

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Confidential Monitoring Program

Rule Number(s): 4731-28-02, 4731-28-03, 4731-28-04, and 4731-28-05

Date: February 9, 2018

Rule Type:

New

Amended

5-Year Review

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

The rules create a non-disciplinary, confidential monitoring program that allows licensees with mental or physical illnesses, other than substance use disorders, to be monitored by the Medical Board without being subjected to formal, public disciplinary action.

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Rule 4731-28-02 sets forth the eligibility criteria for program participants.

Rule 4731-28-03 addresses the participation requirements for individuals in the confidential monitoring program.

Rule 4731-28-04 provides information regarding the disqualification from continued participation in the confidential monitoring program.

Rule 4731-28-05 addresses the termination of the participation agreement for the confidential monitoring program.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Sections 4730.07, 4731.05, 4759.05(A), 4760.19, 4761.03(A), 4762.19, 4774.11, 4778.12, Ohio Revised Code.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

No.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The proposed confidential monitoring program allows for an option for individuals who are unable to safely practice without monitoring due to mental or physical illness, excluding substance use disorders. In the Medical Board's experience, there are individuals who require treatment for a mental or physical illness and monitoring to allow them to be able to safely practice. Currently, the individuals who are unable to practice due to a mental or physical condition receive a formal disciplinary action, which is public and reportable to the National Practitioner Data Bank and employers. The new rules create an option for these individuals to receive treatment and monitoring without triggering a public, formal disciplinary action.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The regulations will be a success if they allow an additional monitoring option for individual licensees who are unable to practice due to a physical or mental illness.

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Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

On April 10, 2017, the Medical Board circulated the draft rules via e-mail to interested parties who have requested notice of rule filings and healthcare associations. See attached.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Board received written comments from nine individuals and groups, which are attached and summarized below:

1. Cheryl No last name given, Massage Therapist: Expressed concern that monitoring individuals with significant mental disorders may pose difficulties.
2. Deborah Taylor, M.D.: Indicated that the rules establishing a confidential monitoring program sounds like a good idea.
3. Leslie Dye, M.D.: Concerned that substance use disorder is not addressed in the proposed rules.
4. Magdalena Kerschner, M.D.: Creation of a confidential monitoring program is a good idea and the Kentucky Medical Board has had one for 25 years.
5. Matthew D. Russell, M.D.: The proposed rules seem harsh and punitive rather than supportive and helpful. Recommend collaboration with the Ohio Physicians Health Program on policy decisions regarding mental health, physical disability or other chronic brain diseases.
6. Scott Weiner, M.D.: Concerned that the proposed confidential monitoring program would jeopardize patient safety.
7. Wendy Jo Marsinek, Massage Therapist: Concerned that the individual would continue working while the investigation was being completed.
8. Jason Boylan, Attorney, Disability Rights Ohio; Joan Englund, Esq., Executive Director, Mental Health and Addiction Advocacy Coalition; and Terry Russell, Executive Director, National Alliance on Mental Illness, Ohio: Concerned that the proposed rules discriminate against licensees with disabilities and do not go far enough to modify the definitions of illness and inability to practice. Recommend that the Board allow for the program to be run by a neutral third party, rather than under the Board's own auspices.
9. Robyn Chatman, M.D., President, Ohio State Medical Association; Elayne Biddlestone, EVP/CEO, The Academy of Medicine of Cleveland and Northern Ohio; Ann Spicer, Executive Vice-President, Ohio Academy of Family Physicians; Robert Falcone, M.D., CEO, Columbus Medical Association; Laura Tiberi, Executive Director, Ohio Chapter, American College Emergency Physicians; James McGovern, Director of Professional

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Licensing, Graff & McGovern, L.P.A.; Jon Wills, Executive Director, Ohio Osteopathic Association; Janet Shaw, Executive Director, Ohio Psychiatric Physicians Association; Jimelle Rumberg, Executive Director, Ohio Foot and Ankle Medical Association; Emily Maurer, Ohio Chapter, American College of Surgeons; Shawn Ryan, M.D., President, Ohio Society of Addiction Medicine; and Richard Whitney, M.D., Medical Director, Shepherd Hill: Concerned that the Board confidential monitoring program is based on diagnosis or condition and not related to conduct; that the program is not truly confidential because members of the Board and Board staff will have access to licensees' medical records, progress notes, diagnosis and prognosis; that it does not account for dual diagnosis situations; and that there is a lack of due process regarding entry into the program, continued participation and termination of the program.

On November 14, 2017, three members of the Board (Mr. Giacalone, Dr. Rothermel and Dr. Schottenstein), Executive Director Groeber and other staff members met with representatives of the groups that sent letters raising concerns with the proposed rules. Those groups included Disability Rights Ohio, Ohio State Medical Association, Ohio Osteopathic Association, Ohio Psychiatric Physicians Association, Ohio Foot and Ankle Medical Association, Ohio Academy of Family Physicians, Columbus Medical Association, and others. On December 8, 2017, the associations in the Medical Association Coalition mailed a follow-up letter, reiterating their concerns to the Board which was reviewed at the December meeting of the Policy Committee.

On January 8, 2018, the Board received a letter indicating that the group of medical associations was withdrawing its concerns so long as the Board shared non-identifiable information regarding outcomes.

On January 9, 2018, the Board determined that the outcome information will need to be developed and shared and that the rules should be filed with the Common Sense Initiative.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The creation of the confidential, non-disciplinary program is based on two goals: (a) encouraging adequate treatment and monitoring for individuals who are unable to practice due to a mental or physical illness and (b) safe practice by licensed individuals. The Board relied on input from two physician Board members, Dr. Schottenstein and Dr. Rothermel, to craft a process that would allow the Board Secretary and Supervising Member to monitor licensees with mental and physical health conditions that allow them to safely practice with monitoring. Research regarding physician burnout and the impact of failure to timely address mental and physical health issues were used as background for the creation of the new non-disciplinary process.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

Prior to developing the current version of the proposed rules, the Board did consider approval of a non-disciplinary agreement signed by the individuals and approved by the full Board as the first step in entering the confidential, non-disciplinary program. However, Board approval of such an agreement would be a public action by the Board, reportable to the National Practitioner Data Bank.

11. Did the Agency specifically consider a performance-based regulation? Please explain.

Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The rules are detailed in establishing the details of the confidential monitoring program, which is necessary to provide clarity to the regulated individuals, the Board and the public.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Medical Board is the sole agency overseeing the licensure of its licensees, including physicians and physician assistants.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The agency plans to keep non-identified specifics regarding the individuals in the program and provide those to the Board and the public on a regular basis.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The scope of the impacted business community encompasses the Board's licensees and their employers, including but not limited to physician practices, hospitals, ambulatory surgery centers, and nursing facilities.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

By providing a non-disciplinary alternative for individuals with mental or physical health conditions, the rules will alleviate costs of defending disciplinary charges and other related actions based on the Board's disciplinary action. Individuals participating in the non-disciplinary monitoring program will likely incur health care costs for evaluations, regular office visits and the provision of monitoring reports to the Board. However, these healthcare costs are also incurred under the current public system.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

These rules will lessen the adverse impact of individuals who are unable to practice without monitoring or supervision due to a mental or physical health condition. Currently, these individuals are required to enter into a public consent agreement or to comply with a public Board order. The public actions may lead to other consequences for the healthcare professional, such as loss of participation in Medicaid or Medicare, loss of hospital privileges or an inability to obtain or maintain specialty Board certification. The proposed rules will allow for a non-disciplinary path which will eliminate these types of consequences.

The health care costs that individuals will incur for participation in this program are likely identical to those that they would incur to comply with a public consent agreement or Board order.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

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The proposed rules will alleviate adverse impact and allow the Board to fulfill its mission of public protection and safe practice.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The rules contemplate a voluntary program, so it is up to the individual licensee to consent to participate in the program. It is offered as an alternative that will allow healthcare practitioners to practice with monitoring if they have a physical or mental condition that makes them unable to safely practice without monitoring.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Individuals participating in this voluntary, non-disciplinary program will not be subject to fines.

18. What resources are available to assist small businesses with compliance of the regulation?

The Medical Board will provide information regarding this voluntary, non-disciplinary program on its website and will provide individualized information to those licensees and applicants who would qualify for the new program.

4731-28-02

Eligibility for confidential monitoring program.

There is hereby created a confidential monitoring program applicable to all individuals licensed under Chapter 4730., 4731., 4760., 4762., 4774., or 4778. of the Revised Code who are determined to be eligible for the program pursuant to this rule. For purposes of the confidential monitoring program, the term "confidentiality statute" refers to division (F) of section 4730.26 of the Revised Code, division (F)(5) of section 4731.22 of the Revised Code, division (E) of section 4760.14 of the Revised Code, division (E) of section 4762.14 of the Revised Code, division (E) of section 4774.14 of the Revised Code, or division (E) of section 4778.18 of the Revised Code, as applicable to the individual.

(A) Under the board's investigative duties pursuant to sections 4730.26, 4731.22, 4760.14, 4762.14, 4774. 14, or 4778.18 of the Revised Code, as applicable to the individual, and subject to the applicable confidentiality statute, the secretary and supervising member of the board may determine that an individual who is the subject of an investigation by the board concerning a mental or physical illness, other than a substance use disorder or chemical abuse/dependency, is appropriate for ongoing investigative observation and monitoring rather than formal disciplinary action. Upon such determination, the board may conduct such observation and monitoring through the individual's participation in a confidential monitoring program overseen by the secretary and supervising member of the board under the board's investigative duties and subject to the applicable confidentiality statute.

(B) In making their determination of an individual's eligibility for participation in the confidential monitoring program, the secretary and supervising member of the board shall use the following criteria:

(1) The board may conduct any investigation necessary to evaluate the totality of circumstances, including requiring the individual to submit to a physical or mental examination under the applicable chapter of the Revised Code;

(2) The individual must provide continuing authorization, through appropriate written consent forms, for the disclosure and release of information between the board, the individual, and any other persons or entities involved in the evaluation, treatment, or monitoring of the individual that is necessary for them to fulfill their respective duties and obligations. This includes, but is not limited to, the exchange of information to and from employers, probation officers, law enforcement agencies, peer assistance programs, health care practitioners, mental health counsellors, social workers, or any other individuals or entities the board determines may have relevant information.

(3) If the individual has not yet undertaken appropriate treatment, monitoring, or supervision related to the mental or physical condition, the information received must demonstrate that the individual is willing to commence such appropriate treatment, monitoring, or supervision;

- (4) If the individual has commenced treatment for the mental or physical illness, the information received must demonstrate that the individual has been significantly compliant with the treatment plan established, including taking all medications as prescribed;
- (5) If the individual was previously a participant in the monitoring program, the individual must have demonstrated full compliance with all program requirements. Any individual who was previously disqualified from participation in the monitoring program shall be ineligible for future participation in the program;
- (6) If the individual was previously the subject of formal public disciplinary action by this board, such action must have been based solely on a violation of division (B)(4) of section 4730.25 of the Revised Code, division (B)(19) of section 4731.22 of the Revised Code, division (B)(5) of section 4760.13 of the Revised Code, division (B)(5) of section 4762.13 of the Revised Code, division (B)(5) of section 4774.13 of the Revised Code, or division (B)(5) of section 4778.14 of the Revised Code, as applicable to the individual, for which the individual subsequently was released from probation without restriction. Any individual who has been issued a notice of opportunity for hearing that remains pending for final adjudication by the board is not eligible for participation in the monitoring program regardless of the basis of the violation alleged in the notice;
- (7) If the individual was previously the subject of confidential monitoring, public monitoring, non-disciplinary monitoring, or formal disciplinary action by or in association with an agency responsible for authorizing, certifying, or regulating the individual to practice a health care occupation in this state or any other jurisdiction, such action must have been based solely on the individual's mental or physical illness;
- (8) No information available to the board about the individual, either concerning past or current allegations or conduct, implicates a possible sexual boundary issue regardless of whether such issue involved patients or non-patients and regardless of whether such issue was caused by or related to the individual's mental or physical illness;
- (9) No information available to the board about the individual, either concerning past or current allegations or conduct, implicates an act of violence against property or persons or threat of violence against property or persons, even if the board is unable to conclusively confirm the credibility of such allegations;
- (10) No information available to the board about the individual, either concerning past or current allegations or conduct, and regardless of whether caused by or related to the individual's mental or physical illness;

- (a) Demonstrates that the individual has been convicted of a felony or misdemeanor, including but not limited to operating a vehicle under the influence or reckless operation, at any time;
 - (b) Indicates that the individual has felony or misdemeanor charges, including but not limited to operating a vehicle under the influence or reckless operation, currently pending; and/or
 - (c) Implicates a possible criminal issue, regardless of whether formal misdemeanor or felony charges were pursued or are anticipated in the future;
- (11) There is no information indicating that the individual is in violation of any provision of the chapter of the Revised Code under which the individual was licensed other than division (B)(4) of section 4730.25 of the Revised Code, division (B)(19) of section 4731.22 of the Revised Code, division (B)(5) of section 4760.13 of the Revised Code, division (B)(5) of section 4762.13 of the Revised Code, division (B)(5) of section 4774.13 of the Revised Code, or division (B)(5) of section 4778.14 of the Revised Code, as applicable to the individual; and
- (12) There is no information indicating that allowing the individual to participate in confidential monitoring will create a significant risk of potential harm to patients.

4731-28-03

Participation in the confidential monitoring program.

(A) Individuals determined to be eligible for participation in the confidential monitoring program established under rule 4731-28-02 of the Administrative Code shall enter into a written participation agreement with the board.

(1) The participation agreement is a non-disciplinary, voluntary, written contract between the individual and the board. The participation agreement shall remain confidential pursuant to the applicable confidentiality statute, as that term is defined in rule 4731-28-02 of the Administrative Code, provided that the individual remains in compliance with the participation agreement and that the board does not otherwise subsequently pursue formal disciplinary proceedings against the individual pursuant to any alleged violation of Chapter 4730., 4731., 4760., 4762., 4774., or 4778. of the Revised Code, as applicable to the individual.

(2) The participation agreement shall be negotiated under the direction of the secretary and supervising member of the board by an appropriate board staff attorney. The participation agreement shall be signed by the individual; the individual's attorney, if any; the secretary of the board; the supervising member of the board; and the appropriate board staff attorney.

(3) The individual's ongoing compliance with the participation agreement shall be monitored by appropriate board staff under the direction of the secretary and supervising member of the board.

(B) The participation agreement shall require, at a minimum, the following terms and conditions:

(1) Stipulation of the individual's mental or physical illness;

(2) The individual must provide continuing authorization, through appropriate written consent forms, for the disclosure and release of information between the board, the individual, and any other persons or entities involved in the evaluation, treatment, or monitoring of the individual that is necessary for them to fulfill their respective duties and obligations. This includes, but is not limited to, the exchange of information to and from employers, probation officers, law enforcement agencies, peer assistance programs, health care practitioners, mental health counsellors, social workers, or any other individuals or entities the board determines may have relevant information;

(3) A requirement that the individual will undertake and/or maintain continued treatment acceptable to the secretary and supervising member of the board pertaining to the individual's mental or physical illness;

(4) Agreement that if the secretary and supervising member of the board, based on information received by the board, determine that the individual has a current inability to practice in accordance with acceptable and prevailing standards of

care, the individual will voluntarily cease practicing until approved to resume practice by the secretary and supervising member of the board;

(5) A requirement that the individual is responsible for all costs associated with participation in the confidential monitoring plan;

(6) Obedience of all federal, state, and local laws, and all rules governing practice in Ohio;

(7) Submission of quarterly declarations under penalty of perjury stating whether there has been compliance with all conditions of the participation agreement;

(8) Periodic appearances, as requested, before the secretary or supervising member of the board or their designated board staff representative;

(9) Submission of witnessed blood, urine, breath, saliva and/or hair specimens for screening for analysis of therapeutic levels of medications that may be prescribed to the individual, drugs and alcohol, or for any other purpose, at the individual's expense upon the board's request and without prior notice;

(10) Acknowledgement and consent of the individual that the confidentiality of the agreement is waived in the event the board subsequently pursues formal disciplinary proceedings against the individual pursuant to any alleged violation of Chapter 4730., 4731., 4760., 4762., 4774., or 4778. of the Revised Code, as applicable to the individual;

(11) A requirement that the individual agree to ongoing monitoring for a minimum period of time appropriate for the individual's particular mental or physical illness, as follows:

(a) For any mental or physical illness associated with a significant degenerative/progressive condition, including but not limited to Parkinson's disease, multiple sclerosis, primary dementia, schizophrenia, or mild cognitive impairment, ongoing monitoring shall be required for as long as the individual retains any current or possible future right to practice.

(b) For all other mental or physical illnesses, the appropriate length of monitoring shall be determined by the secretary and supervising member of the board but shall be for a period of not less than two years.

(c) Agreement of the individual that the participation agreement shall remain in full force and effect until such time that the secretary and supervising member of the board determine that termination of the participation agreement is appropriate.

(d) Acknowledgement pertaining to the applicable disclosure requirements.

(C) This rule shall neither apply to nor limit the authority granted the board under division (M) of section 4730.25 of the Revised Code, division (M) of section 4731.22 of the Revised Code, division (M) of section 4760.13 of the Revised Code, division (M) of section 4762.13 of the Revised Code, division (M) of section 4774.13 of the Revised Code, or division (M) of section 4778.14 of the Revised Code with regard to the surrender of a license or certificate or the withdrawal of an application for a license or certificate.

4731-28-04

Disqualification from continued participation in the confidential monitoring program.

Disqualification from continued participation in the confidential monitoring program established under rule 4731-28-02 of the Administrative Code shall be determined as follows:

- (A) Any alleged violation of the participation agreement, as determined in the sole discretion of the secretary and supervising member of the board, shall constitute grounds for the board to pursue formal disciplinary action against the individual pursuant to section 4730.25, 4731.22, 4760.13, 4762.13, 4774.13, or 4778.14 of the Revised Code, as applicable to the individual. The disciplinary action shall be in accordance with Chapter 119. of the Revised Code.
- (B) If for any reason the secretary and supervising member of the board, in their sole discretion, determine that an individual's participation in the confidential monitoring program is no longer appropriate, they may terminate the participation agreement by notifying the individual in writing. Such termination shall not limit the authority granted the board to take any other action with regard to the individual or the individual's certificate to practice.

4731-28-05

Termination of the participation agreement for the confidential monitoring program.

(A) Upon completion of at least the minimum monitoring term specified in the participation agreement for the confidential monitoring program established in rule 4731-28-02 of the Administrative Code, the individual may submit a written request to the secretary and supervising member of the board requesting termination of the participation agreement. Such request must be accompanied by written documentation from the treating physician overseeing coordination of care for the individual's mental or physical illness indicating that whether all of the following criteria are met:

(1) The individual's condition is currently stable;

(2) The individual's condition is reasonably expected to remain stable contingent upon the individual maintaining compliance with the treatment plan; and

(3) The treating physician supports the individual's request for termination of the participation agreement.

(B) The secretary and supervising member of the board shall review the individual's request for termination of the participation agreement and reach a determination as to whether to such termination is appropriate. In making such determination, they shall consider all of the following criteria:

(1) Whether the individual has demonstrated substantial compliance with the participation agreement during the monitoring period;

(2) The documentation provided by the individual's treating physician related to the termination request;

(3) Whether additional investigation is necessary, including but not limited to requiring the individual to submit to a board-ordered physical examination and/or mental examination; and

(4) Any other relevant investigative information concerning the individual.

(C) The determination of the secretary and supervising member of the board shall be implemented as follows:

(1) If the secretary and supervising member of the board determine that termination of the participation agreement is appropriate, they shall direct appropriate staff to notify the individual in writing that the request for termination of the participation agreement has been granted. Such termination shall constitute successful completion of the monitoring program by the individual.

(2) If the secretary and supervising member determine that termination of the participation agreement is not appropriate, they shall direct appropriate staff

to notify the individual in writing that the request for termination of the participation agreement has been declined. An individual whose request for termination is declined shall continue to be monitored by the board pursuant to the participation agreement for at least an additional six months before being eligible to submit a subsequent request for termination.