STATE BOARD OF HEALTH
REGULARLY SCHEDULED MEETING: 5/11/2022
10:00 a.m. – 12:00 p.m.
Location: Zoom Virtual Meeting

Meeting Link: https://us02web.zoom.us/j/89400972739?pwd=WGxvaGtBVUEzLy81Qkc3TkswWm40UT09
Join by Phone: 312-626-6799
Meeting ID: 894 0097 2739 and **Passcode:** 734860

AGENDA

Board Members: Andrew Allen; Leone Junck; George Kovach, MD; Donald Macfarlane, MD, PhD; Sandra McGrath, RN; Kierstyn Borg Mickelson; Nick Ryan, JD; Chelcee Schleuger, RN, BSN; Michael Wolnerman, RPH, CCIM

In accordance with its statutory duties, the Iowa State Board of Health is the policy-making body for the Iowa Department of Public Health. The board's mission is to protect and promote the health of all Iowans by reviewing the field of public health and making recommendations to the department, the Iowa General Assembly, and the governor on a wide range of public health issues. The board also adopts rules consistent with the law for the protection of the public health and the prevention of substance abuse.

10:00 a.m. Call to order; roll call to determine if a quorum is present.

10:05 a.m. Board Minutes for Consideration of Approval – 3/9/2022

10:10 a.m. Director's Report – Kelly Garcia, Director

10:40 a.m. Alignment Update – Sarah Reisetter, J.D., Deputy Director

10:55 a.m. Health Equity Update – Oliviah Walker, Health Equity Coordinator

11:15 a.m. Legislative Update – Maddie Wilcox, Legislative Liaison & Policy Advisor

11:25 a.m. Administrative Rules – Department of Public Health [641] – Susan Dixon, Bureau Chief for Policy & Workforce Services

1. Notice of Intended Action
    a. Chapter 4, "Center for Congenital and Inherited Disorders"
    b. Chapter 11, "Human Immunodeficiency Virus (HIV) Infection and Acquired Immune Deficiency Syndrome"
    c. Chapter 42, "Permit to Operate Ionizing Radiation Producing Machines or Administer Radioactive Materials"

d. Chapter 73, “Special Supplemental Nutrition Program for Women, Infants, and Children

2. Adopted & Filed

a. Chapter 154, “Medical Cannabidiol Program”

11:45 a.m. Substance Use & Problem Gambling Treatment Program Committee Update

12:00 p.m. Adjourn

**** Immediately following this meeting, the State Board of Health will convene as the PHHS Block Grant Advisory Committee. The Advisory Committee meeting is open to members of the public and will be conducted using the same Zoom link as the 10:00 a.m. meeting.****

The electronic meeting of the State Board of Health is being held in accordance with Iowa Code section 21.8 entitled “Electronic Meetings.” The code states that a governmental body may conduct a meeting by electronic means only if circumstances are such that a meeting in person is impossible or impractical and access is provided to the public. An in-person meeting of the Board is impractical due to the schedules of the Board members. The electronic meeting will originate in the Director’s Conference Room, 6th floor, Lucas State Office Building, 321 E 12th Street, Des Moines and public access meeting shall be provided at this location. Notices and agendas were posted in the building and posted on the Department’s website. Minutes of the meeting will be kept.

All meetings held by the Iowa Department of Public Health are accessible to everyone. If you are a person with a disability who requires reasonable accommodation in order to participate in this meeting, please contact Amy Van Maanen a minimum of five business days in advance at 515-229-8156 or at amy.vanmaanen@idph.iowa.gov. If you have a hearing and/or speech impairment, please call Relay Iowa at 7-1-1 or 1-800-735-2942 (TTY or ASCII). For more information on Relay Iowa Services please view their website at: http://www.relayiowa.com/services/

BOARD MEETING SCHEDULE FOR 2022

- January 12, 2022
- March 9, 2022
- May 11, 2022
- July 13, 2022
- September 14, 2022
- November 9, 2022

IOWA STATE BOARD OF HEALTH
3/9/2022
DRAFT - MEETING MINUTES

Members Present:	Donald Macfarlane, MD, PhD, Chair Andrew Allen, Vice-Chair Kierstyn Borg Mickelson George Kovach, MD Leone Junck Sandra McGrath, RN Nick Ryan, JD Chelcee Schleuger, RN, BSN Michael Wolnerman, RPh, CCIM
Members Absent:	Lisa Czyzewicz, LPN
Staff Present:	Heather Adams, Assistant Attorney General; Kelly Garcia, Interim Director Ken Sharp, Division Director Amy Van Maanen, Recording Officer
Staff Absent:	Sarah Reisetter, J.D., Deputy Director

Call to Order & Roll Call
Ken Sharp called the video meeting to order at 10:04 A.M. Roll call was taken to determine if a quorum was present.

Election of Officers
On a motion by Michael Wolnerman, seconded by George Kovach, all members present voted unanimously to approve Donald Macfarlane as the chairperson of the State Board of Health.

On a motion by Michael Wolnerman, seconded by Sandra McGrath all members present voted unanimously to approve Andrew Allen as the vice chairperson of the State Board of Health.

Approval of Minutes from 1/12/2022
On a motion by Leone Junck, seconded by Nick Ryan, all members present voted unanimously to approve the minutes.

Director's Report
Director Kelly Garcia provided information regarding the work being done related to suicide prevention. An unprecedented number of suicides (10) occurred in Polk County within a 30-day period. Work quickly began to discuss and determine needs and next steps. The department met with federal partners including CDC, SAMSHA, ASTHO, who provided the department with resources and connections to augment the work being done by Iowa Department of Public Health (IDPH) and the Department of Human Services (DHS).

After initial conversations with Polk County, IDPH identified funding to work quickly on a statewide messaging campaign to target two audiences and direct them to Your Life Iowa for suicide and mental health support. The target audiences are 10-24 year olds and "influencers" in their lives (i.e. parents, grandparents, mentors, coaches, cousins). Social media platforms are being used for public service announcements in addition to connected TV. Work is also being done to develop digital toolkit which will allow the department to share the messaging materials with other agencies, groups, and schools

It is anticipated that this work will grow as more structure is added to the Iowa Plan for Suicide Prevention, 988 is implemented, and the ongoing technical assistance and community support the department provides through the Suicide Prevention Director.

Director Garcia provided an update on alignment. For more than a year, the IDPH and DHS have been working with a vendor, Public Consulting Group, to assess the coming together of the two agencies. It is anticipated that the release of the final change package with a functional organizational chart will occur by the end of this month. Communications will occur to walk our stakeholders through the recommendations, to understand what's included and to understand the next steps on this multi-year path. Sarah Reisetter, deputy director, will lead the transition work.

Director Garcia also shared that the department was unable to hire a medical director and will be working on reposting the job.

Legislative Update
Maddie Wilcox, legislative liaison for the department, highlighted the newborn screening legislation. This legislation would expand testing as recommended by Center for Congenital and Inherited Disorders Advisory Committee. This passed out of the Senate yesterday and is up for debate in the House. The other legislation highlighted was related to sports wagering. IDPH will receive a $1.75 million appropriation from sports wagering receipts. These funds will go to the department's prevention and treatment of problem gambling work.

Epidemiology Update
Michael Pentella, M.D., Director, State Hygienic Laboratory (SHL), provided a presentation on the SHL's response to the Omicron surge. In January 2021, SHL began sequencing. Approximately 5% of specimens are sequenced. This is done to understand what variants are circulating in the state. The SHL has sequenced close to 12,000 samples. Dr. Pentella shared it took two weeks for Omicron to spread compared to the 12 weeks it took for Alpha to spread, and seven weeks for Delta to spread. At the end of February 2022, SHL identified the BA.2 variant. Since July 2021, SHL has shipped 449,792 test kits and has processed 230,979 saliva samples. On 1/18/22, Iowans requested 27,800 test kits. Over 1.7 million tests have been performed since 3/2020. Board members expressed appreciation for Dr. Pentella and his staff.

Administrative Rules – Iowa Department of Public Health [641] – Adopted and Filed
Chapter 9, "Outpatient Diabetes Education Programs"
The proposed amendments reflect revisions related to an external organization's name and credential designation. Clarifying revisions are also being proposed for acronyms and a few other items.

On a motion by George Kovach, seconded by Leone Junck, all members present voted unanimously to approve.

Chapter 78, "Personal Responsibility Education Programs and Title V State Sexual Risk Avoidance Education Grant Program Funding and Restrictions"
The purpose of the proposed changes is to adopt the requirements of 2019 Iowa Acts, House File 766, Section 99.

Andrew Allen recused from the discussion and vote.

On a motion by George Kovach, seconded by Nick Ryan, all members present voted unanimously to approve.

Chapter 80, "Local Public Health Services"
The proposed amendments streamline Chapter 80 by focusing the use of Local Public Health Services funds on Public Health Systems work and emphasizing core public health functions, essential services and public health interventions. The proposed amendments also serve to advance population health at a systems level while providing the opportunity to protect and improve the health of every Iowan.

On a motion by Chelcee Schleuger, seconded by Nick Ryan, all members present voted unanimously to approve.

Chapter 154, "Medical Cannabidiol Program"
The proposed amendments implement necessary updates to the rules to formalize waivers currently in effect, reduce compliance burden for licensees and the department, reduce barriers for veteran participation and provide additional authority to certifying practitioners.

One comment was received regarding the notice of cancellation. Additional language was added to identify when the cancellation becomes effective after receiving the notice. Discussion occurred regarding the addition. It was suggested that this be clarified further. No vote was taken and this will be reviewed again at the 5/11/22 meeting.

Substance Use/Problem Gambling Treatment Program Committee Report
The committee approved the following at the 2/9/22 meeting:

- Two – Two year license.

The committee approved the following at the 3/9/22 meeting:

- One – 270 day license;
- One – One year license;
- Two – Two year license;
- One – Three year license;
- Three – Deemed status; and
- One – Denial.

Adjournment
On a motion by Sandra McGrath, seconded by Nick Ryan, all members present voted unanimously to adjourn the meeting at 11:26 A.M.

Health Equity Update

Oliviah Walker, Health Equity Coordinator
5-11-22

Health Equity at IDPH and DHS

Health Equity Guiding Principle

We promote health for all by working to reduce health disparities and focusing on health where people live, learn, work and play.

Health Equity Vision

Building Health Equity for All Communities

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What is health equity?

Health equity is the attainment of the highest possible level of health for all people. It means achieving the environmental, social, economic, and other conditions in which all people have the opportunity to attain their highest possible level of health.

IDPH definition

Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires **removing obstacles to health** such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care.

RWJ definition

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DEI and Health Equity integration

Diversity, Equity, and Inclusion will have a focus on our workforce and organizational structure.

Health Equity will primarily focus on population health outcomes for the communities we serve.

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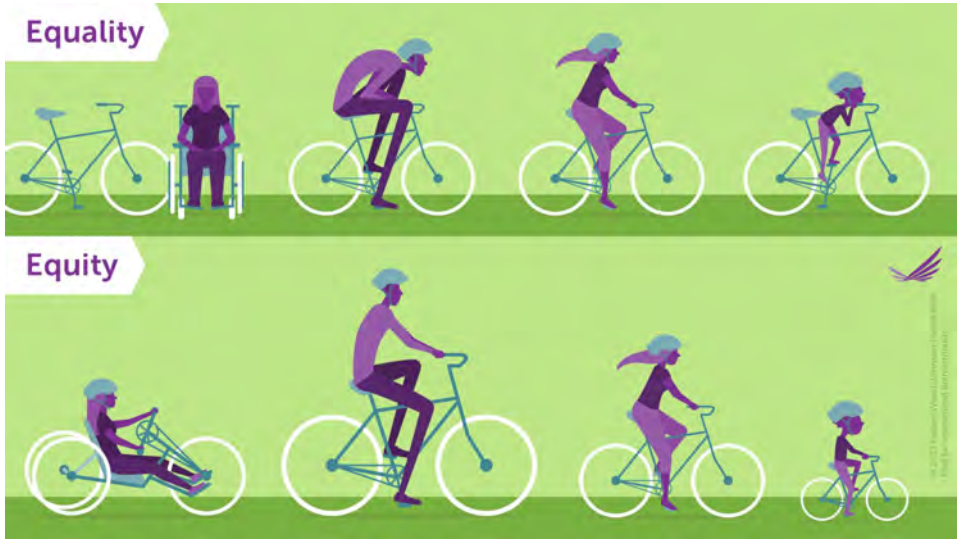
Equity is not the same as equality.



To equalize opportunities, those with worse health and fewer resources need more efforts and opportunities to improve their health.

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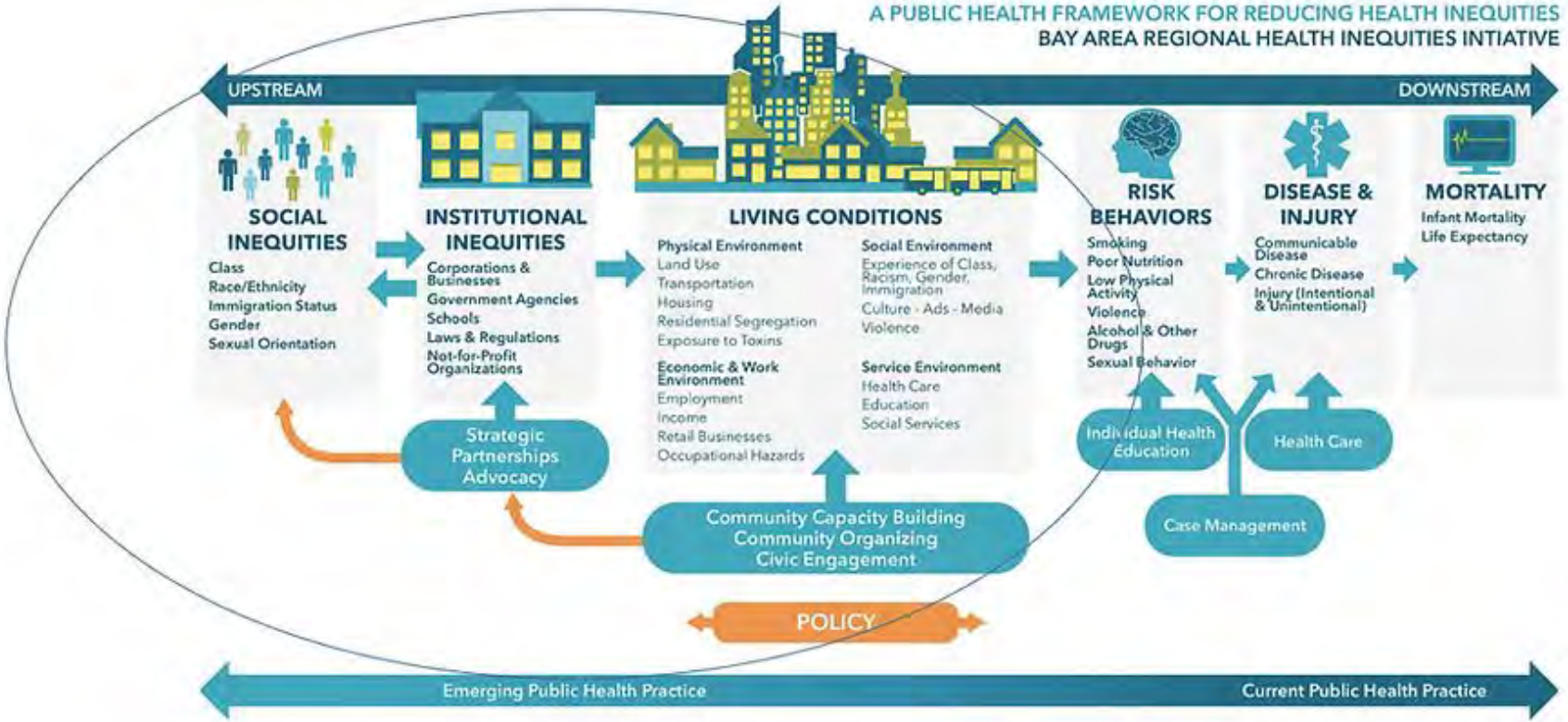
A PUBLIC HEALTH FRAMEWORK FOR REDUCING HEALTH INEQUITIES
BAY AREA REGIONAL HEALTH INEQUITIES INTIATIVE
UPSTREAM
DOWNSTREAM
SOCIAL INEQUITIES
Class
Race/Ethnicity
Immigration Status
Gender
Sexual Orientation
INSTITUTIONAL INEQUITIES
Corporations & Businesses
Government Agencies
Schools
Laws & Regulations
Not-for-Profit Organizations
LIVING CONDITIONS
Physical Environment
Land Use
Transportation
Housing
Residential Segregation
Exposure to Toxins
Economic & Work Environment
Employment
Income
Retail Businesses
Occupational Hazards
Social Environment
Experience of Class, Racism, Gender, Immigration
Culture - Ads - Media
Violence
Service Environment
Health Care
Education
Social Services
RISK BEHAVIORS
Smoking
Poor Nutrition
Low Physical Activity
Violence
Alcohol & Other Drugs
Sexual Behavior
DISEASE & INJURY
Communicable Disease
Chronic Disease
Injury (Intentional & Unintentional)
MORTALITY
Infant Mortality
Life Expectancy
Strategic Partnerships Advocacy
Community Capacity Building
Community Organizing
Civic Engagement
Individual Health Education
Health Care
Case Management
POLICY
Emerging Public Health Practice
Current Public Health Practice

Social Determinants of Health

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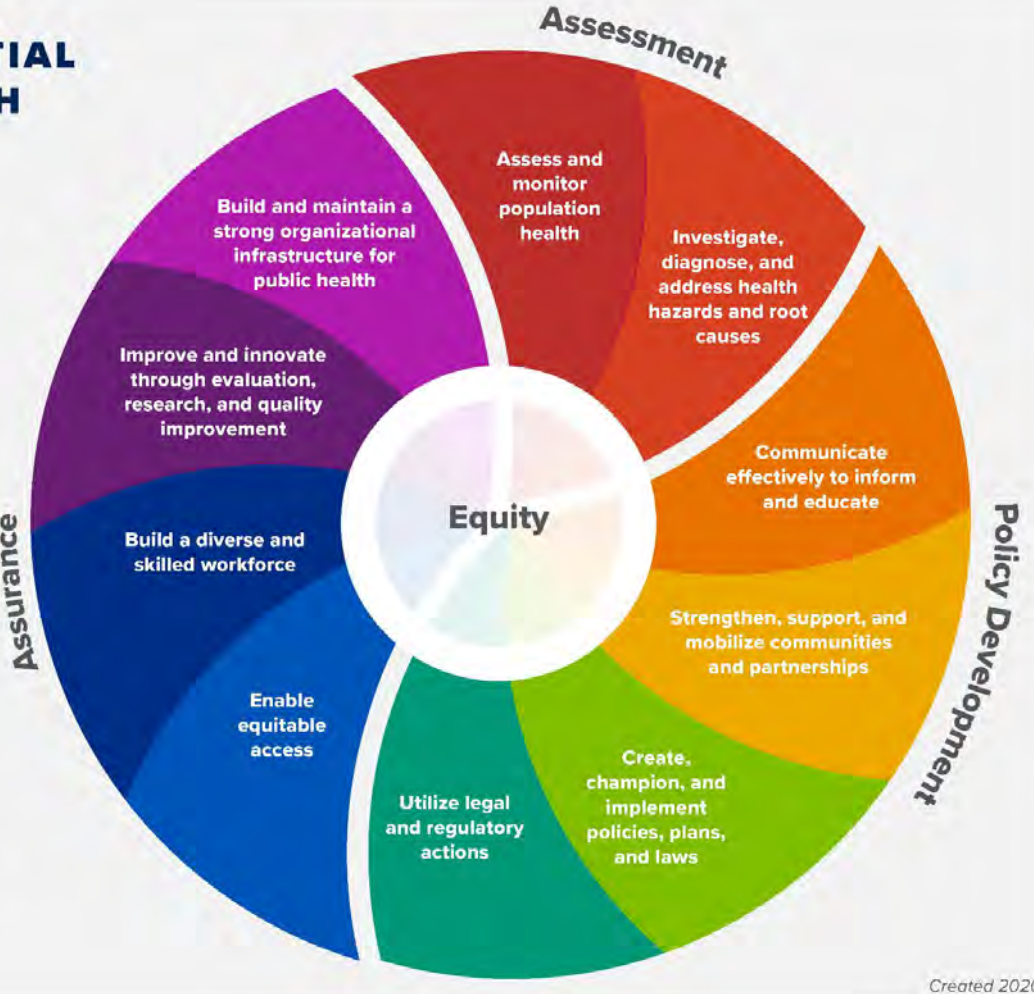
THE 10 ESSENTIAL PUBLIC HEALTH SERVICES

To protect and promote the health of all people in all communities

The 10 Essential Public Health Services provide a framework for public health to protect and promote the health of all people in all communities. To achieve optimal health for all, the Essential Public Health Services actively promote policies, systems, and services that enable good health and seek to remove obstacles and systemic and structural barriers, such as poverty, racism, gender discrimination, and other forms of oppression, that have resulted in health inequities. Everyone should have a fair and just opportunity to achieve good health and well-being.



Created 2020

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Iowa Health and Human Services Alignment

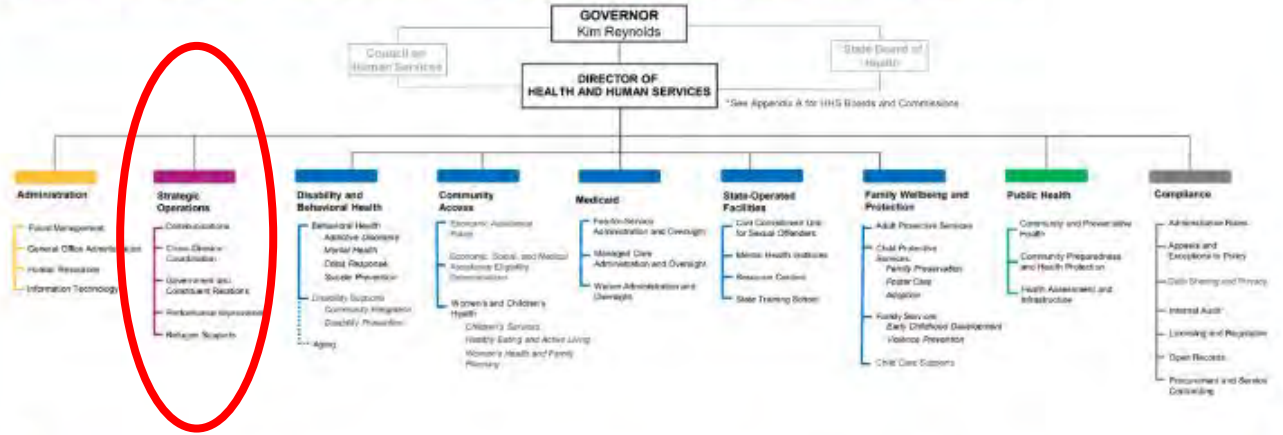
The Iowa Departments of Public Health (IDPH) and Human Services (DHS) are working to become one, single department.

- Align and integrate programs, practices and policies to improve delivery of services and most effectively leverage funding.
- Create an organizational structure that optimizes delivery of services, supports efficiency for staff, and integrates the departments' programs and services with community and other available resources.
- Utilize gained efficiencies and better leverage resources to reinvest in our system and drive improved outcomes for Iowans.

FUNCTIONAL ORGANIZATIONAL CHART

Below is the functional organization chart for an integrated health and human services agency. **This same chart is also found in the Final Change Package.**

This functional organizational chart summarizes the new department's major functions. Additional details are included in the following tabs.



Last rev. 3/23/2022

Office of Equity

Purpose: Advance Health Equity through oversight and strategic support of department-wide equity initiatives

Functions: Communications, training, capacity-building, consultation, technical assistance, *data analysis, grant-making, community collaboration*

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Iowa HHS Health Equity Framework

1. Organizational Culture
2. Internal Policies and procedures
3. Data Equity Framework
4. Planning and Performance Improvement
5. Partnerships and Community Engagement

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Organizational Culture

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Internal Policies and Procedures

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IDPH Health Equity Policy

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Department of Public Health

Health Equity
Policy # AD 10-17-005

Purpose
This policy sets the expectations for the incorporation of health equity into all department functions, including surveillance, planning, implementation, and evaluation. It aims to create institutional changes in Department culture, program activities, and contracted work. This is an iterative and multi-year process, and this policy may evolve as needed.

Definitions
Department: means the Iowa Department of Public Health

Determinants of Health: Health is determined through the interaction of individual behaviors and social, economic, genetic and environmental factors. Health is also determined by the systems, policies, and processes encountered in everyday life. Examples of determinants of health include job opportunities, wages, transportation options, the quality of housing and neighborhoods, the food supply, access to healthcare, the quality of public schools and opportunities for higher education, racism and discrimination, civic engagement, and the availability of networks of social support. Determinants of health may lead to health inequities.

Health Disparity: A population-based difference in health outcomes (e.g., women have more breast cancer than men; people living in sub-standard housing have higher incidence of lead poisoning).

Health Equity: is the attainment of the highest possible level of health for all people. It means achieving the environmental, social, economic and other conditions in which all people have the opportunity to attain their highest possible level of health. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and healthcare disparities.

Health Equity Analysis: Analyzing health inequities requires a process that uses data to identify health differences between population groups, instead of only examining the population as a whole. The process then continues by identifying and examining the causes of these populations differences in health.

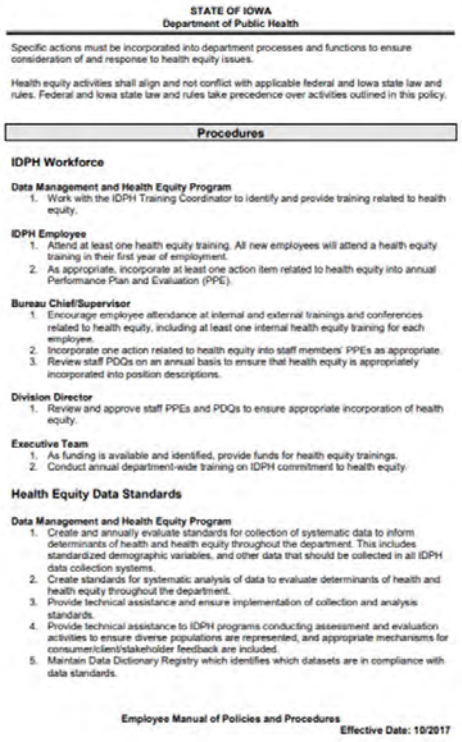
Health Inequity: A health disparity based in inequitable, socially-determined circumstances. Because health inequities are socially determined, change is possible.

Structural Inequities: Structures or systems of society – such as finance, housing, transportation, education, social opportunities, etc. – that are structured in such a way that they benefit one population unfairly (whether intended or not).

Policy
Health equity means creating environmental, social, economic and other conditions in which all people have the opportunity to achieve their highest possible level of health. Achieving population health equity requires health equity analysis, identification of structural inequalities, and purposeful mitigation of the barriers to health. Because most determinants in health are socially constructed, they may also be deconstructed.

It is the Department's intent to promote health for all by working to reduce health disparities focusing on health where people live, learn, work, and play. Department programs must consider health equity when conducting surveillance, planning, implementation, and evaluation activities.

Employee Manual of Policies and Procedures
Effective Date: 10/2017



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Specific actions must be incorporated into department processes and functions to ensure consideration of and response to health equity issues.

Health equity activities shall align and not conflict with applicable federal and Iowa state law and rules. Federal and Iowa state law and rules take precedence over activities outlined in this policy.

Procedures

IDPH Workforce

Data Management and Health Equity Program
1. Work with the IDPH Training Coordinator to identify and provide training related to health equity.

IDPH Employee
1. Attend at least one health equity training. All new employees will attend a health equity training in their first year of employment.
2. As appropriate, incorporate at least one action item related to health equity into annual Performance Plan and Evaluation (PPE).

Bureau Chief/Supervisor
1. Encourage employee attendance at internal and external trainings and conferences related to health equity, including at least one internal health equity training for each employee.
2. Incorporate one action related to health equity into staff members' PPEs as appropriate.
3. Review staff PDQs on an annual basis to ensure that health equity is appropriately incorporated into position descriptions.

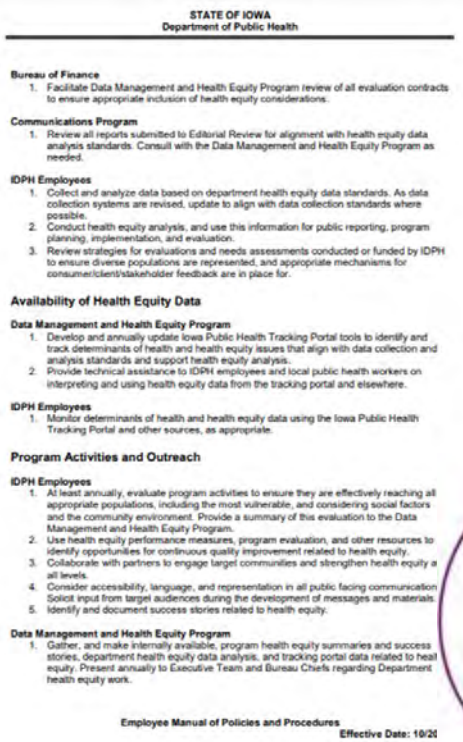
Division Director
1. Review and approve staff PPEs and PDQs to ensure appropriate incorporation of health equity.

Executive Team
1. As funding is available and identified, provide funds for health equity trainings.
2. Conduct annual department-wide training on IDPH commitment to health equity.

Health Equity Data Standards

Data Management and Health Equity Program
1. Create and annually evaluate standards for collection of systematic data to inform determinants of health and health equity throughout the department. This includes standardized demographic variables, and other data that should be collected in all IDPH data collection systems.
2. Create standards for systematic analysis of data to evaluate determinants of health and health equity throughout the department.
3. Provide technical assistance and ensure implementation of collection and analysis standards.
4. Provide technical assistance to IDPH programs conducting assessment and evaluation activities to ensure diverse populations are represented, and appropriate mechanisms for consumer/client/stakeholder feedback are included.
5. Maintain Data Dictionary Registry which identifies which datasets are in compliance with data standards.

Employee Manual of Policies and Procedures
Effective Date: 10/2017



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Bureau of Finance
1. Facilitate Data Management and Health Equity Program review of all evaluation contracts to ensure appropriate inclusion of health equity considerations.

Communications Program
1. Review all reports submitted to Editorial Review for alignment with health equity data analysis standards. Consult with the Data Management and Health Equity Program as needed.

IDPH Employees
1. Collect and analyze data based on department health equity data standards. As data collection systems are revised, update to align with data collection standards where possible.
2. Conduct health equity analysis, and use this information for public reporting, program planning, implementation, and evaluation.
3. Review strategies for evaluations and needs assessments conducted or funded by IDPH to ensure diverse populations are represented, and appropriate mechanisms for consumer/client/stakeholder feedback are in place for.

Availability of Health Equity Data

Data Management and Health Equity Program
1. Develop and annually update Iowa Public Health Tracking Portal tools to identify and track determinants of health and health equity issues that align with data collection and analysis standards and support health equity analysis.
2. Provide technical assistance to IDPH employees and local public health workers on interpreting and using health equity data from the tracking portal and elsewhere.

IDPH Employees
1. Monitor determinants of health and health equity data using the Iowa Public Health Tracking Portal and other sources, as appropriate.

Program Activities and Outreach

IDPH Employees
1. At least annually, evaluate program activities to ensure they are effectively reaching all appropriate populations, including the most vulnerable, and considering social factors and the community environment. Provide a summary of this evaluation to the Data Management and Health Equity Program.
2. Use health equity performance measures, program evaluation, and other resources to identify opportunities for continuous quality improvement related to health equity.
3. Collaborate with partners to engage target communities and strengthen health equity at all levels.
4. Consider accessibility, language, and representation in all public facing communication. Solicit input from target audiences during the development of messages and materials.
5. Identify and document success stories related to health equity.

Data Management and Health Equity Program
1. Gather, and make internally available, program health equity summaries and success stories, department health equity data analysis, and tracking portal data related to heal equity. Present annually to Executive Team and Bureau Chiefs regarding Department health equity work.

Employee Manual of Policies and Procedures
Effective Date: 10/20

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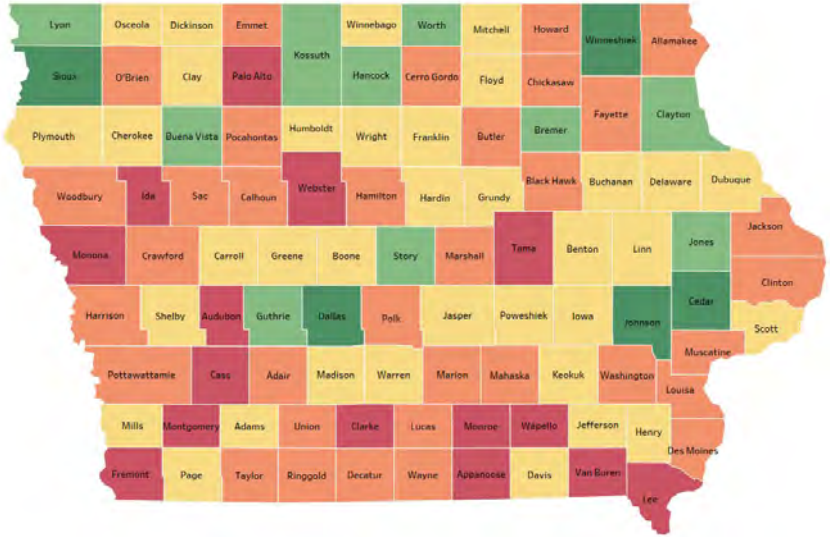
Data Equity



Collecting demographic information allows us to analyze data and identify trends and disparities that may be covered up when looking at the whole population set.

Source: 2021 County Health Rankings

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Iowa Youth Risk Behavior Survey-Data Equity Example

https://idph.iowa.gov/PublicHealthData/Iowa-Youth-Risk-Behavior-Survey

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Planning and Performance Improvement

IDPH Strategic Plan 2017-2022

Goal 1 Strengthen the department's capacity as Iowa's chief health strategist (CHS).

Objectives/Indicators 2. Increase the percentage of staff performance plans with CHS tactics identified (partnerships, performance improvement, **health equity**).

Actions 1.1.2. Develop and support a **data equity** workgroup to provide resources to help staff improve their use of data for health equity efforts.

Goal 2 Strengthen the department's capability and capacity to improve population health through communications, workforce development, performance improvement (PI), and health equity.

Objectives/Indicators Health Equity: 1. Increase IDPH staff participation in health equity training. 2. Increase communication to staff on health equity efforts at IDPH. 3. Increase the number of programs that have identified a performance measure addressing population health disparities.

Actions 2.5.1 Formalize commitment to health equity by adopting the IDPH Health Equity Framework. 2.5.2 Track progress on the IDPH health equity implementation plan. 2.5.3 Implement a health equity assessment tool to assess current IDPH health equity efforts and identify areas for improvement. 2.5.4 Support the integration of health disparities data with IDPH performance measures.

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Community Engagement

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IDPH health equity supports

- IDPH Health Equity Policy
- IDPH data standards
- Public Health Accreditation Standards
- Public Health 10 Essential Services Framework
- IDPH Health Equity Framework
- Health Equity Coordinator
- Health Equity Drivers Forum
- IDPH Health Equity webpage
- Internal resources
  - Contracting guide
  - Performance plan examples
  - Resource library
- Workforce Development training opportunities
- External Resources

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Questions/Comments

Contact information:

Oliviah Walker

Health Equity Coordinator

Oliviah.Walker@idph.iowa.gov

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

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 136A.8.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code135A and 2022 Senate File 2345.

Purpose and Summary

The proposed amendments will accomplish the following:

- Adds a definitions of the Iowa newborn screening panel; the Iowa newborn screening program; and the federal recommended uniform screening panel (per 2022 SF2345 of the 89th General Assembly).
- Rescinds language requiring state board of health approval to add or remove disorders to the newborn screening panel.
- Provides a fax number for the submission of refusal forms.
- Indicates collection of the newborn screening specimen shall not delay critical care to the newborn.
- Describes who is responsible for informing the parent or guardian of the newborn screening procedure.
- Establishes a cap on the amount a facility or provider can charge for the newborn screening panel.

- Requires the physician or other health care professional who undertakes primary pediatric care of a newborn delivered in Iowa to be available on an emergency basis to follow-up on time critical newborn screening results for newborns in their care.
- Describes the authority of the State Hygienic authority to establish the newborn screening fee in collaboration with the department, as per 2022 Iowa Acts SF 2345.
- Moves responsibility for reporting on the number of refusals of newborn screening from the SHL to the STFU program.
- Sections 641.4.3(7) that speak to the release of newborn and maternal prenatal screening data are amended to build consistency with IDPH data sharing policies, HIPAA regulations, and the Common Rule; allows an agent of a state or federal agency to receive the same information as the state or federal agency.
- Removes the term “written” and replaces it with “informed” to allow researchers to obtain parent/guardian consent for use of the infant’s residual DBS specimen by means other than written, e.g., telephonic or electronic “in-app” consent.
- 2022 Iowa Acts SF2345 of the 89th General Assembly provides authorization to the State Hygienic Laboratory at The University of Iowa (SHL) to establish a newborn screening fee, and changes to 641.4.3(10) aim to describe that process.
- Moves references to the Iowa maternal prenatal screening program funding to the IMPSP fee section.
- Removes language indicating the newborn screening fee.
- Removes language of income guidelines of 185 percent of federal poverty level for the medical formula and medical foods program to allow the fiscal administrator (UIHC) of the

program to place individuals on the sliding fee schedule according to the fiscal administrator's established guidelines and policy.

- Expands the list of disorders or conditions for which the Iowa Registry for Congenital and Inherited Disorders (IRCID) may conduct surveillance to include surveillance of pregnancy outcomes in order to understand the effects of emerging and reemerging threats on pregnant women and their infants.
- Describes the authority given through 2022 Iowa Acts SF2345 to the Congenital and Inherited Advisory Committee (CIDAC) to review newborn screening conditions on the federal recommended uniform screening panel (US DHHS Recommended Uniform Screening Panel [RUSP]) for addition to Iowa's newborn screening panel.
- Establishes timelines for CIDAC's review and consideration of RUSP conditions to within 12 months of the condition being added 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.
- CIDAC membership is described pursuant to 2022 Iowa Acts SF2345.

Fiscal Impact

This rule making may have a fiscal impact to the state of Iowa. The addition of disorders to the newborn screening panel as required by SF 2345 will create additional jobs for those with expertise in the disorder(s) added, such as laboratory scientists, bio-informaticists, medical geneticists, genetic counselors, and follow-up nurses. 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.

SF2345 gives authority to the State Hygienic Laboratory at The University of Iowa 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 is dependent on the type of disorders added to the newborn screening panel (each disorder comes with its 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 as assessed.

Jobs Impact

After analysis and review of this rule making, no discernable impact on jobs has been found.

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 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 June 7, 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.pipper@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 action proposed:

ITEM 1. Adopt the following **new** definitions of "Iowa newborn screening panel" or "newborn screening panel", ""Iowa newborn screening program" or "INSP" and "Federal recommended uniform screening panel" in rule **641—4.2(136A)**:

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

"*Federal recommended uniform screening panel*" means the list of disorders the US department of health and human services recommends states screen as part of their state newborn screening panels.

ITEM 2. Amend rule **641—4.2(136A)**, definition of "Specialty genetics provider," as follows:

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

ITEM 3. 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 4. Amend subrules 4.3(2) and 4.3(3) as follows:

4.3(2) *Newborn blood spot screening procedure for facilities and providers.*

a. Educating parent or guardian. Before a specimen from an infant is obtained, the prenatal care provider, attending health care provider, or a representative of either shall inform the parent or guardian ~~shall be informed~~ of the type of specimen, how it is obtained, the nature of the disorders for which the infant is being screened, the consequences of treatment and nontreatment, and the retention, use and disposition of residual specimens.

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 or its designee 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.

c. Collection of specimens. A filter paper blood specimen shall be collected from the infant between 24 to 48 hours after the infant's birth. A specimen shall not be collected from an infant less than 24 hours after birth except as follows:

(1) A blood specimen must be collected before any initial transfusion, even if the infant is less than 24 hours old.

(2) A blood specimen must be collected before the infant leaves the hospital, whether by discharge or by transfer to another hospital, even if the infant is less than 24 hours old, unless collection of the blood specimen would delay critical care to the infant.

d. Submission of specimens. All specimens shall be delivered via courier service or, if courier service is not available, forwarded by first-class mail or other appropriate means within 24 hours after collection to the SHL.

e. The facility or health care provider collecting and submitting the newborn screening specimen shall charge a fee for the newborn screening panel that does not exceed the newborn screening fee listed in the fee schedule established by the SHL.

~~*e. Informed consent for the release of residual specimens for research use.*~~ Rescinded ARC 2929C, IAB 2/1/17, effective 3/8/17.

4.3(3) *Primary health care provider responsibility.*

a. The attending health care provider shall ensure that infants under the provider's care are

screened.

b. Procedures for specimen collection for newborn blood spot screening shall be followed in accordance with 4.3(2).

c. A physician or other health care professional who undertakes primary pediatric care of an infant delivered in Iowa shall arrange for the newborn screening if a newborn screening result is not in the infant's medical record.

d. A primary health care provider who undertakes primary pediatric care of an infant delivered in Iowa, or their designee, shall be available on an emergency basis to follow-up on time-critical newborn screening results for the infant in their care.

ITEM 5. Amend subparagraph **4.3(3)"d"(1)** as follows:

(1) The infant is discharged ~~or transferred to another facility~~ before the infant is 24 hours old.

ITEM 6. Adopt the following **new** paragraph**4.3(5)"a"**:

a. Establish the newborn screening fee schedule pursuant to Iowa Code section 136.3A(6).

Item 7. Rescind subparagraph **4.3(5)"h"(5).**

ITEM 8. Renumber subparagraphs **4.3(5)"h"(6)** to **4.3(5)"h"(7)** as **4.3(5)"h"(5)** to **4.3(5)"h"(6).**

Item 9. Reletter paragraphs **4.3(5)"a"** to **4.3(5)"k"** as **4.3(5)"b"** to **4.3(5)"i."**

ITEM 10. Rescind paragraphs **4.3(5)"i" to "k."**

ITEM 11. Adopt the following **new** subparagraph(s) **4.3(6)"b"(3)**:

(3) Number of refusals for screening,

ITEM 12. Renumber subparagraph **4.3(6)"b"(3)** as **4.3(6)"b"(4).**

ITEM 13. Amend subparagraphs **4.3(7)"b"(3)** and **(4)** as follows:

(3) A representative or agent of a state or federal agency to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency and its agents will be subject to confidentiality regulations which are the same as or more stringent than those in the state of Iowa.

(4) ~~A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.~~ The department may permit the use of data from the Iowa newborn screening program for research purposes subject to conditions the department may impose to ensure the use of the data is limited to such research purposes. No data shall be furnished from the Iowa newborn screening program for research purposes until the department has prepared in writing the conditions under which the data may be used and has received an agreement signed by a responsible agent of a research organization agreeing to meet and conform to such conditions.

ITEM 14. Amend paragraph **4.3(8)"c"** as follows:

c. Research. A residual newborn screening specimen may be released for research purposes only if ~~written~~ informed consent has been received by the researcher from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied:

(1) Investigators shall submit proposals to use residual newborn screening specimens to the center. Any intended use of the requested specimens as part of the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board, the congenital and inherited disorders advisory committee, and the department.

(3) Research on residual newborn screening specimens shall be allowed only in instances where research would further: newborn screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health.

(4) For specimens collected prior to January 1, 2016, a parent or guardian may send a letter stating that the newborn's specimen is not to be released for research purposes. This letter shall include the parent's or guardian's name, the newborn's name at birth, and the newborn's date of birth. The letter of notice shall be sent to the State Hygienic Laboratory at Newborn Screening Program, State Hygienic Laboratory, 2220 S. Ankeny Blvd., Ankeny, Iowa 50023-9093.

ITEM 15. 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 16. Amend subrule 4.3(10) as follows:

4.3(10) *INSP ~~and IMPSP fee~~ Fees*.

a. In consultation with the department, the State Hygienic Laboratory 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. ~~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.~~

b. The ~~department~~ State Hygienic Laboratory 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.*~~ *d.* 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.*~~ *e.* ~~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 17. Amend paragraph **4.3(11)"d"** as follows:

d. Provisions of special medical formula and foods through this funding allocation shall be available to an individual only after the individual has shown that all benefits from third-party payers including, but not limited to, health insurers, health maintenance organizations, Medicare, Medicaid, WIC and other government assistance programs have been exhausted. In addition, a full fee and a sliding fee scale shall be established and used for those persons able to pay all or part of the cost. Income and resources shall be considered in the application of the sliding fee scale. ~~Individuals whose income is at or above 185 percent of the federal poverty level shall be charged a fee for the provision of special medical formula and foods.~~ Placement of individuals on the sliding fee scale shall be determined and reviewed at least annually.

ITEM 18. Amend rule 641—4.7(136A), introductory paragraph, as follows:

641—4.7(136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited disorders. These disorders may include birth defects, neuromuscular disorders, metabolic or other inherited disorders, and all stillbirths. The program may also conduct active statewide surveillance of pregnancy outcomes to understand the effects of emerging and reemerging threats on pregnant women and their infants and ~~The program also may~~ conduct active statewide surveillance of live births without a reportable congenital or inherited disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited disorders will be conducted for the period of time that adequate financial support is available.

ITEM 19. Amend paragraph **4.7(1)"a"** as follows:

a. Birth defects shall be defined as any major structural abnormality or ~~metabolic~~ heritable disorder that may adversely affect a child's health and development. The abnormality or disorder must be diagnosed or its signs and symptoms must be recognized within the first two years of life.

ITEM 20. Amend paragraph **4.7(3)"b"** as follows:

b. The IRCID shall use the birth defects, neuromuscular disorders, metabolic or other inherited disorders, and stillbirth coding schemes developed by the Centers for Disease Control and Prevention (CDC).

ITEM 21. Amend paragraph **4.7(6)"e"** as follows:

e. Researchers, in accordance with the following:

(1) All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher's institutional review board. Proposals shall then be reviewed and approved by the department and ~~the IRCID's internal advisory committee~~ CIDAC before research can commence.

(2) The IRCID shall submit to ~~the IRCID's internal advisory committee~~ CIDAC for approval a protocol describing any research conducted by the IRCID in which the IRCID deems it necessary to contact case subjects and controls.

ITEM 22. Amend rules 641—4.11(136A) to 641—4.12(136A) as follows:

641—4.11(136A) Purpose. 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 and access to quality genetic and genomic health care services for all Iowans. ~~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.~~

641—4.12(136A) Duties of the 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 twelve 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, including the current newborn screening capacity to screen for the new condition and the resources necessary to screen for the new condition going forward. If the advisory committee recommends inclusion of a new condition, the department shall include the new condition in the newborn screening within eighteen months of receipt of the recommendation.

(4) Within twelve 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.

(5) If the advisory committee recommends inclusion of a new condition, the department shall include the new condition in the newborn screening panel within eighteen 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.

ITEM 23. Amend rule 641—4.13(136A), introductory paragraph, as follows:

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.

ITEM 24. Amend subrule 4.13(1), introductory paragraph, as follows:

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

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 11, "Human Immunodeficiency virus (HIV) Infection and Acquired Immune Deficiency Syndrome," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code chapter 141A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 141A.3 (1).

Purpose and Summary

The proposed amendments increase the eligibility for the AIDS Drug Assistance Program (ADAP) from 400% Federal Poverty Level (FPL) to 500% FPL for medication and insurance assistance. The proposed amendments also modify the requirements for medication assistance to account for some health plans that do not allow ADAP to assist with insurance costs or that are not cost-effective for ADAP to support.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

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 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 June 7, 2022. Comments should be directed to:

Randall Mayer

Department of Public Health

Lucas State Office Building

321 East 12th Street

Des Moines, Iowa 50319

Email: Randall.mayer@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 action proposed:

ITEM 1. Amend rule 641—11.43(141A) as follows:

641—11.43(141A) Eligibility requirements.

11.43(1) An applicant is eligible to participate in the ADAP medication assistance program if the applicant:

a. Applies for enrollment in ADAP on a form provided by the department;

b. Has no health insurance to cover the cost of the drugs that are or may become available from ADAP, or has insurance that is determined by the department to be incompatible with or cost ineffective for the ADAP insurance assistance program;

c. Is currently being prescribed a drug on the ADAP formulary;

d. Has an annual income that is less than or equal to ~~400~~ 500 percent of the poverty level as determined by the most recent federal poverty guidelines published annually by the U.S. Department of Health and Human Services for the size of the household;

e. Has a medical diagnosis of HIV infection or AIDS or is an unborn infant or an infant under 18 months of age who has an HIV-infected mother; and

f. Is a resident of Iowa.

11.43(2) An applicant is eligible to participate in the ADAP health insurance assistance program if the applicant:

a. Applies for enrollment in ADAP on a form provided by the department;

b. Has creditable health insurance coverage or meets the enrollment qualifications for an ADAP-sponsored health plan;

c. Is currently being prescribed a drug on the ADAP formulary;

d. Has an annual income that is less than or equal to ~~400~~ 500 percent of the poverty level as determined by the most recent federal poverty guidelines published annually by the U.S. Department of Health and Human Services for the size of the household;

e. Has a medical diagnosis of HIV infection or AIDS or is an unborn infant or an infant under 18 months of age who has an HIV-infected mother; and

f. Is a resident of Iowa.

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 42, "Permit to Operate Ionizing Radiation Producing Machines or Administer Radioactive Materials," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 136C.12.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136C.

Purpose and Summary

The proposed amendments address changes made in the American Registry of Radiologic Technologist (ARRT) policies and procedures. ARRT is the national certification entity recognized by CMS, national accreditation entities, and regulatory bodies (to include IDPH) as the certification for radiologic technologists, nuclear medicine technologists, radiation therapists, and radiologist assistants. ARRT also provides the examination for limited technologists approved by IDPH as eligible to take the examination. IDPH tries to align with ARRT requirements whenever possible to reduce duplication, conflicting requirements, and burden on the regulated community.

42.9 e (3) removes the requirement for limited technologists to pay a fee to the Department for the limited radiography examination administered by ARRT through an agreement with IDPH. ARRT is now charging this fee directly to the applicant, so applicants will not need to pay the Department a fee for this service.

42.18(2) b and c change the CE limitation for repeating certain continuing education courses. The ARRT made a change to allow a CE to be repeated in future bienniums, so IDPH is removing this restriction from rule to remove the conflict with the ARRT requirements.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

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 comments concerning this proposed rulemaking. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on June 7, 2022. Comments should be directed to:

Angela Leek

Public Health Department

321 East 12th Street

Des Moines, Iowa 50319

Email: radhealthia@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 action proposed:

ITEM 1. Amend subparagraph **42.9(2)"e"(3)** as follows:

(3) Each individual making application to take an examination as a limited radiologic technologist in 42.9(2)*"e"*(1)"1" or "3"must submit an application to the department each time the individual takes the examination. Applicants must also submit ~~and nonrefundable~~ the examination fee ~~of~~ $~~200~~ directly to the ARRT ~~to the department~~ each time the individual takes the examination.

ITEM 2. Amend paragraph **42.18(2)"b"** as follows:

b. Continuing education activities ~~that are lecture presentations~~ may not be repeated for credit in the same biennium but may be repeated across different biennia.

ITEM 3. Rescind paragraph **42.18(2)"c."**

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 73, "Special Supplemental Nutrition Program for Women, Infants, and Children," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 135.11.

State or Federal Law Implemented

This rule making implements, in whole or in part, federal law 42 U.S.C. Section 1786, and Iowa Code section 135.11(12).

Purpose and Summary

The proposed amendment will ensure Iowa can move forward with the WIC Online Ordering Pilot Project in order for a WIC participant, vendor, or contract agency to participate in the project. The rule will state "Notwithstanding any conflicting provision of law to the contrary, a participant, vendor, or contract agency may participate in the WIC Online Ordering Project, provided that such participation conforms to the terms and conditions of the Iowa WIC Policy and Procedural Manual as modified to incorporate the WIC Online Ordering Project."

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

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 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 June 7, 2022. Comments should be directed to:

Jill Lange

Department of Public Health

Lucas State Office Building

321 East 12th Street

Des Moines, Iowa 50319

Email: Jill.lange@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 action proposed:

ITEM 1. Adopt the following **new** rule(s) 641—73.26(135):

641—73.26(135) WIC Online Ordering Project. Notwithstanding any conflicting provision of law to the contrary, a participant, vendor, or contract agency may participate in the WIC Online Ordering Project, provided that such participation conforms to the terms and conditions of the Iowa WIC Policy and Procedural Manual as modified to incorporate the WIC Online Ordering Project.

This rule is intended to implement federal law 42 U.S.C. Section 1786, and Iowa Code section 135.11(12).

PUBLIC HEALTH DEPARTMENT [641]

Adopted and Filed

The Public Health Department hereby amends Chapter 154, "Medical Cannabidiol Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code chapter 124E.11.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124E.2, 124E.4 and 124E.11.

Purpose and Summary

The amendments implement necessary updates to the rules regarding the medical cannabidiol program to formalize waivers currently in effect, reduce compliance burden for licensees and the Department, reduce barriers for veteran participation, and provide additional authority to certifying practitioners. Updates include:

- Providing certifying practitioners the authority to request cancellation of a patient's medical cannabidiol registration card for reasons including, but not limited to, suspected abuse or fraud and violation of health network standard operating procedures;
- Clarifying registration card application language based on program evaluation;
- Formalizing administrative rule waivers that are currently in effect, including for waste disposal processes;
- Striking the real-time requirement for transmission of manufacturing data to the Department to allow for the implementation of a simpler, more cost-effective solution;

- Removing certain low-value waste tracking requirements because of unnecessary difficulties with tracking for licensees and enforcement for the Department;
- Allowing veterans to be eligible for the reduced application fee option when enrolling in the program when confirming documentation is provided.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 26, 2022, as **ARC** 6159C. The department received one comment requesting the inclusion of a grace period between the date the written request for card cancellation is received and the effective date of the card cancellation. After discussion about the potential impacts of cancellations for the reasons set forth in 641 IAC 154.6, the department determined a 30 day grace period was necessary in some situations for the patient or primary care giver to receive sufficient notice of the card cancellation following the department's receipt of the request to cancel the registration card. A 30 day grace period was added into Item 5 when cancellation of the card is due to receipt of a request for cancellation by a third party. Card cancellations requested by cardholders themselves and upon the department's receipt of notification that the cardholder is deceased will be effective as soon as the request is received. The subsequent original Items 5 through 14 were renumbered to 6 through 15. This refinement is the only change from the Notice of Intended Action.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on March 9, 2022.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

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.

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).

Effective Date

This rule making will become effective on May 11, 2022.

The following rule-making action is adopted:

ITEM 1. Renumber subrule **154.2(4)** as **154.2(5)**.

ITEM 2. Adopt the following **new** subrule 154.2(4):

154.2(4) A health care practitioner may make a written request to the department to rescind a written certification the practitioner provided to a patient or caregiver, based on reasons deemed appropriate by the health care practitioner.

ITEM 3. Amend subparagraph **154.3(1)"d"(2)** as follows:

(2) A copy of the patient's valid photo identification. Acceptable photo identification includes:

1. and 2. No change.

3. An alternative form of valid photo identification. A patient who possesses or is eligible for

an Iowa driver's license or an Iowa nonoperator's identification card shall present such document as valid photo identification. A patient who is ineligible or unable to obtain an Iowa driver's license or an Iowa nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the patient's identity through a process established by the department to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

ITEM 4. Amend rule 641—154.6(124E) as follows:

641—154.6(124E) Denial and cancellation. The department may deny an application for a medical cannabidiol registration card, or may cancel a medical cannabidiol registration card, for any of the following reasons:

1. to 6. No change.

7. A health care practitioner requests in writing that the department rescind the written certification the practitioner provided to a patient or caregiver.

8. A patient requests in writing that the department cancel the patient's primary caregiver's medical cannabidiol registration card.

ITEM 5. Amend rule 641—154.7(124E) as follows:

154.7(124E) Appeal.

154.7(1) *Written notice of denial or cancellation.* If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation, ~~and~~ state the reasons for the denial or cancellation in writing, and state the effective date of the denial or cancellation. If the department cancels a card upon request from a patient or primary care giver, or the department becomes aware of the death of a patient or primary caregiver, the cancellation is effective immediately upon issuance of the

written notice of cancellation. If the department cancels a card upon any other ground listed in subrule 154.6, the cancellation shall become effective thirty days following issuance of the written notice of cancellation.

154.7(2) *Effect of written notice of cancellation on use and possession of medical cannabidiol.* A cardholder is authorized to purchase, possess, and use medical cannabidiol up to and including the effective date of the cancellation. For purposes of the affirmative defenses in Iowa Code section 124E.12, a patient or primary caregiver shall be deemed to be in possession of a valid medical cannabidiol registration card up to and including the effective date of the cancellation.

154.7(3) *Request for Appeal.* An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173. In the event of a timely appeal of a cancellation of a medical cannabidiol registration card, cancellation of the card shall be deemed to be suspended pending the outcome of the contested case proceeding. If the cancellation is affirmed following the contested case proceeding, the card cancellation shall become effective thirty days following issuance of the department's final agency action.

ITEM 6. Amend subrule 154.9(1) as follows:

154.9(1) A cardholder seeking renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department ~~at least 60 days prior to the date of expiration~~.

a. and *b.* No change.

ITEM 7. Amend subrule 154.12(1) as follows:

154.12(1) *Patient medical cannabidiol registration card fee.*

a. Each application fee is $100 unless the patient qualifies for a reduced fee as described in paragraph 154.12(1)*"b."*

b. Each reduced application fee is $25 if the patient attests to receiving social security disability benefits, supplemental security income payments, proof of veteran status, or is enrolled in the medical assistance program as defined in rule 641—154.1(124E).

~~*c.* Each renewal fee is the same as the initial card application fee.~~

ITEM 8. Amend subrule 154.16(4) as follows:

154.16(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

a. Inventory of plant material ~~,~~ and medical cannabidiol~~, and waste material~~;

b. to *e.* No change.

ITEM 8. Amend subparagraph **154.17(1)"b"(1)** as follows:

(1) Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

1. to 3. No change.

~~4. The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;~~

~~5.~~ 4. The disposal methods for all waste materials;

~~6.~~ 5. Employee training methods for the specific phases of production. A manufacturer

may make operating documents for these procedures available on site only;

~~7.~~ 6. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only;

~~8.~~ 7. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;

~~9.~~ 8. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;

~~10.~~ 9. Medical cannabidiol packaging and labeling procedures;

~~11.~~ 10. Procedures for recall and market withdrawal of medical cannabidiol;

~~12.~~ 11. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary. A manufacturer may make operating documents for these procedures available on site only;

~~13.~~ 12. A business continuity plan. A manufacturer may make this operating document available on site only;

~~14.~~ 13. Records relating to all transport activities; and

~~15.~~ 14. Other information requested by the department.

ITEM 10. Amend paragraph **154.17(2)"e"** as follows:

e. Sell or distribute medical cannabidiol to any person or business other than a dispensary or manufacturer licensed by the department under Iowa Code chapter 124E;

ITEM 11. Amend rule 641—154.22(124E) as follows:

641—154.22(124E) Transportation of medical cannabidiol and plant material.

154.22(1) *Transport of medical cannabidiol.* A manufacturer is authorized to transport medical

cannabidiol to and from:

a. to *c.* No change.

d. A manufacturer licensed by the department under Iowa Code chapter 124E;

~~*d.*~~ *e.* Other sites only with departmental approval.

154.22(2) *Transport of plant material.* A manufacturer is authorized to transport cannabis plant material from its manufacturing facility to:

a. A waste disposal site;

b. A manufacturer licensed by the department under Iowa Code chapter 124E;

~~*b.*~~ *c.* Other sites only with departmental approval.

154.22(3) *Chain-of-custody tracking system.*

a. No change.

b. Before transporting medical cannabidiol, a manufacturer shall:

(1) Record in the secure sales and inventory tracking system or on the manifest information about the material to be transported; and

(2) Notify the dispensary, laboratory, manufacturer licensed by the department under Iowa Code chapter 124E, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, manufacturer, or waste facility, if applicable.

c. to *e.* No change.

154.22(4) No change.

ITEM 12. Amend rule 641—154.23(124E) as follows:

641—154.23(124E) Disposal of medical cannabidiol and plant material.

154.23(1) No change.

154.23(2) *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure,

and manage medical cannabidiol waste and plant material waste in accordance with all applicable federal, state, and local regulations.

a. and *b.* No change.

c. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable. ~~by grinding and incorporating the waste with a greater quantity of nonconsumable, solid wastes including:~~

~~(1) Paper waste;~~

~~(2) Cardboard waste;~~

~~(3) Food waste;~~

~~(4) Yard waste;~~

~~(5) Vegetative wastes generated from industrial or manufacturing processes that prepare food for human consumption;~~

~~(6) Soil; or~~

~~(7) Other waste approved by the department.~~

154.23(3) No change.

154.23(4) *Waste-tracking requirements.* A manufacturer shall ~~use forms approved by the department to~~ maintain ~~accurate and comprehensive~~ records regarding waste material. The records shall account for~~, reconcile, and evidence~~ all waste activity related to the disposal of medical cannabidiol waste and plant material waste.

ITEM 13. Amend subparagraph **154.24(3)"c"(4)** as follows:

(4) Inventory records~~, including disposal of waste~~.

ITEM 14. Amend subrule 154.24(4) as follows:

154.24(4) *Entry into the department's secure sales and inventory tracking system.* Unless

otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the department's secure sales and inventory tracking system.

a. A manufacturer shall enter data in real time for data related to:

(1) Transport of medical cannabidiol, plant material, waste material, and laboratory samples; and

(2) Sales of medical cannabidiol to dispensaries.

b. A manufacturer shall enter data on changes to inventory of plant material ~~,~~ and medical cannabidiol~~, and waste material~~ by the end of the business day in which the changes occurred.

c. No change.

ITEM 15. Amend subrule 154.27(3) as follows:

154.27(3) ~~*Real-time inventory*~~ *Inventory tracking required.* A manufacturer shall use the department-approved secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary. The manufacturer shall use the system to maintain a ~~real-time~~ record of the manufacturer's inventory of plant material and medical cannabidiol to include:

a. The quantity and form of medical cannabidiol maintained by the manufacturer at the manufacturing facility on a daily basis;

b. The amount of plants being grown at the manufacturing facility on a daily basis; and

~~*c.* The names of the employees or employee conducting the inventory; and~~

~~*d.*~~ *c.* Other information deemed necessary and requested by the department.