CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Prescribing to persons not seen by the physician

Rule Number(s): 4731-11-01 and 4731-1-09

Date: _____

Rule Type:

- X New
- X Amended
- X 5-Year Review
- X Rescinded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.

Rule 4731-11-01 defines terms used in the rules in Chapter 4731-11, including rule 4731-11-09. It is amended to include definitions of "cross-coverage," "active patient," and "consult" to facilitate the understanding of the requirements of proposed rule 4731-11-09. The dates

cited in the definitions of "active patient" and "consult" reflect the date it is anticipated that the rule will be effective because when a rule references a provision of the Code of Federal Regulations, the rule must specify the version of the regulation referenced.

Rule 4731-11-09 sets standards for a physician's prescribing of or otherwise providing drugs to patients for whom the physician has not established a physician-patient relationship by the performance of an in-person physical examination. The rule is applicable to all situations but many people will refer to it as the "telemedicine" rule.

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

   The rules are authorized by Section 4731.05 of the Revised Code. Rule 4731-11-09 is specifically authorized by Section 4731.74 of the 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.

   The rules do not implement a federal requirement.

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

   Rule 4731-11-09's provisions related to prescribing controlled substances are consistent with federal law.

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 public purpose of Rule 4731-11-01 is to define for physicians, other health care workers, and the public the terms that are used in Chapter 4731-11 rules.

   The public purpose of Rule 4731-11-09 is to implement the policy of the State of Ohio to authorize remote medical care, including the provision of non-controlled substances, when standards facilitating protection of the public are met. The rule clarifies for physicians, other health care workers, and the public the standards for establishing a physician-patient relationship for the purposes of prescribing or otherwise providing drugs when the physician is remote from a patient and on whom the physician has never conducted a physical examination.

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

Rule 4731-11-09 seeks to clarify the steps required by physicians to meet the minimum standards of care in establishing the physician-patient relationship and providing care via technology when the physician and patient are not in the same location. There has been confusion among physicians regarding these requirements. The success of Rule 4731-11-09 will be gauged by the level of compliance by physicians.

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.

The proposed language for Rule 4731-11-09 was developed over the course of several years. The basic premise of the current rule is that a physician must conduct an in-person physical examination of a patient to establish the physician/patient relationship that is necessary before a physician prescribes any medication to a patient. The current rule provides specific exceptions to the general requirement.

For several years the Medical Board has received inquiries and accepted comments about the rule from interested parties, including physicians and vendors of telemedicine devices, concerning technological advances subsequent to the effective date of the current rule. Inquiries, comments, and letters were received from, but not limited to: Teladoc, a telemedicine provider; Iagnosis, a dermatology telemedicine provider; and American Well, a telemedicine provider.

Of particular note are the following:

- The Medical Board heard a presentation from OptumHealth, a division of United Health Group, concerning the NowClinic on January 12, 2011. The NowClinic software uses a webcam to allow face-to-face visits between patients and a remote physician, but does not provide a means of conducting any sort of physical examination.
- In March 2012, Medical Board members and staff visited Central Ohio Primary Care in Columbus to view the Healthspot kiosk, which provides a means for a physician who is remote from the patient's location to conduct a physical examination using diagnostic medical equipment that transports real-time information and images of the patient's condition to the remote physician. Healthspot ceased operation in January 2016.

- In September 2012, the Medical Board issued an interpretative guideline for Rule 4731-11-09 that recognized that a physician using interactive medical devices may be able to conduct an appropriate physical examination of the patient while the physician is at a location remote from the patient. The Medical Board planned to amend rule 4731-11-09 to incorporate the interpretive guideline into the rule itself.
- On September 18, 2013, Medical Board staff members participated in a teleconference held by the Upper Midwest Telehealth Resource Center, which included discussion of current rule 4731-11-09.
- In March 2014, Medical Board members and staff visited CareSpace, a service by Optimized Care. CareSpace's model is to have the patient in a room with an RN, who applies the examination tools to the patient for the remote physician who appears in the room via a hologram.
- During July and August 2014, Medical Board staff members reviewed proposed language with Mark Hurst, M.D., the Medical Director for the Ohio Department of Mental Health and Addiction Services.
- In September 2014, input on possible changes to the current rule was solicited from the members of the Physician Assistant Policy Committee, a statutorily created advisory committee to the Medical Board.
- In October 2014, a draft rule was sent to interested parties including, but not limited to: Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland/Northern Ohio Medical Association, Ohio Hospital Association, various healthcare attorneys, Ohio Board of Nursing, Teladoc, American Well, Ohio Association of Physician Assistants, and physicians who have asked to be notified of Medical Board rule activities.
- In October 2014, in cooperation with the Medical Board, Health Policy Institute of Ohio circulated the draft rule for comments to members of that organization.
- On November 10, 2014, Medical Board staff members met with staff and representatives of Teladoc, a telemedicine provider.
- On November 18, 2014, Medical Board staff members met with staff and representatives of University of Pittsburgh Medical Center's telemedicine program.
- On January 21, 2015, a Medical Board staff member gave a presentation on proposed Rule 4731-11-09 via teleconference for the Upper Midwest Telehealth Resource Center.

- In January 2015, a revision to draft amended language was sent to interested parties for comment. The interested parties included those listed above, and also a representative on behalf of the University of Pittsburgh Medical Center.
- In February 2015, the proposed language was reviewed by the Physician Assistant Policy Committee.
- On February 19, 2015, Medical Board staff members met with representatives of Anthem via teleconference to discuss its telemedicine model, which uses the American Well platform.
- In March 2015, two Medical Board members met via telephone conference with a representative of Teladoc to discuss the language of the proposed rule.
- In May 2015, the members of the Physician Assistant Advisory Committee reviewed the draft rule language as amended to reflect the more robust role of physician assistants and advanced practice registered nurses in medical practice.
- On May 13, 2015, the Medical Board approved the proposed rule to be filed with the Common Sense Initiative Office. However, proposed rule 4731-11-09 was not filed with CSI because the Medical Board received word that there would be legislation on the subject.
- Language addressing the prescribing of drugs via telemedicine was originally included in H.B. 64, the budget bill, at the request of Teladoc. It was subsequently removed from the bill.
- Language enacting Section 4731.74 of the Revised Code was enacted in S.B. 188, effective March 23, 2016.
- On January 11, 2016, the Medical Board sent via email an invitation for anyone wishing to provide input on formulation of the rule to do so at the February 10, 2016 Medical Board meeting. The invitation was sent to the medical organizations such as the Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland/Northern Ohio Medical Association; Ohio Hospital Association; various healthcare attorneys; Ohio Board of Nursing; Teladoc; American Well; University of Pittsburgh Medical Center; Ohio Association of Physician Assistants; physicians who have asked to be notified of Medical Board rule activities; and other organizations and individuals who had previously provided comments concerning current Rule 4731-11-09 and proposed amendments.

- On January 19, 2016, representatives of the Medical Board met with the telemedicine group of the Ohio Hospital Association to solicit input on the content of the rule as required by S.B. 188.
- On February 10, 2016, the members of the Medical Board heard testimony on the proposed language for the rule. Oral or written testimony was given by the Academy of Family Physicians, University of Pittsburgh Health System, Teladoc, Cleveland Clinic, University of Cincinnati Health, Upper Midwest Telehealth Resource Center, and Ohio Health.
- On March 12, 2016, a part of a panel discussion on telemedicine, a representative of the Medical Board addressed physicians and attorneys attending the Medical-Legal Summit in Cleveland, explained the requirements of S.B. 188, and solicited comments on the content of the rule.
- On April 15, 2016, proposed language for rules 4731-11-01 and 4731-11-09 was sent to interested parties for comment. The interested parties included, but were not limited to, the following: Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland/Northern Ohio Medical Association, Ohio Hospital Association, various healthcare attorneys, Ohio Board of Nursing, Teladoc, American Well, Ohio Association of Physician Assistants, physicians who have asked to be notified of Medical Board rule activities, and other organizations and individuals who had previously provided comments concerning the proposed rules.
- On April 22, 2016, an email blast with information concerning the proposed rules and how to submit comments was sent to all physicians and physician assistants for whom the Medical Board has an email address.
- Comments were received from: Teladoc; Devin Namaky, M.D.; L. Eugene Arnold, M.D.; Ellen McGee, M.D.; Zipnosis; Ohio Hospital Association; The Center for Health Affairs; LiveHealth Online; American Well; and an attorney representing a pediatric facility.
- On June 8, 2016, the Medical Board reviewed the comments and approved amendments to the rule based on specific comments.

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

Comments on proposed Rule 4731-11-09 were wide and varied. Some comments received about the rule proposed in 2015 continue to be relevant, while others were rendered no longer relevant by the language of S.B. 188.

Several comments submitted in 2015, including those on behalf of the Ohio Department of Mental Health and Addiction Services, Ohio Hospital Association, and the Ohio Psychiatric Physician Association, asked that the proposed rule authorize the prescribing on controlled substances, such as ADHD medications, with a telemedicine visit without requiring a previous examination of the patient. However, the federal Controlled Substance Act prohibits such prescribing. See 21 U.S.C. §829.

In 2015 Teladoc submitted several comments suggesting that evaluation and treatment of certain conditions may be made via telephone conversation based upon the patient's report of medical history and report of conditions, in part because its physicians are cross-covering for the patient's primary care physician (if there is one). However, the Medical Board believes that in medicine the term "cross-coverage" requires that there be an arrangement between the physician being cross-covered and the physician who is cross-covering, and there is not such arrangement in the Teladoc model. This is consistent with the federal Controlled Substance Act, 21 U.S.C. §829(e)(2)(C).

In 2015, the medical director of the Cerebrovascular Center, Distance Health at Cleveland Clinic, and the Iagnasis company commented that there should not be a requirement that diagnostic medical equipment be capable of transmitting the patient's physical condition in "real-time." They suggested that the "store-and-forward" technology should be allowed for the physician to make a diagnosis from a picture of the physical condition submitted by the patient. However, the Medical Board sought the input of well-respected dermatologists who consult with physicians on patient dermatological conditions using store-and-forward technology. The advice was that store-and-forward technology is appropriate for physician to physician consultation but not for direct patient access to care. The advice from these experts was recently affirmed by a study conducted of telemedicine's use of the store and forward technology available directly to patients. See "Choice, Transparency, Coordination, and Quality Among Direct-to-Consumer Telemedicine Websites and Apps Treating Skin Disease," Resneck, Abrouk, Steuer, Tam, Yen, Lee, Kovarik, and Edison; *JAMA Dermatology*, published online May 15, 2016, http://archderm.jamanetwork.com/article.aspx?articleid=2522336.

At the February 2016 Medical Board meeting, the following testimony was received:

- A representative from Cleveland Clinic testified that the Cleveland Clinic does not support using telephone-only interactions with new patients and that the addition of

video is invaluable in creating the proper physician-patient relationship. In a follow-up letter dated March 29, 2016, Cleveland Clinic stated that it supports allowing providers to use their medical discretion to determine what signs and symptoms and diagnoses would require the use of diagnostic medical equipment. The letter noted that ophthalmologists and some other medical specialty practitioners do not obtain physical data or a patient's vital signs during a visit. It also stated that requiring the technology to transmit "real-time" data would hamper the ability to diagnose skin conditions based on the store and forward technology. The letter presented examples of conditions for which a personal computer or smartphone along with a secure video connection would provide sufficient interaction between the physician and patient.

- A representative from Teladoc stated that their physicians do not act as primary care physicians but more like acute general medical services provided in an urgent care or cross-coverage with no continuing primary care relationship. He further testified that Teladoc only works through a plan sponsor such as a health plan, employer, or hospital system and therefore has a contained pool of patients rather than a direct to consumer program. He stated that approximately sixty percent of Teladoc visits are by telephone only and may include a store and forward picture of a rash or lesion. He stated that the Teladoc physicians have access to electronic medical records for the patient.
- The representative from University of Cincinnati Health testified that its position is that the physician-patient relationship cannot be established by telephone only. He stated that technology does not yet enable replication of an in-person examination. The representative also stated that the ability to prescribe non-controlled medications via telemedicine to a patient the physician has not previously examined under the "on call" situation requires there to be an established agreement between the patient's personal physician and the physician providing the "on call." She added that the proponents for the relaxation of telehealth regulations are often vendors or vendor-oriented organizations and that decisions as to the standards should be made by individuals and bodies devoid of commercial interests, such as the Medical Board. Finally, he stated that the University of Cincinnati Health supports the language of Section 4731.74, Ohio Revised Code, as written.
- The representative from the University of Pittsburgh Medical Center ("UPMC") testified that its patient base includes patients of physicians employed by UPMC hospitals, patients of independent physicians who practice at UPMC hospitals, and UPMC health plan members, including residents of Ohio. He stated that their system uses an asynchronous questionnaire, and in some cases the physician will call the patient to get more information or schedule a video visit.

- A letter submitted on behalf of the Ohio Academy of Family Physicians stressed that the minimal standards of care require the physician to have established a physician-patient relationship with the patient by conducting a physical examination that is consistent with that which would be conducted in-person and that the minimal standards for an appropriate exam would be difficult to meet via today's audio and video technology. The letter also stated that the physician who has conducted an in-person examination of the patient is vastly better equipped to conduct a virtual visit with a patient. It also stated that telemedicine should not be used to further fragment patient care and patients should be encouraged to first seek care from their personal physician. The letter also expressed concerns about the prescribing of antibiotics to unestablished patients since the overuse of antibiotics and antibiotic resistance are well documented. The letter also stated that prescribing antibiotics for strep throat without having carefully examined the patient's throat, ears, and nose and listening to the patient's heart and lungs is inappropriate.
- In a letter submitted on behalf of Ohio Health, a representative stated that that organization provides telehealth services to established patients, so that the telemedicine provider has access to the electronic medical record.
- In a letter submitted on behalf of the Upper Midwest Telehealth Resource Center in January 2015, a representative discussed the requirements of other states for the establishment of a physician-patient relationship for prescribing via telemedicine. The letter stated that approximately twenty states allow the relationships to be established via an interactive face-to-face videoconferencing platform or other technology.

Comments received after the proposed rule was sent for interested party comment in April 2016 were as follows:

- ✓ Teledoc aadvised that paragraph (C)(3) of the draft rule requires the physician to obtain the patient's consent to forward the medical record to the patient's primary care provider or other health care provider. Under HIPAA, the patient's consent to share medical records with another provider is voluntary. Teledoc recommended changing paragraph (C)(3) to read as follows: "the physician shall request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other healthcare provider, if applicable or to refer the patient to an appropriate health care provider or health care facility;." The recommendation is included in the rule filed with CSI.
- ✓ Devin Namaky, M.D., FACOG, a gynecologist in Cincinnati, expressed a concern that the language of 4731-11-09 may conflict with the Expedited Partner Therapy,

which allows physicians to write prescriptions for sexual partners of patients diagnosed with sexually transmitted disease, without the physician having examined the sexual partners. The Expedited Partner Therapy prescribing is set by statute, which would supersede this rule. In order to make this clear, the language in what is now paragraph (H) was added.

- ✓ L. Eugene Arnold, M.D., M.Ed, a professor of psychiatry stated that the rule needs to allow for a physician covering for another who is away and whose patient runs out of chronic medication and needs a refill. If the covering physician is sure that the patient has been taking the drug in question, he or she should be allowed to prescribe it for a reasonable time without seeing the patient. The rule already allows for a covering physician to prescribe to a patient he or she has not seen so long as the requirements of paragraph (C) of the rule are met.

- ✓ Ellen McGee, M.D., Associate Medical Director for Signature Health, stated that she is concerned that psychiatrists may not be able to meet the general requirement to conduct a physical examination prior to prescribing. The rule as drafted requires that any physical examination be appropriate for the condition for which the patient is seeking treatment.
- ✓ Rebecca J. Hafner-Fogarty, M.D., MBA, FAAFP, Chief Medical Officer for Zipnosis, asked for the definition of telemedicine in the Ohio Revised Code to be changed to remove the requirement that the physician be located out of the state. Section 4731.296, O.R.C. defines the practice of telemedicine as the practice of medicine in this state through the use of any communication, including oral, written, or electronic communication by a physician located outside this state. Changing the statute is beyond the scope of this particular rule draft. In addition, the practice of medicine as defined by Section 4731.34, O.R.C., includes the use of telemedicine so holders of regular Ohio medical licenses do not need a telemedicine certificate to practice telemedicine. Section 4731.296, O.R.C., solely applies to a telemedicine certificate, which is a separate license type authorizing an out-of-state practitioner to provide services to Ohio patients via telemedicine.
- ✓ Sean McGlone, Senior Vice President and General Counsel for the Ohio Hospital Association, provided comments regarding five parts of the draft rule.
    1. The draft rule eliminates the specific exceptions where prescribing was permitted without seeing the patient and replaces it with a list of requirements that must be

met in all situations. Subsection (C)(5) requires the physician to establish a diagnosis and treatment plan and subsection (C)(6) requires the physician to document the patient's history. These requirements would be redundant in an on-call or cross-coverage situation. The OHA requested an exception for physicians in on-call or cross-coverage situations to not have to meet the requirements to take a history or establish a diagnosis and treatment plan.

In response, paragraph (C)(5) was amended to state that the physician shall establish or confirm, as applicable, a diagnosis and treatment plan. Paragraph (C)(6) was amended to state that the physician shall document in the patient's medical record the pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications and any referrals to appropriate health care providers, including primary care providers or health care facilities.

2. The rule does not address any elements that must be met by nurse practitioners or physician assistants.

   The Medical Board does not set the standards for nurse practitioners. The Board of Nursing can make this rule applicable to nurse practitioners. The Medical Board can make this rule applicable to physician assistants, and the draft rule has been reviewed by Physician Assistant Policy Committee and will be made applicable to physician assistants through a rule in Chapter 4730, Ohio Administrative Code.

3. In the current rule, there is an exception where drugs may be prescribed to a person the physician has accepted as a patient pending the scheduling of an appointment.

   This language was included in the current rule 4731-11-09 for controlled and non-controlled substances prior to the passage of the Ryan Haight amendments to the federal Controlled Substances Act. The OHA suggestion was not accepted by the Medical Board for the following reasons: This exception is not permitted under federal law, so it would not be appropriate for controlled substances. With respect to non-controlled substances, the Board opined in 2013, in the matter involving Miles Drake, M.D., that a physician-patient relationship is established when the physician sees the patient and provides care.

4. Section (C)(4) requires that the physician complete the remote evaluation through interaction with the patient. OHA suggests removing the words,

"through interaction with the patient" because it does not contemplate those situations where the physician talks with the patient's parent or legal guardian.

This request was not adopted because of concerns that removal of the phrase in question could allow for examination via questionnaire, a historical problem with telemedicine regulation.

5. Section (G) requires informed consent to include the patient's signed authorization. This could be difficult in some situations.

   Language indicating that the physician must document the patient's agreement was added to the rule.

- ✓ Bill Ryan, President and CEO for The Center for Health Affairs, expressed concern that the draft rule requires the physician to meet the same standards in a remote examination as if the care was provided in a face-to-face visit and this could mean less access to remote examinations and prescribing for patients.

  The Medical Board did not modify the proposed language because Section 4731.74, Ohio Revised Code, requires that the remote examinations meet the minimal standards of care for in-person care.

- ✓ John Jesser, President of LiveHealth Online, Vice President, Provider Engagement Strategy for Anthem BlueCross BlueShield, recommended adding more definition to the word's "colleague" and "cross-coverage" and suggested changes to paragraph (C)(3) to remove the requirement that the patient must consent to forward the record.

  The patient consent issue is addressed in paragraph (C)(3) of the rule.

- ✓ Kofi Jones, Vice-President of Government Affairs for American Well, suggested changes to paragraph (C)(3) to address that the patient's consent to forward the medical record should be obtained when clinically appropriate and the means exist. She also suggested adding clear definitions of the required elements of an on-call or cross-coverage arrangement between health care providers.

  The patient consent issue was addressed as discussed in the Teladoc comment discussion in this BIA. The Medical Board believes the definition of "cross-coverage" contained in Rule 4731-11-01(C), together with the definition of "active patient" as defined in Rule 4731-11-01(D), provides a sufficient definition of "cross coverage" that is consistent with federal law.

- ✓ Stephen Kleinman, an attorney representing a pediatric facility, stated that the pediatric facility is looking for an exception to prescribe prophylactically to family members when a child is diagnosed with an infectious disease.

  This appears to be very similar to the Expedited Partner Therapy discussed above. If there is a statutory provision allowing for the prophylactic prescribing of antibiotics, then paragraph (H) of the rule would provide an exception to the rule, as discussed above. Mr. Kleinman was advised that statutory authorization may be the best route for his client.

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?**

   As to the use of "store and forward" technology for the purpose of sending pictures of rashes and other skin conditions to a remote physician, the Medical Board sought the input of recognized experts in the use of the technology. As discussed in paragraphs 8, above, the advice was that the technology should only be allowable when one physician is consulting with another and not for direct access by patients. The advice from these experts was affirmed by a study conducted of telemedicine's use of the store and forward technology available directly to patients. See "Choice, Transparency, Coordination, and Quality Among Direct-to-Consumer Telemedicine Websites and Apps Treating Skin Disease," Resneck, Abrouk, Steuer, Tam, Yen, Lee, Kovarik, and Edison; *JAMA Dermatology*, published online May 15, 2016, http://archderm.jamanetwork.com/article.aspx?articleid=2522336.

   The Medical Board also reviewed the laws and rules of other states related to telemedicine prescribing.

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?**

    The alternative regulation proposed were amended to the current proposal based upon the enactment of Section 4731.74, Ohio Revised Code, and interested party comments during the rule-drafting steps.

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 proposed rule is performance-based in that it sets standards while allowing discretion in the process used for meeting the standards.

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

    The Medical Board is the only agency authorized to promulgate rules regulating physician practice. In addition, Section 4731.74, Ohio Revised Code, expressly requires the Medical Board to promulgate the rule

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 Medical Board will distribute the rule to all licensed physicians, all individuals and organizations that provided input during the rule-making stages, and all individuals and organizations who receive notice of rule-making activities. Should there be a time when a physician is charged with violation of the rule by not practicing within the minimal standards of care, an expert witness will testify as to the minimal standard of care applicable to the situation in question.

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 impacted business community includes physicians who wish to provide medical services via telemedicine, health systems who have physicians (whether employed or independent contractor) deliver medical services via telemedicine, telemedicine companies, and insurance companies and employers who wish to offer telemedicine services to their customers or employees.

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

       The regulation balances patient convenience with patient safety. The nature of the adverse impact is that physicians will not be able to prescribe non-controlled drugs to persons on whom they have not conducted a physical examination strictly based upon a questionnaire or where one of the situations described in paragraph (D) of the rule does not exist. The rule does provide clarification that the initial physician-patient relationship can be safely established when the

physician and patient are in different locations. The burden of compliance o the physician may include increased time examining a patient and keeping accurate documentation of the examination as well as increased technology costs to achieve an appropriate examination.

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.

The expected adverse impact cannot be quantified in terms of dollars, hours to comply, or other factors. The adverse impact will depend upon the technology chosen to maintain patient records, to interact with the patient, and to examine the patient and other factors that are specific to the medical practice of each telemedicine provider.

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

The rule is required by Section 4731.74, Ohio Revised Code, and echoes the language of the statute.

Regulatory Flexibility

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

There are not exemptions or alternative means of compliance for small businesses. Many physician practices are small businesses. All Ohio patients should receive medical care under the same standards.

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?

There are no requirements for submitted paperwork to the Medical Board.

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

Medical Board staff will be available to answer any questions concerning the rule. If needed, a guidance document will be created, distributed, and posted on the Medical Board's website.

4731-11-01 Definitions.

As used in Chapter 4731-11 of the Administrative Code:

(A) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V pursuant to the provisions of Chapter 3719. of the Revised Code.

(B) "Controlled substance stimulant" means any drug, compound, mixture, preparation, or substance which is classified as a stimulant in controlled substance schedule II, III, or IV listed in section 3719.41 of the Revised Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to section 3719.43 or 3719.44 of the Revised Code.

(C) "Cross-coverage" means an agreement between Ohio-licensed physicians under which one physician covers the established active patients of the other when that physician is not available. This type of agreement includes on-call coverage for after hours and weekends.

(D) For purposes of paragraph(D) of Rule 4731-11-09 of the Administrative Code, "active patient" as that term is used in paragraph (C) of this rule means that within the previous twenty-four months, the physician conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice telemedicine as that term is defined in 21 C.F.R. 1300.04, in effect on March 23, 2017.

(E) "Consult" means a request for treatment in the physical presence of a practitioner as defined in 21 C.F.R. 1300.04, in effect on March 23, 2017.

(~~C~~F) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.

(~~D~~G) "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States food and drug administration (hereinafter, "F.D.A.") approved labeling for the drug, or which the board determines to be accepted as a contraindication.

(~~E~~H) "The board" means the state medical board of Ohio.

(~~F~~I) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.

(~~G~~J) "Physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(~~H~~K) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(1) Subspecialty board certification in addiction psychiatry from the American board of psychiatry and neurology;

(2) Board certification in addiction medicine from the American board of addiction medicine;

(3) Certification from the American society of addiction medicine; or

(4) Board certification with additional qualification in addiction medicine from the American osteopathic association.

(~~I~~L) "Office based opioid treatment", or "OBOT", means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.

(~~J~~M) "Opioid treatment program", or "OTP", sometimes referred to as a "methadone clinic", means a program licensed by the state to administer or dispense schedule II controlled substance narcotics in the maintenance or detoxification treatment of opioid addiction.

4731-11-09 **Prescribing to persons not seen by the physician TO BE RESCINDED.**

(A) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

(B) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any dangerous drug which is not a controlled substance to a person who the physician has never personally physically examined and diagnosed, except in accordance with one of the following requirements:

(1) The physician is providing care in compliance with both of the following:

(a) The care provided is in consultation with another physician who:

(i) Has an ongoing professional relationship with the patient; and

(ii) Has agreed to supervise the patient's use of the drug or drugs to be provided.

(b) The care provided meets all applicable standards of care and all applicable statutory and regulatory requirements.

(2) The psychiatrist is providing telepsychiatry to one patient per session who is located at the Ohio office of an Ohio licensed physician or a community mental health clinic certified by the Ohio department of mental health, and all of the following requirements are met:

(a) The psychiatrist has reviewed records from a physical examination of the patient that was conducted by a physician licensed under Chapter 4731. of the Revised Code within a reasonable period of time prior to the telepsychiatry visit;

(b) A licensed healthcare professional is available during the telepsychiatry visit to provide various physical findings in accordance with the

licensed healthcare professional's scope of practice that the psychiatrist may need to complete an adequate assessment;

(c) The psychiatrist agrees to do both of the following:

(i) Be available to consult with another physician who has an ongoing professional relationship with the patient; and

(ii) Supervise the patient's use of the drug or drugs prvided;

(d) The psychiatrist's care of the patient meets all applicable standards of care and all applicable statutory and regulatory requirements.

(C) A physician shall not advertise or offer, or permit the physician's name or certificate to be used in an advertisement or offer, to provide any dangerous drug in a manner that would violate paragraph (A) or paragraph (B) of this rule.

(D) Paragraphs (A) and (B) of this rule do not apply to or prohibit the provision of drugs to a person who is admitted as an inpatient to or is a resident of an institutional facility. For purposes of this rule, "institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code. This paragraph does not authorize or legitimize practices that would violate other applicable standards or legal requirements.

(E) Paragraphs (A) and (B) of this rule do not apply to or prohibit:

(1) The provision of controlled substances or dangerous drugs by a physician to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on call or cross coverage arrangement between the physicians;

(2) The provision of controlled substances or dangerous drugs by a physician to a person who the physician has accepted as a patient, if the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment;

(3) The provision of controlled substances or dangerous drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals, in accordance with protocols approved by the state board of pharmacy pursuant to rule 4729-5-01 of the Administrative Code; or

(4) The provision of controlled substances or dangerous drugs by a nurse practicing in accordance with a standard care arrangement that meets the requirements of Chapter 4723. of the Revised Code and rules promulgated by the board of nursing pursuant thereto.

(5) The provision of controlled substances or dangerous drugs by a physician who is a medical director or hospice physician of a hospice program licensed pursuant to Chapter 3712. of the Revised Code, to a patient who is enrolled in that hospice program.

This paragragh does not authorize or legitimize practices that would violate other applicable standards or legal requirements.

(F) For purposes of this rule, "controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(G) For purposes of this rule, "dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(H) A violation of any provision of this rule, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(I) For purposes of this rule:

(1) "Licensed healthcare professional" means any of the following:

(a) An individual licensed under Chapter 4731. of the Revised Code to practice allopathic medicine and surgery or osteopathic medicine and surgery;

(b) A physician assistant licensed under Chapter 4730. of the Revised Code who is practicing in compliance with all applicable statutory and rule requirements; and

(c) A nurse licensed under Chapter 4723. of the Revised Code who is practicing in compliance with all applicable statutory and rule requirements.

(2) "Psychiatrist" means an individual licensed under Chapter 4731. of the Revised Code to practice allopathic medicine and surgery or osteopathic medicine and surgery who has successfully completed an approved psychiatry training program, as specified in the accreditation requirements that must be met to qualify as graduate medical education under section 4731.091 of the Revised Code.

(3) "Telepsychiatry" means the provision of psychiatric care via real-time, adequate resolution audio and video telecommunications when all of the following requirements are met:

(a) Videoconferencing picture resolution, at a minimum, shall have a data rate of 30 frames per second (fps), with each frame containing 288 lines and 352 pixels per line.

(b) Systems shall have a minimum of 384 kilobytes per second (Kbps) of bandwidth, and the provider site shall have the capacity to zoom and to follow the patient at the remote site.

4731-11-09 **Prescribing to persons not seen by the physician.**

(A) Except as provided in paragrah (D) of this rule, a physician shall not prescribe, dispense, otherwise provide, or cause to be provided, any controlled substance to a person on whom the physician has never conducted a physical examination.

(B) Except as provided in paragraph (C) of this rule, a physician shall not prescribe, dispense, otherwise provide, or cause to be provided, any prescription drug that is not a controlled substance to a person on whom the physician has never conducted a physical examination.

(C) A physician may prescribe, dispense, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a person on whom a physician has never conducted a physical examination and who is at a location remote from the physician when the physician complies with all of the requirements of this paragraph.

(1) The physician shall establish the patient's identity and physical location;

(2) The physician shall obtain the patient's informed consent for treatment through a remote examination;

(3) The physician shall request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other health care provider, if applicable, or to refer the patient to an appropriate health care provider or health care facility;

(4) The physician shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care;

(5) The physician shall establish or confirm, as applicable, a diagnosis and treatment plan, which includes documenation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;

(6) The physician shall document in the patient's medical record the pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;

(7) The physician shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;

(8) The physician shall make the medical record of the visit available to the patient;

(9) The physician shall use appropriate technology that is sufficient for the physician to conduct all steps in this paragraph as if the medical evaluation occurred in an in-person visit.

(D) A physician may prescribe, dispense, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person on whom the physician has not conducted a physical examination and who is at a location remote from the physician so long as the physician meets all steps in paragraph (C) and one of the following situations exists:

(1) The person is an active patient, as that term is defined in paragraph (D) of rule 4731-11-01 of the Administrative Code, of a health care provider who is a colleague of the physician and the drugs are provided pursuant to an on call or cross coverage arrangement between the health care providers;

(2) The physician is engaged in the practice of telemedicine as that term is defined in 21 C.F.R. 1300.04, in effect as of March 23, 2017.

(3) The person has been admitted as an inpatient to or is a resident of an institutional facility. For purposes of this rule, "institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code.

(E) Nothing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.

(F) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:

(1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;

(2) "Selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; or

(3) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(G) For purposes of this rule, "informed consent" means a process of communication between a patient and physician discussing the risks and benefits of, and alternatives to, treatment through a remote examination that results in the patient's signed authorization or agreement to be treated through an examination conducted

through appropriate technology when the physician is in a location remote from the patient.

(H) This rule shall not apply to any prescribing situations specifically authorized by the Revised Code.