Regulatory Analysis

Notice of Intended Action to be published: 653—Chapter 24
"Complaints and Investigations"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 17A, 147, 148 and 272C

State or federal law(s) implemented by the rulemaking: Iowa Code chapters 17A, 147, 148 and 272C

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 5, 2024 9 a.m.	6200 Park Avenue Des Moines, Iowa Information on virtual participation will be available on the Department of Inspections, Appeals, and Licensing's website prior to the hearing.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis, which must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking is intended to provide guidance on complaint and investigation procedures. The rulemaking ensures that licensees are aware of the investigative process and understand their rights and responsibilities related to the complaint and investigative process. The rulemaking sets forth information such as the process for submitting a complaint, duties of the licensee in reporting the licensee's own malpractice or disciplinary actions, and duties of the licensee in reporting firsthand knowledge of violations from other licensees. The rulemaking also provides the procedure to issue investigatory subpoenas, initiate the peer review process and require Board of Medicine appearances by the licensee.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

There is not a direct cost to the licensee to comply with this rulemaking. However, a licensee does have to pay licensing application and renewal fees, which in turn gives the professional licensing boards the ability to hire staff to investigate the complaints. The licensee could also incur costs if the licensee decides to retain counsel to represent the licensee during the investigative process.

The agency bears the cost of staff to review complaints and investigate complaints. The time needed to manage this rulemaking is generally in the form of written and verbal correspondence,

issuing subpoenas, gathering records, conducting interviews and preparing investigative reports. The Board reviews the investigative information at Board meetings. The Board members are paid a per diem for official board duties ($50 per day) and mileage. Peer reviews require additional costs. An executive officer supports the full scope of work of this Board. Additionally, there are seven full-time medical investigators. Staff salaries to support the work of the Board are covered by the Licensing and Regulation Fund established in 2023 Iowa Acts, Senate File 557. Licensing fees go to the fund to cover operations of the regulated professional licensing boards.

- Classes of persons that will benefit from the proposed rulemaking:

The public and licensees benefit from the proposed rulemaking. The rulemaking ensures that licensees have knowledge of the complaint and investigative processes. This ensures licensees understand their responsibilities and rights surrounding complaints and investigations. The investigative process also benefits the Board because it permits the Board to gather needed information to determine whether a violation of Board rules did occur. In turn, the public benefits because the investigatory process is the primary mechanism the boards have to ensure the public's safety and welfare.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

The Board receives approximately 700 complaints per year for which these processes are used to investigate the complaints. The Board receives a higher number of complaints than many other boards and issues public discipline in approximately 5 percent of its cases. However, the Board also issues letters of warning or education in 10 to 15 percent of its cases. In 2022, the Board received 660 complaints and issued public discipline. Medicine is a very large profession at approximately 17,000 licensed individuals. The number of complaints filed indicate that there is public support for the work the Board conducts in its investigations.

- Qualitative description of impact:

The purpose of complaints and investigations is to address allegations against licensees, enable the Board to make informed decisions, and protect the public from unscrupulous practice. Eliminating complaints and investigations would allow acts detrimental to the public to go unchecked, which would ultimately be harmful to the public's safety and welfare. The process proposed by this rulemaking works to allow staff to obtain necessary information and for the Board to then evaluate the extent to which a complaint does or does not violate Board rules. This process is fairly similar across the country for regulated professions.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

The Department bears costs to enforce this chapter; however, the costs to support Board staff salaries are paid by the fund. The fund is funded through licensing fees. An executive officer supports the full scope of work of this Board. Additionally, there are seven full-time medical investigators.

- Anticipated effect on state revenues:

This rulemaking has no anticipated impact on state revenues. Staff salaries to support the work of the Board are covered by the fund. Licensing fees go to the fund to cover the operations of the regulated professional licensing boards.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The purpose of this rulemaking is to provide a method whereby the public can submit complaints to the Board for violations of Board rules by a licensee. The rulemaking further allows the Board a process to investigate the complaints and determine whether said violation did occur. When there is a violation, licensees are held accountable for the violation to ensure the protection of the public's safety and welfare. Eliminating the Board's ability to receive complaints and conduct investigations would allow acts detrimental to the public to go unchecked and cause harm to the public.

The public and State bear no costs to implement this rulemaking because the Board's costs are funded through the fund. The fund is created through licensing fees paid by the licensees for initial and renewal licenses and is used to cover the operations of the regulated professional licensing boards.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

The Board's investigative process is largely dictated by statute in Iowa Code chapter 272C. This rulemaking sets forth the mechanisms to implement Iowa Code chapter 272C as required. The majority of the time and costs to implement this rulemaking come from the resources to investigate and the Board's time to review and deliberate on the investigative findings. The Board does utilize cost-effective measures to reduce the costs, such as letter correspondence when available instead of conducting personal interviews. After reviewing similar practices in states across the country, it was found that the investigative process in Iowa is fairly similar to the processes used across the country for regulated and licensed professionals.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

Staff held conversations on alternative methods to implement and enforce this rulemaking. After reviewing the processes used in surrounding states, staff found that the complaint and investigative process in Iowa is similar to the processes used across the country to investigate licensed professionals. Due to the state government alignment, this Board is now part of the Department. The Department's Licensing Division continues to assess and implement opportunities to increase efficiencies and standardize board processes across all professional licensing boards. The updates to this chapter support this effort. The Department is actively pursuing a single licensing platform to assist in standardizing licensing.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

The Board's ultimate goal is ensuring the public's safety and welfare. The purpose of this rulemaking is to allow a method for the public to bring complaints against licensed professionals and allow the Board to investigate complaints. The Board needs the ability to investigate complaints, gather information, and make informed decisions on whether a rule has been violated. Without this process, acts detrimental to the public will go unchecked and ultimately harm the public.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

The proposed rulemaking relates to high-stakes public safety concerns that are present whether the business is a small business or a large corporation. The licensees affected by this rulemaking come from a variety of settings. While some licensees could be running a small business, some also work for large hospitals, clinics and retailers. To exempt small businesses from adhering to this rulemaking

would jeopardize any member of the public who sought services from that small business. The risk to the public is greater than the potential harm or cost to the small business to comply with this rulemaking. Additionally, if a licensee subject to this chapter is a small business and has identified a rule that is overly burdensome and the goals of which could be achieved in a manner that would reduce the impact on the small business, the licensee could utilize the Department's established waiver process.

Text of Proposed Rulemaking

ITEM 1. Rescind 653—Chapter 24 and adopt the following **new** chapter in lieu thereof:

CHAPTER 24
COMPLAINTS AND INVESTIGATIONS

653—24.1(17A,147,148,272C) Complaints.

24.1(1) *Form and content of the complaint.* A complaint will be made in the form deemed acceptable by the board. The complaint will contain the following information:

a. The full name, address and telephone number of the complainant, except in instances in which the identity of the complainant is unknown.

b. The full name, address and telephone number, if known, of the licensee.

c. A clear and accurate statement of the facts that apprises the board of the allegations against the licensee.

24.1(2) *Place and time of filing of the complaint.* A written complaint may be delivered in person, by mail or electronically to the board office. The office address is Iowa Board of Medicine, 6200 Park Avenue, Des Moines, Iowa 50321.

24.1(3) *Immunity.* A person is not civilly liable as a result of filing a report or complaint with the board or peer review committee, or for the disclosure to the board or its agents or employees, whether or not pursuant to a subpoena of records, documents, testimony or other forms of information that constitute privileged matter concerning a recipient of health care services or some other person, in connection with proceedings of a peer review committee, or in connection with duties of the board. However, such immunity from civil liability is not applicable if such act is done with malice.

653—24.2(17A,147,148,272C) Processing complaints and investigations.

24.2(1) *Complaint and investigative files.* Board staff shall open a complaint file upon receiving a complaint or other appropriate information or upon a motion of the board. A complaint file becomes an investigative file once an investigation is ordered.

a. If the board does not have legal jurisdiction over a matter, staff may close the complaint file administratively without investigation or review by the board. All other complaints will be sent to the complaint review committee.

b. A complaint file will be labeled as such and is not a public record. A complaint file will become part of the licensee's history with the board.

c. Any time an investigation is ordered, a complaint file will be relabeled as an investigative file. An investigative file is not a public record. The investigative file will become part of the licensee's history with the board and may be shared with another licensing authority upon request.

24.2(2) *Complaint review committee.*

a. The complaint review committee includes the medical advisor, executive director, general counsel for the board, and chief investigator.

b. The complaint review committee reviews each complaint the board has received and takes one of the following four actions:

(1) Close a complaint file administratively for any of these reasons:

1. The board does not have legal jurisdiction over the matter;
2. The case involves a matter that the board is already addressing; or

3. The case is appropriate for referral to the board's Iowa physician health program, and investigation is not warranted.

(2) Recommend to the board's screening committee that the board close the complaint file without investigation.

(3) Request a letter of explanation from the physician, medical records, or both.

(4) Request a full investigation.

c. The complaint review committee uses the following to guide its decision making:

(1) Serious public safety issues include but are not limited to the following:

1. A clear violation of the laws and rules governing the practice of medicine, genetic counseling, or acupuncture, as applicable;

2. Significant investigative history that raises serious concerns about the licensee's ability to practice in a competent and safe manner;

3. Significant investigative history that raises serious concerns that the licensee has engaged in a pattern of unprofessional conduct or disruptive behavior that interferes with, or has the potential to interfere with, patient care or the effective functioning of health care staff;

4. Serious quality of care cases that include severe patient harm, a pattern of inappropriate treatment, or serious medical errors;

5. Serious criminal conduct;

6. Substance abuse or other impairment that significantly impacts the licensee's ability to practice the licensee's respective practice in a competent and safe manner;

7. Sexual misconduct;

8. Severe unprofessional conduct or disruptive behavior;

9. Disciplinary action by another regulatory authority; or

10. Unlicensed practice of medicine, genetic counseling, or acupuncture.

(2) Less serious public safety issues include but are not limited to the following:

1. Less serious quality of care cases that do not involve serious patient harm and are isolated occurrences rather than a part of a pattern of inappropriate treatment or serious medical errors;

2. A single incident involving a billing dispute;

3. A single incident involving rude behavior or personality conflicts;

4. A single incident of communication problems; or

5. Poor recordkeeping practices that are not repeated or ongoing in nature and do not significantly affect patient care.

d. The board may at any time reopen for review and reconsideration any complaint or investigative file that has been closed administratively.

e. The complaint review committee will indicate high-priority cases when they are assigned for investigation. The committee may provide recommendations to investigators regarding the nature of investigation to be completed. The medical advisor will provide medical advice to the investigators as part of the investigative process.

24.2(3) *Screening committee.* The screening committee will review the recommendations of the complaint review committee and take one of the following actions:

a. Recommend to the board that the complaint file be closed without investigation.

b. Request a letter of explanation from the physician, medical records, or both.

c. Review the materials acquired pursuant to paragraph 24.2(3)*"b"* and recommend to the board that the investigative file be closed, with or without issuing an informal letter.

d. Request an investigation for board review.

24.2(4) *Board action.*

a. The board will review the screening committee's recommendations and take one of the following actions:

(1) Close the complaint file without investigation. The board will notify the complainant and the licensee of the decision.

(2) Close the investigative file that has been partially or fully investigated, with or without issuing an informal letter. The board will notify the complainant and the licensee of the decision.

(3) Request further investigation.

b. The board may reconsider and reopen a closed complaint or investigative file at a later date should it be deemed appropriate.

24.2(5) *Investigations.*

a. Complainants. At the time an investigation is opened, the complainant will be sent a letter with the name of the investigator assigned to the case and the investigator's contact information and a statement encouraging the complainant to submit any further information that would assist the investigator with the case.

(1) The complainant may request a meeting with the investigator prior to the completion of the investigation.

(2) The complainant will be informed of the confidentiality of the investigative information as provided in subrule 24.2(8).

(3) The complainant may contact the chief investigator with questions or concerns about the investigation.

b. Investigative subpoenas.

(1) Issuance of an investigative subpoena. The executive director or a designee may, upon the written request of a board investigator or upon the executive director's own initiative, subpoena books, papers, records, and other real evidence necessary for a board investigation.

(2) Request for subpoena. A written request for a subpoena will contain the following:

1. The name and address of the person to whom the subpoena will be directed;
2. A specific description of the books, papers, records or other real evidence requested;
3. An explanation of why the evidence sought to be subpoenaed is necessary for the board to determine whether it should institute a contested case proceeding; and
4. In the case of a subpoena request for mental health records, confirmation that the conditions described in subparagraph 24.2(5)*"b"*(4) have been satisfied.

(3) Contents of subpoena. Each subpoena will contain the following:

1. The name and address of the person to whom the subpoena is directed;
2. A description of the books, papers, records or other real evidence requested;
3. The date, time and location for production or inspection and copying;
4. The time within which a motion to quash or modify the subpoena must be filed;
5. The signature, address and telephone number of the executive director or designee;
6. The date of issuance; and
7. A return of service attached to the subpoena.

(4) Subpoena for mental health records. A subpoena for mental health records shall meet the requirements of subparagraph 24.2(5)*"b"*(3). The board shall document the following prior to the issuance of a subpoena for mental health records:

1. The nature of the complaint reasonably justifies the issuance of a subpoena;
2. Adequate safeguards have been established to prevent unauthorized disclosure;
3. An express statutory mandate, articulated public policy, or other recognizable public interest favors access; and
4. An attempt was made to notify the patient and to secure an authorization from the patient for release of the records at issue.

(5) Motion to quash or modify subpoena.

1. Any person who is adversely affected by compliance with the subpoena and desires to challenge the subpoena must file with the board a motion to quash or modify the subpoena within 14 days of service, or before if the time specified is less than 14 days. The motion shall describe the legal reasons why the subpoena should be quashed or modified and may be accompanied by legal briefs or factual affidavits.

2. Hearing on motion. Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to hold a hearing and issue a decision, or the board may conduct a hearing and issue a decision. Oral argument may be scheduled at the discretion of the administrative law judge or the board. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

3. Appeal of decision on motion. A person who is aggrieved by a ruling of an administrative law judge and who desires to challenge that ruling must appeal the ruling to the board by serving on the board's executive director, either in person or by certified mail, a notice of appeal within ten days after service of the decision of the administrative law judge.

4. Final agency action. If the person contesting the subpoena is not the person under investigation, the board's decision is final for purposes of judicial review. If the person contesting the subpoena is the person under investigation, the board's decision is not final for purposes of judicial review until either the person is notified that the investigation has been concluded with no formal action or there is a final decision in the contested case.

c. Licensee response. Before a contested case begins, the investigator will attempt to reach the licensee at the licensee's listed address to allow the licensee to respond to the allegations. If the licensee cannot be found there, reasonable efforts to locate the licensee will be made. If the licensee cannot be located, the investigation will proceed without the licensee's response, and the findings will be sent to the board. Contact and response from the licensee can be in writing or through a personal interview.

d. Investigative report. Upon completion of an investigation, the investigator will prepare a report for the board's consideration. The report will set forth the information obtained in the course of the investigation and the response, if any, of the licensee.

e. Board review. The board will review the investigative record, discuss the case, and take one of the following actions:

(1) Close the investigative file without action. The board will notify the complainant and the licensee of the decision. The board may reconsider and reopen a closed complaint or investigative file at a later date should it be deemed appropriate.

(2) Request further investigation, including peer review.

(3) Meet with the licensee. The board or the licensee may request that the licensee appear before the board to discuss a pending investigation. The board has discretion on whether to grant a licensee's request for an appearance. By electing to participate in the appearance, the licensee waives any objection to a board member's both participating in the appearance and later participating as a decision maker in a contested case proceeding on the grounds that:

1. Board members have personally investigated the case, and

2. Board members have combined investigative and adjudicative functions.

If the executive director or director of legal affairs participates in the appearance, the licensee further waives any objection to having the executive director or director of legal affairs assist the board in the contested case proceeding.

(4) Issue an informal letter of warning or education. If the board concludes that there is not probable cause to file disciplinary charges, the board may issue the licensee an informal letter of warning or education. A letter of warning or education is an informal communication between the board and the licensee and is not formal disciplinary action or a public document.

(5) File a statement of charges. If the board determines that there is probable cause for taking formal disciplinary action against a licensee, the board shall file a statement of charges, thereby commencing a contested case proceeding.

Prior to the initiation of formal disciplinary charges in a case involving the supervision of a physician assistant, the board shall forward a copy of the investigative report to the board of physician assistants for its advice and recommendation. The board of physician assistants shall respond within six weeks or sooner if requested by the board of medicine. The board of medicine shall consider the advice and recommendation of the board of physician assistants.

(6) Request a combined statement of charges and settlement agreement. At the board's discretion, the board and the licensee may enter into a combined statement of charges and settlement agreement to resolve a contested case proceeding.

24.2(6) *Licensee-patient privileged communications.* The privilege of confidential communication between the recipient and the provider of health care services do not extend to afford confidentiality to medical records maintained by or on behalf of the subject of an investigation by the board, or records maintained by any public or private agency or organization, which relate to a matter under investigation by the board. No provision of Iowa Code section 622.10, except as it relates to an attorney of the licensee, or the stenographer or confidential clerk of the licensee's attorney, shall be interpreted to restrict access by the board or its staff or agents to information sought in an investigation being conducted by the board.

24.2(7) *Investigation of malpractice lawsuits, judgments and settlements.* The board will review reports received from insurance carriers and licensees involving malpractice lawsuits, adverse judgments, and settlements. The board may choose to investigate such reports in the same manner as is prescribed in these rules for the review and investigation of other complaints to determine whether there is probable cause under applicable statutes or administrative rules for licensee discipline.

24.2(8) *Confidentiality of investigative information.* All investigative information gathered by the board or its employees or agents, including peer reviewers, is confidential and privileged. The information cannot be obtained through discovery, subpoena, or other legal means except by the licensee and the board. This information is not admissible in any judicial or administrative proceeding, except in cases involving licensee discipline. However, the board's statement of charges, settlement agreements, or decisions in disciplinary proceedings are public records.

653—24.3(272C) Peer review. The board may assign any case to peer review for evaluation of the professional services rendered by the licensee and report to the board.

24.3(1) *Registration of peer reviewers.* The board may register peer reviewers by maintaining a list of peer reviewers in the board office. The board will enter into a contract with peer reviewers to provide peer review services.

24.3(2) *Case referral for peer review.* The board or board staff will determine which peer reviewer(s) will review a case and what investigative information is referred to a peer reviewer.

24.3(3) *Board assistance to peer reviewers.* The board may provide investigatory and related services to assist the peer reviewer(s).

24.3(4) *Confidentiality.* Peer reviewers shall observe the confidentiality requirements imposed by Iowa Code section 272C.6(4).

24.3(5) *Liability, defense and indemnity.* Peer reviewers are not liable for acts, omissions or decisions made in connection with service on the peer review committee. However, such immunity from civil liability does not apply if such act is done with malice. Peer reviewers are to be provided a defense by the state for civil lawsuits related to board peer review and will be indemnified for all such judgments or settlements as provided by applicable law and administrative rules.

24.3(6) *Written peer review report.* Peer reviewers will review the information provided by the board and provide a written report to the board.

a. The written report will contain a statement of facts, an opinion of the peer reviewers whether the licensee violated the standard of care, and the rationale supporting the opinion.

b. The written report shall be signed by all peer reviewers concurring in the report.

c. If the peer reviewers find that they are unable to review the case, the investigative information shall be returned to the board.

653—24.4(272C) Order for physical, mental, or clinical competency evaluation. All licensees will undergo a physical, mental, or clinical evaluation as directed by the board. This evaluation may be ordered if there is probable cause of a mental, physical, or behavioral condition, including professional misconduct, disruptive behavior, or substance abuse. The evaluation may include various assessments

for disruptive behavior or neuropsychological, psychiatric, sexual misconduct, or substance abuse evaluations. Clinical competency evaluations can be ordered if there is probable cause of professional incompetence. All evaluation orders and related information are confidential according to Iowa Code section 272C.6(4). The licensee will bear the cost, and orders will be delivered via personal service or certified mail, return receipt requested.

24.4(1) *Content of order.* A board order shall include the following items:

a. Probable cause. A showing by the board that there is probable cause to order the licensee to complete an evaluation.

b. Nature of evaluation or screening. A description of the type of evaluation or screening that the licensee needs to complete.

c. Evaluation facility. The name and address of the examiner or evaluation or treatment or screening facility that the board has identified to perform the evaluation.

d. Scheduling the evaluation. The amount of time in which the licensee must schedule the required evaluation.

e. Completion of the evaluation. The amount of time in which the licensee must complete the evaluation.

f. Board release. A requirement that the licensee sign all necessary releases for the board to communicate with the evaluator or the evaluation or treatment program and to obtain any reports generated by the program.

24.4(2) *Alternatives.* Following issuance of the evaluation order, the licensee may request additional time to schedule or complete the evaluation or to request the board to approve an alternative evaluator or treatment facility. The board will determine whether to grant such a request.

24.4(3) *Objection to order.* A licensee who is the subject of a board evaluation order and who objects to the order may file a request for hearing. The request shall be filed within 14 days of issuance of the evaluation order. A licensee who fails to timely file a request for hearing to object to an evaluation order waives any future objection to the evaluation order in the event formal disciplinary charges are filed for failure to comply with the evaluation order or on any other grounds. The request for hearing shall specifically identify the factual and legal issues upon which the licensee bases the objection. The hearing will be considered a contested case proceeding and will be governed by the provisions of 653—Chapter 25.

24.4(4) *Closed hearing.* Any hearing on an objection to the board order will be closed pursuant to Iowa Code section 272C.6(1).

24.4(5) *Order and reports confidential.* An evaluation order and any subsequent evaluation reports issued in the course of a board investigation are confidential investigative information pursuant to Iowa Code section 272C.6(4). However, all investigative information related to an evaluation order will be provided to the licensee in the event the licensee files an objection under 24.4(3), in order to allow the licensee an opportunity to prepare for hearing.

24.4(6) *Admissibility.* In the event the licensee submits to evaluation and subsequent proceedings are held before the board, all objections will be waived as to the admissibility of the licensee's testimony or evaluation reports on the grounds that they constitute privileged communication. The medical testimony or examination reports will not be used against the licensee in any proceeding other than one relating to licensee discipline by the board.

24.4(7) *Failure to submit.* Failure of a licensee to submit to a board-ordered mental, physical, clinical competency or substance abuse evaluation or alcohol or drug screening constitutes a violation of the rules of the board and is grounds for disciplinary action.

These rules are intended to implement Iowa Code chapters 17A, 147, 148, and 272C.