATIONS

EXTERNAL RELATIONS
- Communications
- Government Relations

REFUGEE SUPPORTS

TRANSFORMATION AND PERFORMANCE
- Performance
- Transformation

MEDICAID

MANAGED CARE REPORTING AND OVERSIGHT

MEDICAID CONTRACTING

LONG TERM SERVICES AND SUPPORTS POLICY

PROGRAM INTEGRITY AND COMPLIANCE

QUALITY INNOVATION AND MEDICAL POLICY

STATE-OPERATED FACILITIES

CIVIL COMMITMENT UNIT FOR SEXUAL OFFENDERS

ELDORA STATE TRAINING SCHOOL

MENTAL HEALTH INSTITUTES
- Independence
- Cherokee

RESOURCE CENTERS
- Woodward
- Glenwood

BEHAVIORAL HEALTH AND DISABILITY SERVICES

COMMUNITY-BASED PREVENTION, SERVICES, AND INTEGRATION FOR PEOPLE WITH DISABILITIES
- Case Management
- Community Integration
- Disability Prevention

PERFORMANCE, INNOVATION, AND MENTAL HEALTH
- Behavioral health Performance and Innovation
- Community Mental Health
- Crisis and Suicide Prevention and Response

SUBSTANCE USE DISORDER PREVENTION, TREATMENT, AND RECOVERY
- Substance Use Disorder Prevention
- Substance Use Disorder Treatment
- Substance Use Disorder Recovery

PUBLIC HEALTH

HEALTH PROMOTION, DISEASE, AND INJURY PREVENTION
- Health Promotion and Chronic Disease Prevention
  - Screening
  - Intervention
- Tobacco Use Prevention and Control

HEALTH PROTECTION
- Environmental Health
- Radiological Health
- EMS and Trauma
- Emergency Preparedness and Response

HEALTH STATISTICS AND PRIMARY AND RURAL HEALTH
- Health Statistics Issuance
- Health Statistics Legal Actions
- Rural and Primary Care Support

INFECTIOUS DISEASE PREVENTION AND RESPONSE
- Immunization and Tuberculosis
- HIV, STI, and Hepatitis
  - HIV and Hepatitis Program
  - STI Program
- CADE
  - Infectious Disease Surveillance
  - Foodborne and Field

OPERATIONS
- Performance
- Public Health Surveillance and Data Strategy

STATE MEDICAL EXAMINER

COMMUNITY ACCESS

CHILD SUPPORT SERVICES
- Regional Operations
- Administration
- Policy and System Support
- Policy and Case Management Support

OPERATIONS (cross-functional)
- Quality Control
- Quality Assurance and Improvement

ECONOMIC ASSISTANCE
- Field Operations
- Specialized Eligibility
  - Income Maintenance Customer Service Center, Centralized Eligibility Unit
  - Child Care Assistance Eligibility Unit, Child Care Registration
  - Health Insurance Premium Payment, Rent Reimbursement, Integrated Claims Recovery Unit, Continuous Case Improvement Unit
- Health Policy
- Financial Assistance, Food Assistance, and Work Supports
- Support and Training
- ELIAS

WELLNESS AND PREVENTIVE HEALTH
- Family Health
  - Reproductive Health
  - Child and Adolescent Health
  - Oral Health
- Nutrition and Physical Activity
  - WIC

FAMILY WELL-BEING AND PROTECTION

ADULT PROTECTION AND SERVICES

CHILD CARE AND FAMILY SERVICES
- Operations
  - Centers
  - Homes
- Policy
- Family Services

CHILD PROTECTION AND SERVICES
- Field Operations
- Policy
- Title IV-E Foster Care, Interstate Compact on the Placement of Children

OPERATIONS (cross-functional)
- Quality Assurance and Improvement
- Support and Training
- Centralized Service Intake Unit

DRAFT Last Revised 29 July 2022

ARC 6432C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to the center for congenital and inherited disorders and providing an opportunity for public comment

The Public Health Department hereby proposes to amend Chapter 4, "Center for Congenital and Inherited Disorders," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 136A.8 and 2022 Iowa Acts, Senate File 2345.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136A and 2022 Iowa Acts, Senate File 2345.

Purpose and Summary

The proposed amendments will accomplish the following:

- Add definitions of "Iowa newborn screening panel," "Iowa newborn screening program," and "federal recommended uniform screening panel" (pursuant to 2022 Iowa Acts, Senate File 2345).
- Rescind language requiring State Board of Health approval to add disorders to or remove disorders from the newborn screening panel.
- Provide a fax number for the submission of refusal forms.
- Remove language establishing the newborn screening fee and describe the authority given to the State Hygienic Laboratory (SHL) to establish the newborn screening fee, pursuant to Senate File 2345.
- Describe the authority given through Senate File 2345 to the Congenital and Inherited Disorders Advisory Committee (CIDAC) to review newborn screening conditions on the federal recommended uniform screening panel (U.S. Department of Health and Human Services Recommended Uniform Screening Panel (RUSP)) to determine whether to add them to Iowa's newborn screening panel.
- Establish timelines for CIDAC's review and consideration of RUSP conditions (within 12 months of the addition of the condition to the RUSP) and for the Department to add the condition(s) to the state newborn screening panel (within 18 months of CIDAC's recommendation).
- Add a description of CIDAC membership pursuant to Senate File 2345.

Fiscal Impact

This rule making may have a fiscal impact to the State of Iowa. There will be additional expenses for laboratory equipment and infrastructure to support the testing, including test supplies, education materials, and training provided to expecting parents and providers. 2022 Iowa Acts, Senate File 2345, gives authority to the SHL to establish a newborn screening fee schedule in a manner sufficient to support the newborn screening system of care.

The costs of the additional jobs, equipment, supplies, trainings, and educational materials are dependent on the type of disorders added to the newborn screening panel; each disorder comes with specific testing methodology and expertise requirements, so costs are unknown until such time as the capacity of the current system and the administration, laboratory, clinical, and follow-up needs for expansion of the panel for the specific disorder(s) can be assessed.

Jobs Impact

The addition of disorders to the newborn screening panel as required by 2022 Iowa Acts, Senate File 2345, may create additional jobs for those with expertise in the disorder(s) added, such as laboratory scientists, bioinformaticians, medical geneticists, genetic counselors, and follow-up nurses.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on August 16, 2022. Comments should be directed to:

Kimberly Piper
Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Email: kimberly.piper@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend subrule 4.1(1) as follows:

4.1(1) *Advisory committee.* The center for congenital and inherited disorders advisory committee represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The advisory committee advises the director of the department of public health regarding issues related to genetics and hereditary and congenital disorders and makes recommendations about the design and implementation of the center's programs.

ITEM 2. Adopt the following **new** definitions of "Federal recommended uniform screening panel," "Iowa newborn screening panel" and "Iowa newborn screening program" in rule **641—4.2(136A)**:

"Federal recommended uniform screening panel" means the list of disorders for which the U.S. Department of Health and Human Services recommends states screen as part of their state newborn screening panels.

"Iowa newborn screening panel" or *"newborn screening panel"* means the list of disorders for which the department screens Iowa newborns.

"Iowa newborn screening program" or *"INSP"* means a program that provides screening of live-born Iowa newborns for the disorders listed on the Iowa newborn screening panel.

ITEM 3. Amend rule **641—4.2(136A)**, definitions of "Committee" and "Specialty genetics provider," as follows:

"~~Committee~~ Advisory committee" means the congenital and inherited disorders advisory committee (CIDAC).

"Specialty genetics provider" means a medical geneticist, genetic nurse, or genetic counselor.

ITEM 4. Amend paragraphs **4.3(1)"a"** and **"b"** as follows:

a. All newborns and infants born in the state of Iowa shall be screened for all congenital and inherited disorders on the Iowa newborn screening panel as specified by the center ~~and approved by the state board of health~~.

b. As new disorders are recognized and new technologies and tests become available, the center shall follow protocols developed by the department in regard to the addition of disorders to or the deletion of disorders from the screening panel. ~~The state board of health shall provide final approval for the addition of disorders to or the deletion of disorders from the screening panel.~~

ITEM 5. Amend paragraph **4.3(2)"b"** as follows:

b. Refusal of screening. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal of screening form to the central laboratory within six days of the refusal. The birthing facility or attending health care provider may submit refusal forms via the courier service established for the transportation of newborn screening specimen collection forms or via secure facsimile to (319)384–5116.

ITEM 6. Amend subparagraph **4.3(9)"a"(2)** as follows:

(2) Refusal. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal form to the central laboratory within six days of the refusal. The birthing facility or attending health care provider may submit refusal forms via the courier service established for the transportation of newborn screening specimen collection forms or via secure facsimile to (319)384–5116.

ITEM 7. Amend subrule 4.3(10) as follows:

4.3(10) *INSP and IMPSP fees.*

a. ~~The department shall annually review and determine the fee to be charged for all activities associated with the INSP and the IMPSP. The review and fee determination shall be completed at least one month prior to the beginning of the fiscal year. The newborn screening fee is $122.~~ In consultation with the department, the SHL shall establish the newborn screening fee schedule in a manner sufficient to support the newborn screening system of care including, but not limited to, laboratory screening costs, short-term and long-term follow-up program costs, the newborn screening developmental fund, and the cost of the department's newborn screening data system.

b. The ~~department~~ SHL shall include as part of the INSP fee an amount ~~determined by the committee and department~~ to fund the provision of special medical formula and foods for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the programs.

c. Funds collected through newborn screening fees shall be used for newborn screening program activities only.

d. Funds collected through maternal prenatal screening fees shall be used for maternal prenatal screening activities only.

e. In order to support newborn and maternal prenatal screening activities, the department shall authorize the expenditure and exchange of newborn screening and maternal prenatal screening developmental funds between the SHL (as designated fiscal agent) and the department.

f. ~~Upon department approval of proposed budgets, a~~ A portion of INSP and IMPSP fees shall be distributed to the department to support activities of the INSP and the IMPSP at the center for congenital and inherited disorders (CCID).

ITEM 8. Amend rules 641—4.11(136A) to 641—4.13(136A) as follows:

641—4.11(136A) Purpose. ~~CIDAC represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The committee advises the director regarding issues related to genetics and hereditary and congenital disorders.~~ A congenital and inherited disorders advisory committee (CIDAC or advisory committee) is established to assist the center for congenital and inherited disorders and the department in the development of programs that ensure the availability of and access to quality genetic and genomic health care services for all Iowans.

641—4.12(136A) Duties of the advisory committee. CIDAC shall perform the following duties:

4.12(1) Make recommendations about the design and implementation of the center's programs, including but not limited to:

a. The Iowa newborn screening program~~;~~, including management of the Iowa newborn screening panel.

(1) The advisory committee shall assist the center for congenital and inherited disorders and the department in designating the conditions to be included in the newborn screening and in regularly evaluating the effectiveness and appropriateness of the newborn screening.

(2) Beginning July 1, 2022, the advisory committee shall ensure that all conditions included in the federal recommended uniform screening panel as of January 1, 2022, are included in the newborn screening.

(3) Within 12 months of the addition of a new condition to the federal recommended uniform screening panel, the advisory committee shall consider and make a recommendation to the department regarding inclusion of the new condition in the newborn screening panel, including the current newborn screening capacity to screen for the new condition and the resources necessary to screen for the new condition going forward.

(4) If the advisory committee recommends inclusion of a new condition, the department shall include the new condition in the newborn screening panel within 18 months of receipt of the recommendation;

b. The regional genetics consultation service;

c. The maternal prenatal screening program;

d. The neuromuscular and related genetic disorders program; and

e. The Iowa registry for congenital and inherited disorders.

4.12(2) Support the development of special projects and conferences regarding genetic and genomic health care services and issues.

4.12(3) Advocate for quality genetic and genomic health care services for all residents in the state of Iowa.

641—4.13(136A) Membership. The members of the advisory committee shall be appointed by the director and shall include persons with relevant expertise and interest including parent representatives. Membership will be comprised of representatives of professional groups, agencies, legislators, parents, consumers, and professional health care providers.

4.13(1) CIDAC ~~shall be comprised of regular, ex officio, and honorary members~~ membership.

a. to *e.* No change.

4.13(2) No change.

4.13(3) The director will appoint regular and honorary advisory committee members for three fiscal years. Reappointment of regular and honorary members shall be at the discretion of the director.

ITEM 9. Amend subrule 4.14(1) as follows:

4.14(1) Meetings of the advisory committee will be held as necessary and at the call of the director or the chairperson. There shall be a minimum of four meetings per year.

ITEM 10. Amend subparagraph **4.14(6)"b"(1)** as follows:

(1) A designee of similar standing must be able to reasonably fulfill the member's role on the advisory committee in discussions.

Iowa Newborn Screening Panel Management: Structure and Plans

July 2022

CIDAC

Why are we discussing this now?

Recent Legislation

The Iowa Legislature passed SF 2345

- Signed by the Governor on April 21, 2022
- Full text:

https://www.legis.iowa.gov/legislation/BillBook?ga=89&ba=sf2345

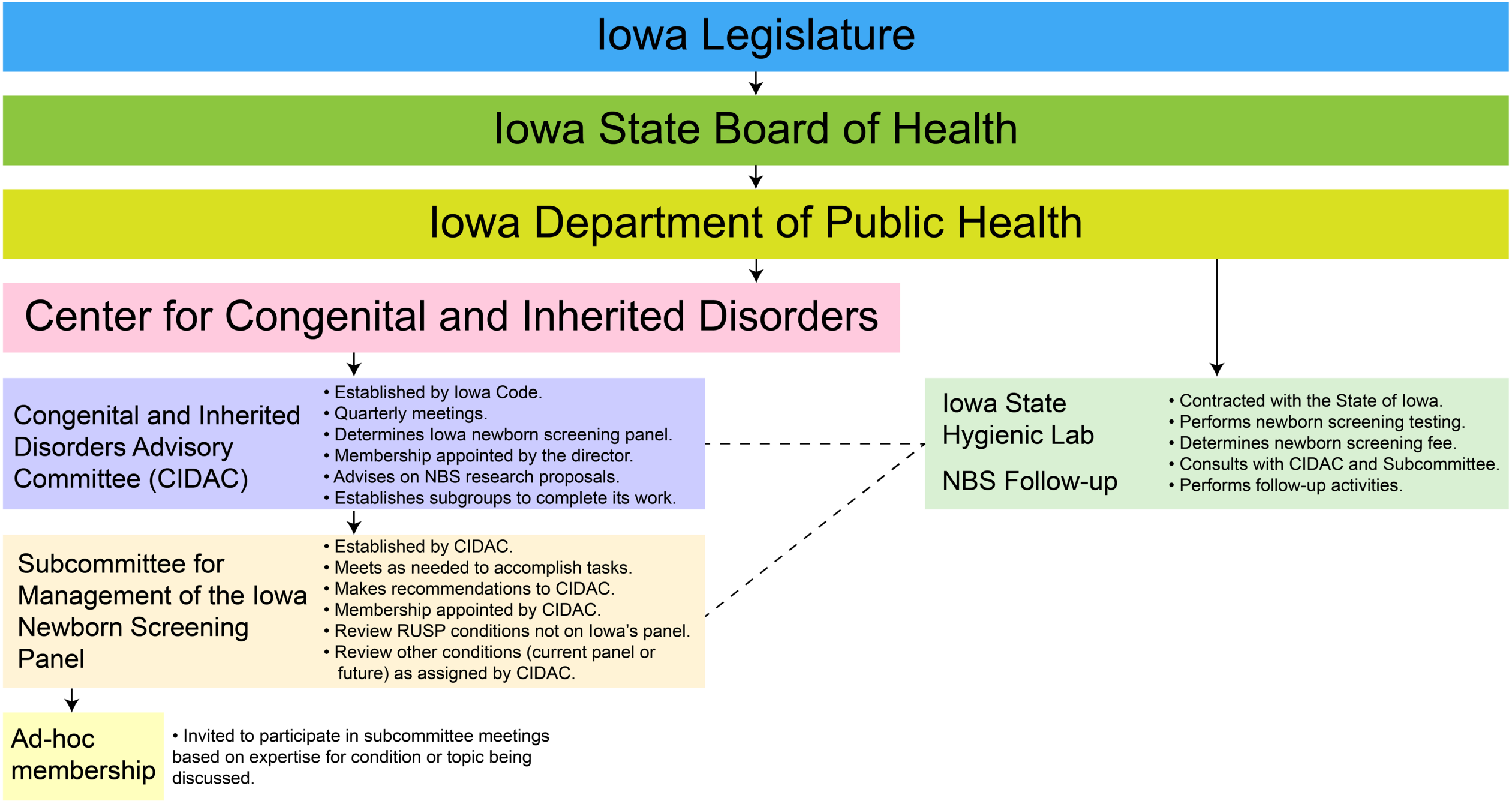
Key Provisions of SF 2345

- All conditions on the RUSP as of January 1, 2022, shall be added to Iowa's newborn screening panel
- Within 12 months of the addition of other conditions to the RUSP, the advisory committee (CIDAC) shall consider and make recommendation about adding the new condition to Iowa's panel
- Once CIDAC recommends the addition of a new condition, IDPH must add the condition to the Iowa newborn screening panel within 18 months
- Annual report due by December 31st
- State Hygienic Lab shall determine the newborn screening fee

Implications

- X-ALD, Pompe, and MPS-1 will continue moving forward to implementation
- Significant changes to CIDAC's responsibilities
- Need a process for CIDAC to quickly review and make recommendation about future conditions and manage Iowa's panel
  - Two conditions have been recommended by ACHDNC and are awaiting decision from HHS
  - Several other conditions are in advanced stages of the ACHDNC review process
  - CIDAC needs input from experts and community members to support development of recommendations

Structure and Responsibilities

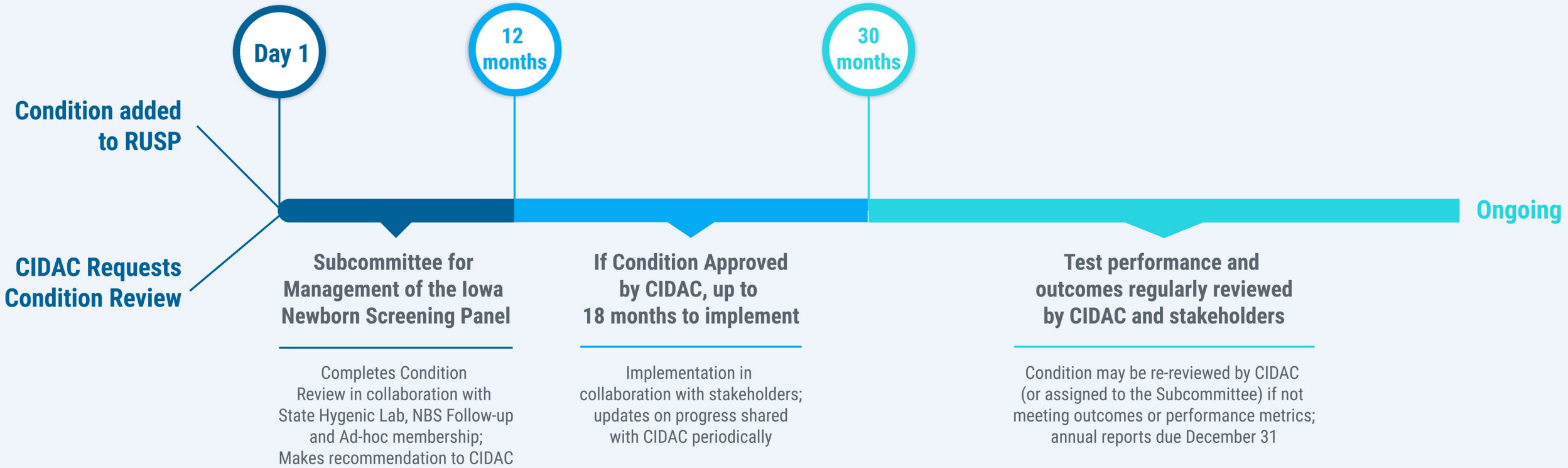

Iowa Legislature
Iowa State Board of Health
Iowa Department of Public Health
Center for Congenital and Inherited Disorders
Congenital and Inherited Disorders Advisory Committee (CIDAC)
• Established by Iowa Code.
• Quarterly meetings.
• Determines Iowa newborn screening panel.
• Membership appointed by the director.
• Advises on NBS research proposals.
• Establishes subgroups to complete its work.
Subcommittee for Management of the Iowa Newborn Screening Panel
• Established by CIDAC.
• Meets as needed to accomplish tasks.
• Makes recommendations to CIDAC.
• Membership appointed by CIDAC.
• Review RUSP conditions not on Iowa's panel.
• Review other conditions (current panel or future) as assigned by CIDAC.
Ad-hoc membership
• Invited to participate in subcommittee meetings based on expertise for condition or topic being discussed.
Iowa State Hygienic Lab
NBS Follow-up
• Contracted with the State of Iowa.
• Performs newborn screening testing.
• Determines newborn screening fee.
• Consults with CIDAC and Subcommittee.
• Performs follow-up activities.

Congenital and Inherited Disorders Advisory Committee (CIDAC)

- Quarterly meetings
- Determines Iowa Newborn Screening Panel
- Membership appointed by the director
- Advises on newborn screening research proposals
- Responsible for submitting annual report (by December 31)
- Make decisions based on greatest benefit to the population of Iowa and in accordance with Iowa law
- Collaborate with State Hygienic Laboratory and NBS follow-up program
- Oversight for any / all subcommittee groups

Subcommittee for Management of the Iowa Newborn Screening Panel

- In consultation with CIDAC, establish condition review policy and framework
- Reviews new conditions as assigned by CIDAC (including new RUSP conditions and nominated conditions)
- Presents recommendations for newborn screening panel additions, deletions, or modifications to CIDAC
- Consult with State Hygienic Laboratory and NBS follow-up program
- Invite ad-hoc members, based on expertise, to provide information to enhance recommendations to CIDAC
- Provide updates to CIDAC
- Support the creation of CIDAC's annual report
- Meet as needed to accomplish tasks



Condition Review and Implementation Timeline

Next Steps

Iowa's Newborn Screening Panel

- Continue forward progress in adding RUSP conditions not currently on Iowa's Panel (MPS-1, Pompe, X-ALD)

Subcommittee for Management of the Iowa Newborn Screening Panel

- CIDAC move forward with subcommittee's initial membership
- CIDAC charge subcommittee with initial tasks
  - Elect chair, CIDAC liaison, and secretary
  - Monitor progress and provide input on implementation of screening for Pompe, MPS-1, and X-ALD
  - Update policy and framework for condition review
  - Propose process for review of current panel conditions
  - Prepare for review of conditions with forthcoming RUSP approvals
  - Begin collecting information for inclusion in the 2022 report

Purpose and Function of the Congenital and Inherited Disorders Advisory Committee's (CIDAC) Subcommittee for Management of the Iowa Newborn Screening Panel

Purpose of CIDAC Subcommittee for Management of the Iowa Newborn Screening Panel

It shall be the policy of the Iowa Department of Public Health (IDPH) to provide for an orderly and equitable process for decision-making about which conditions shall be included on Iowa's newborn screening panel. Decisions will be made to provide the greatest benefit to the population of Iowa, and in accordance with Iowa Law. According to Iowa Code Chapter 136A, the Congenital and Inherited Disorders Advisory Committee (CIDAC) shall assist the Center for Congenital and Inherited Disorders (CCID) and IDPH in designating the conditions to be included in the newborn screening (NBS) panel and in regularly evaluating the effectiveness and appropriateness of the NBS panel. To accomplish this, there shall be established a CIDAC Subcommittee for management of the Iowa NBS panel (the "Subcommittee for Management of the Iowa Newborn Screening Panel"). The Subcommittee will report to, and receive direction from, CIDAC.

Expectations

CIDAC

- Regular meetings scheduled quarterly.
- Determine the Iowa Newborn Screening Panel using recommendations from the Subcommittee and other stakeholders as appropriate.
- Establish the purpose and charge of subcommittee, including assigning the conditions to be reviewed.
- Appoint Subcommittee members.
- Approve Subcommittee's framework for management of the newborn screening panel.
- Establish timeline for review of conditions.
- Establish reporting structure.
- Beginning July 1, 2022, ensure that all conditions included in the federal recommended uniform screening panel as of January 1, 2022 (Pompe disease, Mucopolysaccharidosis Type I (MPS I) and X-linked Adrenoleukodystrophy (X-ALD) are the RUSP conditions that are not currently fully implemented in Iowa), are included in the newborn screening panel.
- Ensure that all conditions added to the RUSP are reviewed within 12 months of addition to the RUSP. Provide a rationale for RUSP conditions that CIDAC does not recommend for addition to the Iowa newborn screening panel.
- Assure that IDPH adds the new condition(s) to the newborn screening panel within 18 months of receipt of the CIDAC recommendation to add the condition. Provide a rationale for conditions that are not implemented within 18 months of recommendation to the Iowa newborn screening panel.
- Review/approve/make recommendations for resources needed for the Subcommittee's review process and implementation of screening for new conditions.
- Review/approve/make recommendations for resources needed for implementation of screening for approved conditions.

Subcommittee for Management of the Iowa NBS Panel

- Meetings held as needed.

- Establish framework for management of newborn screening panel and sends to CIDAC for approval.
- Decide ad hoc membership based upon condition(s) under review and submit to CIDAC chairs for approval.
- Review new conditions assigned by CIDAC according to established framework.
- Present recommendations to CIDAC for the addition of condition(s).
- See *Figure 1* for a summary of the timeline.
- The subcommittee shall work with CIDAC to ensure that all conditions included in the federal recommended uniform screening panel as of January 1, 2022, are included in the newborn screening panel.
- Review RUSP conditions that are not currently on the Iowa NBS panel and make recommendations for addition to the panel within 12 months.
- Conduct an ongoing review of conditions as they are added to the RUSP and make recommendations for addition to the panel within 12 months of addition to the RUSP.
- Conduct a review of conditions as assigned by CIDAC for addition to the panel.
- Report to CIDAC at regular CIDAC meetings and as needed
- Provide assistance to CIDAC and IDPH in drafting the annual report due to the legislature December 31 of each year.

Support from IDPH Center for Congenital and Inherited Disorders Executive Officer

- Schedule all meetings and manage logistics
- Support communication with CIDAC and subcommittee members and relevant stakeholders
- Provide background materials (e.g., sample frameworks, list of RUSP conditions)
- Facilitate all meetings and serve as ex-officio subcommittee member
- Distribute materials
- Draft all reports to IDPH and LSA
- Request resources as determined by CIDAC

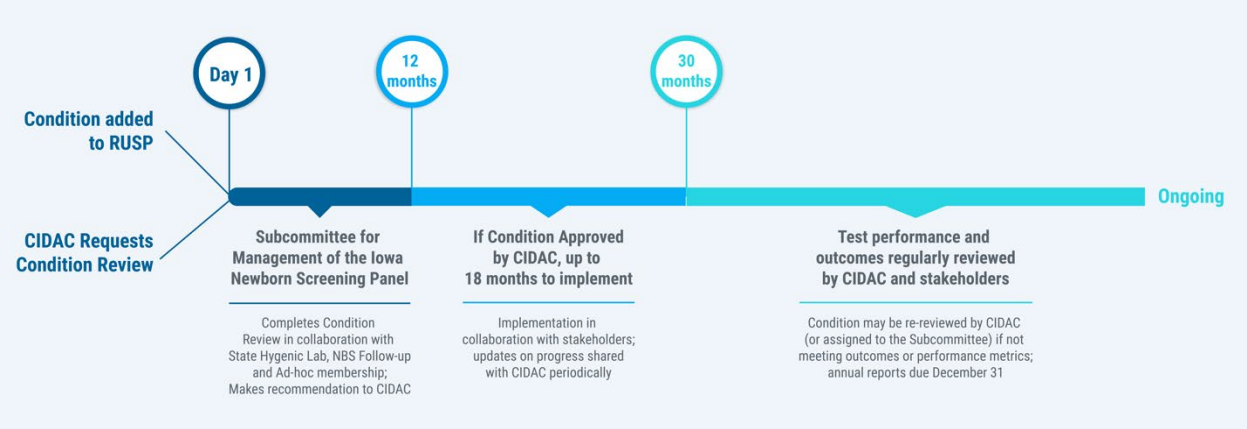


Figure 1. Timeline for condition review.