STATE BOARD OF HEALTH
REGULARLY SCHEDULED MEETING: 1/12/2022
10:00 a.m. – 12:00 p.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: Fred Schuster, Chair; Donald Macfarlane, MD, PhD, Vice-Chair; Andrew Allen; Lisa Czyzewicz, LPN; Leone Junck; George Kovach, MD; 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 – 11/10/2021

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

10:40 a.m. Performance Management & Quality Improvement–Andrea Bentzinger, Ph.D. and Rob Stewart

10:55 a.m. Changes to Local Public Health Services Program – Marisa Roseberry

11:10 a.m. Legislative Update – HHS Priorities – Maddie Wilcox
Legislative Timetable - https://www.legis.iowa.gov/docs/publications/SESTT/current.pdf

11:25 a.m. Administrative Rules – Department of Public Health [641] – Susan Dixon

1. Notice of Intended Action
    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”

2. Adopted & Filed
   a. Chapter 8, “Iowa Care For Yourself (IA CFY) Program”
   b. Chapter 38, “General Provisions for Radiation Machined and Radioactive Materials,” and Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials”
   c. Chapter 108, “Medical Residency Training State Matching Grants Program”
   d. Chapter 109, “Prescription Drug Donation Repository Program”

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

12:00 p.m. Adjourn

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
11/10/2021
DRAFT - MEETING MINUTES

Members Present:	Andrew Allen Kierstyn Borg Mickelson George Kovach, MD Leone Junck Donald Macfarlane, MD, PhD Sandra McGrath, RN Nick Ryan, JD Chelcee Schleuger, RN, BSN Fred Schuster Michael Wolnerman, RPh, CCIM
Members Absent:	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
Sarah Reisetter called the video meeting to order at 10:02 A.M. Roll call was taken to determine if a quorum was present.

Approval of Minutes from 9/8/2021
On a motion by George Kovach, seconded by Nick Ryan, all members present voted unanimously to approve the minutes.

Director's Report
Director Kelly Garcia provided an update on realignment efforts. Work is being done on session priorities, legislative and policy bills and budget for the new health and human services system (HHS). Staff is also reflecting on the lessons learned in pandemic and how to prepare for any future pandemics. The department has received a significant amount of federal funds which will help lay the ground work with these initiatives.

Work is also being done with the departments' behavioral health systems, identifying how we can best support Iowans, including our workforce and identifying gaps in services across the HHS system.

Work continues on the maternal health strategic plan.

Data modernization efforts are occurring. This process involves looking at how to bring our many systems together for better data collection. Having easy access to good data will help drive decision making processes.

Director Garcia also provided an update on funding the department has received. Approximately two dozen applications were submitted for the CDC disparities grant. Staff is in the process of reviewing and making the awards. Local public health agencies will receive funds to support and expand lab and epidemiological capacity. Twenty partner organizations have received funds from the COVID-19 vaccine health equity grants.

The medical director position is posted. This position was updated to split out the epidemiologist functions. The state epidemiologist position will be posted next.

Vaccine Update
Ken Sharp, director for the Division of Acute Disease Prevention, Emergency Response, and Environmental Health, shared information regarding vaccine distribution, pediatric vaccine, third doses and booster doses.

Iowa will be receiving approximately 99,000 doses of the pediatric vaccine, which is a two dose series. Vaccine orders are placed every other week. In the first week, over 7000 doses were administered.

Staff is working on visualizations for third dose and pediatric vaccination information.

The third dose is being used for individuals with high risk conditions.

Communications Update
Sarah Ekstrand, public information officer for IDPH, provided an update on current vaccination campaigns. Communication is not only focusing on the importance of vaccinations for one's health, but also in protecting health care resources. Communication has changed during the pandemic from encouraging citizens to be patient for a vaccine to the importance of getting vaccinated. A variety of media platforms are being used – radio, TV, social media. The department is partnering with the Iowa Alcoholic Division to wrap six semi-trailers with vaccination messaging.

The influenza vaccination campaign used paid advertising and was paired with COVID-19 messaging. Director Garcia participated in an AARP town hall on vaccination. Work is being done with a number of partners on vaccine equity and trusted messaging.

Michael Wolernman encouraged the department to use pharmacists in their messaging efforts. He shared that over half of vaccine administrations are done by a pharmacist. Healthy individuals tend to go to pharmacists for a vaccination and sick/ill individuals tend to go to their physicians for a vaccination.

Legislative Update
Maddie Wilcox, legislative liaison for the department, shared information regarding her role at IDPH and the upcoming legislative session. Maddie is the department's registered lobbyist. Throughout the year, she communicates with legislators and their staff providing updates on the departments work. The legislative session starts on 1/10/22. IDPH is not submitting any pre-file legislation. Maddie will provide updates to the board throughout the legislative session.

COVID Recovery Iowa
Karen Hyatt from the Department of Human Services (DHS) presented information regarding the COVID Recovery Iowa program. The program is funded by the Federal Emergency Management Agency through

a contract with DHS to provide free counseling, virtual activities and to assist connecting individuals with other resources. This is a free service that is available to any Iowan affected by the pandemic.

Administrative Rules – Iowa Department of Public Health [641] – Notice of Intended Action
Chapter 8, "Iowa Care for Yourself Program"
The proposed 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.

No action was required.

Chapter 38, "General Provision for Radiation Machined and Radioactive Materials" and Chapter 41, Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"
The proposed 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 proposed 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.

No action was required.

Chapter 109, "Prescription Drug Donation Repository Program"
The proposed amendment will fix an unintended 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.

No action was required.

Administrative Rules – Iowa Department of Public Health [641] – Adopted and Filed
Chapter 10, "Iowa Get Screened: Colorectal Cancer Program"
The amendments update screening eligibility requirements for the Iowa Get Screened: Colorectal Cancer Program to align with federal guidelines. It will encourage access to services and align with a CDC grant that is in year two of a five year program. Language is also being removed in order to allow for diagnostic services for eligible Iowans, who had an initial positive screening test performed outside the program.

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

Chapter 95, "Vital Records: General Administration" and Chapter 99, "Vital Records Modifications"
The amendments add provisions to Iowa Code section 144 to allow an adult adoptee to obtain a non-certified copy of their original certificate of birth. The provision also allows biological parents the ability to complete a contact preference form and medical history form.

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

Chapter 139, "Emergency Medical Services-Training Programs-Students-Complaints and Investigations"
The amendments meet the requirements of 2021 Iowa Acts, Senate File 615 that allows a medical care ambulance service or non-transport service, which has received authorization from the department to conduct emergency medical care service training.

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

Substance Use/Problem Gambling Treatment Program Committee Report
The committee approved the following:

- Two - one year licenses;
- One - Deemed status; and
- Approved the recommendations with one complaint.

Election of Officers
On a motion by Donald Macfarlane, seconded by Nick Ryan all members present voted unanimously to approve Fred Schuster as the chairperson of the State Board of Health.

On a motion by Fred Schuster, seconded by Chelcee Schleuger all members present voted unanimously to approve Donald Macfarlane as the vice chairperson of the State Board of Health.

Adjournment
Sarah Reisetter adjourned the meeting at 11:46 A.M.

Performance Improvement

2021 Efforts and Plans for 2022

IDPH
IOWA Department of PUBLIC HEALTH
Jan 2022

Bureau of Public Health Performance

Andrea Bentzinger - QI Coordinator
Rob Stewart - PM Coordinator

Quality Improvement

- Deliberate and defined
- Continuous and ongoing
- Yields measurable improvement

+

Performance Management

- Knowing where we were, where we are, and where we want to be
- Working toward intended outcomes for our primary customers
- Ensuring appropriate accountability

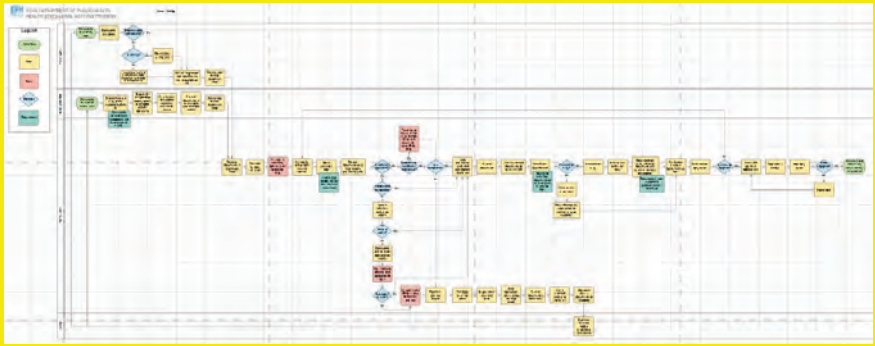
=

Performance Improvement

- What we measure and how we measure it
- How we look at processes and outcomes
- How we use QI and PM to improve

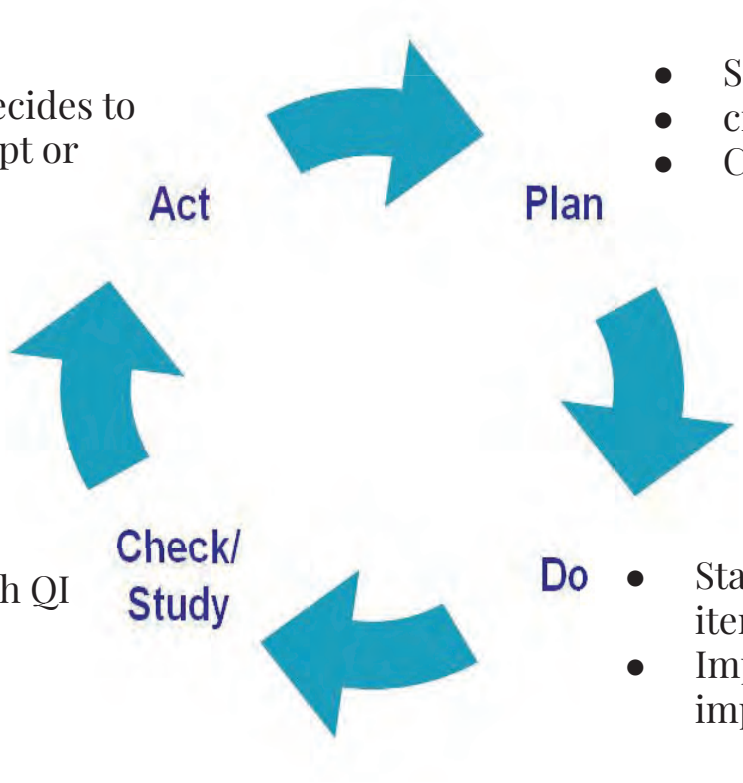
QI in 2021

- 142 employees formally participated (33% of staff)
- 28 QI training sessions; 206 attendees
- 3 QI adventures completed (2 additional started)
- 2 facilitated discussions



QI Adventure Process

- QI team decides to adopt, adapt or abandon



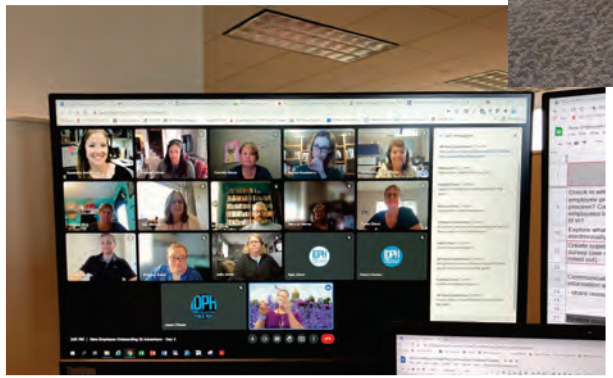
- Set scope
- create AIM statement
- Customer, Health Equity

- Staff complete action items
- Improvement is implemented

- Check-ins with QI Council

Adding a facilitator series in 2022

We are back in person!



But are able to flex to virtual

Performance Management Goals

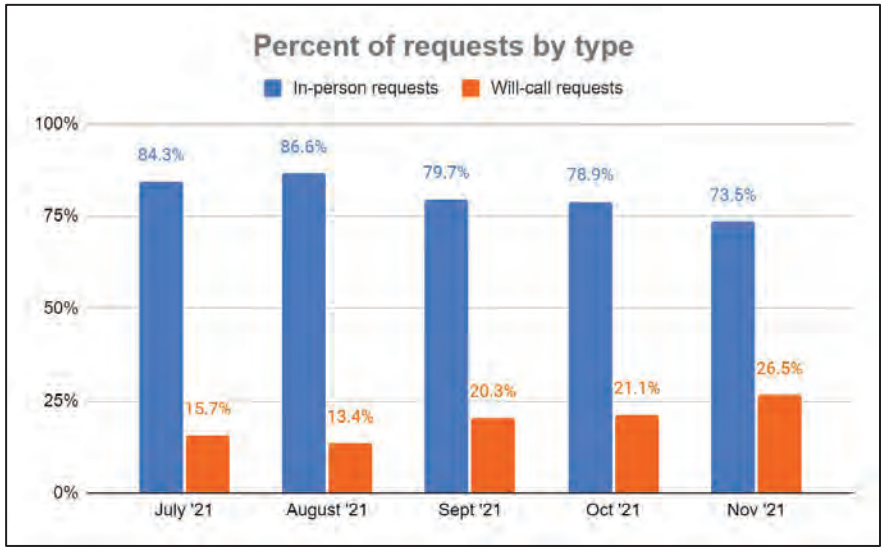
PM System

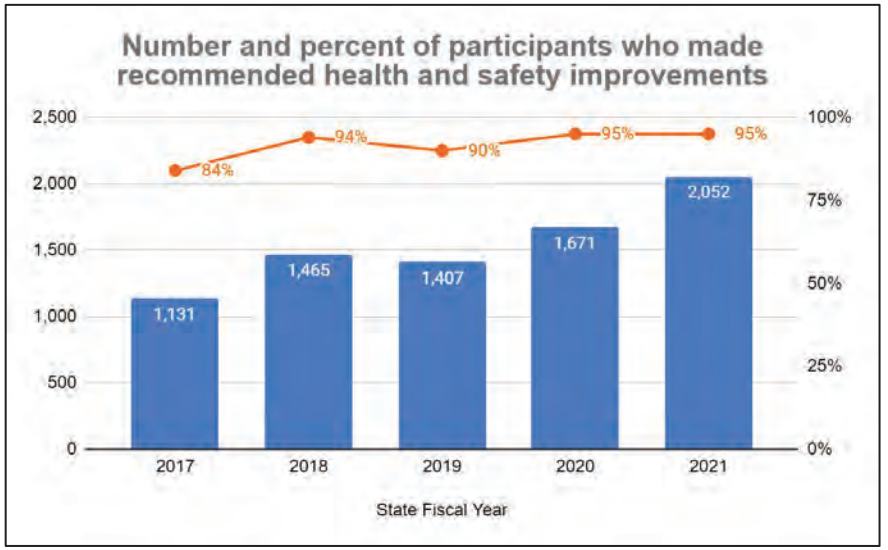
1. Improve outcomes for IDPH customers
2. Improve the efficiency and efficacy of IDPH programs and services
3. Increase collaboration among IDPH teams and break down silos at the department
4. Highlight the department's contribution to population health outcomes

PM Workshops

1. Develop strategies to improve performance
2. Identify opportunities for quality improvement
3. Increase collaboration and break down silos

Performance Measure Examples





Measures are published on the IDPH website at https://idph.iowa.gov/about/performance-measures

PM in 2021

- 121 employees formally participated (28% of staff)
- 28 teams inducted
- 8 quarterly PM workshops held
- 23 teams participated in at least one PM workshop

PM in 2022

- Induct teams
- Host quarterly workshops
- Evaluate workshop efficacy & make improvements as needed
  - Participant surveys
  - Workshop action reports
- Strengthen connections between PM, QI, and health equity

Questions?

LOCAL PUBLIC HEALTH SERVICES PROPOSED PROGRAM CHANGES

January 2022

Essential Public Health Services Funds

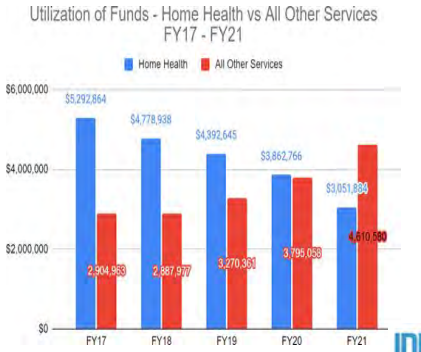
Current State Funding Allocation: $7.6 million

Formula based allocation to all 99 local boards of health

- Considers population, elderly population, low-income residents

Current State

- 19 Possible Billable Activities Through Contract
- Approximately 50% of funds statewide are spent on home health, nursing, or homemaker care.



FOCUS ON POPULATION HEALTH
STARTING FY23

Proposed changes will be made to:

- Structure of the Contract
- Utilization of Funds
- Iowa Administrative Code

Why Change Now?

1. The current spotlight on public health has created the opportunity to do more in communities…leading to initiatives with newfound and existing partners

   (Systems Development)

2. Because of how the LPHS contract is currently designed we are missing how everything ties together to protect and improve the health of all people in all communities

Tying Everything Together
What Iowans Should Expect from Local Public Health

STRUCTURE

Moving away from a fee-for-service model

Funding will be provided to cover the following areas:

- Salary and Fringe
- Subcontract
- Other

Applicants will develop a work plan to indicate what areas of work will be provided as a part of this contract

WORK PLAN - AREAS OF WORK

Required Areas of Work – Areas that LPH MUST work on during the fiscal year as a part of the LPHS contract

Optional Areas of Work – Areas that LPH CAN choose to work on during the fiscal year as a part of the LPHS contract

REQUIRED AREAS OF WORK
Basic Public Health Services

Leadership And Governance

Health Promotion

Strengthen Local Public Health Infrastructure

OPTIONAL AREAS OF WORK

Non-population health activities

Home health and homemaker services

Individual screenings and assessments

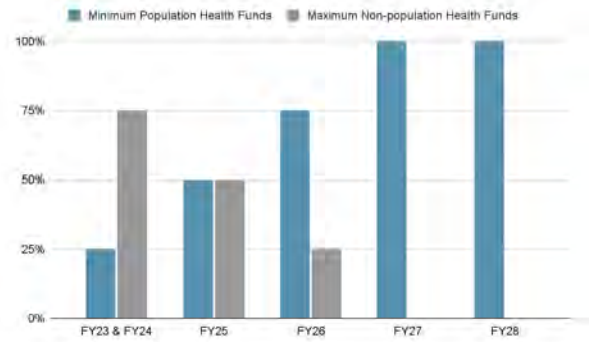
LPHS CONTRACT PROPOSED CHANGES
A TIERED APPROACH

FY23 will allow for time to plan for the provision of basic public health services (a.k.a. required areas of work)

Technical assistance (TA) and education will be provided

IDPH Bureau of Public Health Performance staff and local public health agencies will work together to advance population health at a systems level

Proposed Utilization of LPHS Funds



OPERATIONAL SKILLS

Basic public health services plus:

- Community Health Assessment and Community Health Improvement Planning (CHA CHIP)
- Strategic Planning
- Workforce Development
- Performance Improvement

Designed to build upon previous operational skills while giving agency staff the opportunity to learn new skills during a specific fiscal year and report out the following year.

FY23 FY24 FY25 FY26 FY27

Public Health System Survey

Community Health Assessment & Community Health Improvement Plan

Strategic Planning

Workforce Development

Performance Improvement

Operational Skills

Proposed Changes to Contract Structure = Proposed Changes to Chapter 80

How Would Chapter 80 Change?

- More emphasis on core public health functions and essential services through the implementation of public health interventions
- Revises definitions and removes those that are no longer applicable
- Promotes utilization of local policies rather than prescribing specific rules related to agency operations (Consumer Right to Appeal, documentation, billing)
- Removes job descriptions and staff qualifications (Coordination of Public Health Services, Coordination of Home Care Aide Services, Home Care Aide Services)

How Would Chapter 80 Change?

- Eliminates language related to home care, often misinterpreted and in conflict with other state programs (i.e. Case Management, Direct Care Worker Registry, etc.).
- Removes detailed billing/reimbursement criteria (Funder of Last Resort, Cost Analysis, Fees and Donations).
- Removes references to regulations cited elsewhere (General Conditions, Professional Licensure, Department of Inspections & Appeals (DIA), Department of Human Services (DHS), Federal Codes).

What Would Remain The Same In Chapter 80?

- Promoting healthy people in healthy communities throughout the lifespan
- LBOH still remains the contractor
- Formula for distribution of LPHS funds unchanged
- Planning processes for utilization of LPHS funds still required
- Compliance with local, state, and federal requirements

QUESTIONS?

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 9, "Outpatient Diabetes Education Programs," 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, Iowa Code section 135.11.

Purpose and Summary

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

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 February 15, 2022. Comments should be directed to:

Jill Myers-Geadelmann

Department of Public Health

321 East 12th Street

Des Moines, Iowa 50319

Email: jill.myers-geadelmann@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** definition of "*ADCES*" and "*Certified Diabetes Care and Education Specialist*" in rule **641—9.9(135)**:

"*ADCES*" means the Association of Diabetes Care & 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)**, definition of "*Accredited*," and "*Pharmacist"* as follows:

"Accredited" means that a program is currently accredited by the Association of Diabetes Care & 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~~ for certification aligned with the National Standards for Diabetes Self-Management Education and Support published by the American Diabetes Association and the Association of Diabetes Care and Education Specialists/American Association of Diabetes Educators.

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 Association of Diabetes Care & Education Specialists/American Association of Diabetes Educators-accredited programs. When a program is recognized by the American Diabetes Association or accredited by the Association of Diabetes Care & Education Specialists/American

Association of Diabetes Educators, 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 ADA or the Certificate of Accreditation provided by ~~AADE~~ ADCES/AADE.

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

9.4(3) The name~~s~~ and email address of the program coordinator, and the names of the 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 Association of Diabetes Care & 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 ADA-recognized program or the ADCES/AADE-accredited program shall submit the following to the department:

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

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

9.5(3) The name~~s~~ and email address of the program coordinator, and the names of the 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 Association of Diabetes Care & 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 ADA or accredited by ADCES/AADE shall provide the following information:

a. Name, address and telephone number for the program, program physician and program coordinator. Email address of the program coordinator. 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 ADCES/AADE for accreditation including:

(1) Diabetes overview: includes content about the diabetes disease process, pathophysiology and treatment/management options.

(2) Stress and psychological adjustment: includes developing personal strategies to address psychological issues, healthy coping, and problem solving.

(3) Family involvement and social support: includes strategies for safety and risk reduction and creating healthy environments and social supports.

(4) Nutrition: includes incorporating nutritional management (healthy eating) into lifestyle.

(5) Exercise and activity: includes incorporating physical activity (being active) into lifestyle.

(6) Medications: includes using medications safely and for maximum therapeutic benefit.

(7) Monitoring and use of results: includes monitoring blood glucose and other health indicators or parameters and interpreting and using the results for self-management decision making.

(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; eye; skin and dental care; immunizations,~~;~~ and kidney function testing as indicated.

(9) Behavior change strategies, goal setting, risk-factor reduction, and problem solving: includes personal goals and strategies to address risks and build positive habits.

(10) Preconception care, pregnancy, and gestational diabetes.

(11) Use of health care systems and community resources.

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

9.7(1) Pertinent information related to the recent medical history, physical examination, and test results performed by the participant's health care provider shall be provided when the participant is referred to the program. Program staff shall remain in contact with the participant's health care provider and shall make recommendations relative to the medical care and treatment of the participant's diabetes when appropriate.

9.7(2) When the participant completes the program, arrangements shall be made by program staff for optimal follow-up care.

9.7(3) Program staff members shall take an active role in the care of the participant's diabetes during the course of the program to optimize diabetes control. The program staff shall be prepared to make necessary recommendations to the referring health care provider in the participant's diabetes management which may include the following:

a. Changes in the insulin regimen.

b. Changes in the medications.

c. Changes in the food plan.

d. Changes in exercise.

9.7(4) Written materials supporting the program curriculum are to be made available to the participants. Educational materials from commercial sources shall be carefully evaluated by staff and be consistent with the program curriculum.

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

9.8(1) A program coordinator and a program physician shall be designated.

a. The program coordinator shall provide direction and supervision of the program, including, but not limited to, planning, arranging implementation, and assuring quality. If the program coordinator is an instructor, the program coordinator shall be a health care professional and meet the requirements for primary or supporting instructor.

b. The program physician shall provide medical direction for the program. The program physician shall maintain contact with the participant's attending physician and shall make recommendations relative to the medical care and treatment of the participant's diabetes where appropriate.

9.8(2) The program shall have an advisory committee composed of at least one physician, one registered nurse, one licensed dietitian and one pharmacist to oversee the program. It is recommended the advisory committee include an individual with behavioral science expertise, a consumer, and a community representative. The advisory committee shall participate in the annual planning process, including determination of target audience, program objectives, participant access mechanisms, instructional methods, resource requirements, participant follow-up mechanisms, and program evaluation.

9.8(3) The primary instructors shall be one or more of the following health care professionals: physicians, registered nurses, licensed dietitians, and pharmacists who are knowledgeable about the disease process of diabetes and the treatment of diabetes. If there is only one primary instructor, there shall be at least one supporting instructor. The supporting instructor shall be from one of the four professions listed as possible primary instructors, but a different profession from the single primary instructor.

9.8(4) The program may have additional supporting instructors including, but not limited to, dentist, exercise physiologist, health educator, ophthalmologist, pediatric diabetologist, podiatrist, psychologist, psychiatrist, or social worker.

9.8(5) The names of the program physician, program coordinator, all primary and supporting instructors, and advisory committee members shall be included with the program application, with copies of their current Iowa licenses.

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 Diabetes Care and Education Specialist/Certified 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 Diabetes Care and Education Specialist/Certified Diabetes Educator.

9.8(8) The four professionals required in 9.8(2) to be on the advisory committee shall have completed eight hours of continuing education in diabetes within the past four years.

9.8(9) The program coordinator shall determine that each primary or supporting instructor has current licensure or registration required to practice in Iowa.

9.8(10) The program coordinator shall determine that new primary or supporting instructors, who join the program staff during a certification period, meet the requirements for initial certification in 9.8(6) or 9.8(7) within six months of when they join the program staff.

641—9.9(135) Renewal application procedures for programs not recognized by the American Diabetes Association or accredited by the Association of Diabetes Care & 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, email address of the program coordinator, and ~~with~~ names of instructional staff and advisory committee members and copies of current licenses for all Iowa-licensed professionals.

9.9(2) Identification of the target population, an estimate of program caseload, and the number of participants served in the certification period.

9.9(3) A description of goals and objectives, participant referral mechanism, and means of coordinating between the community, physicians, and program staff.

9.9(4) A description of the program evaluation process.

9.9(5) A description of any changes from the previous application.

9.9(6) A list of new program staff by name, license number or registration number, and position with the program. New staff who will serve as primary instructors shall submit documentation of their training in diabetes as addressed in 9.8(6). New staff serving as supporting instructors shall submit documentation of their training as addressed in 9.8(7).

9.9(7) Documentation of continuing education hours accrued since the previous application for current staff and new staff.

a. All primary instructors shall complete a minimum of 24 hours of continuing education in diabetes, diabetes management, or diabetes education within the past four years.

b. All supporting instructors shall complete a minimum of 12 hours of continuing education in diabetes, diabetes management, or diabetes education within the past four years.

c. The four professionals required in 9.8(2) to be on the advisory committee shall complete a minimum of seven hours of continuing education in diabetes within the past four years.

641—9.10(135) Annual report. Summary data shall be completed annually by each program and sent to the department at a time determined by the department. 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]

Notice of Intended Action

The Public Health Department hereby proposes to adopt 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 proposed under the authority provided in General Assembly 88, House File 766, Section 99.

State or Federal Law Implemented

This rule making implements, in whole or in part, General Assembly 88, House File 766, Section 99.

Purpose and Summary

The purpose of proposed Chapter 178 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, the prohibition specified in this section 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 personal responsibility education program or sexual risk avoidance education grant program services but does not perform abortions or maintain or operate as a facility where abortions are performed.

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 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 February 15, 2022. Comments should be directed to:

Marcus Johnson-Miller

Department of Public Health

321 East 12th Street

Des Moines, Iowa 50319

Marcus.johnson-miller@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** 631—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, ch99) Purpose. PREP is the personal responsibility education program as specified in 42 U.S.C. §713. SRAE is the sexual risk avoidance education grant program authorized pursuant to section 510 of Tit. V of the federal Social Security Act, 42 U.S.C. §710, as amended by section 50502 of the federal Bipartisan Budget Act of 2018, Pub. L. No. 115-123, and as further amended by division S, Title VII, section 701 of the federal Consolidated Appropriations Act of 2018, Pub. L. No. 115-141.

641—78.2(88GA, HF766, ch99) Definitions.

* *Copy or delete the formatting from the generated framework to draft the new rules.*

"*Administer*" means the implementation of the PREP or SRAE programs through contracts entered into by the department and selected private, governmental, and non-profit organizations to provide PREP or SRAE programming directly to youth participants. "Administer" does not mean the evaluation of the PREP or SRAE programs or the management of federal performance measures data collection for the PREP or SRAE programs. "Administer" does not mean the providing of 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.

"*Regularly*" means recurring, routine and conducted in conformity with established or prescribed rules or policy.

641—78.3(88GA, HF766, ch99) 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 county(s) 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 the PREP or SRAE programs 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 personal responsibility education program or sexual risk avoidance education grant program services 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 the PREP or SRAE programs 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 88GA, HF766, ch99.

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to rescind and replace Chapter 80, "Local Public Health Services," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code Chapter 135.11(13).

State or Federal Law Implemented

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

Purpose and Summary

The proposed amendments streamline 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. The proposed amendments to Chapter 80 serve to advance population health at a systems level while providing the opportunity to protect and improve the health of every Iowan.

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 February 15, 2022. Comments should be directed to:

Marisa Roseberry

Department of Public Health

321 East 12th Street

Des Moines, Iowa 50319

Marisa.roseberry@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. Rescind 641—Chapter 8 and adopt the following **new** chapter in lieu thereof:

CHAPTER 80[1*]

LOCAL PUBLIC HEALTH SERVICES

[Prior to 8/3/94, "Homemaker-Home Health Aide Services"]

[Prior to 4/11/07, see also 641—Ch. 79]

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

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, or 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.

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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 Chapter §135.11(13) to determine the amount of available funds to be distributed to each county.

"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) (All Ages in Poverty) 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 Assurance.

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 ensure 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. Workforce is 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 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;

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 LPHS 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) Local Public Health Service funds.

80.5(1) *Allocation for Local Public Health Service funds.* Allocation for Local Public Health Service funds to each contractor is determined by the following formula:

a. Eighteen percent of the total Local Public Health Service 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 Local Public Health Service funds shall be allocated to each county according to the county's population based upon the published data by the U.S. Census Bureau, which is the data available three months prior to the release of the LPHS application.

c. Forty-four percent of the total Local Public Health Service funds shall be allocated according to the proportion of state residents who are elderly persons living in the 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 Local Public Health Service funds shall be allocated according to the proportion of state residents who are low-income persons living in the county based upon the U.S. Census Bureau's small area income and poverty estimates (SAIPE).

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

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

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

Legal Authority for Rule Making

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

State or Federal Law Implemented

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

Purpose and Summary

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

- Provide certifying practitioners the authority to cancel a patient's medical cannabidiol registration card, for reasons including, but not limited to: suspected abuse, violation of health network SOPs, etc;
- Clarifying registration card application language based on program evaluation ;
- Formalizing administrative rule waivers that are currently in effect, including: 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;
- Removal of certain low-value waste tracking requirements, due to unnecessary difficulties with tracking by licensees and enforcement by the Department;

- Allow Veterans to be eligible for the reduced application fee option when enrolling in the program when confirming documentation is provided;

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 February 15, 2022. Comments should be directed to:

Owen Parker

Department of Public Health

321 East 12th Street

Des Moines, Iowa 50319

Email: owen.parker@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. Renumber subrule **154.2(4)** as **154.2(5)**.

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

154.2(4) A healthcare practitioner reserves the right to make a written request to the Department to rescind a written certification they provided to a patient or caregiver, based on reasons deemed appropriate by the healthcare 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. A valid Iowa driver's license,

2. A valid Iowa nonoperator's identification card, or

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. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4."

3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

4. A patient, the patient's legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient's medical cannabidiol registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver's patient has been canceled.

5. A primary caregiver requests in writing that the department cancel the primary caregiver's medical cannabidiol registration card. The department shall notify a patient in writing when the registration card of the patient's primary caregiver has been canceled.

6. The department becomes aware of the death of a patient or primary caregiver.

7. The department receives a written request from a healthcare practitioner to rescind the written certification they provided to a patient or caregiver. Upon receipt, the department will notify the patient or caregiver in writing that their medical cannabidiol registration card will be cancelled in 90 days.

8. A patient requests in writing that the department cancel their primary caregiver's medical cannabidiol registration card. The department shall notify a caregiver in writing that their registration card will be canceled in 90 days.

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. A patient applying for renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

b. A primary caregiver applying for a renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

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, veteran status as defined by Iowa Code section 35.1(2), 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. Transport of plant material, waste material, and laboratory samples;

c. Application and use of crop inputs and other solvents and chemicals;

d. Sales of medical cannabidiol to dispensaries;

e. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

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. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

2. The methods of planting, harvesting, drying, and storing cannabis. A manufacturer may make operating documents for these procedures available on site only;

3. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

~~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 9. 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 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. Dispensaries;

b. A laboratory for testing;

c. A waste facility for disposal;

d. Manufacturers 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. Manufacturers 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. A manufacturer shall use the secure sales and inventory tracking system, if available, or a department-approved manifest system to track shipping of medical cannabidiol. The system shall include a chain of custody that records:

(1) The name and address of the destination;

(2) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;

(3) The date and time the medical cannabidiol shipment is placed into the transport vehicle;

(4) The date and time the shipment is accepted at the delivery destination;

(5) The person's identity, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment; and

(6) Any handling or storage instructions.

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. Each transport shall be approved electronically or in writing by:

(1) An authorized manufacturer employee when the transport vehicle is departing the manufacturing facility; and

(2) An authorized employee of the receiving dispensary, laboratory, or waste facility.

d. An authorized employee at the dispensary, laboratory, or waste facility receiving medical cannabidiol shall:

(1) Verify and document the type and quantity of the transported medical cannabidiol against the information in the secure sales and inventory tracking system or written manifest;

(2) Approve the transport electronically or return a signed copy of the manifest to the manufacturing facility; and

(3) Record the medical cannabidiol that is received as inventory in the secure sales and inventory tracking system, if available. If a manifest system is being used, the dispensary, laboratory, or waste facility shall also maintain a signed copy of manifest, and shall maintain records of the inventory received consistent with these rules.

e. A manufacturer shall maintain all manifests for at least five years and make them available upon request of the department.

ITEM 11. Amend rule 641—154.23(124E) as follows:

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

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. The manufacturer shall dispose of medical cannabidiol waste at a waste facility according to federal and state law and in a manner which renders it unusable.

b. The manufacturer shall dispose of plant material waste at an approved solid waste disposal facility, according to federal and state law.

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) *Liquid and chemical waste disposal.* A manufacturer shall dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabidiol in accordance with all applicable federal, state, and local regulations.

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(4)"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 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. A manufacturer shall enter data within five business days for data related to:

(1) Application and use of crop inputs and other solvents and chemicals; and

(2) Other manufacturing and production records not related to inventory of plant material, medical cannabidiol, and waste material.

ITEM 14. Amend subrule 154.27(3) as follows:

154.27(3) ~~*Real-time*~~ *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.

PUBLIC HEALTH DEPARTMENT [641]

Adopted and Filed

The Public Health Department hereby adopts Chapter 8, "Iowa Care for Yourself (IA CFY) Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 135.11(1) and 135.39.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 135.

Purpose and Summary

The amendments include changes to clarify statements, match medical definitions, and allow for cervical cancer services to be provided by the IA CFY program to an expanded population of persons 21 to 39 years of age who do not have access to other programs providing these services. The IA CFY program will also now be able to provide breast cancer services to asymptomatic persons under 40 years of age who are identified as at high risk for breast cancer.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 17, 2021, as **ARC** 6050C. 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 January 12, 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 March 16, 2022.

The following rule-making action is adopted:

ITEM 1. Amend rule 641—8.1(135) as follows:

641—8.1(135) Definitions. For purposes of this chapter, the following definitions apply:

"Abnormal screen" means a suspicion of breast or cervical cancer or laboratory values of total cholesterol or blood glucose and average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

1. A suspicion of breast cancer includes clinical breast examination findings of: palpable breast mass, breast dimpling, nipple retraction, bloody nipple discharge, palpable lymph nodes

around clavicle or axilla, nipple erythema and scaliness, a mammography result of breast imaging reporting and data systems (BI-RADS) category 4 (suspicious abnormality suggesting need for biopsy) or category 5 (highly suggestive of malignancy) (ICD-10 R92.0, R92.1, R92.2, R92.8), breast biopsy result of ductal cancer in situ (ICD-10 D05.10, D05.11, D05.12), lobular cancer in situ (ICD-10 D05.00, D05.01, D05.02) or breast or lymph node (or other) biopsy result of breast cancer.

2. Suspicion of cervical cancer is a Pap test result of atypical squamous cells cannot exclude high-grade squamous intraepithelial lesions (ASC-H) (ICD-10 R87.611 or ~~R87.622~~ R87.621), atypical glandular cells (AGC) (ICD-10 R87.619 or R87.629), low-grade squamous intraepithelial lesions (LSIL) (ICD-10 R87.612 or R87.622), or high-grade squamous intraepithelial lesions (HSIL) (ICD-10 R87.613 or R87.623), leukoplakia of the cervix (ICD-10 N88.0), or cervical biopsy result of cervical intraepithelial neoplasia II (ICD-10 N.87.1) or III (ICD-10 D06.0, D06.1, D06.7 or D06.9), or cancer in situ (ICD-10 D06.0, D06.1, D06.7 or D06.9).

3. Abnormal value means laboratory values of total cholesterol or blood glucose (HbA1c if diagnosed diabetic) and average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

"ACR" or *"American College of Radiology*" means one of the Food and Drug Administration-recognized accreditation bodies for minimum quality standards for personnel, equipment, and record keeping in facilities that provide breast imaging.

"Advanced registered nurse practitioner" means an individual licensed to practice under 655—Chapter 7.

"Alert value" means laboratory values of total cholesterol, blood glucose or average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood

Institute guidelines.

"BCCPTA" or *"Breast and Cervical Cancer Prevention and Treatment Act of 2000"* means a federal law that provides each state with the option of extending Medicaid eligibility to individuals who were diagnosed with breast or cervical cancer through the National Breast and Cervical Cancer Early Detection Program.

"BCCT option of Medicaid" or *"breast and cervical cancer treatment option of Medicaid"* means the optional program of medical aid designed for individuals who are unable to afford regular medical service and are diagnosed with breast or cervical precancer or cancer through the National Breast and Cervical Cancer Early Detection Program or through funds from family planning centers, community health centers, or nonprofit organizations. The individuals who receive screening or services meet eligibility requirements established by the Iowa care for yourself program. The BCCT option of Medicaid is financed by federal and state payment sources and is authorized by Title XIX of the Social Security Act.

"Benign" means a noncancerous condition that does not spread to other parts of the body.

"Biopsy" means the removal of a sample or an entire abnormality for microscopic examination to diagnose a problem. Examples of a sampling would be a core biopsy or incisional biopsy; an example of entire removal would be an excisional biopsy.

"BI-RADS" or *"breast imaging reporting and data systems"* means a standardized reporting system for mammography, breast ultrasound and breast magnetic resonance imaging (MRI) reports.

"Blood glucose" means a simple sugar found in the blood that is an important energy source in living organisms and is a component of many carbohydrates.

"Blood pressure" means the force of blood against the circulatory system. The systolic blood

pressure is the force caused when the heart contracts and pushes out the blood. The diastolic blood pressure is when the heart relaxes and fills with blood.

"BMI" or *"body-mass index"* means ~~an index for relating weight to height~~ a person's weight in kilograms divided by the square of the person's height in meters. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems.

"Breast ultrasound" means an imaging technique commonly used to screen for tumors and other breast abnormalities. The breast ultrasound uses high-energy sound waves to produce a detailed image of the inside of the breast.

"Cancer" means a group of diseases involving abnormal cell growth with the potential to invade or spread to other parts of the body.

"Carcinoma in situ" means a group of abnormal cells found only in the place where they first formed in the body.

"Cardiologist" means a physician licensed to practice under Iowa Code chapter 148 who specializes in the study or treatment of the heart and its action and diseases.

"Cardiovascular disease" means a broad term used to describe a range of diseases that affect the heart and, in some cases, blood vessels.

"Cardiovascular disease risk factors" means identifiable factors that make some people more susceptible than others to cardiovascular disease. Cardiovascular disease risk factors include:

1. Obesity.
2. Physical inactivity.
3. High blood pressure.
4. High blood cholesterol.

5. Diabetes.

6. Tobacco use.

Risk factors that cannot be changed are age, gender and family history. The more cardiovascular disease risk factors a person has increases the person's chance of developing cardiovascular disease.

"Case management" means the IA CFY program component that involves establishing, brokering, and sustaining a system of available clinical and essential support services for all individuals enrolled in the program.

"CBE" or *"clinical breast examination"* means complete examination of an individual's breast and axilla with palpation by a health care provider trained to recognize many different types of abnormalities and warning signs.

"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services, a federal agency that conducts and supports health promotion, prevention and preparedness activities in the ~~U.S.~~ United States, with the goal of improving overall public health.

"Cholesterol" means a waxy, fat-like substance made in the liver and other cells and found in certain foods, such as foods from animals, for example, dairy products, eggs and meat. Types of cholesterol are as follows:

1. Low density lipoprotein or LDL, also called "bad" cholesterol. LDL can cause buildup ~~of plaque on the walls of arteries. The more LDL there is in the blood, the greater~~, which narrows the arteries and increases the risk of cardiovascular disease.

2. High density lipoprotein or HDL, also called "good" cholesterol. HDL helps the body get rid of bad cholesterol in the blood. If levels of HDL are low, risk of cardiovascular disease

increases.

3. Very low density lipoprotein or VLDL. VLDL is similar to LDL cholesterol in that it contains mostly fat and not much protein. It differs in that VLDL carries triglycerides, whereas LDL carries mainly cholesterol.

4. Total cholesterol means the sum of the very low, low and high density lipoproteins.

"CLIA" or *"Clinical Laboratory Improvement Acts of 1988*" means the federal regulatory standards that apply to all clinical laboratory testing performed on humans in the ~~U.S~~ United States. These standards establish minimum quality standards for personnel and quality assurance methods that monitor patient test management and assess quality control, proficiency testing, and personnel handling of laboratory and pathology specimens.

"CLIA-waived tests" means simple laboratory examinations and procedures that are cleared by the federal government for home use, that employ methodologies that are so simple and accurate that erroneous results would be negligible, or that pose no reasonable risk of harm to the patient if the test is performed incorrectly.

"CMS" or *"Centers for Medicare and Medicaid Services*" is a federal agency within the United States Department of Health and Human Services that administers health care programs, including Medicare, Medicaid, the children's health insurance program (CHIP) and health insurance exchanges, in partnership with state governments.

"Colposcopy" means a medical procedure that allows close examination of the surface of the cervix with a high-powered microscope.

"Community referral" means to direct individuals elsewhere to obtain needed information, mutual support or community resources through help lines or other methods.

"Community resource" means a source of information, service or expertise that is available

within the community, including respite care services, health and mental health services and other social services.

"Cooperative agreement" means a signed contract between the department and another party, for example, a health care facility, which allows the ~~department~~ department's IA CFY program to pay the health care facility for providing services to IA CFY program participants.

"CPT" or *"current procedural terminology*" ~~is~~ means a listing of descriptive terms and identifying codes for uniform language to report medical services and procedures performed by qualified health care professionals and allows clinicians, statisticians, politicians, health insurance programs, health planners and others to speak a common language.

"Creditable coverage" means any insurance that pays for medical bills incurred for the screening, diagnosis, or treatment of breast and cervical cancer. Creditable coverage as described by the Health Insurance Portability and Accountability Act of 1996 includes, but is not limited to, group health plans or health insurance coverage consisting of medical care under any hospital or medical service policy, health maintenance organization, Medicare Part A or B, Medicaid, armed forces insurance, or state health risk pool. An individual who has creditable coverage shall not be eligible for coverage under the breast and cervical cancer treatment option of Medicaid.

"Creditable coverage circumstances" means those instances in which an individual has creditable coverage but is not actually covered for treatment of breast or cervical cancer.

1. When there is a preexisting-condition exclusion or when the annual or lifetime limit on benefits has been exhausted, an individual is not considered to have creditable coverage for this treatment.

2. If an individual has limited coverage, such as a high deductible, limited drug coverage, or a limited number of outpatient visits, the individual is still considered to have creditable coverage

and is not eligible for coverage under the breast and cervical cancer treatment option of Medicaid.

3. If an individual has a policy with a limited scope of coverage, such as only dental, vision, or long-term care, or has a policy that covers only a specific disease or illness, the individual is not considered to have creditable coverage unless the policy provides coverage for breast and cervical cancer treatment.

4. For the purposes of this program, eligibility for Indian Health Services or tribal health care is not considered creditable coverage (according to P.L. 107-121, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001).

"Cytology" means the branch of biology that studies the structure and function of a cell.

"Cytopathology" means the branch of pathology that studies and diagnoses disease on the cellular level.

"Cytotechnologist" means a laboratory professional who studies cells and cellular abnormalities.

"Department" means the Iowa department of public health.

"DHS" or *"department of human services"* means the Iowa department of human services, a state agency that provides a wide range of services, including health care coverage for low-income uninsured individuals diagnosed with breast or cervical cancer or precancer and requiring treatment.

"Diagnostic mammography" means a radiological examination performed for clinical indications, such as breast mass(es), other breast signs or symptoms (spontaneous nipple discharge, skin changes), or special cases, such as a history of breast cancer with breast conservation or augmented breasts.

"Facility" means a place where health care is provided, including hospitals, clinics, outpatient

care centers, laboratories, and specialized care centers that have completed enrollment paperwork with the IA CFY program.

"Family planning clinic" means a Title X family planning program site dedicated to the provision of family planning and related preventive health services to low-income and underserved populations.

"FDA" or *"Food and Drug Administration*" means the federal governmental body which certifies that a breast imaging facility meets minimum quality standards for personnel, equipment, and record keeping.

"Follow-up" means the IA CFY program component that ~~involves a system for seeking information about or reviewing an abnormal condition, rescreening, or recall for annual visits~~ ensures provision of timely and adequate services for participants who have abnormal screening results.

"Gynecologist" means a physician licensed to practice under Iowa Code chapter 148 who specializes in treating diseases of the female reproductive organs ~~in women~~ and providing well-woman health care that focuses primarily on the reproductive organs.

"HbA1c" or *"glycosylated hemoglobin*" means a clinical laboratory test for the purposes of diagnosing diabetes or determining control of diabetes over the past two to three months.

"Health care provider" means any physician, pharmacist, advanced registered nurse practitioner, or physician assistant who is authorized to practice by the state; who is performing within the scope of the practice as defined by state law; and who provides care to IA CFY program-enrolled individuals.

"IA BCCEDP" or *"Iowa breast and cervical cancer early detection program*" means a comprehensive breast and cervical cancer screening program established and funded under Title

XV of the federal Public Health Service Act and administered by the Iowa department of public health, with the delegated responsibility of implementation and evaluation from the CDC, Division of Cancer Prevention and Control.

"IA CFY program" or *"Iowa care for yourself program*" means an integrated comprehensive breast and cervical cancer screening program and cardiovascular risk factor screening and intervention program administered by the Iowa department of public health.

"IA WISEWOMAN" or *"Iowa well-integrated screening and evaluation for women across the nation*" means a cardiovascular-related risk factor screening and intervention program to provide standard preventive screening services, including blood pressure measurements, cholesterol testing, blood glucose testing, and lifestyle interventions that target poor nutrition, physical inactivity, and tobacco use. The program is authorized by the federal government and administered by the CDC to help reduce deaths and disability from cardiovascular disease and stroke.

"ICD-10" or *"International Classification of Disease, 10th edition*" means a standardized classification of diseases, injuries, and reasons of death, by cause and anatomic localization, which is systematically put into a number of up to seven digits and which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both in the United States and internationally.

"Infrastructure" means the basic framework of sufficient staff and adequate support systems to plan, implement, and evaluate the components of the IA CFY program.

"In need of treatment" means that a medical or surgical intervention is required because of an abnormal finding of breast or cervical cancer or precancer that was determined as a result of a screening or diagnostic procedure for breast or cervical cancer/precancer.

"Intervention" means services that promote a cardiovascular-healthy diet and physical activity

~~and~~ that are based on screening results, which include blood pressure, cholesterol, blood glucose, weight, height, personal medical history, family medical history, and health behavior and readiness-to-change assessments.

"MAB" or *"medical advisory board"* means a body that may be utilized by the IA CFY program to offer knowledge and experience as related to the fields of expertise of the members of the board. Duties of the MAB may include, but are not limited to, the following:

1. Reviewing and making recommendations for clinical service expansion.
2. Reviewing program-developed clinical protocols.
3. Providing recommendations related to other clinical and participant-related issues.
4. Providing input related to quality assurance issues.
5. Reviewing program screening and diagnostic data.

"MDEs" or *"minimum data elements"* means a set of standardized data elements used to collect ~~patient-level screening records~~ demographic and clinical information on individuals served ~~through the~~ with NBCCEDP ~~in order~~ funds. The MDEs are reported to the CDC to evaluate whether programs are meeting clinical standards and programmatic priorities.

"Medicaid" means a health care program that assists low-income families or individuals in paying for doctor visits, hospital stays, long-term medical care, custodial care costs and more; the program is financed by federal and state payment sources and authorized by Title XIX of the Social Security Act and administered by the Iowa department of human services.

"Medicare" means the program of federal payment source for health benefits, especially for the aged, which is authorized by Title XVIII of the Social Security Act. Medicare is administered by CMS.

"MRI" or *"magnetic resonance imaging"* means a medical imaging technique used in

radiology to form pictures of the anatomy and the physiological processes of the body. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body.

"NBCCEDP" or *"National Breast and Cervical Cancer Early Detection Program"* means a program established with the passage of the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). The law authorizes the CDC to establish a program of grants to states, tribes, and territories for increasing the early detection of breast and cervical cancer, particularly among low-income, uninsured, and underserved individuals.

"Nonprofit organization" means a group organized for purposes other than generating profit and in which no part of the organization's income is distributed to its members, directors, or officers, except under limited circumstances.

"Oncologist" means a physician licensed to practice under Iowa Code chapter 148 who is a specialist in treating or studying the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment.

"Outreach" means the IA CFY program component that involves recruiting targeted populations or individuals who never or rarely utilize preventive health services.

"Pap test" or *"Papanicolaou screening test"* means ~~the Papanicolaou screening test that collects~~ a procedure to collect cells from the cervix for examination under a microscope. The Pap test can detect abnormal cells or precancerous cells before cancer develops.

"Pathologist" means a physician licensed to practice under Iowa Code chapter 148 who is a specialist ~~in identifying~~ who interprets and diagnoses the changes caused by diseases ~~by studying cells and tissues under a microscope~~ in tissues and body fluids.

"Patient navigation" means an IA CFY program component that assists individuals in

overcoming ~~health care system~~ barriers and facilitates timely access to quality screening and diagnostics as well as initiation of breast or cervical cancer treatment services.

"Pharmacist" means an individual licensed to practice under Iowa Code chapter 155Awho is able to receive or process prescription drug orders in accordance with the pharmacy laws.

"Physician" means an individual licensed to practice medicine and surgery or osteopathic medicine and surgery under Iowa Code chapter 148.

"Physician assistant" means an individual who has successfully completed an approved program and passed an examination approved by the board or is otherwise found by the board to be qualified to perform medical services under the supervision of a physician and is licensed to practice under Iowa Code chapter 148C.

"Precancerous" means a condition or lesion involving abnormal cells that are associated with an increased risk of developing into cancer.

"Program and fiscal management" means the IA CFY program component that includes planning, organizing, directing, coordinating, managing, budgeting for, and evaluating program activities.

"Quitline Iowa" means a toll-free, statewide ~~smoking~~ tobacco cessation telephone counseling hotline through which trained counselors provide assistance in making an individualized tobacco use quit plan and provide ongoing support through optional follow-up calls.

"Radiologist" means a physician licensed to practice under Iowa Code chapter 148 who specializes in the branch of medicine that diagnoses injuries and diseases using medical imaging procedures such as X-rays, sound waves, or other types of energy.

"Rarely or never been screened" means, as defined for the NBCCEDP, that an individual has not had cervical cancer screening within the last ~~five years~~ 3,469 days (9.5 years) or has never

been screened for cervical cancer.

"Recruitment" means the IA CFY program component that involves ~~enrolling targeted populations or individuals~~ finding new individuals to enroll in the IA CFY program for ~~preventive~~ breast and cervical health services.

"Referral" means the IA CFY program component that involves directing individuals with abnormal/alert screening results or barriers to services to appropriate resources for follow-up action.

"Screening mammography" means the use of X-ray of the breasts of asymptomatic individuals in an attempt to detect abnormal lesions of the breast when they are small, nonpalpable, and confined to the breast.

"Service delivery" means providing, either directly or through contractual arrangements, comprehensive breast and cervical cancer screening and cardiovascular disease and stroke risk factor screening, diagnosis, and treatment services through tracking of screening intervals, timeliness of diagnosis, and timeliness of treatment of individuals.

"Surgeon" means a physician licensed to practice under Iowa Code chapter 148 who treats disease, injury, or deformity by physical operation or manipulation.

"Surveillance" means the IA CFY program component that involves the systematic collection, analysis, and interpretation of health data.

"TBS" or *"the Bethesda system"* means a system for reporting cervical or vaginal cytologic diagnoses, used for reporting Pap test results.

"Triglycerides" means a type of fat that is carried in the blood by very low density lipoproteins. Excess calories, alcohol, or sugar in the body are converted into triglycerides and stored in fat cells throughout the body.

ITEM 2. Amend paragraph **8.2(2)"a"** as follows:

a. The IA CFY program shall cover breast and cervical cancer screening and diagnostic services including, but not limited to, the following when those services are provided by a participating health care provider ~~who~~ whose facility has a cooperative agreement with the Iowa department of public ~~health~~ health's IA CFY program. Payment shall be based on Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(1) to (10) No change.

ITEM 3. Amend paragraph **8.2(2)"f"** as follows:

f. A health care provider ~~that~~ whose facility has a cooperative agreement with the IA CFY program shall be subject to the following:

(1) to (7) No change.

ITEM 4. Adopt the following **new** paragraph **8.3(1)"f"**:

f. If the applicant is 21 through 39 years of age and asymptomatic for breast cancer, the applicant may receive an office visit for a cervical cancer screening according to IA CFY protocol. If the applicant is determined to be at high risk for developing breast cancer using a risk assessment model that relies on family history, the applicant may receive breast services, including a mammogram and an MRI, in accordance with IA CFY protocols. EXCEPTION: This categorized group is not eligible for cardiovascular services under this program.

ITEM 5. Amend paragraph **8.3(3)"c"** as follows:

c. Individuals who have creditable coverage, Medicaid, or Medicare Part B are eligible for patient navigation if declaring a barrier to services.

ITEM 6. Amend subrule 8.3(5) as follows:

8.3(5) *Ineligible.* The IA CFY program does not provide coverage for ~~:~~ men.

~~*a.* Men.~~

~~*b.* Individuals 39 years of age and younger unless they have symptoms of breast cancer.~~

ITEM 7. Adopt the following **new** paragraph **8.5(1)"e"**:

e. Fifth priority shall be given to individuals 21 through 39 years of age.

ITEM 8. Amend paragraph **8.7(1)"a"** as follows:

a. The individual was enrolled in the IA CFY program when diagnosed; has had at least one of the screening services (Pap test, screening mammogram, CBE or MRI) or diagnostic procedures paid for by the IA CFY program or with funds from family planning centers, community health centers, or nonprofit organizations; and must be in need of treatment for breast or cervical cancer or precancerous conditions; or

PUBLIC HEALTH DEPARTMENT [641]

Adopted and Filed

The Public Health Department hereby adopts Chapter 38, "General Provisions for Radiation Machines and Radioactive Materials," and Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code chapter 136C.

State or Federal Law Implemented

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

Purpose and Summary

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 of Iowa relinquished the role of AB effective January 1, 2021. 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 manufacturers. Additional amendments will align the Department's rules with the Food and Drug Administration (FDA) on certain requirements outlined in the Mammography Quality Standards Act (MQSA).

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 17, 2021, as **ARC** 6051C. 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 January 12, 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 March 16, 2022.

The following rule-making action is adopted:

ITEM 1. Amend paragraph **38.8(1)"b"** as follows:

b. Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

1. $1,575 for the first unit and, if the facility has additional units at the address of the first unit, a fee of $375 for each additional unit; or

2. $1,575 per portable unit for each site ~~where the unit is off-loaded and used and where the processing and patient films are stored~~; or

3. Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or

4. $675 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; or

5. $1,575 for each stereotactic breast biopsy unit.

~~(2) Mammography interpretation fees of $100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.~~

~~(3)~~ (2) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of $900 for the first unit and $225 for each additional unit.

~~(4)~~ (3) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of $450 for the first unit and $130 for each additional unit.

ITEM 2. Rescind paragraph **38.8(1)"f."**

ITEM 3. Amend subrule 41.6(1) as follows:

41.6(1) *Definitions.* In addition to the definitions provided in 641—38.2(136C), 641—

40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

"Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

"Acquisition workstation" or *"AWS*" means the soft copy display workstation used in conjunction with the mammography unit.

"Action limits" or *"action levels*" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;
2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and
3. Use of personnel who do not meet the applicable requirements of this chapter.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

"Annually" means within 10 to 14 months of previous occurrence.

"Artifact" means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

"Automatic exposure control systems" means automatic exposure control systems, often referred

to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

"Average glandular dose" means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: "Dose."

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

"Category 1" means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

"Certificate" means the certificate described in 41.6(2)*"a"*(2).

"Certification" means the process of approval of a facility by the FDA or this agency to provide mammography services.

"Clinical image" means a mammogram.

"Compression device" means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

"Computed radiography mammography" means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

"Contact hour" means an hour of training received through direct instruction.

"Continuing education unit" or *"continuing education credit*" means one contact hour of training.

"Craniocaudal view" means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Digital breast tomosynthesis" or *"DBT*" means mammography that uses reconstructions to create three-dimensional images of the breasts.

"Direct detector technology" means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

"Direct instruction" means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

"Direct supervision" means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

2. During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

"Dose" means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

"EQUIP" means enhancing quality using the inspection program and uses inspection questions related to the image quality regulations of MQSA to emphasize the significance of continuous clinical image quality.

"Exposure" means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen=2.58 × 10E-4 Coulombs of charge per kilogram of air.

"Facility" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

"FDA" means the Food and Drug Administration.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

"Full field digital mammography" or *"FFDM*" means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Image noise." See "Radiographic noise."

"Image receptor support device" means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

"Inspection" means to assess and determine compliance with regulations.

"Interpreting physician" means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)*"a."*

"Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

"Laterality" means the designation of either the right or left breast.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are

left to the discretion of the facility.

"Mammogram" means a radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography, ~~xeromammography, and~~ full field digital mammography and digital breast tomosynthesis.

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

"Mammography equipment evaluation" means an on-site assessment of the mammography unit or ~~image processor performance~~ review workstation by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

"Mean optical density" means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)*"c."*

"Mediolateral view" means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

"MQSA" means the Mammography Quality Standards Act of 1992.

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Oblique mediolateral view" means one of the standard two views of the breast. The detector system ~~(cassette holder assembly)~~ is angled 30-60 degrees from horizontal so that the ~~cassette assembly~~ detector system is parallel to the pectoral muscle and the corner of the ~~cassette holder~~ detector system fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

"Patient" means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

"Phantom" means an artificial test object used to simulate radiographic characteristics of

compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Phantom image" means a radiographic image of a phantom.

"Physical science" means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

"Provisional certification" means the six-month certification time period in which a facility has to complete the accreditation/certification process.

"Qualified instructor" means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

"Quality control technologist" means an individual meeting the requirements of 41.6(5)*"a"*(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting

physician or to the medical physicist.

"Radiographic equipment" means X-ray equipment used for the production of static X-ray images.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)*"b."*

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Reinstatement" means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

"Review workstation" or *"RWS*" means soft copy display device intended for use in mammography interpretations.

"Screen-film mammography" means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent

glandular and 50 percent adipose tissue.

~~*"Supplier*" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.~~

"Survey" means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

ITEM 4. Amend paragraph **41.6(2)"b,"** introductory paragraph, as follows:

b. Each facility wishing to perform mammography shall apply for ~~agency approval~~ authorization by providing or verifying the following information for each mammography machine:

ITEM 5. Amend paragraphs **41.6(2)"f"** to **"i"** as follows:

f. ~~The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility~~

~~will:~~ An application for authorization shall be submitted to the department and processed for agency approval. A mammography authorization is effective for three years.

~~(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:~~

~~1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,~~

~~2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and~~

~~3. Each mammography examination must have been interpreted as a "negative" or "benign" examination.~~

~~(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)*"f"*(1).~~

~~(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.~~

~~(4) Be billed the fee for the quality review process as set forth in 641 subparagraph 38.8(1)*"b"*(2).~~

~~(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)*"f"*(3).~~

g. ~~Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or~~

~~reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.~~ A phantom image taken with the authorized unit(s) shall be reviewed at the time of annual inspection by the agency.

h. No change.

i. ~~Soft copy review workstation~~ Review workstation (RWS) requirements.

(1) ~~Soft copy review workstations~~ RWS used for final interpretation of mammogram images must ~~be a configuration of two monitors that meet one of~~ meet the following criteria:

1. Have 5 megapixel resolution; or

2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the ~~image receptor~~ mammography unit manufacturer's quality control manual ~~or that outlined by the image receptor~~, that outlined by the RWS monitor manufacturer's ~~designated soft copy review workstation~~ quality control manual or the quality control program outlined by an FDA-approved accrediting body.

ITEM 6. Amend subrule 41.6(3) as follows:

41.6(3) *Mammography personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. Interpreting physicians. All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)"a"(3)"1" applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. and 2. No change.

- Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

- Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)"a"; and

3. and 4. No change.

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have ~~at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality or~~ at least ~~8~~ eight hours of training in the new mammographic modality ~~provided by a vendor manufacturing the new mammographic modality equipment~~. ~~An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.~~

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3) *"a"*(1) were completed, the interpreting physician shall have read or

multi-read at least 960 mammographic examinations during the ~~prior~~ 24 months immediately preceding the date of the facility's annual MQSA inspection, during the 24-month period ending on the last day of the ~~previous~~ calendar quarter preceding the inspection, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3) *"a"*(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the ~~prior~~ 36 months immediately preceding the date of the facility's annual MQSA inspection, during the 36-month period ending on the last day of the ~~previous~~ calendar quarter preceding the inspection, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)*"a"*(2)"2" even if the course is taught multiple times during the previous 36 months.

4. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) and (4) No change.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)*"b"*

before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of ~~at least a two-year~~ a formal radiography training program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)*"b"*; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3) *"b"*(2)"3," the technologist shall have at least ~~8~~ eight hours of continuing education units in the new modality. The ~~8~~ eight hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3) *"b"*(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the ~~prior~~ 36 months immediately preceding the date of the facility's annual MQSA inspection, during the 36-month period ending on the last day of the ~~previous~~ calendar quarter preceding the inspection, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)*"b"*(3)"1" even if the course is taught multiple times during the previous 36

months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)*"b"*(3)"1" shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. ~~Continuing qualifications must be met and an~~ An Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3) *"b"*(1) and (2) were completed, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the ~~prior~~ 24 months immediately preceding the date of the facility's annual inspection, during the 24-month period ending on the last day of the ~~previous~~ calendar quarter preceding the inspection, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

~~3. Continuing qualifications must be met and an Iowa permit to practice radiography must be~~

~~in effect whenever mammogram procedures are performed by the radiologic technologist.~~

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)*"c"*(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and

2. Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics; and

3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have at least eight hours of training in surveying units of a new modality other than the one for which the physicist received training to qualify under 41.6(3)*"c"*(1)"3" before independently performing the new mammographic modality; and

~~4.~~ 5. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a

medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:

- A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics.
- Forty contact hours of documented specialized training in conducting surveys of mammography facilities.
- Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.
- ~~At least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.~~ Have at least eight hours of training in surveying units of a new modality other than the one for which the physicist received training to qualify under 41.6(3)*"c"*(1)"3" before independently performing the new mammographic modality.

(3) and (4) No change.

d. No change.

ITEM 7. Amend paragraph **41.6(4)"f"** as follows:

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) to (5) No change.

~~(6) Cassette/screen identification.~~

~~(7)~~ (6) Mammography unit identification, if there is more than one unit in the facility.

ITEM 8. Amend subrule 41.6(5) as follows:

41.6(5) *Quality assurance program.*

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program, EQUIP included, meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) and (3) No change.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized

for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5)*"e"* through ~~*"k."*~~ *"j."*

b. to *d.* No change.

e. Performance monitoring. The ~~supplier~~ facility shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored ~~for film-screen mammography~~ shall include ~~but not be limited to:~~ all testing as outlined in the manufacturer's mammography unit's quality control manual and the RWS quality control requirements of 41.6(2)*"i"*(2).

~~(1) Processor performance (through daily sensitometric-densitometric means).~~

~~(2) Half-value layer.~~

~~(3) Output reproducibility and linearity.~~

~~(4) Automatic exposure control reproducibility and linearity.~~

~~(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).~~

~~(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.~~

~~(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.~~

~~(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.~~

f. ~~Frequency of monitoring.~~ Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

~~(1) Processor performance shall be accomplished daily before processing patient films.~~

~~(2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.~~

~~(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.~~

g. Evaluation of monitoring results. ~~Full field digital~~ FFDM and DBT mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed ~~100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or~~ 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in ~~41.6(5)*"k."* If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if~~ 41.6(5)*"j."* If any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

~~*h.* Retake analysis program – film-screen and full field digital.~~

~~(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.~~

~~(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.~~

~~(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.~~

~~*i.*~~ *h.* Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) to (3) No change.

~~*j.*~~ *i.* Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance

requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

~~*k.*~~ *j.* Quality assurance—equipment.

(1) Daily , weekly, bi-weekly, monthly, quarterly, semiannual and annual quality control tests. ~~Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.~~ Facilities shall perform quality control tests as required by the manufacturer's mammography unit's quality control manual, the RWS quality control requirements of 41.6(2)*"i"*(2) or the quality control program outlined by an FDA-approved accrediting body.

~~1. The base plus fog density shall be below plus 0.03 of the established operating level.~~

~~2. The mid-density shall be within plus or minus 0.15 of the established operating level.~~

~~3. The density difference shall be within plus or minus 0.15 of the established operating level.~~

~~(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.~~

~~1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.~~

~~2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.~~

~~3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.~~

4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

● Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

● The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range

~~of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.~~

~~● The optical density of the film in the center of the phantom image shall not be less than 1.20.~~

~~2. kVp accuracy and reproducibility.~~

~~● The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.~~

~~● At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.~~

~~3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.~~

~~● Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.~~

~~● The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.~~

~~● When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.~~

~~● When more than one SID is provided, the test shall be performed at the SID most commonly~~

used clinically.

● Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

● Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

● All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

● The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of

homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.

- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;

- A continuous display of the override status; and

- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in

~~41.6(5)*"k"*(5)"6."~~

~~(7) Use of test results.~~

~~1. After completion of the tests specified in 41.6(5)*"k,"* the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.~~

~~2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)*"k."*~~

~~3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer's quality control manual or in accordance with the appropriate FDA-approved alternative requirements.~~

~~(8)~~ (2) Surveys.

1. At least ~~once a year~~ annually, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. ~~At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)*"k"*(5) and (6), the weekly phantom image quality test described in 41.6(5)*"k"*(2) and the quarterly retake analysis results described in 41.6(5)*"h."*~~ The survey shall include testing as required by the manufacturer's mammography unit's quality control manual, the RWS quality control manual or the quality control program outlined by the accrediting body.

2. The ~~results of all tests conducted by the facility in accordance with 41.6(5)*"k"*(1) through~~

~~(7) for film-screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full-field digital mammography units shall be conducted as described in the appropriate manufacturer's quality control manual. The~~ results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

~~(9)~~ (3) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations ~~or film processing~~. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

~~(10) Facility cleanliness.~~

~~1. The facility shall establish and implement adequate protocols for maintaining darkroom,~~

~~screen, and viewbox cleanliness.~~

~~2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.~~

~~(11)~~ (4) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

~~(12)~~ (5) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

~~*l.*~~ *k.* Mammography procedures and techniques for mammography of patients with breast implants.

(1) and (2) No change.

~~*m.*~~ *l.* Consumer complaint mechanism. Each facility shall:

(1) to (4) No change.

~~*n.*~~ *m.* Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

~~*o.*~~ *n.* Additional mammography review and patient notification.

(1) and (2) No change.

ITEM 9. Amend subrule 41.6(6) as follows:

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. and *b.* No change.

c. Image receptor systems:

(1) Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

~~(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.~~

~~(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.~~

~~(3)~~ (2) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. to *f.* No change.

~~*g.* Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.~~

~~*h.*~~ *g.* Focal spot: The focal spot size, magnification factor and source to image receptor

distance (SID) shall be appropriate for mammography. and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. *h.* Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each Each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6)*"i"*(6)

41.6(6)*"h"*(6) and (7).

(4) Except as provided in ~~41.6(6)*"i"*(5),~~ 41.6(6)*"h,"* the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor. Equipment intended by the manufacturer's design not to be straight and parallel to the edge of the image receptor shall meet the manufacturer's design specifications and maintenance requirements.

(7) The chest wall edge of the compression paddle may ~~be bent upward to~~ allow for patient comfort but shall not appear on the image.

~~*j.*~~ *i.* Grids: Shall have the capability for using antiscatter grids.

~~*k.*~~ *j.* AEC: Shall have automatic exposure control such that:

~~(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.~~

~~(2)~~ (1) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
- The selected position of the detector shall be clearly indicated.

~~(3)~~ (2) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

~~*l.*~~ *k.* Control panel: Shall have a control panel that:

(1) to (5) No change.

~~*m.*~~ *l.* mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

~~*n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.~~

~~*o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.~~

~~*p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.~~

~~*q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.~~

~~*r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.~~

~~*s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.~~

~~*t.* Mobile units and vans – film-screen.~~

~~(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.~~

~~(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.~~

~~*u.*~~ *m.* Mobile units and vans~~ – full-field digital~~. Appropriate manufacturer's quality control manual procedures and criteria shall be met.

ITEM 10. Amend paragraph **41.6(7)"e"** as follows:

e. Records of all ~~inspections,~~ inspection reports ~~,~~ and ~~consultations~~ medical physicist surveys shall be maintained for at least seven years.

~~Mo/Mo Target Filter X-Ray Voltage (kVp)~~												~~W/Al Target Filter Combination~~
~~HVL~~	~~23~~	~~24~~	~~25~~	~~26~~	~~27~~	~~28~~	~~29~~	~~30~~	~~31~~	~~32~~	~~33~~	
~~0.23~~	~~109~~											
~~0.24~~	~~113~~	~~116~~										
~~0.25~~	~~117~~	~~120~~	~~122~~									
~~0.26~~	~~121~~	~~124~~	~~126~~	~~128~~								
~~0.27~~	~~126~~	~~128~~	~~130~~	~~132~~	~~134~~							
~~0.28~~	~~130~~	~~132~~	~~134~~	~~136~~	~~138~~	~~139~~						
~~0.29~~	~~135~~	~~137~~	~~139~~	~~141~~	~~142~~	~~143~~	~~144~~					
~~0.30~~	~~139~~	~~141~~	~~143~~	~~145~~	~~146~~	~~147~~	~~148~~	~~149~~				~~170~~

Mo/Mo Target Filter X-Ray Voltage (kVp)												W/Al Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36 mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.

~~*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.~~

ITEM 11. Amend rule 641—41.6(136C), Appendix II, as follows:

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure

~~4.5 cm~~ 4.2 cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

ITEM 12. Adopt the following **new** definitions of "Phantom" and "Stereotactic training phantom" in subrule **41.7(1)**:

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Stereotactic training phantom" means a training or practice tool or medium used for stereotactically guided breast biopsy procedures.

ITEM 13. Amend subrule 41.7(3) as follows:

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. ~~Perform at least 12 stereotactically guided breast biopsies per year.~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast

biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following, and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME or three hours of training approved by the agency in ~~stereotactically guided~~ stereotactic-guided breast biopsy ~~every~~ during the 36 months immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These

CMEs cannot be obtained by the performance of supervised procedures.

3. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. ~~Perform or participate in at least 12 stereotactically guided breast biopsies per year or~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures

under direct supervision of a qualified training physician or an agency–approved manufacturer applications specialist before resuming unsupervised procedures.

2. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME ~~or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. ~~Perform at least 12 stereotactically guided breast biopsies per year or~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or

a written report.

- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME ~~or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)*"c"*) performing stereotactically guided breast biopsy independently are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)*"a."*

2. ~~Perform at least 12 stereotactically guided breast biopsies per year or~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

3. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met,

obtain at least three hours of Category 1 CME ~~or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

4. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

ITEM 14. Amend subrule 41.7(5) as follows:

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"b."*

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641—41.7(136C).

(2) Three contact hours ~~of continuing education~~ in stereotactically guided breast biopsy. ~~The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.~~

c. Maintenance of proficiency and continuing education and experience requirements.

(1) Following the first anniversary in which the requirements of this subrule were met, ~~have performed at least 12 stereotactically guided breast biopsies per year or~~ completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of

the chosen combination needs to be clearly documented:

1. Stereotactic breast biopsy procedures.

2. Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.

3. Stereotactic breast biopsy case review, must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic images, biopsy needle pre-fire and post-fire images, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.

4. Mammographic-guided, stereotactic-guided, or both, wire localization procedures.

5. Ultrasound-guided breast biopsy procedures.

6. MRI-guided breast biopsy procedures.

If experience is not maintained, the radiologic technologist must requalify by performing ~~3~~ three stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5).

(2) Following the third anniversary in which the requirements of this subrule were met, ~~have~~ obtain at least three hours of continuing education in stereotactically guided breast biopsy ~~system physics~~ during the ~~previous~~ 36 months immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection, or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24

months ~~.~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)*"b"*(4)"1."

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

(5) An Iowa permit to practice radiography must be in effect whenever stereotactic procedures are performed by the radiologic technologist.

ITEM 15. Amend subparagraph **41.7(7)"d"(1)** as follows:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

- ~~Digital —~~X-ray field must not extend beyond the image receptor by more than 5 mm on any side.

- ~~Film-screen — On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.~~

- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

- ~~Digital —~~Focal spot must not degrade from initial measurement. If reduction in lp/mm is

found, focal spot must be corrected within 30 days of survey.

~~● Film-screen – Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.~~

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose ~~4.5~~ 4.2 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

● ~~Digital –~~ Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

~~● Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.~~

● Failures must be corrected before further procedures are performed.

9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field

must be corrected within 30 days of the survey.

10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test "lesion" in the sample chamber. Failures must be corrected before further procedures are performed.

ITEM 16. Amend subrule 41.7(9) as follows:

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

~~*b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.*~~

~~*c.*~~ *b.* Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

~~*d.*~~ *c.* Equipment shall be shockproof and grounded to protect against electrical hazards.

~~*e.*~~ *d.* Records of all ~~inspections,~~ inspection reports and ~~consultations~~ medical physicist surveys shall be maintained for at least seven years.

PUBLIC HEALTH DEPARTMENT [641]

Adopted and Filed

The Public Health Department hereby amends Chapter 108, "Medical Residency Training State Matching Grants Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 135.176 and 2021 Iowa Acts, House File 891.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 135.176 and 2021 Iowa Acts, House File 891.

Purpose and Summary

2021 Iowa Acts, House File 891, division XVII, designates an additional activity that can be funded from the Medical Residency Training Matching Grants Program for the time period beginning July 1, 2021, and ending June 30, 2026. Sponsors that are not covered under Iowa Code chapter 669 may apply to the program to fund the payment by the sponsor of medical residency program liability costs subject to provision by the sponsor of dollar-for-dollar matching funds used for the payment of such costs. The amendments to Chapter 108 implement these changes to Iowa Code section 135.176

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on September 22, 2021, as **ARC** 5927C. 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 January 12, 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 March 16, 2022.

The following rule-making action is adopted:

ITEM 1. Amend rule 641—108.1(135) as follows:

641—108.1(135) Scope and purpose. The medical residency training state matching grants

program is established to provide greater access to health care by increasing the number of practicing physicians in Iowa through the expansion of residency positions in Iowa. The department shall provide funding to sponsors of accredited graduate medical education residency programs for the establishment, expansion, or support of medical residency training programs that will increase the number of residents trained. For the period beginning July 1, 2021, and ending June 30, 2026, the department shall provide funding to sponsors of accredited medical education residency programs for the support of medical residency training program liability costs. Funding for the program may be provided through the health care workforce shortage fund, medical residency training account, and is specifically dedicated to the medical residency training state matching grants program as established in Iowa Code section 135.176. These rules shall be implemented only to the extent funding is available.

ITEM 2. Amend rule 641—108.3(135) as follows:

641—108.3(135) Eligibility criteria—establishment or expansion. To be eligible for a matching grant for the establishment or expansion of medical residency training programs, a sponsor shall satisfy the following requirements and qualifications:

108.3(1) to **108.3(5)** No change.

ITEM 3. Renumber rules **641—108.4(135)** and **641—108.5(135)** as **641—108.5(135)** and **641—108.6(135)**.

ITEM 4. Adopt the following **new** rule 641—108.4(135):

641—108.4(135) Eligibility criteria—support. To be eligible for a matching grant for the support of medical residency training program liability costs, a sponsor shall satisfy the following requirements and qualifications:

108.4(1) A sponsor shall be financially and organizationally responsible for a residency training program that is accredited by the ACGME or by the AOA.

108.4(2) A sponsor shall not be subject to Iowa Code chapter 669.

108.4(3) A sponsor shall demonstrate through documented financial information that funds have been budgeted and will be expended by the sponsor in the amount required to provide dollar-for-dollar matching funds for the cost of the medical residency program liability.

108.4(4) A sponsor shall demonstrate that the funding of the medical residency program liability costs falls within the period of July 1, 2021, and June 30, 2026.

ITEM 5. Amend renumbered rules 641—108.5(135) and 641—108.6(135) as follows:

641—108.5(135) Amount of grant.

108.5(1) The department shall award funds based upon the funds budgeted as demonstrated in the request, as identified in subrule 108.3(2)or 108.4(3).

108.5(2) Grant award per activity.

a. The total amount of a grant awarded to a sponsor proposing the establishment of a new or alternative campus accredited medical residency training program shall be limited to no more than 100 percent of the amount of funds the sponsor has budgeted as demonstrated through a line-item budget for each residency sponsored for the purpose of the residency program.

b. The total amount of a grant awarded to a sponsor proposing the provision of a new residency position within an existing accredited medical residency or fellowship training program, or a sponsor funding residency positions which are in excess of the federal residency cap, shall be limited to no more than 25 percent of the amount of funds the sponsor has budgeted as demonstrated through a line-item budget for each residency position sponsored for the purpose of the residency program.

c. The total amount of a grant awarded to a sponsor proposing to fund medical residency program liability costs shall be limited to no more than 50 percent of the total cost the sponsor has budgeted as demonstrated through a line-item budget for the medical residency program liability costs.

108.5(3) A sponsor shall receive funds based on budgeted expenses that include but are not limited to:

a. Stipends and fringe benefits for residents and fellows;

b. The portion of teaching physician salaries and fringe benefits associated with teaching and supervision of residents and fellows;

c. Other direct costs that can be attributed to medical education (e.g., clerical salaries, telephone, office supplies).

108.5(4) An individual sponsor that establishes a new or alternative campus accredited medical residency training program shall not receive more than 50 percent of the state matching funds available each year to support the program. An individual sponsor proposing the provision of a new residency position within an existing accredited medical residency or fellowship training program, ~~or~~ a sponsor funding residency positions which are in excess of the federal residency cap, or the funding of the payment by the sponsor of medical residency program liability costs subject to provision by the sponsor of dollar-for-dollar matching funds used for payment of such costs shall not receive more than 25 percent of the state matching funds available each year to support the program.

641—108.6(135) Application and review process.

108.6(1) and **108.6(2)** No change.

108.6(3) Each request for proposal issued by the department will identify one or more of the

following purposes for use of the funding:

a. The establishment of new or alternative campus accredited medical residency training programs;

b. The provision of new residency positions within existing accredited medical residency or fellowship training programs; ~~or~~

c. The funding of residency positions which are in excess of the federal residency cap~~.~~; or

d. The funding of the payment by the sponsor of medical residency program liability costs subject to provision by the sponsor of dollar-for-dollar matching funds used for the payment of such costs for the period beginning July 1, 2021, and ending June 30, 2026. The funding shall not apply to medical residency programs to which Iowa Code chapter 669 applies.

108.6(4) No change.

PUBLIC HEALTH DEPARTMENT [641]

Adopted and Filed

The Public Health Department hereby adopts Chapter 109, "Prescription Drug Donation Repository Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code chapter 135M.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 135M.

Purpose and Summary

These amendments update outdated citations within Chapter 109 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 amendment to the definition of "centralized repository" in Item 1 is a permanent solution that will remove the need for the waiver. Other amendments remove references to repealed Iowa Code chapters and a rescinded rule and update an Iowa Code citation.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 17, 2021, as **ARC** 6053C.

No public comments were received. There are no changes from the Notice.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on January 12, 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 March 16, 2022.

The following rule-making action is adopted:

ITEM 1. Amend rule **641—109.1(135M)**, definitions of "Centralized repository" and "Physician," as follows:

"Centralized repository" means ~~a distributor~~ an entity approved by the contractor and licensed pursuant to ~~657 IAC Chapter 17~~ applicable regulations of the Iowa board of pharmacy that accepts donated drugs, conducts a safety inspection of the drugs, and ships the donated drugs to a local repository to be dispensed in compliance with this chapter and federal and state laws, rules and regulations.

"Physician" means an individual licensed under Iowa Code chapter 148~~, 150, or 150A~~.

ITEM 2. Amend subrule 109.5(3) as follows:

109.5(3) Repositories shall destroy donated noncontrolled substances that are not suitable for dispensing and make a record of such destruction according to board of pharmacy ~~rule 657—8.8(124,155A)~~ 657—subrule 8.7(5). The destruction record shall be made in the same manner as prescribed for the record of return or destruction of a controlled substance in subrule 109.5(4).

ITEM 3. Amend subrule 109.14(1) as follows:

109.14(1) The department may receive prescription drugs and supplies directly from the prescription drug donation repository contractor and dispense prescription drugs and supplies through licensed personnel during or in preparation for a disaster emergency proclaimed by the governor pursuant to Iowa Code section 29C.6 or during or in preparation for a public health disaster as defined in ~~2009~~ Iowa Code ~~Supplement~~ section ~~135.140, subsection 6~~ 135.140(6).