

Protecting and Improving the Health of Iowans

Kim Reynolds, Governor

Adam Gregg, Lt. Governor

Kelly Garcia, Interim Director

# STATE BOARD OF HEALTH REGULARLY SCHEDULED MEETING: 3/9/2022 10:00 a.m. – 11:30 a.m. Location: Zoom Virtual Meeting

Meeting Link: https://us02web.zoom.us/j/84456905100?pwd=SGdZbEZkVVVYWmZXN3FHeXpLanNwQT09

# Join by Phone: 312-626-6799 Meeting ID: 844 5690 5100 and Passcode: 336506

# AGENDA

**Board Members:** Andrew Allen; Lisa Czyzewicz, LPN; 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.** Election of Officers
- **10:10 a.m.** Board Minutes for Consideration of Approval 1/12/2022
- 10:15 a.m. Director's Report Kelly Garcia
- **10:35 a.m.** Legislative Update Maddie Wilcox, Legislative Liaison
- **10:45 a.m.** Epidemiology Update Michael Pentella, M.D., Director, State Hygienic Laboratory
- **11:00 a.m.** Administrative Rules Department of Public Health [641] Susan Dixon
  - 1. Adopted & Filed
    - a. Chapter 9, "Outpatient Diabetes Education Programs"
    - b. Chapter 78, "Personal Responsibility Education Program and Title V State Sexual Risk Avoidance Education Grant Program Funding and Restrictions"
    - c. Chapter 80, "Local Public Health Services"
    - d. Chapter 154, "Medical Cannabidiol Program"

11:20 a.m. Substance Use & Problem Gambling Treatment Program Committee Update

11:30 a.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 lowa 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 1/12/2022 DRAFT - MEETING MINUTES

Members Present:	Fred Schuster, Chair Donald Macfarlane, MD, PhD, Vice-Chair Andrew Allen George Kovach, MD Leone Junck Sandra McGrath, RN Nick Ryan, JD Chelcee Schleuger, RN, BSN Michael Wolnerman, RPh, CCIM
Members Absent:	Kierstyn Borg Mickelson Lisa Czyzewicz, LPN
Staff Present:	Heather Adams, Assistant Attorney General; Kelly Garcia, Interim Director Sarah Reisetter, J.D., Deputy Director Amy Van Maanen, Recording Officer
Staff Absent:	None

# Call to Order & Roll Call

Fred Schuster called the video meeting to order at 10:03 A.M. Roll call was taken to determine if a quorum was present.

### Approval of Minutes from 11/10/2021

On a motion by George Kovach, seconded by Donald Macfarlane, all members present voted unanimously to approve the minutes.

### **Director's Report**

Director Kelly Garcia introduced Jill Stuecker, division director for the Division of Professional Licensing and Regulation. Jill was recently hired for this position and previously served as the executive director for the Iowa Dental Board. This newly created division and position will oversee the Bureau of Professional Licensure, Iowa Board of Medicine, Iowa Board of Nursing, Iowa Board of Pharmacy and the Iowa Dental Board.

Interviews were conducted for the medical director position at the end of December. Director Garcia is currently in ongoing conversations with a candidate and anticipate having an update by the next meeting in March.

Work continues on aligning the Departments of Public Health and Human Services. Work has begun on developing a functional organizational chart. Governor Reynolds will introduce legislation for the health and human services system.

Monitoring of COVID-19 in Iowa continues. The Omicron variant has driven up the number of cases of COVID-19 as well as the demand for testing. The State Hygienic Lab has received over 550,000 orders for the Test Iowa at home test kits. The focus of Test Iowa is diagnosis and not testing for travel, social events, etc. Providers for programs in the department have been allowed to move to remote work during the next four to six week due to the increase in positive cases.

Director Garcia and Ken Sharp, division director for the Division of Acute Disease Prevention, Emergency Response and Environmental Health, shared information on therapeutics and monoclonal antibodies. Iowa will receive two types of oral antivirals in limited quantities mid-January. The medications will be allocated to select pharmacies and clinical providers. The department has also begun to receive a limited amount of pre-exposure therapeutics for high risk groups. It is anticipated that the allocation monoclonal antibodies will eventually end as the Omicron variant becomes the dominant strain in Iowa.

Board member, Sandra McGrath, shared guidance from the department early in the response was helpful. Resuming webinars for local public health workers was discussed.

# **Performance Management & Quality Improvement**

Andrea Bentzinger, Ph.D. and Rob Stewart from the Bureau of Public Health Performance presented information about the department's work on quality improvement and performance management. Quality improvement follows the Plan, Do, Check, Act model/process. In 2021, 33% of staff participated in a quality improvement adventures. Quality improvement is meant to be a process that is deliberate, defined, continuous, and yields measurable improvement.

The goal of performance management is to improve outcomes, efficiency, increase collaboration, and highlight the department's contribution to population health outcomes. Performance measures are published on the department's website. In 2021, 28% of staff participated in performance management workshops.

The goal for 2022 is to strengthen connections between performance management, quality improvement, and health equity.

### **Changes to Local Public Health Services Program**

Marisa Roseberry, bureau chief for Public Health Performance, shared information regarding the proposed changes to the local public health services program (LPHS). The state currently allocates \$7.6 million to LPHS. The department receives the funds and passes it on to local public health agencies. The proposed changes will focus the use of LPHS funds on public health systems work and emphasize core public health functions, essential services and public health interventions. Changes to support population health will occur over the next five years to give the department and LPHS an opportunity to work through this transition.

### **Legislative Update**

Maddie Wilcox, legislative liaison for the department, shared the Governor's priorities for this session - taxes, childcare, workforce, and biofuels. January 21, 2022 is the deadline for individual bill requests and February 18, 2022 is the first funnel date.

# Administrative Rules – Iowa Department of Public Health [641] – Notice of Intended Action 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.

No action was required.

<u>Chapter 78, "Personal Responsibility Education Programs and Title V State Sexual Risk Avoidance</u> <u>Education Grant Program Funding and Restrictions"</u>

The purpose of the proposed changes is to adopt the requirements of 2019 Iowa Acts, House File 766, Section 99.

No action was required.

## 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 lowan.

No action was required.

# 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.

Interest was expressed in learning more about the medical cannabidiol program.

No action was required.

# Administrative Rules – Iowa Department of Public Health [641] – Adopted and Filed

Chapter 8, "Iowa Care for Yourself Program"

The amendments include changes to clarify statements, match medical definitions and to allow for the provision of services to an expanded population who do not have access to the programs providing the services.

A question was asked regarding the Quitline's effectiveness. The Quitline is an effective best practice. A seven month follow-up was conducted on those that used the Quitline and of those that used the Quitline, 35% had quit smoking. Adult cigarette smoking has decreased. No change in smokeless rates.

On a motion by Donald Macfarlane, seconded by Andrew Allen, all members present voted unanimously to approve.

<u>Chapter 38, "General Provision for Radiation Machined and Radioactive Materials" and Chapter 41, Safety</u> <u>Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"</u>

The amendments to Chapter 38 strike the fee related to the State of Iowa as a mammography accrediting body (AB) and providing services for mammography interpretation fees and accreditation fees. The State relinquished the role of AB effective 1/1/21. The fees are being removed to reflect the current fee collections by the Bureau of Radiological Health.

The amendments to Chapter 41 align with the current changes in technology of x-ray machines for mammography and stereotactic breast biopsy and reflect the requirements of the quality control programs outlined by the unit manufactures. Additional amendments will align IDPH and FDS on certain requirements outlined in the Mammography Quality Standards Act.

Concerns were expressed regarding the 30 day window for reporting. This requirement is based on the Food and Drug Administration (FDA) standard. If the state would want to be more restrictive, work would need to occur with the FDA. Heather Adams, assistant attorney general, recommended the board proceed with adoption and staff can work on addressing this concern separately.

On a motion by Sandra McGrath, seconded by Michael Wolnerman, all members present voted unanimously to approve.

<u>Chapter 108, "Medical Residency Training State Matching Grants Program"</u> The amendments implement changes made to Iowa Code section 135.176.

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

# Chapter 109, "Prescription Drug Donation Repository Program"

The amendments update outdated citations and address an unintentional issue that occurred from some new wording in different legislation that was not intended to apply to the program covered by Chapter 108. The department provided a waiver in 2019 to address the situation. The proposed amendment to the definition of "centralized repository" is a permanent solution that will remove the need for a waiver.

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

# Substance Use/Problem Gambling Treatment Program Committee Report

The committee approved the following:

- One 270 day license; and
- Two One year licenses.

# Adjournment

On a motion by Donald Macfarlane, seconded by Leone Junck, all members present voted unanimously to adjourn the meeting at 12:03 P.M.

### **PUBLIC HEALTH DEPARTMENT [641]**

## **Adopted and Filed**

The Public Health Department hereby amends Chapter 9, "Outpatient Diabetes Education Programs," Iowa Administrative Code.

## Legal Authority for Rule Making

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

# State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 135.11.

# Purpose and Summary

The amendments reflect revisions related to an external organization's name and a credential designation. Clarifying revisions are also adopted for acronyms and a few other items.

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** 6156C. No public comments were received. No changes from the Notice have been made.

# 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. Adopt the following <u>new</u> definitions of "ADCES" and "Certified diabetes care and education specialist" in rule **641**—**9.2(135)**:

"ADCES" means the Association of Diabetes Care and Education Specialists.

*"Certified diabetes care and education specialist"* means a person currently certified by the Certification Board for Diabetes Care and Education.

ITEM 2. Amend rule **641—9.2(135**), definitions of "Accredited" and "Pharmacist," as follows:

*"Accredited"* means that a program is currently accredited by the American Association of Diabetes Care and Education Specialists (ADCES)/American Association of Diabetes Educators (AADE).

"*Pharmacist*" means a person currently licensed to practice pharmacy under Iowa Code chapter 155 155A.

ITEM 3. Amend subrule 9.3(1) as follows:

**9.3(1)** Develop minimum standards in coordination with the American Diabetes Association for certification aligned with the National Standards for Diabetes Self-Management Education and Support published by the ADA and the American Association of Diabetes Educators ADCES/AADE.

ITEM 4. Amend subrule 9.3(5) as follows:

**9.3(5)** Assign a program site number and an expiration date and issue a certificate to each program that meets the standards. A certificate shall be valid for four years from issuance unless specified otherwise on the certificate or unless sooner revoked.

ITEM 5. Amend rules 641—9.4(135) to 641—9.10(135) as follows:

641—9.4(135) Application procedures for American Diabetes Association-recognized and American Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators-accredited programs. When a program is recognized by the American Diabetes Association <u>ADA</u> or accredited by the American Association of Diabetes Educators <u>ADCES/AADE</u>, the program shall apply for certification by submitting the following to the department:

**9.4(1)** A copy of the Certificate of Recognition provided by <u>the</u> ADA or the Certificate of Accreditation provided by <u>AADE</u> the ADCES/AADE.

9.4(2) The name, address and telephone number for the program.

**9.4(3)** The names <u>name and email address</u> of the program coordinator , <u>and the names of the</u> program physician, primary and supporting instructors, and advisory committee members.

9.4(4) Copies of current licenses for all Iowa-licensed professionals named in 9.4(3).

9.4(5) The name and a copy of both the Iowa licenses and continuing education hours of any

pharmacist who serves as program staff. A pharmacist shall be a primary or supporting instructor or advisory committee member and shall meet the education requirements in 9.8(6), 9.8(7) or 9.8(8).

641—9.5(135) Renewal procedures for American Diabetes Association-recognized and American Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators-accredited programs. Programs shall renew their certification every four years, at least 30 days prior to the expiration date. To apply for renewal of certification, the ADArecognized program or the AADE ADCES/AADE-accredited program shall submit the following to the department:

**9.5(1)** A copy of the new ADA Certificate of Recognition or <u>AADE ADCES/AADE</u> Certificate of Accreditation.

**9.5(2)** The name, address and telephone number for the program.

**9.5(3)** The <u>names name and email address</u> of the program coordinator , <u>and the names of the</u> program physician, primary and supporting instructors, and advisory committee members.

9.5(4) Copies of current licenses for all Iowa-licensed professionals named in 9.5(3).

**9.5(5)** The name and a copy of both the Iowa licenses and continuing education hours of any pharmacist who serves as program staff. A pharmacist shall be a primary or supporting instructor or advisory committee member and shall meet the continuing education requirements in 9.9(7).

641—9.6(135) Application procedures for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.

9.6(1) Each program shall apply for certification with the department.

9.6(2) Applications from programs not recognized by the ADA or accredited by AADE the

<u>ADCES/AADE</u> shall provide the following information:

*a*. Name, address and telephone number for the program, program physician and program coordinator <u>and email address of the program coordinator</u>. The names of instructional staff and advisory committee members and copies of their current Iowa licenses shall also be included.

*b.* Identification of the target population, an estimate of the program caseload, estimated number of programs to be conducted annually, minimum and maximum class size, and a calendar identifying the hours per day and number of days per week scheduled in individual or group instruction to meet the minimum course requirements.

*c*. A description of goals and objectives, participant referral mechanism, and means of coordinating between the community, physicians, and program staff.

d. Evaluation methods designed by individual programs and samples of documents to be used.

*e*. A description of the curriculum designed to instruct the participant with diabetes how to achieve self-management competency. The curriculum shall cover the same content areas as are required by the ADA for recognition or the <u>AADE ADCES/AADE</u> for accreditation including:

(1) to (7) No change.

(8) Reducing risks: includes prevention, detection, and treatment of acute complications (including hypoglycemia, hyperglycemia, diabetic ketoacidosis, sick days, and severe weather or crisis supply management) and chronic complications ;(including foot, skin eye and dental care; exams; immunizations; and kidney function testing as indicated).

(9) to (11) No change.

641—9.7(135) Diabetes program management for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.

**9.7(1)** to **9.7(4)** No change.

641—9.8(135) Program staff for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.

**9.8(1)** to **9.8(5)** No change.

**9.8(6)** All primary instructors shall show evidence of knowledge about the disease process of diabetes and the treatment and management of people with diabetes by documentation of one or more of the following:

*a*. Within the last four years, completion of a minimum of 32 hours of continuing education in diabetes, diabetes management, or diabetes education; or.

*b*. Equivalent training or experience including, but not limited to, endocrinology fellowship training or masters level preparation in diabetes nursing/nutrition. Unsupervised teaching of patients is not an acceptable equivalent.

*c*. Current certification as a certified <u>diabetes care and education specialist/certified</u> diabetes educator.

**9.8(7)** All supporting instructors shall show evidence of knowledge about the disease process of diabetes and the treatment and management of people with diabetes by documentation of completion of a minimum of 16 hours of continuing education in diabetes, diabetes management, or diabetes education within the last four years or have current certification as a certified <u>diabetes</u> <u>care and education specialist/certified</u> diabetes educator.

9.8(8) to 9.8(10) No change.

641—9.9(135) Renewal application procedures for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Care

and Education Specialists/American Association of Diabetes Educators. Every four years, programs shall provide the following information to the department at least 30 days prior to the expiration date.

**9.9(1)** Name, address and telephone number of the program, program physician and program coordinator, with; email address of the program coordinator; and names of instructional staff and advisory committee members and copies of current licenses for all Iowa-licensed professionals.

**9.9(2)** to **9.9(7)** No change.

**641**—**9.10(135) Annual report.** Summary data shall be completed annually by each program and sent to the department <u>at a time determined by the department</u>. The data shall include but not be limited to the number of times the program was presented, the number of outpatients that participated, and a summarized description of program participants including type of diabetes, age, race and sex.

### **PUBLIC HEALTH DEPARTMENT [641]**

## **Adopted and Filed**

The Public Health Department hereby adopts new Chapter 78, "Personal Responsibility Education Program and Title V State Sexual Risk Avoidance Education Grant Program Funding and Restrictions," Iowa Administrative Code.

## Legal Authority for Rule Making

This rule making is adopted under the authority provided in 2019 Iowa Acts, House File 766, section 99.

### State or Federal Law Implemented

This rule making implements, in whole or in part, 2019 Iowa Acts, House File 766, section 99.

## Purpose and Summary

The purpose of Chapter 78 is to adopt the requirements of 2019 Iowa Acts, House File 766, section 99, to exclude, as an eligible applicant, any entity that performs abortions, promotes abortions, maintains or operates a facility where abortions are performed or promoted, contracts or subcontracts with an entity that performs or promotes abortions, becomes or continues to be an affiliate of any entity that performs or promotes abortions, or regularly makes referrals to an entity that provides or promotes abortions or maintains or operates a facility where abortions are performed. However, this prohibition shall not be interpreted to include a nonpublic entity that is a distinct location of a nonprofit health care delivery system, if the distinct location provides programming through the Personal Responsibility Education Program (PREP) or the Title V State Sexual Risk Avoidance Education Grant Program (SRAE) but does not perform abortions or maintain or operate as a facility where abortions are performed.

## 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** 6160C. No public comments were received. No changes from the Notice have been made.

# 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:

Adopt the following <u>new</u> 641—Chapter 78:

### CHAPTER 78

# PERSONAL RESPONSIBILITY EDUCATION PROGRAM AND TITLE V STATE SEXUAL RISK AVOIDANCE EDUCATION GRANT PROGRAM FUNDING AND RESTRICTIONS

**641**—**78.1(88GA,HF766) Purpose.** The purpose of this chapter is to set forth guidelines and limitations for the use of funds from the Personal Responsibility Education Program (PREP) and the Title V State Sexual Risk Avoidance Education Grant Program (SRAE).

## 641-78.2(88GA,HF766) Definitions.

"Administer" means to implement PREP or SRAE through contracts entered into by the department and selected private, governmental, and nonprofit organizations to provide programming directly to youth participants. "Administer" does not mean the evaluation of PREP or SRAE or the management of federal performance measures data collection for PREP or SRAE programming. "Administer" also does not mean providing training and technical assistance.

*"Affiliate"* means a business, corporate, or financial relationship in which an entity is controlled by or under common control with an entity that performs or promotes abortions.

"Department" means the Iowa department of public health.

"Nonprofit health care delivery system" means an Iowa nonprofit corporation that controls, directly or indirectly, a regional health care network consisting of hospital facilities and various ambulatory and clinic locations that provide a range of primary, secondary, and tertiary inpatient, outpatient, and physician services.

"PREP" means the Personal Responsibility Education Program as specified in 42 U.S.C. Section 713.

"Regularly" means recurring, routine, and conducted in conformity with established or

prescribed rules or policy.

"SRAE" means the Sexual Risk Avoidance Education Grant Program authorized pursuant to Section 510 of Title V of the federal Social Security Act, 42 U.S.C. Section 710 as amended by Section 50502 of the federal Bipartisan Budget Act of 2018, Public Law 115-123, and as further amended by Division S, Title VII, Section 701 of the federal Consolidated Appropriations Act of 2018, Public Law 115-141.

**641—78.3(88GA,HF766) Distribution of grant funds.** Distribution of grant funds shall be made in a manner that continues access to PREP and SRAE programming.

**78.3(1)** *Priority.* The department shall distribute all grant funds received to eligible private, governmental, and nonprofit organizations or agencies that are able to deliver services to a county or counties as defined and prioritized by the department.

### **78.3(2)** Funds restrictions—abortion.

*a.* Any contract entered into on or after July 1, 2019, by the department to administer PREP or SRAE shall exclude as an eligible applicant any applicant entity that performs abortions, promotes abortions, maintains or operates a facility where abortions are performed or promoted, contracts or subcontracts with an entity that performs or promotes abortions, becomes or continues to be an affiliate of any entity that performs or promotes abortions, or regularly makes referrals to an entity that provides or promotes abortions or maintains or operates a facility where abortions are performed.

*b*. This prohibition shall not be interpreted to include a nonpublic entity that is a distinct location of a nonprofit health care delivery system, if the distinct location provides programming through PREP or SRAE but does not perform abortions or maintain or operate a facility where abortions are performed.

c. For the purposes of these rules, "abortion" does not include any of the following:

(1) The treatment of a woman for a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death.

(2) The treatment of a woman for a spontaneous abortion, commonly known as a miscarriage, when not all of the products of human conception are expelled.

# **78.3(3)** Distinct provider identification number and attestation.

*a*. Each distinct location of a nonprofit health care delivery system receiving funds from the department under these rules shall be assigned a unique identification number by the department.

*b*. Each distinct location of a nonprofit health care delivery system receiving funds from the department under these rules to administer PREP or SRAE shall provide to the department, on forms provided by the department, a signed attestation that abortions are not performed at the distinct location. The attestation will be completed annually during the application process.

These rules are intended to implement 2019 Iowa Acts, House File 766, section 99.

### **PUBLIC HEALTH DEPARTMENT [641]**

## **Adopted and Filed**

The Public Health Department hereby rescinds Chapter 80, "Local Public Health Services," Iowa Administrative Code, and adopts a new Chapter 80 with the same title.

### Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 135.11(13). *State or Federal Law Implemented* 

This rule making implements, in whole or in part, Iowa Code section 135.11(13).

# Purpose and Summary

The amendment streamlines Chapter 80 by focusing the use of local public health services (LPHS) funds on public health systems work and emphasizing core public health functions, essential services, and public health interventions. Revisions incorporated in new Chapter 80 serve to advance the health of the population through a systems-level approach while providing opportunities to protect and improve the health of every Iowan.

### 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** 6158C. One public comment was received, expressing appreciation of the new rules streamlined and focused nature. No changes from the Notice have been made.

## Adoption of Rule Making

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

# Fiscal Impact

his 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:

Rescind 641—Chapter 80 and adopt the following <u>new</u> chapter in lieu thereof:

# CHAPTER 80

# LOCAL PUBLIC HEALTH SERVICES

641—80.1(135) Purpose. The purpose of the local public health services (LPHS) contract is to assure core public health functions are met, to assure essential public health services are delivered, and to increase the capacity of local boards of health to meet the unique needs of the population while promoting healthy people in healthy communities throughout their life spans.

**641**—**80.2(135) Definitions.** For the purposes of these rules, the following definitions apply: *"Allocation"* means the process to distribute funds.

"Appropriation" means the funding amount approved in the state budget.

"*Community*" means the aggregate of persons with common characteristics such as race, ethnicity, age, occupation, or other similarities such as location.

"Contractor" means a local board of health (LBOH).

"Core public health functions" means the functions of assessment, policy development, and assurance:

1. Assessment means regular collection, analysis, interpretation, and communication of information about health conditions, risks, and assets in a community.

2. Policy development means formulation, implementation, and evaluation of plans and policies, for public health in general and priority health needs in particular, in a manner that incorporates scientific information and community values in accordance with state public health policy.

3. Assurance means that programs and interventions, which maintain and improve health, are carried out by encouragement, regulation, or direct action.

"Department" means the Iowa department of public health.

"Elderly" means an individual aged 60 years and older.

*"Essential public health services"* means a framework for public health to promote and protect the health of all people in all communities.

"Formula" means the mathematical calculation applied to the state appropriation and granted to each local board of health pursuant to Iowa Code section 135.11(13) to determine the amount of available funds to be distributed to each county.

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"Local board of health" or "LBOH" means a county or district board of health as defined in Iowa Code chapter 137.

"Low income" means the U.S. Census Bureau's small area income and poverty estimates (SAIPE) used to determine low income.

"LPHS" means local public health services.

"Public health intervention" means an organized effort to promote behaviors and habits that can improve physical, mental, and emotional health for specific groups of people.

*"Work plan"* means the plan established by the contractor to identify the details for implementing core functions and essential public health services.

### 641-80.3(135) Contractor assurances.

**80.3(1)** The contractor may directly provide or subcontract all or part of the delivery of essential public health services and public health interventions.

**80.3(2)** The contractor shall make certain the following:

*a*. A work plan is submitted annually through an application process that identifies the intended public health interventions and essential public health services for the designated fiscal year;

*b*. Staff are available to meet the core public health functions, deliver essential public health services, and implement the public health interventions outlined in the work plan;

*c*. As applicable, contractors will assure that policies and procedures are available for public health interventions and essential public health services identified in the work plan;

d. Fiscal accountability of funds is monitored;

*e*. Contract-required documentation, including performance metrics, is submitted by the established deadline;

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f. A local appeal process is available for public health interventions identified in the work plan; and

g. All applicable local, state, and federal requirements are met.

**641**—**80.4(135)** Utilization of LPHS contract funding. The contractor may bill the department for staff time, salaries and benefits, and other necessary costs to implement the approved work plan.

**80.4(1)** *Planning process.* Annually, the contractor shall conduct a planning process to identify the utilization of LPHS contract funding that considers the unique and changing needs of the communities served.

**80.4(2)** *Reallocation*. The department will annually determine the potential for unused funds from contracts. Reallocation of the funds shall be at the discretion of the department.

### 641-80.5(135) LPHS funds.

**80.5(1)***Allocation for LPHS funds*. Allocation for LPHS funds to each contractor is determined by the following formula:

*a*. Eighteen percent of the total LPHS funds shall be divided so that an equal amount is available for use in each county in the state.

*b*. Eight percent of the total LPHS funds shall be allocated to each county according to the county's population based upon the published data of the U.S. Census Bureau, which is the most recent data available three months prior to the release of the LPHS application.

*c*. Forty-four percent of the total LPHS funds shall be allocated according to the proportion of state residents who are elderly persons living in a county based upon the bridged-race population estimates produced by the U.S. Census Bureau in collaboration with the National Center for Health Statistics (NCHS).

*d*. Thirty percent of the total LPHS funds shall be allocated according to the proportion of state residents who are low-income persons living in a county based upon the U.S. Census Bureau's small area income and poverty estimates (SAIPE).

# 80.5(2) Reserved.

These rules are intended to implement Iowa Code section 135.11(13).

### **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;

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• 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 a grace period of 90 days for a card cancellation. The grace period was inadvertently not included in the Notice and it has been added into Item 4. This addition is the only change from the Notice.

# 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 **<u>new</u>** 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 <u>or unable</u> 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. The card cancellation shall become

effective 90 days following receipt of request for cancellation.

8. A patient requests in writing that the department cancel the patient's primary caregiver's

medical cannabidiol registration card. The card cancellation shall become effective 90 days following receipt of request for cancellation.

ITEM 5. 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 6. 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, <u>proof of veteran status</u>, 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 7. 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. <u>4.</u> The disposal methods for all waste materials;

6. <u>5.</u> Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;

7. <u>6.</u> 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;

 $9 \cdot 8$ . 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;

<u>11.</u> <u>10.</u> Procedures for recall and market withdrawal of medical cannabidiol;

<u>12.</u> <u>11.</u> 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. <u>12.</u> A business continuity plan. A manufacturer may make this operating document available on site only;

14. <u>13.</u> Records relating to all transport activities; and

15. <u>14.</u> Other information requested by the department.

ITEM 9. Amend paragraph 154.17(2)"e" as follows:

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

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ITEM 10. 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;

<u>*d*.</u> 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. <u>c.</u> 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, <u>manufacturer licensed by the department under Iowa</u> <u>Code chapter 124E</u>, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, <u>manufacturer</u>, or waste facility, if applicable.

c. to e. No change.

154.22(4) No change.

ITEM 11. 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 12. Amend subparagraph 154.24(3)"c"(4) as follows:

(4) Inventory records, including disposal of waste.

ITEM 13. 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 <u>medical cannabidiol</u>, 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 14. Amend subrule 154.27(3) as follows:

154.27(3) <u>Real time-inventory Inventory tracking</u> 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

<u>*d*.</u> Other information deemed necessary and requested by the department.