STATE BOARD OF HEALTH
REGULARLY SCHEDULED MEETING: SEPTEMBER 8, 2021
10:00 am – 12:00 pm
Location: Zoom Virtual Meeting

Meeting Link: https://us02web.zoom.us/j/87495785452?pwd=azVUd09KcUwyTlVOTkZ4UTkwcTJLQT09
Join by Phone: 312 626 6799
Meeting ID: 874 9578 5452 and **Passcode:** 777667

AGENDA

Board Members: Andrew Allen; Lisa Czyzewicz; Leone Junck; George Kovach, M.D.; Donald McFarland; Sandra McGrath; Kierstyn Borg Mickelson; Nick Ryan; Chelcee Schleuger; Fred Schuster; 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.

OPEN SESSION

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

A. Board Minutes for Consideration of Approval
   a. 5/12/21

B. Director's Report

C. Program Reports
   a. Proposal to Add Spinal Muscular Atrophy to Iowa Newborn Screening Panel – Kim Piper, Center for Congenital & Inherited Disorders

D. Administrative Rules – Department of Public Health [641]
   a. Handout – Information on Rulemaking Process
   b. Notice of Intended Action
      i. Chapter 10, "Iowa Get Screened: Colorectal Cancer Program"
      ii. Chapter 95, "Vital Records: General Administration" and Chapter 99, "Vital Records Modifications"

iii. Chapter 108, “Medical Residency Training Matching Grants Program”
iv. Chapter 139, “Emergency Medical Services-Training Programs-Students-Complaints & Investigations”

c. Adopted & Filed
i. Chapter 203, “Standards for Certificate of need Review”

E. Committee Reports
a. Substance Use/Problem Gambling Treatment Program Committee

F. Committee Appointments

G. New Board Member Orientation – Heather Adams
a. Legal Overview for New Board & Commission Members

H. Adjourn

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 2021

- January 13, 2021
- February 24, 2021
- March 10, 2021
- May 12, 2021
- July 14, 2021
- September 8, 2021
- November 10, 2021

IOWA STATE BOARD OF HEALTH
5/12/2021
MEETING MINUTES

Members Present:	Jay Hansen, Chair Chris Atchison Karie Foster George Kovach, M.D. Jay Hansen Jason Harrington, FACHE Leone Junck Vickie Lewis Michael Wolnerman, RPH, CCIM
Members Absent:	Kierstyn Mickelson
Staff Present:	Heather Adams, Assistant Attorney General; Kelly Garcia, Interim Director Julie McCauley, Recording Officer Sarah Reisetter, J.D., Deputy Director Amy Van Maanen
Staff Absent:	None

Call to Order & Roll Call
Jay Hansen called the video meeting to order at 10:02 AM. Roll call was taken to determine if a quorum was present.

Approval of Minutes from 3/10/21
On a motion by George Kovach, seconded by Chris Atchison, all members present voted unanimously to approve the minutes.

Administrative Rules – Iowa Department of Inspections and Appeals
Notice of Intended Action – Iowa Administrative Code 481-Chapter 6
The proposed amendments removes references to the Hospital Licensing Board. The Hospital Licensing Board was eliminated through 2020 Iowa Acts, House File 2627.

No action was required.

Notice of Intended Action – Iowa Administrative Code 481-Chapters 6, 41, 50, 51, 57, 58, 60, 61, 63, 64, 65, 71
The proposed amendments update the rules in accordance with changes included in 2020 Iowa Acts, House File 2389. The legislation called for the removal of the word "variance" when the word is used in relation to "waiver." The proposed amendments also removes a reference to granting a waiver upon the Department's own motion, updates an outdated term for administrative rules, and updates references to the Department's attached units.

No action was required.

Notice of Intended Action – Iowa Administrative Code 481-Chapters 57, 58, 63, 65, 71
The proposed amendments update rules in accordance with changes included in 2020 Iowa Acts, House File 2585. The legislation requires changes to the terminology used in relation to deaf and hard-of hearing persons.

No action was required.

Administrative Rules – Iowa Department of Public Health
Notice of Intended Action – Iowa Administrative Code 641-Chapter 203
The proposed amendments eliminate portions of the rules that are outdated and no longer needed or used, and updates the remaining portions to modern radiation therapy standards.

No action was required.

Adopted and Filed – Iowa Administrative Code 641-Chapter 41
The amendments provide clarity and updates for issues that have evolved over the years and are largely already in practical use in the industry. The department did not receive any comments and no changes were made from the Notice of Intended Action.

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

Adopted and Filed – Iowa Administrative Code 641-Chapter 69
The amendment updates the definition of "Dust-lead hazard". The dust-lead hazard levels changed in 2020 and the amendment is required to reflect the current definition. The department did not receive any comments and no changes were made from the Notice of Intended Action.

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

Adopted and Filed – Iowa Administrative Code 641-Chapter 70
The amendments implement 2020 Iowa Acts, House File 2627; standardize when a certification can be denied due to criminal convictions; and provide an opportunity for an eligibility determination. The department did not receive any comments and no changes were made from the Notice.

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

Adopted and Filed – Iowa Administrative Code 641-Chapter 131
The amendments incorporate language from 2020 Iowa Acts, House File 2627. The proposed amendments reflect the model language for adoption that is being adopted by all boards impacted by 2020, Iowa Acts, House File 2627 where relevant.

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

Substance Use/Problem Gambling Treatment Program Committee Report
Vickie Lewis, chair of the committee, provided a report on the committee's actions for April and May. The committee approved the following:

- Two - 270 day licenses;
- Two - one year licenses;
- Three - two year licenses;
- Four - Deemed status;
- One - completed complaint investigation; and
- One - denial.

Department Reports
Director's Report
Director Kelly Garcia provided an update on the program alignment between IDPH and DHS. PCG has been hired as the consultant to work with both departments on realignment. Work has begun on this process. There will be an external website with updates and a place to provide feedback.

The agency requested money for the State Medical Examiner's Office(SME) from the legislature and it was approved by House and Senate. The SME has also hired a new forensic pathologist. Discussions are being planned with the SME on preparing for other disasters/emergencies.

Work is being done with division directors on how to best leverage the COVID funds that the department has received.

A shift is occurring to look at the whole picture between both departments when reviewing health and well-being of Iowans. Dr. Klein and Dr. Pedati are assisting DHS in their review of child welfare cases. Looking at how the system served or did not serve the family.

The current vaccine message is being geared towards teens and parents. Dr. Pedati went to Woodward Resource Center to answer questions from staff about the vaccine.

Deputy Director Sarah Reisetter informed the board that there will be an appeal hearing at the July board meeting.

Medical Director's Report
Caitlyn Pedati, M.D. provided an update on the status of COVID-19. Dr. Pedati indicated that as individuals begin resuming normal activities, IDPH will begin the Epi Updates to remind Iowans about other issues such as Lyme disease related to tick bites, food borne illness, etc.

COVID-19 Update
Ken Sharp, provided an update on the COVID-19 vaccine in Iowa. Counties are working together to share doses to prevent waste. Guidance to providers initially was not to waste doses and that is shifting in order to recognize waste may need to occur to get individuals vaccinated.

Most counties have stopped mass vaccination clinics. They are shifting to micro clinics by going to where the people are located in an attempt to reach more Iowans. IDPH has been able to push $20 million dollars to local public health agencies to support their vaccination efforts.

The FDA issued an emergency use authorization for 12 to 15 year olds. They are currently waiting for guidance from the Advisory Committee on Immunization Practices on how to proceed.

Legislative Update

Maddie Wilcox provided an update on the legislative session. Both Health and Human Service bills included Funding for the SME. The Block grant bill that includes maternal and child health, substance abuse, and preventive health funds, added in another level for COVID-19 funds.

Adjournment

On a motion by Chris Atchison, seconded by George Kovach, all members present voted to unanimously to adjourn at 11:30 am.

Consideration of Spinal Muscular Atrophy for Iowa's Newborn Screening Panel

Presentation to Iowa State Board of Health

September 8,2021

Kimberly Noble Piper

Center for Congenital and Inherited Disorders

Iowa Department of Public Health

Spinal Muscular Atrophy (SMA)

- SMA is characterized by muscle weakness and wasting, which gets worse with age.
- SMA is a heritable condition caused by a defect in the SMN1 gene, which is the gene responsible for making most of the protein that maintains the function of motor neurons – the brain and spinal cord cells that send signals to the skeletal muscles. The cells die without this protein, and signals are not getting to the muscles to tell them how and when to work.
- The number of copies a person has of the SMN2 gene modifies the severity of the condition, and helps determine which type of SMA the person has.
- Effects 1 in 8,000 to 20,000 people worldwide. In Iowa – we would expect to identify through newborn screening 1-2 babies a year with a type of SMA.

Types of SMA

- Type 0 - evident before birth and is the rarest and most severe form of the condition. Many infants are stillborn or die in infancy due to respiratory failure
- Type I - is the most common form of the condition. It is a severe form of the disorder with muscle weakness evident at birth or within the first few months of life. Most children with spinal muscular atrophy type I do not survive past early childhood due to respiratory failure.
- Type II - is characterized by muscle weakness that develops in children between ages 6 and 12 months. The life span of individuals with spinal muscular atrophy type II varies, but many people with this condition live into their twenties or thirties.
- Type III - typically causes muscle weakness after early childhood. Individuals with this condition can stand and walk unaided, but over time, walking and climbing stairs may become increasingly difficult. Many affected individuals require wheelchair assistance later in life. People with spinal muscular atrophy type III typically have a normal life expectancy.
- Type IV - rare and often begins in early adulthood. Affected individuals usually experience mild to moderate muscle weakness, tremors, and mild breathing problems. People with spinal muscular atrophy type IV have a normal life expectancy.

Treatment of SMA

- Patients with SMA require ongoing care and support for their physical needs such as respiratory care, food and nutrition, orthopedic, and palliative care. This is regardless of other treatments.
- Early treatment offers the best chance for a child to stay as healthy as possible.
- Without any treatment, babies with the most severe cases of SMA lose 90% of their motor neurons by the time they are six months old.
- Once lost, motor neurons cannot be replaced. The body does not generate new motor neurons, and none of the treatments available or being researched will do so either. That means that the best treatment may be before a baby shows signs of being sick. The goal is to save the greatest possible number of motor neurons so a baby's muscles develop and function properly.

Treatment for SMA, continued

- SPINRAZA™ (nusinersin).
  - Intrathecal injection (into the lower back, directly into the spinal canal).
  - Four “loading” doses in the first two months, then a maintenance dose once every four months thereafter.
  - Expected costs - $300,000 for the first year, and $100,000 each year thereafter (drug cost only; does not include costs of administration and monitoring). Insurance has been covering all costs.
- ZOLGENSMA® (onasemnogene abeparvovec-xioi) is given as a one-time infusion into the child’s vein. Gene therapy that is designed to replace the function of the nonworking or missing gene that causes SMA.
  - One-time IV dose
  - Costs - $425,000/year for 5 years (annual installments) ($2.1 Million). Insurance has been covering costs. (Iowa Medicaid receives a “discount” of $1.7 million.)
- Risdiplam (Evrysdi) – daily liquid medication taken by mouth of feeding tube for the duration of life.
  - Cost - At max dose (5mg/day) $27,926.08/month; $335,112.91/year. Insurance has been covering costs.

Aim of newborn screening for SMA

Some tenets of newborn screening:

- Newborn screening determines a newborn's risk for a heritable condition that occurs in the newborn period (not childhood or adult)
- Not diagnostic
- There must be an acceptable testing methodology that can identify newborns at risk (true positives/no false negatives), and not falsely identify those who are not at risk (true negatives/false positives)
- Must be resources for management of the condition and treatment(s) available

Congenital and Inherited Disorders Advisory Committee (CIDAC) Recommendation

- In October 2018, the Congenital and Inherited Disorders Advisory Committee (CIDAC) commissioned a pre-implementation assessment of the Iowa Newborn Screening Program's (INSP) capacity to conduct a pilot screening program and to achieve universal newborn screening for Spinal Muscular Atrophy (SMA).
- The INSP Leadership Team conducted a pre-implementation assessment in accordance with the Center for Congenital and Inherited Disorders Policy #003 – Management of Iowa's Newborn Screening Panel.
- On Friday, April 19, 2019 after review of subcommittee reports and recent evidence; and testimony from parents, experts, and industry; the Congenital and Inherited Disorders Advisory Committee (CIDAC) voted to recommend the addition of SMA to Iowa's newborn screening panel, pending a successful newborn screening pilot.
- The INSP began an implementation pilot for SMA newborn screening on July 1, 2020. Pilot is supported by cooperative agreement grant from the Centers for Disease Control and Prevention (CDC).
- After hearing results of the SMA newborn screening pilot and additional comments from the public at the April 23, 2021 meeting, CIDAC confirmed their recommendation to add SMA to the Iowa newborn screening panel.

Results from SMA Pilot

- Based on metrics developed by INSP leadership and a steering committee, the pilot has been determined to be successful.
- Three newborns were found to have a “presumptive positive” result for SMA. Follow-up testing and referrals to the Neuromuscular Program at The University of Iowa Stead Family Department of Pediatrics allowed these babies to receive testing that confirmed they had SMA. Each baby received treatment (Nusinersin or Zolgensma) within 10 days from birth. The first newborn was discovered during the test validation phase before the “official” start of the pilot, with the newborn screening results confirmed by the Minnesota newborn screening laboratory.

SMA Newborn Screening Pilot Metrics

Metric	Target (working days)	Status Project Yr1*
Birth to SMA NBS results	7 days	**2 days (internal reporting) 3 days official report**
Birth to SMA diagnosis	19 days	**10 days**
Birth to referred to specialist	8 days	**2 days (internal communication) 5 days referral to neuromuscular from attending physician**
Seen by specialist after referral made	5 days	**5 days**
Birth to diagnostic blood collection	14 days	**5 days**
Birth to diagnostic results available	19 days	**10 days**
Birth to therapeutic planning and intervention(s)	**19 days**	**10 days**

*Based on one case identified January 2021

Request of the Iowa State Board of Health

With the success of the pilot, the INSP is now making a request to the Iowa State Board of Health to add SMA to Iowa's newborn screening panel, in accordance with Iowa Administrative Code 641 IAC 4.3(1)*b*.

641 IAC 4.3(1)b states "As new disorders are recognized and new technologies and tests become available, the center shall follow protocols developed by the department in regard to the addition of disorders or the deletion of disorders from the newborn screening panel. The state board of health shall provide final approval for the addition of disorders or the deletion of disorders from the screening panel."

Next

- September 8, 2021 - BOH approval to add SMA to NBS panel
- By September 10, 2021 - Letters and messages of notification of SMA screening sent to all newborn screening providers (primary care providers, community-based birth providers, hospital birthing centers, and hospital-based clinical laboratories) and insurance companies.
- September 13, 2021 – Universal statewide screening for SMA as part of the Iowa newborn screening panel begins.

Understanding Administrative Rules in Iowa State Government

Summary of Iowa's Administrative Rules Process

Provided for your information is a general overview of how administrative rules are adopted in Iowa. The process described concerns the standard procedures and timelines used for filing and adopting administrative rules that are put into place by executive state agencies to implement policies and programs. Administrative rules may also be adopted through an “emergency rulemaking process” which is used on a case by case basis. If you have additional questions about the administrative rules process expert resources are provided at the end of this summary. If you would like to see a flowchart of this information click on Rulemaking Flowchart (/info/rule-flowchart).

Bill Becomes a Law

A bill is a proposal for a law. Ideas for bills may come from many different sources such as a legislative constituent, business, government agency, professional association, or interest group. When a legislator decides to put an idea into policy it is put into the form of a legislative bill. In Iowa, only legislators are able to introduce bills to the Iowa General Assembly.

Bills are sponsored by a Senator or Representative, or by a Senate or House committee. All bills must be approved by both the Senate and the House before being sent to the Governor. The Governor has three options: 1) sign the bill, 2) veto the bill and send it back to the Legislature, or 3) take no action.

In the case of a veto, the Legislature may override the veto with two-thirds of the members of each chamber voting to pass the bill again. If during the legislative session the Governor does not sign or veto a bill, the bill will become law after three days. Bills that are received by the Governor during or after the last three days of the session must either be signed or vetoed within thirty days.

Administrative Rules Implement the Law

After the bill becomes law it becomes part of the Iowa Code. The bill which resulted in the new law may require or authorize a state government agency to adopt administrative rules. Administrative rules are the regulations which the responsible agency puts into action to implement the law. The Administrative rules then become part of the Iowa Administrative Code (IAC). Sometimes the Code of Iowa and the Iowa Administrative Code are both referred to as “the Code.”

Notice of Intent to Adopt Rules (Iowa Code §17A.4)

State agencies often draft administrative rules or propose to modify or change existing administrative rules. Rules may be proposed because of new laws, or because changes are needed to existing programs or simply to keep current with federal regulations. Some programs and responsibilities that are carried out by state agencies require that state laws be at least as strict as federal laws.

Proposed rules must be formatted in a certain way as outlined in Iowa Code, Chapter 17A (Iowa Administrative Procedure Act). The most important thing to know is that old rule language is shown with a strike through and the proposed rule language is shown using underlined text. In the Iowa Administrative Bulletin, new language is indicated by italics, rather than underlining.

Proposed new rules are reviewed and approved by the administrative head of each agency. The rules are then filed in an action which is called the “Notice of Intended Action.” The rules are filed with the Governor’s Administrative Rules Coordinator. The Administrative Rules Coordinator is responsible for coordinating all rules that are proposed by the Governor’s executive branch agencies. This part of the process usually takes about fifty to sixty five days to complete.

Iowa Administrative Bulletin (IAB)

Next the proposed rule is published in the Iowa Administrative Bulletin (IAB) about nineteen days after the Administrative Rules Review Coordinator has received the rules. The IAB publications are available on the Internet (Iowa Administrative Code (IAC) (https://www.legis.iowa.gov/law/administrativeRules/agencies)) and in paper form in most public libraries.

Public Comment Period and Public Hearings

Concurrent with the publication of the “Notice of Intent to Adopt Rules” in the IAB the first twenty days of this period is reserved for the public to comment on any aspect of the proposed rules. The state agency may decide to extend public comment period at their discretion. A public hearing by the state agency to take comments is not required unless at least twenty-five persons demand a hearing. Some state agencies will schedule a public hearing for each of their proposed rule changes regardless of the number of comments received.

At a public hearing people are encouraged to submit their comments in writing for the record, and orally if they chose. The hearing is not intended to be a debate session but rather an opportunity for the public to submit comments. Any individual or organization desiring to comment on the proposed rule may submit comments from the time the Notice of Intent is filed through the public comment period. The state agency may revise a rule in response to comments received but is not required to do so.

Agency Adopts Rules

The administrative head of the state agency may adopt the proposed rules not less than thirty-five days from time that the “Notice of Intended Action” was first published in the IAB.

The rules must be “adopted” by the state agency so it can take the next step and file the “Adopted and Filed” version of the rules with the Governor’s Administrative Rules Review Coordinator for a second time. This part of the process takes about nineteen days. Once this is completed the rules are again published in the IAB and become a part of the IAC. The first possible day that the rules can become effective is thirty five days after they published for the second time.

Legislative Review

At some point during this process, the proposed rule is reviewed by the legislature's Administrative Rules Review Committee (ARRC). Generally, the proposed rule is evaluated by the ARRC after the “Adopted and Filed” version is published in the IAB.
The ARRC does have the discretion to object to a rule. (If objection does occur this effectively eliminates the presumption that the rule was valid in the event the rule is taken up in a subsequent judicial review.) The ARRC may also delay the effective date of a proposed rule pending additional review by the General Assembly. Although it does not occur frequently the Iowa General Assembly has the ability to rescind any administrative rule by joint action of both the Senate and the House chambers. This oversight power is held by only a few state legislatures.

Additional Information

For additional information on the administrative rules process, please contact:
Joe Royce, Senior Legal Council, Iowa General Assembly, Joe.Royce@legis.state.ia.us (mailto:Joe.royce@legis.state.ia.us) or 515-281-3084 (tel:+15152813084)
Kristin Hardt, Governor’s Office, State of Iowa, Kristin.Hardt@iowa.gov (mailto:Kristin.Hardt@iowa.gov) or 515-281-3502 (tel:+15152813502)

Overview of Iowa Administrative Procedures Act (IAPA) 👉 (/info/iapa-overview)

👈 How Do Rules Work? (/info/rules-overview)

About

Welcome to the State of Iowa’s Administrative Rules Website. Public participation in the formulation of administrative rules helps our state to reform burdensome rules and prevent overregulation or red tape, encouraging efficiency, economic growth and job creation.

The purpose of this website is to allow members of the public the opportunity to comment on administrative rules in the Notice process. Members of the public have 20 days to comment on a rule from the date of publication. You may comment on all administrative rules open for comment on this website.

Office of the CIO

200 East Grand Avenue
Des Moines, Iowa 50309
(515) 281-3462 (tel:5152813462)
administrative-rules@iowa.gov (mailto:administrative-rules@iowa.gov?subject=Question From Website)
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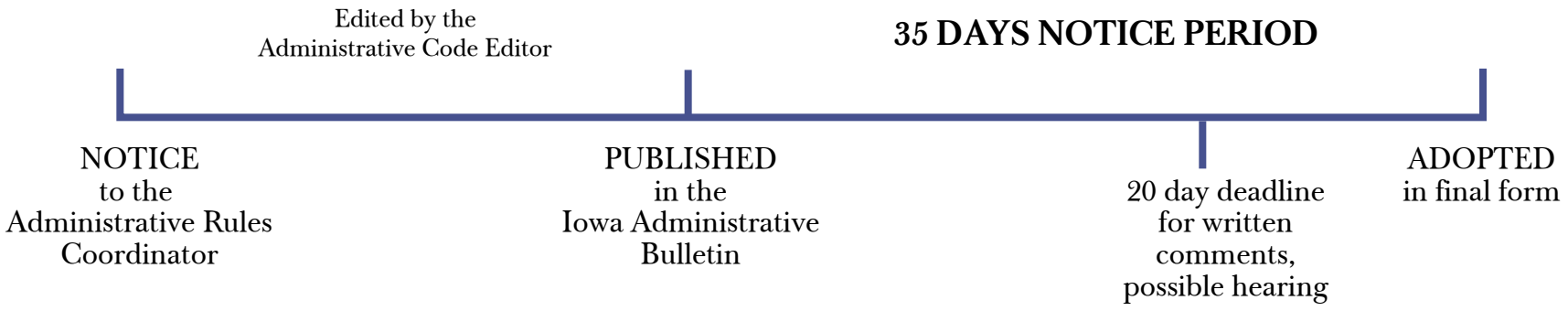
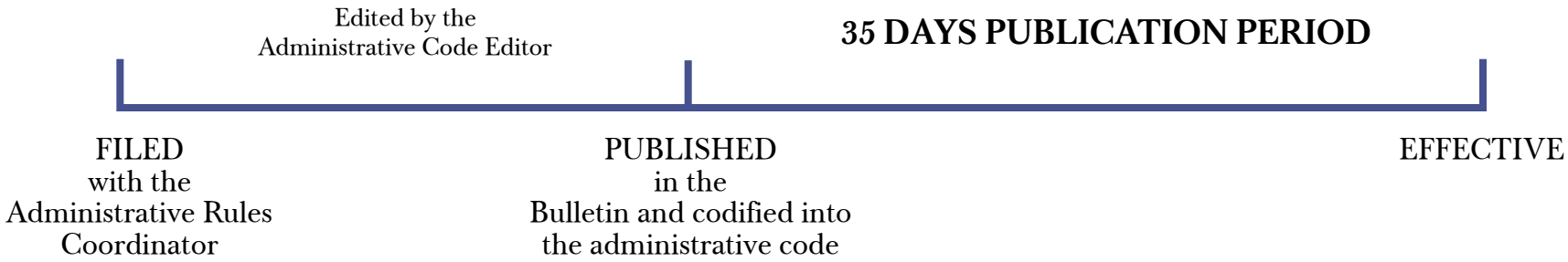
THE IOWA RULEMAKING PROCESS

NOTICE OF INTENDED ACTION



ADOPTION and PUBLICATION



THE RULE-MAKING PROCESS TAKES AT LEAST

108 DAYS

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 10, "Iowa Get Screened: Colorectal Cancer Program," 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 updates screening eligibility requirements for the program to align with federal guidelines (USPSTF). It will encourage access to services and align with a CDC grant that is in year 2 of a 5 year program. Additionally, language is removed in order to allow for diagnostic services for eligible Iowans, who had an initial positive screening test performed outside the program.

Fiscal Impact

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

Jobs Impact

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

Waivers

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

Public Comment

Any interested person may submit comments concerning this proposed rulemaking. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on October 12, 2021. Comments should be directed to:

Victoria Brenton

Department of Public Health

321 East 12th Street

Des Moines, Iowa 50319

Email: Victoria.brenton@idph.iowa.gov

Public Hearing

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

Review by Administrative Rules Review Committee

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

The following rule-making action proposed:

ITEM 1. Amend rule 641—10.1(135) as follows:

641—10.1(135) Purpose. The Iowa get screened (IGS): colorectal cancer program is administered by the department. The goal of the IGS program is to reduce the incidence, mortality and prevalence of colorectal cancer in Iowa by increasing the number of men and women who receive colorectal cancer screenings. Through the program, colorectal cancer screenings, including, but not limited to fecal immunochemical tests (FITs) and colonoscopies are provided to eligible Iowans. Along with providing screenings, the program also facilitates supportive services and referral for diagnosis and treatment to Iowans with abnormal screening results. Iowans who are eligible to enter the program must be ~~50~~ 45 to 75 years of age, be underinsured or uninsured, have incomes of up to 300 percent of the federal poverty level (FPL) and have an average or increased risk for developing colorectal cancer.

ITEM 2. Adopt the following **new** definition of "*Stool DNA test"* or *"sDNA*" in rule **641—10.2(135)**:

"*Stool DNA test"* or *"sDNA"* means using a test that uses stool samples to detect abnormal DNA and small amounts of blood shed into the stool from colon cancer or colon polyps.

ITEM 3. Amend paragraphs **10.3(2)"a"** and **"b"** as follows:

a. The IGS program provides reimbursement for the following screening tests, procedures, preparations and tissue analyses when those services are provided by a participating health care provider who has a provider agreement with the IGS program. Payment is based on Medicare Part B participating provider rates (Title XIX).

(1) Fecal immunochemical tests annually;

(2) Colonoscopy every 10 years from initial screen or as prescribed by a physician in accordance with USPSTF recommendations;

(3) Biopsy/polypectomy during a colonoscopy;

(4) Bowel preparation;

(5) Moderate sedation for colonoscopy;

(6) One office visit related to IGS program-covered colorectal cancer tests;

(7) One office visit related to colorectal cancer follow-up diagnostic test results;

(8) Total colon examination with either colonoscopy (preferred) or double contrast barium enema if medically prescribed by doctor;

(9) Pathology services.;

(10) CT colonography (or virtual colonoscopy) as recommended by provider;

(11) Stool DNA (sDNA) test every three years;

(12) Care or services for complications that result from screening or diagnostic tests provided by the IGS program at the discretion of the Department and based on the availability of funds.

b. The IGS program does not provide reimbursement for the following:

(1) Screening tests requested at intervals sooner than recommended by the USPSTF;

~~(2) CT colonography (or virtual colonoscopy) as a primary screening test;~~

~~(3)~~(2) Computed tomography scans (CT or CAT scans) requested for staging or other purposes;

~~(4)~~(3) Surgery or surgical staging;

~~(5)~~(4) Any treatment related to the diagnosis of colorectal cancer;

~~(6) Any care or services for complications that result from screening or diagnostic tests provided by the IGS program;~~

~~(7)~~(5) Medical evaluation of symptoms that make individuals at high risk for CRC;

~~(8) Diagnostic services for participants who had an initial positive screening test performed outside of the program;~~

~~(9)~~(6) Management and testing (e.g., surveillance colonoscopies and medical therapy) for

medical conditions, including inflammatory bowel disease, ulcerative colitis or Crohn's disease;

~~(10)~~(7) Genetic testing for participants who present with a history suggestive of a hereditary nonpolyposis colorectal cancer (HNPCC) or familial adenomatous polyposis (FAP); and

~~(11) Use of propofol as anesthesia during endoscopy, unless specifically required and approved by the IGS program in cases where the participant cannot be sedated with standard moderate sedation; and~~

~~(12)~~(8) Treatment for colorectal cancer.

ITEM 3. Amend paragraph **10.3(3)"c"** as follows:

c. If the enrolled participant has an abnormal colorectal cancer screening test, the health care provider or local coordinator shall provide to the participant a comprehensive referral directing the participant to appropriate additional diagnostic or treatment services. When the results of a ~~FIT screen~~ screening test are positive, the local coordinator shall work with the participant and enrolled health care provider to schedule a colonoscopy.

ITEM 5. Amend subrule 10.5(1) as follows:

10.5(1) *Age.* Individuals ~~50~~ 45 through 75 years of age shall be the target population to receive colorectal cancer screening.

ITEM 6. Amend subrule 10.5(6) as follows:

10.5(6) *Ineligible.* The IGS program does not provide coverage for:

a. Individuals with Medicare Part B coverage.

b. Individuals ~~49~~ 44 years of age and younger.

c. Individuals 76 years of age and older.

d. Individuals who do not have a primary care provider.

e. Individuals at high risk for developing colorectal cancer. Individuals at high risk include:

(1) A genetic diagnosis of familial adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer (HNPCC),

(2) A clinical diagnosis or suspicion of FAP or HNPCC, or

(3) A history of inflammatory bowel disease (ulcerative colitis or Crohn's disease).

~~*f.* Individuals experiencing the following gastrointestinal symptoms:~~

~~(1) Rectal bleeding, bloody diarrhea, or very dark blood in the stool within the past six months;~~

~~(2) Prolonged change in bowel habits;~~

~~(3) Persistent/ongoing abdominal pain;~~

~~(4) Recurring symptoms of bowel obstruction; or~~

~~(5) Significant unintentional weight loss.~~

ITEM 7. Amend subrule 10.7(2) as follows:

10.7(2) In the event that the financial demand abates, the program director shall withdraw the financial shortfall certification, at which time the individual shall be eligible for program services in accordance with rule ~~641—10.5~~ 641--10.4(135).

ITEM 8. Renumber rules **641—10.5(135)** to **641—10.9(135)** as **641—10.4(135)** to **641—10.8(135)**.

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 95, "Vital Records: General Administration," and Chapter 99, "Vital Records Modifications," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code Section 144.3.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 144 and 2021 Iowa Acts House File 855

Purpose and Summary

2021 Iowa Acts House File 855 adds provisions to Iowa Code section 144 to allow an adult adoptee to obtain a non-certified copy of their original certificate of birth and provides biological parents the ability to complete a contact preference form and medical history form. The proposed amendments implement this change.

Fiscal Impact

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

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a

waiver of the discretionary provisions, if any, pursuant to the Department's waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit comments concerning this proposed rulemaking. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on October 12, 2021. Comments should be directed to:

Melissa Bird

Department of Public Health

Lucas State Office Building

321 East 12th Street

Des Moines, Iowa 50319

Email: Melissa.bird@idph.iowa.gov

Public Hearing

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

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special

meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action proposed:

ITEM 1. Amend subrules 95.6(1) to 95.6(5) as follows:

95.6(1) *Fees for services provided by state registrar or county registrar.* The following fees shall be charged and remitted for the various services provided by the state registrar or the county registrar.

a. The state registrar or county registrar, as applicable, shall charge a fee of ~~$20~~ $15 for a certified copy of a vital record. If, following a search, no record is found and no certified copy is printed, the ~~$20~~ $15 fee may be retained. ~~On and after July 1, 2019, this fee will revert to $15.~~

b. The state registrar shall charge a fee of ~~$20~~ $15 to prepare an adoption certificate, ~~to~~ amend a certificate, ~~to~~ amend a certificate of live birth to reflect a legal change of name, ~~to~~ prepare a delayed certificate, ~~to~~ process other administrative or legal actions, prepare a non-certified copy of an original certificate of birth pursuant to Iowa Code section 144.24A or for preparation of copies of supporting documents on file in the state registrar's office. ~~On and after July 1, 2019, this fee will revert to $15.~~ No fee shall be charged for establishment of paternity.

c. The state registrar shall charge a fee of $25 to file a completed application for the mutual consent voluntary adoption registry.

d. The state registrar shall charge a fee of $5 to update applicant information maintained in the mutual consent voluntary adoption registry and the declaration of paternity registry.

e. The state registrar shall charge a fee of ~~$20~~ $15 to amend an abstract or other legal documentation in support of the preparation of a new certificate. ~~On and after July 1, 2019, this fee will revert to $15.~~

f. The state registrar shall charge a fee of $35 to issue a commemorative copy of a certificate of birth or a certificate of marriage pursuant to Iowa Code section 144.45A. Fees collected shall be deposited in the emergency medical services fund established in Iowa Code section 135.25.

g. The state registrar shall charge a fee of ~~$20~~ $15 for the purpose of issuing an uncertified copy of a certificate of birth resulting in stillbirth pursuant to Iowa Code section 144.31A. ~~On and after July 1, 2019, this fee will revert to $15.~~

95.6(2) *Overpayments.* Any overpayment of $5 or less received by the state registrar for the copying of vital records or for the preparation or amending of a certificate shall not be refunded and shall be retained by the department.

95.6(3) *Certified copy of modified vital record.* When an individual is in possession of a previously issued certified copy of a vital record and the original record is subsequently modified, the individual may request and receive a certified copy of the modified record without charge if the certified copy prior to modification is relinquished to the registrar's office that issued the certified copy, unless otherwise directed by the state registrar.

95.6(4) *Search of county registrar's records—fee for uncertified copy.* A person who is requesting an uncertified copy of a vital record in the custody of the county registrar shall conduct the search of the county files to locate the record. If a copy is requested, the county registrar may charge a fee ~~of no more than $5 for an uncertified copy of the county record~~ pursuant to Iowa Code section 22.3. The fee shall be retained by the county.

95.6(5) *Distribution of fees.*

a. All fees collected by the county registrar and the state registrar shall be distributed as follows:

(1) For fees collected by a county registrar, with the exception of the fee in subrule 95.6(4), the

county registrar shall retain $4 of each ~~$20~~ $15 fee collected by that office. ~~On and after July 1, 2019, this $20 fee will revert to $15.~~ Fees collected shall be divided as follows:

1. For a birth certificate or a marriage certificate, the state registrar shall receive ~~$13~~ $8, and $3 shall be deposited in the general fund of the state, except for the fee collected pursuant to paragraph 95.6(1)*"f."* ~~On and after July 1, 2019, the amount received by the state registrar will revert to $8.~~

2. For a death certificate, the state registrar shall receive ~~$11~~$6, the office of the state medical examiner shall receive $3, and $2 shall be deposited in the general fund of the state. ~~On and after July 1, 2019, the amount received by the state registrar will revert to $6.~~

(2) For fees collected by the state registrar, the state registrar shall retain all fees, with the exception of the fees in paragraph 95.6(1)*"a,"* of which the state registrar shall retain ~~$14~~ $9 of each ~~$20~~ $15 fee collected for the issuance of certified copies. ~~On and after July 1, 2019, the fee collected will revert to $15 and the amount retained by the state registrar will revert to $9.~~ The $6 balance of certified copy fees collected by the state registrar shall be divided as follows:

1. For a birth certificate or a marriage certificate, $6 shall be deposited in the general fund of the state.

2. For a death certificate, the office of the state medical examiner shall receive $3, and $3 shall be deposited in the general fund of the state.

b. All fees retained by the state registrar shall be added to the vital records fund established by the department pursuant to Iowa Code section 144.46A.

c. All fees received by the office of the state medical examiner shall be added to the operating budget established for the operation of that office.

ITEM 2. Renumber rules **641—95.14(144)** to **641—95.16(144)** as **641—95.15(144)** to **641—95.17(144)**.

ITEM 3. Adopt the following **new** rule(s) 641—95.14(144):

641 – 95.14 Access to original certificate of birth prior to adoption

95.14(1) Notwithstanding any provision of law to the contrary, an adopted person who was born in this state and whose original certificate of birth was substituted with a new certificate of birth pursuant to Iowa Code section 144.24 based upon the adoption, or an entitled person, may apply for and obtain a noncertified copy of the original certificate of birth of the adopted person who is the subject of the original certificate of birth in accordance with this section, including with any required redaction of personally identifiable information pursuant to Iowa Code section 144.24A(2).

a. (1) If an adopted person who is the subject of the original certificate of birth is submitting the application, the adopted person shall be at least eighteen years of age at the time the application is filed.

(2) If an entitled person is submitting the application, the adopted person who is the subject of the original certificate of birth shall be deceased at the time the application is filed.

b. The adopted person or the entitled person requesting a noncertified copy of the original certificate of birth shall file a written application with the state registrar on a form and in the manner prescribed by the state registrar.

c. Upon receipt of the written application, proof of identification pursuant to subrule 95.9(3)”a”, and payment of a fee pursuant to subrule 95.6(1)”b”, the state registrar shall issue a noncertified copy of the original certificate of birth to the applicant in accordance with this section, including with any required redaction of personally identifiable information pursuant to

Iowa Code section 144.24A(2). At the time of such issuance, the state registrar shall also provide to the applicant any contact preference form or medical history form completed and submitted to the state registrar including with any required redaction of personally identifiable information pursuant to Iowa Code section 144.24A(2).

(3) A biological parent may file a contact preference form prescribed by the state registrar in accordance with the provisions outlined in Iowa Code section 144.24A(2) and state the biological parent's preference for contact by an adopted person or an entitled person following application for and issuance of the noncertified copy of the original certificate of birth under this section. The contact preference form shall be provided to the biological parent in accordance with Iowa Code section 600A.4. A contact preference form may be completed or updated by the biological parent at any time at the request of the biological parent.

(4) A biological parent may file a medical history form prescribed by the state registrar in accordance with the provisions outlined in Iowa Code section 144.24A(3) and provide medical history of the biological parent and any blood relatives. The medical history form shall be provided to the biological parent in accordance with Iowa Code section 600A.4. A medical history form may be completed or updated by the biological parent at any time at the request of the biological parent.

(5) Upon receipt of a completed contact preference form or medical history form, the state registrar shall attach any such completed form to the original certificate of birth.

(6) For the purposes of this section, *"entitled person"* means the spouse of the adopted person who is deceased or an adult related to the adopted person who is deceased within the second degree of consanguinity.

(7) An application may be submitted under this section by an adopted person or an entitled

person to obtain a noncertified copy of an adopted person's original certificate of birth in accordance with this section, if the adopted person who is the subject of the original certificate of birth was born before January 1, 1971.

(8) Beginning January 1, 2022, an application may be submitted under this section by an adopted person or an entitled person to obtain a noncertified copy of an adopted person's original certificate of birth in accordance with this section, notwithstanding the date of birth of the adopted person who is the subject of the original certificate of birth prescribed under paragraph *"b"*.

This rule is intended to implement 2021 Iowa Acts House File 855.

ITEM 4. Amend rules 641—99.5(144) to 641—99.14(144) as follows:

641—99.13(144) Minimum information required to establish a new certificate of live birth.

99.13(1) A request to establish a new certificate of live birth shall be submitted to the state registrar and include at a minimum the following information:

a. The full name of the child as stated on the original certificate of live birth;

b. The full name of the child to be listed on the new certificate of live birth;

c. The date and place of birth as stated on the original certificate of live birth;

d. The full name of the parent or parents as listed on the original certificate of live birth; and

e. The full name, place of birth, date of birth, and complete residential address of the parent or parents to be listed on the new certificate of live birth.

99.13(2) The new certificate of live birth shall contain the same state file number and registration file date as were assigned to the original certificate of live birth.

99.13(3) The clerk of the court shall, within thirty days of issuance, deliver one certified copy of any adoption decree, and any contact preference form or medical history form associated with

the certified copy of any adoption decree for the purposes of Iowa Code section 144.24A, and fee pursuant to 95.6 to the state registrar of vital statistics to prepare a certificate of birth as prescribed in Iowa Code section 144.19.

641—99.14(144) Establishment of new certificate of live birth following adoption.

99.14(1) Upon receipt of a completed Certificate of Adoption Report form or a certified copy of the decree of adoption from a court of competent jurisdiction and the information required pursuant to rule 641—99.13(144), the state registrar shall establish a new certificate of live birth for a person who was born in Iowa and has been adopted.

99.14(2) The new certificate of live birth shall not be marked "amended."

99.14(3) When a new certificate of live birth is established, the actual date and place of birth shall be shown on the certificate.

99.14(4) The county registrar and state registrar shall seal the original certificate of live birth. The state registrar shall place the original certificate of live birth and all related adoption information in a sealed file, and the file shall not be opened and inspected except by the state registrar for administrative purposes or upon an order from a court of competent jurisdiction pursuant to Iowa Code section 144.24 or as provided in Iowa Code section 144.24A.

99.14(5) The new certificate of live birth after adoption shall not be on file at the county registrar's office.

99.14(6) The state registrar shall reveal the date of the adoption and the name and address of the court that issued the adoption decree upon the receipt of a completed, notarized Revelation of County of Adoption form from an adult adopted person, a biological parent, an adoptive parent, or the legal representative of the adult adopted person, the biological parent, or the adoptive parent

pursuant to Iowa Code section 144.24.

99.14(7) Administrative and certified copy fees shall be charged and remitted pursuant to rule 641—95.6(144).

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 108, "Medical Residency Training Matching Grants Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed 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 HF891 Division XVII added 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 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 proposed amendments to Chapter 108 incorporate these Iowa Code 135.176 changes.

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 October 12, 2021. Comments should be directed to:

Susan Dixon

Department of Public Health

Lucas State Office Building

Des Moines, Iowa 50319

Email: susan.dixon@idph.iowa.gov

Public Hearing

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

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special

meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action proposed:

ITEM 1. Amend **641—Chapter 108** as follows:

CHAPTER 108

MEDICAL RESIDENCY TRAINING STATE MATCHING GRANTS PROGRAM

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.

[**ARC 1480C**, IAB 6/11/14, effective 7/16/14]

641—108.2(135) Definitions. For the purposes of these rules, the following definitions shall apply:

"Accredited medical residency training program" means a graduate medical education program approved by the Accreditation Council for Graduate Medical Education (ACGME) or by

the American Osteopathic Association (AOA).

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Health professional shortage areas" means federal designations that are based on general health professional shortage area (HPSA) designation criteria, plus additional criteria and guidelines specific to each of the three types of designations from the Health Resources and Services Administration Federal Office of Shortage Designations. The three types of designations include primary care, dental and mental health.

"In excess of the federal residency cap" means a residency position for which no federal Medicare funding is available because the residency position is a position beyond the cap for residency positions established by the federal Balanced Budget Act of 1997, Pub. L. No. 105-33.

"New or alternative campus accredited medical residency training program" means a program that is accredited by a recognized entity approved for such purpose by the ACGME or the AOA with the exception that a new medical residency training program that, by reason of an insufficient period of operation is not eligible for accreditation on or before the date of submission of an application for a grant, may be deemed accredited if the ACGME or the AOA finds, after consultation with the appropriate accreditation entity, that there is reasonable assurance that the program will meet the accreditation standards of the entity prior to the date of graduation of the initial class in the program.

"Primary care" means care that shall include psychiatry, obstetrics, gynecology, family medicine, internal medicine, and emergency medicine.

"Sponsor" means a hospital, school, or consortium located in Iowa that sponsors and maintains

primary organizational and financial responsibility for a graduate medical education residency program in Iowa and is accountable to the accrediting body.

[**ARC 1480C**, IAB 6/11/14, effective 7/16/14; **ARC 5334C**, IAB 12/16/20, effective 1/20/21]

641—108.3(135) Eligibility criteria. 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) A sponsor shall be financially and organizationally responsible for a residency training program that is accredited by the ACGME or by the AOA.

108.3(2) 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 matching funds for each residency proposed in the request for state matching funds. A sponsor shall document this requirement by providing with its request a line-item budget showing sponsor funding amounts and state matching funds requested.

108.3(3) A sponsor shall demonstrate a need for such residency program in the state by providing with its request for state matching funds objective evidence of such need including:

a. Workforce data, including state and federal workforce data and data from tracking databases;

b. Population data, including community health needs assessments;

c. Supply and demand data, including health professional shortage area designations; and

d. Other related research including unique community- or state-level factors which establish a need for such residency program.

108.3(4) A sponsor shall submit with its request for state matching funds a recruitment and retention plan to encourage residents to enter practice in Iowa with a preference for health

professional shortage areas and to demonstrate over time the impact on Iowa's workforce.

108.3(5) A sponsor shall offer persons to whom a primary care residency position is awarded the opportunity to participate in a rural rotation to expose the resident to the rural areas of the state.

[**ARC 1480C**, IAB 6/11/14, effective 7/16/14; **ARC 2179C**, IAB 9/30/15, effective 1/13/16; **ARC 4830C**, IAB 12/18/19, effective 1/22/20; **ARC 5334C**, IAB 12/16/20, effective 1/20/21]

641—108.4(135) Eligibility criteria. To be eligible for a matching grant for the support of a 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.

~~641—108.4(135)~~ 641—108.5(135) Amount of grant.

~~108.4(1)~~ 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).

~~108.4(2)~~ 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.

~~108.4(3)~~ 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).

~~108.4(4)~~ 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.

[**ARC 1480C**, IAB 6/11/14, effective 7/16/14; **ARC 2179C**, IAB 9/30/15, effective 1/13/16; **ARC 4830C**, IAB 12/18/19, effective 1/22/20]

~~641—108.5(135)~~ 641—108.6(135) Application and review process.

~~108.5(1)~~ 108.6(1) The department shall follow requirements for competitive selection contained in 641—Chapter 176 in awarding these funds.

~~108.5(2)~~ 108.6(2) The department shall establish a request for proposal process for sponsors eligible to receive funding. The request for proposal and review process and review criteria for preference in awarding the grants shall be described in the request for proposal, including preference in the residency specialty and preference for candidates who are residents of Iowa, attended and earned an undergraduate degree from an Iowa college or university, or attended and earned a medical degree from a medical school in Iowa. The residency specialty preference may be reflective of a subspecialty where particular demands for services have been demonstrated, of geographic areas of preference, or of other particular preferences that advance the objectives of the program.

~~108.5(3)~~ 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.

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.

~~**108.5(4)**~~ **108.6(4)** An applicant may appeal the denial of a properly submitted request for proposal. Appeals shall be governed by rule 641—176.8(135,17A).

[**ARC 1480C**, IAB 6/11/14, effective 7/16/14; **ARC 4830C**, IAB 12/18/19, effective 1/22/20]

These rules are intended to implement Iowa Code section 135.176.

PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

The Public Health Department hereby proposes to amend Chapter 139, "Emergency Medical Services---Training Programs---Students---Complaints and Investigations," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code chapter 147A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 147A sand 2021 Iowa Acts, Senate File 615.

Purpose and Summary

The proposed 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.

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 October 12, 2021. Comments should be directed to:

Rebecca Curtiss

Department of Public Health

Lucas State Office Building

321 East 12th Street

Des Moines, Iowa 50319

Email: rebecca.curtiss@idph.iowa.gov

Public Hearing

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

Review by Administrative Rules Review Committee

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

The following rule-making action proposed:

Item 1. Amend rule **641—139.2(147A)**, definition of "*EMS training program*," or "*training program*" as follows:

"EMS training program" or *"training program*" means an Iowa college approved by the Higher Learning Commission, ~~or~~ an Iowa hospital ~~authorized by the department~~, or a service program that has received authorization from the department to conduct emergency medical care training.

ITEM 2. Amend subrule 139.4(1) as follows:

139.4(1) *Education standards.* A training program shall:

a. Have a sponsoring institution that ~~is accredited by the Higher Learning Commission, or its equivalent, that is recognized by the United States Department of Education as an approved Iowa college, or that is an Iowa licensed hospital that is approved by the department~~ has received authorization from the department to conduct emergency medical care services training.

b. Use the United States Department of Transportation's Instructional Guidelines (January 2009) for any courses leading to Iowa certification.

c. Use the Iowa CCP curriculum (January 2016) for courses leading to the CCP endorsement.

d. Be accredited by, or have submitted a self-study application to, the CAAHEP if graduating students at the paramedic certification level.

e. Document equivalent training and what portions of any course have been waived for equivalency. A training program may waive portions of the required emergency medical care provider training for students currently certified as emergency medical care providers or licensed in other health care professions, including but not limited to nursing, physician assistant, respiratory therapist, dentistry, and military.

PUBLIC HEALTH DEPARTMENT [641]

Adopted and Filed

The Public Health Department hereby amends Chapter 203, "Standards for Certificate of Need Review," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 135.62(2)"e"(5).

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 135.61(18)"m"(4) and 135.61(18)"g" to "j."

Purpose and Summary

Rule 641—203.3(135) sets out radiation therapy standards for the purpose of writing and reviewing Certificate of Need applications for the initiation of external beam radiation therapy services or the purchase of associated equipment (e.g., a linear accelerator). The rules related to radiation therapy were originally promulgated in the late 1970s when the Certificate of Need program was implemented in Iowa. Based on research conducted on the history of rule 641—203.3(135), this rule has not been updated since it was written. The rule is outdated, and parts no longer apply in review of applications. The amendments to the rule eliminate those portions that are completely outdated and are no longer needed or used, and update the remaining portions to modern radiation therapy standards.

After consultation with and approval from the State Health Facilities Council, a stakeholder group of individuals was created representing various health systems—University of Iowa Hospitals and Clinics, MercyOne, UnityPoint Health, Methodist Jennie Edmundson Hospital—

and radiation therapy-related occupations including radiation physicists, health physicists, radiation oncologist (retired), and others involved in radiation oncology services. Additional participants included two attorneys who represent health facilities on Certificate of Need-related issues, a hospital president, the director of operations for the Iowa Cancer Registry, and the Iowa Hospital Association. The stakeholder group had several meetings from February 2020 through October 2020 to review the contents of the rule and propose changes/updates as needed. The State Health Facilities Council, pursuant to Iowa Code section 135.62(2)"e"(5), has the duty to review and approve, prior to promulgation, all rules adopted by the Department under this subchapter and is also fulfilling this role through this rule-making process.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on May 19, 2021, as **ARC** 5633C. One letter of support for the amendments was 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 September 8, 2021.

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 November 10, 2021.

The following rule-making action is adopted:

Amend rule 641—203.3(135) as follows:

641—203.3(135) Radiation therapy ~~or radiotherapy~~ standards.

203.3(1) *Purpose and scope.*

a. These standards ~~are measures of some of those~~ provide guidelines to assist the council in applying those criteria ~~1 (a to q) and 3 found~~ in Iowa Code ~~section 135.64~~ sections 135.64(1)*"a"* to *"r"* and 135.64(3). Criteria which are measured by a standard are cited in parentheses following each standard.

b. Certificate of need applications which are to be evaluated against these radiation therapy standards include:

(1) Proposals to commence or expand the kind or capacity of megavoltage radiation therapy services.

(2) Proposals to replace a megavoltage radiation therapy unit.

(3) Any other applications which relate to megavoltage radiation therapy.

203.3(2) *Definitions.*

~~*a. Radiation modality.* The method of applying ionizing radiation in the treatment of patients with malignant disease. Externally applied modes.~~

~~*Superficial X-ray therapy.* The use of a conventional X-ray machine, which generates X-rays of up to 150 kilovolts (150 kv), to treat superficial lesions, such as skin cancer.~~

~~*Orthovoltage X-ray therapy.* The use of a conventional X-ray machine which generates X-rays between 150 kv up to and including 800 kvs. (These X-rays are of insufficient energy to avoid preferential bone absorption or to be "skin sparing".)~~

~~*Megavoltage therapy.* The use of ionizing radiation in excess of one million electron volts. Energies above one million electron volts cause considerably less skin damage, increase depth dose markedly, and result in much less scatter from the therapeutic beam. Megavoltage machines are classified as follows:~~

~~1. Particle accelerators. These machines use a supply of electrons, which are accelerated into high energy beams. These beams are either caused to strike a target resulting in high energy X-ray production, or are used themselves as the treatment beam. Particle accelerators generate from 4 million up to as many as 45 million electron volts. Most common particle accelerators are the linear accelerator and the betatron.~~

~~2. Isotope sources (gamma ray teletherapy units).~~

~~Cobalt 60 units – emit gamma rays of approximately 1.2 million electron volts.~~

~~Cesium teletherapy units – utilize gamma rays of approximately 650 kv.~~

~~*b. Megavoltage therapy unit.* A piece of megavoltage therapeutic radiologic equipment.~~

~~*c. Radiation therapy facility.* A piece of megavoltage therapeutic radiologic equipment, the accompanying support equipment, and the physical space which houses the equipment.~~

~~*d. Treatment (procedure).* All those radiation fields applied in a single patient visit. Interstitial/intracavitary treatment counts as one visit.~~

~~*e. Dosimetrist.* A technologist who calculates, verifies, and develops maps for the dose distribution of radiation within the patient. The technologist is an essential member of the treatment planning team.~~

~~*f. Radiation therapist (radiation oncologist).* A physician who is board certified or board eligible in therapeutic radiology or in general radiology and who devotes full time to the practice of radiation therapy.~~

~~*g. Radiation therapy technologist.* An individual registered or eligible for registration by the American Board of Radiologic Technologists, or its equivalent, in radiation therapy.~~

~~*h. Transverse tomograms.* A special diagnostic X-ray procedure to determine the depth of the tumors inside the body.~~

~~*i. Conjoint radiation oncology center (cancer center).* A multi-institution, multidisciplinary network to provide radiation therapy for cancer patients. Each institution has an equal voice in decision making and direction of the work of the center. Integration of patient care management, common utilization of personnel and equipment, and a single system of records between center institutions assures optimal care regardless of entry portal. A common cancer registry of all patients treated by center hospitals is maintained.~~

~~*j. Simulator.* Used to reproduce the geometry of the external beam treatment technique, and consists of an isocentrically mounted X-ray source with X-rays passing per a collimation system to reproduce the therapy beam.~~

~~*k. New patient.* A patient receiving treatment for the first time at a given radiation therapy facility.~~

"Conjoint radiation oncology center" or *"cancer center"* means a multi-institution, multidisciplinary network to provide radiation therapy for cancer patients. Integration of patient care management, common utilization of personnel and equipment, and a single system of records between center institutions ensures optimal care regardless of entry portal.

"Dosimetrist" means a staff member who calculates, verifies, and develops treatment plans for the radiation dose distributions that will be delivered to patients. The dosimetrist is an essential member of the treatment planning team and works closely with radiation oncologists and radiation physicists.

"Megavoltage therapy" means the use of ionizing radiation in excess of one million electron volts. Energies above one million electron volts cause considerably less skin damage, increase depth dose markedly, and result in much less scatter from the therapeutic beam. Megavoltage machines are classified as follows:

1. Electron accelerator. A machine such as a linear accelerator that uses a supply of electrons, which are accelerated into high energy beams. These electron beams are either caused to strike a target resulting in high energy X-ray production or are used themselves as the treatment beam. Electron accelerators generate over one million electron volts.

2. Heavy Particle Accelerator. A machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater than that of an electron.

3. Isotope sources (gamma ray teletherapy units).

Cobalt 60 units—emit gamma rays of approximately 1.2 million electron volts.

"Megavoltage therapy unit" means a piece of megavoltage therapeutic radiologic equipment that provides megavoltage therapy.

"New occurrence" means a course of treatment for a new occurrence on a given patient at a given radiation therapy facility. First-time radiation therapy at a new facility is based on each round of treatment.

"Radiation modality" means the method of applying ionizing radiation in the treatment of patients with malignant disease using megavoltage external beam equipment.

"Radiation oncologist" means a physician authorized user trained in accordance with 641—subrule 41.3(5).

"Radiation therapy facility" or *"facility*" means the physical space which houses a megavoltage therapy unit and accompanying support equipment.

"Radiation therapy physicist" means an individual who works closely with radiation oncologists and is responsible for the safe and accurate delivery of radiation to patients. A radiation therapy physicist conducts quality control programs for the equipment and procedures, as well as calibrating the equipment. A radiation therapy physicist shall practice in accordance with 641—subrule 41.3(6).

"Radiation therapy technologist" means an individual who possesses an Iowa permit to practice as a radiation therapist in accordance with rule 641—42.7(136C).

"Service area" means the county in which the facility is located and any other counties from which the applicant expects to draw patients with a cancer diagnosis who are in need of radiation therapy treatment.

"Simulation" means the precise mock-up of a patient treatment with an apparatus that uses planar X-rays, magnetic resonance imaging device, or computed tomography scanner, which is used in reproducing the two-dimensional or three-dimensional internal or external geometry to the patient, for use in treatment planning and delivery.

"Superficial X-ray therapy" means the use of a conventional X-ray machine, which generates X-rays of up to 150 kilovolts (150 kv), to treat superficial lesions, such as skin cancer.

"Treatment" means radiation fields applied in a single patient visit fraction or delivery session.

203.3(3) *Availability.*

a. Minimum utilization. (Sections 135.64(1)*"c," "g," "h"*)

(1) A megavoltage radiation therapy unit ~~which is of relatively low energy, including small linear accelerators (4-10 MEVs),~~ and cobalt units ~~and cesium teletherapy units, should serve a population of at least 200,000 persons, and~~ should treat at least ~~300~~ 250 new ~~patients~~ occurrences annually within three years after initiation of the service.

~~(2) A megavoltage radiation therapy unit which is of medium energy, including linear accelerators of 12-20 MEVs should only be placed in facilities which are currently treating with megavoltage radiation therapy a minimum of 500 new patients annually.~~

~~(3) A megavoltage radiation therapy unit which is of high energy, including those linear accelerators of greater than 20 MEVs, should only be placed in facilities which are currently treating at least 750 new patients annually with megavoltage radiation therapy.~~

~~(4)~~ (2) ~~To determine the~~ The expected number of new ~~patients~~ occurrences needing megavoltage radiation therapy annually in a service area ~~, the following formula shall be applied~~ should be calculated as follows:

1. Multiply the service area population times ~~.00304~~ 0.00582 (~~3.04/1,000~~ 5.82/1,000 population was the mean cancer incidence rate in ~~1976~~ 2017 in Iowa as filed by the Surveillance, Epidemiology, and End Results (SEER) Program~~ SEER~~). ~~A service area population is determined by each facility's catchment area as reported in the most recent patient origin study of the Iowa department of public health.~~

2. Multiply this product times .5 (50 percent of all new ~~cancer patients require~~ occurrences receive radiation therapy).

(3) The expected volume of utilization sufficient to support the need for a new megavoltage therapy unit should be calculated as follows: each unit shall provide a minimum of 5,000 treatments per annum. Megavoltage treatments should be projected by multiplying the number of projected new occurrences needing megavoltage therapy times 20, which will result in no fewer than 5,000 treatments per annum.

(4) Applicants shall account for other providers of radiation therapy in the service area including, but not limited to, factors such as technological capability and quality. Applicants shall address in their application other providers and the impact on those providers in the service area and compare technological capability and quality.

(5) Applicants should provide a map of the expected service area.

~~(5)~~ (6) Institutions which form a conjoint oncology center should have at least 500 new ~~patients~~ occurrences annually ~~who are amenable to megavoltage therapy~~.

~~*b. Expansions.* (Sections 135.64(1)*"c," "d," "e," "g," "h"*)~~

~~(1) There should be no additional megavoltage units of comparable size approved unless each existing megavoltage unit of that size within 90 minutes travel time of the proposed unit is performing at least 6,000 treatments per annum.~~

~~(2) Proposed new small megavoltage units within 90 minutes travel time of other small units must identify an unserved population base of 200,000 apart from that 200,000 currently served by institutions in the service area.~~

~~(3) Megavoltage treatments per annum should be projected by multiplying the number of projected new patients needing megavoltage therapy times 20.~~

~~(4) There should be no additional megavoltage radiation therapy units of comparable size within 90 minutes surface travel time of existing units which would reduce the projected volume of treatments per annum in existing units of comparable size to less than 6,000 treatments per annum and which would result in less than 300 projected new patients per annum for that existing unit. The applicant will attempt and demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur.~~

~~(5) New conjoint centers should be justified if more than 3,000 new patients are currently being treated by radiation therapy in an existing center.~~

~~*c.*~~ *b.* Simulator availability. A simulator ~~which can accurately reproduce the geometry of each external beam technique should be available for every two megavoltage units in~~ should be available within a radiation oncology department.

~~203.3(4)~~ ~~*Costs.*~~

~~*a. Financial feasibility.* (Sections 135.64(1)*"f," "i," "p"*)~~

~~(1) Megavoltage radiation therapy units should be depreciated over a period no shorter than that indicated by "Estimated Useful Lives of Depreciable Hospital Assets" published by the American Hospital Association. Associated remodeling should be depreciated according to generally accepted accounting principles and over a period no shorter than indicated in the above-named publication.~~

~~(2) Recognizing anticipated volume rate structure, and third party reimbursement, the applicant should present a breakeven analysis for the service. If the analysis shows breakeven will fail to occur after three years of the service's initiation, the applicant should demonstrate why operating a service with the revenues below costs appears desirable.~~

~~(3) Charges will be based on actual or projected yearly treatments, but not less than 6,000~~

~~treatments.~~

~~*b. Cost-effectiveness.* (Section 135.64(1)*"e"*) Costs per unit of service should not exceed 10 percent of the state average unit cost for the service. If costs exceed 10 percent of that average the applicant shall demonstrate how the proposal represents the most cost-effective way to deliver the service and explain why the project was chosen instead of alternative ways of meeting the need for the service.~~

~~**203.3(5)**~~ **203.3(4)** *Accessibility.* (~~Sections~~ Iowa Code section 135.64(1)*"c," "d"*)

~~*a. Travel distance shall be within 90 minutes auto travel time for the projected service area population.*~~

~~*b.*~~ Radiation therapy services should be provided regardless of ability to pay, in consideration of those programs available in the state which serve the medically indigent.

~~**203.3(6)**~~ **203.3(5)** *Quality.* (~~Sections~~ Iowa Code section 135.64(1)*"i," "k"*)

a. Minimum staffing requirements for radiation therapy facilities:

(1) Each facility shall have the services of at least one radiation ~~therapists which should be staffed at a level of one therapist per 400 new cancer patients needing treatment~~ oncologist.

(2) Each facility shall have the services of at least one radiation ~~physicists which should be staffed at a level of one physicist per 800 new patients~~ therapy physicist.

(3) Each facility shall have the services of radiation therapy technologists which should be staffed at a level of two technologists per megavoltage unit.

(4) Each facility should have the services of nurses.

(5) Each facility should have the services of ~~dosimetrists which should be staffed at a level of one dosimetrist per 500 new patients~~ at least one dosimetrist.

(6) Each facility should have the services of one radiation therapist or radiation technologist

competent to operate a CT simulator.

~~*b.* Reserved.~~

~~*c.*~~ *b.* Each conjoint center shall have at least two cancer biologists available.

~~*d.*~~ *c.* Each conjoint center shall have one radiation technologist available for each simulator.

~~*e.* Replacement or development of orthovoltage treatment should not occur.~~

~~*f.*~~ *d.* The long-range plans for radiation therapy services shall be submitted to the Iowa department of public health.

~~*g.*~~ *e.* Multidisciplinary tumor boards should be established in all institutions housing megavoltage ~~or orthovoltage~~ machines.

~~*h.*~~ *f.* A source of continuing education should exist within each conjoint center to reach participating community referral hospitals and physicians.

~~*i.*~~ *g.* Each conjoint center should have a unified training program in radiation therapy for radiation ~~therapists~~ oncologists.

~~*j.*~~ *h.* Each radiation therapy facility should offer psychosocial counseling services and nutritional counseling.

~~203.3(7)~~ 203.3(6) *Continuity.* (~~Sections~~ Iowa Code section 135.64(1)*"g," "h," "i," "k"*)

~~*a.*~~ The applicant should demonstrate that an attempt was made to solicit letters and establish referral agreements from area hospitals and physicians to indicate their willingness to participate in a cooperative endeavor to refer to the proposed service.

~~*b.* A minimum of 75 percent of all radiation therapy procedures should be projected to be done on an outpatient basis. If the applicant believes that 75 percent is inappropriate for its facility, then documentation which shows how its facility is different and why it sufficiently justifies not~~

~~meeting this 75 percent outpatient rate, shall be provided.~~

~~**203.3(8)** *Acceptability.* (Section 135.64(1)*"c"*) Facilities with radiation therapy services shall document a willingness to observe and respect the rights of patients as stated in the "Patients Bill of Rights" adopted by the American Hospital Association February 6, 1973, and reprinted in 1975. Provisions for counseling services shall be available.~~

Legal Overview for New State Board of Health Members

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This overview incorporates portions of an outline prepared by Pamela Griebel and Emily Willits, Directors of the Licensing and Administrative Law Division. This outline provides a general overview of laws related to the State Board of Health and is not intended to cover all applicable laws or the nuances of applicable laws.

Last Updated November 2019

Mission and Authority

1. The State Board of Health (SBOH) is created by a statute enacted by the Iowa General Assembly – Iowa Code chapter 136 – to act as the policy and rulemaking body for the Department of Public Health (Department).

2. The SBOH possesses only that authority granted by law. The main duties of the SBOH are contained in Iowa Code chapter 136, although several other provisions of law grant the SBOH with additional duties and responsibilities.

a. Iowa Code chapter 136 provides that the SBOH shall provide a forum for the development of public health policy in the state of Iowa and shall have the following powers and duties:

1. Consider and study legislation and administration concerning public health.
2. Advise the department on any issue related to the promotion and protection of the health of Iowans including but not limited to:
a. Prevention of epidemics and the spread of disease, including communicable and infectious diseases such as zoonotic diseases, quarantine and isolation, sexually transmitted diseases, and antitoxins and vaccines.
b. Protection against environmental hazards.
c. Prevention of injuries.
d. Promotion of healthy behaviors.
e. Preparing for, responding to, and recovering from public health emergencies and disasters.
3. Establish policies governing the performance of the department in the discharge of any duties imposed on it by law.
4. Provide guidance to the director in the discharge of the director's duties.
5. Assure that the department complies with Iowa Code and administrative rules. For this purpose the board shall have access at any time to all documents and records of the department.
6. Assure that the department prepares and distributes an annual report.
7. Advise or make recommendations to the director of public health, governor, and general assembly relative to public health and advocate for the importance of public health standards for state and local public health.
8. Offer consultation to the governor in the appointment of the director of the department.

9. Adopt, promulgate, amend, and repeal rules and regulations consistent with law for the protection of the public health and prevention of substance abuse, and for the guidance of the department. All rules adopted by the department are subject to approval by the board.
10. Act by committee, or by a majority of the board.
11. Keep minutes of the transactions of each session, regular or special, which shall be public records and filed with the department.
12. Perform those duties authorized pursuant to chapter 125. The board may appoint a substance abuse and gambling treatment program committee to approve or deny applications for licensure received from substance abuse programs pursuant to chapter 125 and gambling treatment programs pursuant to chapter 135 and to perform any other function authorized by chapter 125 or 135 and delegated to the committee.

b. Other laws establish additional duties of the SBOH, including: (1) approving rules for entities licensed by the Department of Inspections and Appeals such as health care facilities, hospitals, and hospices (135B.7, 135C.14, 135J.7); (2) establishing immunization requirements (139A.8); (3) performing duties related to substance abuse prevention and treatment (125.7), and (4) approving the congenital and inherited disorders screening panel (136A.5).

3. All state boards and commission, including the SBOH, may not expand their authority beyond that granted by law.

4. New members should read - and reread - the laws governing the board.

a. Staff, other board members, prior minutes of meetings, and websites are good sources of information, but board terms are staggered for a reason: new board members bring a new perspective and vitality.

b. Don't rely exclusively on what others tell you about the mission of the board or its authority.

5. A board's mission is <u>always</u> serving a public purpose. When serving on the SBOH, you are representing the citizens of Iowa; always make decisions with the board's public purpose in mind.

Rulemaking

1. The SBOH has rulemaking authority.

2. Rules are in a very real way the department and the board's laws – administrative rules have the force and effect of law.

3. Rules must be authorized by and consistent with statutes.

4. Rulemaking is a powerful authority. Rules:

    a. Describe the organization and procedures of the department.

    b. State how the department will implement laws.

    c. Inform people about guidelines and policy choices that impact their legal rights and duties.

5. The Governor, Legislature, Attorney General, and the public all have a role to play when boards adopt rules -- there are many checks and balances. All boards and other agencies are required to review rules on a five-year rolling cycle.

6. In addition to consistency with statutes, rules should be:

    a. Easy to read and understand.

    b. Tied to specific needs and objectives.

    c. Sensitive to costs - benefits should outweigh costs.

    d. Effective.

    e. Developed with input by those affected.

    f. Fair - use rulemaking power wisely.

Decision making

1. No single board member makes decisions for the SBOH.

2. Boards make decisions by taking votes at board meetings.

3. A "quorum" of the board is needed to take a vote. A majority of the board members (6 of 11) constitutes a quorum for the SBOH.

4. Once a quorum is attained, most board action is taken upon a majority vote of those participating – but there are important exceptions.

    a. Boards may only go into closed session upon a public vote by two-thirds of the members or all members present.

    b. Discipline can only be imposed on a licensee by a majority vote of members or a higher percentage if required by law.

    Tip: Before you vote, determine if there is a quorum and how many "aye" votes are required to take the particular action.

5. The votes of all members must be public and clear during the meeting and in the minutes. No secret voting allowed!

Board Meetings – Open Meetings Law

1. The SBOH is governed by the Open Meetings Law at Iowa Code chapter 21. The law requires: (1) providing public notice of the SBOH's meetings, (2) posting an agenda of the meeting, (3) the keeping of minutes, and (4) allowing the public to be present.

2. Count Heads! If a majority of the board is present (in person or electronically), do not discuss board business unless you are at a board meeting preceded by proper notice to the public and a posted agenda.

3. Purely social or ministerial gatherings are not meetings as long as no board business is discussed, but be careful to avoid even the appearance of holding an illegal meeting.

4. Agendas are a board's invitation to the public to watch the board in action.

    a. Post agendas at least 24 hours in advance.

    b. Identify all topics on which votes will be taken and matters that will be discussed.

    Tip: Read the agendas posted for your board over the past year. Can you tell what the board planned to vote on or discuss? If not, advocate more detail in your board's agendas.

5. Stick to the posted agenda. If a new idea comes up at a meeting and there is no emergency requiring immediate action, place the topic on the agenda for the next meeting.

6. Lights! Cameras! Action! The public has a right to observe the open sessions of your board meetings and may record them or take photographs.

7. The public does not have the right to participate in your meetings, but boards may provide an opportunity for public comment at meetings.

Board Meetings - Minutes

1. Minutes of board meetings create a permanent record of who met, when they met, what they discussed, what they decided, and by what votes.

2. Accurate minutes are a key tool for conducting the public's business in an open and accountable way.

   a. Minutes are a vital organizational tool for boards.

   b. Minutes are a crucial way for citizens to review public action taken on their behalf.

3. Minutes of open sessions must always include:

   a. The date, time, and place of a meeting.

   b. Which members were present.

   c. Actions taken, with sufficient information to reflect members' votes.

   Tip: Read your board's minutes for the past year. Can you tell what the board voted on or discussed? If not, advocate more detail in your board's minutes.

4. If a closed session is held, the minutes of the open session must include the legal grounds for a closed session, the vote of each member on whether to go into closed session, and any final action taken – no final votes may be taken in closed session.

5. When applicable, minutes must also explain the legal basis for holding a telephonic meeting, an emergency meeting (less than 24 hours notice), or a meeting at a time or place not reasonably accessible to the public.

Board Meetings - Closed Sessions

1. Closed sessions are serious business! Never ask the public to leave the meeting so the board can talk in private – unless the board has a legal basis to hold a closed session.

2. In order to go into closed session, a board must first meet in open session with proper advance notice and posted agenda.

3. A board can only close an open session if expressly authorized by statute. For example, a board is authorized to go into closed session to discuss confidential records, pending litigation with counsel, certain personnel matters, or the decision to be issued in a contested case.

   Tip: You should always ask your board's assigned AAG for legal advice if you are not confident you have grounds to vote to go into closed session. Get the advice in writing or make sure the advice is reported in the minutes of the meeting.

4. After announcing the legal basis for a closed session, take a roll call vote. Remember, a board can only close a session upon an affirmative vote of two-thirds of the members or all members present.

5. While in closed session, boards must:

   a. Record the session (and keep the recording at least a year).

   b. Take detailed minutes.

   c. Limit the discussion to the announced basis for the closed session.

6. Final action must be taken in open session. When the closed session discussion is finished, return to open session and allow those who left the room for the closed session to return. Then make a motion and take a vote on any final action in open session.

Board Records - Public Records Law

1. The SBOH is subject to the Public Records Law at Iowa Code chapter 22. Board records are open to public examination unless specifically made confidential under law.

2. Public records can be in any form, including e-mail. Board members should not commingle official board business emails with personal emails. Your board's staff or AAG can advise on methods of separating emails.

3. Assume any record you create or receive as a board member is a public record that may be open to the public upon request.

   Tip: Practice that old adage – only say what you would be comfortable reading on the front page of your local newspaper!

4. The public records contact for your board is the Department's communications director.

   a. Requests for public records should be referred to your board's public records contact.

   b. The public records contact is familiar with the law and can assure proper response to requests for public records.

5. Be aware of any board records you create or receive which may be confidential – but note it is rare for SBOH members to receive confidential information.

   a. There may be severe penalties for releasing some types of confidential records -- another good reason to refer all requests for records to the board's public records contact!

   b. Examples of records that may be fully or partially confidential include applications containing social security numbers or credit card numbers, mental health or other health records, complaints against licensees, and criminal history background reports.

Sunshine Law Enforcement

1. Actions to enforce Iowa's Open Meetings and Public Records Laws can be brought by a citizen of Iowa, a person who pays taxes of any type to the state of Iowa, a person individually aggrieved by a violation, a county attorney, and the Attorney General. Such actions may be brought in court or before the Iowa Public Information Board.

2. Complaints about alleged violations may be made directly to the board, its staff or counsel, or to the Ombudsman's Office, Attorney General, the Governor's Office, the Iowa Public Information Board or legislators.

3. Take all alleged violations seriously.

4. Remedies include removal from office upon a second violation, damages (up to $2,500 for a knowing violation), expenses and attorney fees, and injunctive relief.

   Tip: Iowa public officials, by and large, will comply with Iowa's Sunshine laws when they know what they are. Educate yourself and ask staff or the AAG assigned to the board if you are unsure.

5. Even an honest mistake can be a violation of Iowa's Sunshine laws, but individual board members can avoid personal liability when they rely upon the advice of counsel, formally given in writing or provided orally and memorialized in the minutes.

6. Attorney General Tom Miller has issued dozens of "Sunshine Advisories" to educate public officials and the public about Iowa's Open Meetings and Public Records Laws. The advisories (with index) are found at: https://www.iowaattorneygeneral.gov/about-us/sunshine-advisories/. You may also wish to consult the web page of the Iowa Public Information Board at: https://www.ipib.iowa.gov.

Board Members as Judges

1. The SBOH operates as the appeal body for substance use disorder and problem gambling program licensure appeals. The board makes a final decision after an administrative law judge (ALJ) conducts a hearing and issues a proposed decision.

2. Board members who conduct hearings or review proposed decisions of an ALJ are governed by the Administrative Procedure Act (APA) and a Code of Administrative Judicial Conduct.

3. The Code of Administrative Judicial Conduct may be found at: https://www.legis.iowa.gov/docs/iac/chapter/01-30-2019.481.15.pdf

4. "A presiding officer shall uphold and promote the independence, integrity, and impartiality of the administrative judiciary." Canon I.

    a. All parties are entitled to unbiased, fair treatment – free from improper influences of family, social, political, or other relationships, or prejudgment of the facts.

    b. All decisions must be made solely on the record in the case. Board members shall not communicate with a party to the case without notice to and an opportunity for all parties to participate.

    c. Board members may not personally investigate facts and then sit in judgment on those facts.

    Tip: Board members acting in the role of judge generally receive specific training on this important role. During hearings, boards are aided by an ALJ and board staff.

Additional Laws Governing Board Members

1. Gift Law. Board members may not accept gifts (i.e., receiving something for free or for less than it is worth) from those they regulate or contract with. Ask your AAG, board staff, or the Ethics and Campaign Disclosure Board http://www.iowa.gov/ethics for guidance on gift law compliance.

2. Sales or leases of goods or services. If you sell or lease goods or services to those regulated by your board, ask the board's AAG, board staff, or the Ethics and Campaign Disclosure Board for guidance on applicable laws.

3. Lobbyist. The Department has a designated, registered lobbyist who represents the board. Individual board members should not lobby legislators on behalf of the board or the Department. The SBOH is authorized as a body to advise and make recommendations to the general assembly relative to public health matters. Seek advice from the board's AAG if you have specific lobbying questions.

4. Conflicts of interest. Conflicts of interest should be avoided, but how and when they arise can be unique to certain boards, especially because the law often requires the appointment of at least some persons who are regulated by the board. Anytime your objectivity may be impaired or there is an appearance of impropriety, seek advice from your board's AAG.

5. Judicial review. All board action (or inaction) is subject to review in court on a variety of grounds including whether the action is:

    a. Compliant with the U.S. or Iowa Constitution, statutes or rules.
    b. Consistent, nonarbitrary, logical, and reasonable.
    c. Supported by the facts and law.

6. Litigation. If the SBOH or its individual members are sued related to board action, board members acting in good faith in their official board capacity are generally defended by the Attorney General and indemnified by the State.