CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Dental Board

Regulation/Package Title: 2015 – Chapter 6

Rule Number(s): 4715-6-01

Date: December 7, 2015

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- ✓ Rescinded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.

   Rescind and New

   4715-6-01 Standards and procedures for review of Ohio Automated Rx Reporting System (OARRS).: This rule sets forth the guidelines for accessing the Ohio Automated Rx Reporting System by licensed dentists in Ohio. The rule as proposed is to be amended by more than fifty percent and, therefore, the current rule is to be rescinded and the amended language adopted as a new rule. The rule establishes the standards and procedures for a dentist's review of the Ohio Automated Rx Reporting System (OARRS). The amendments reflect the provisions of O.R.C. 4715.302, effective April 1, 2015, and the state policy that

dentists should utilize OARRS information when prescribing controlled substances. The rule incorporates the exceptions contained in O.R.C. 4715.302.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**
   O.R.C. 4715.302 Dentist's review of patient information available through drug database.

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.

   These regulations do not implement a federal requirement nor were they implemented to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program.

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

   This question is not applicable since the regulations do not implement a federal requirement.

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 new Rule 4715-6-01 replaces current Rule 4715-6-01 to implement the authorization granted to the Board in Section 4715.302 of the Revised Code to promulgate rules to establish standards and procedures to be followed by a physician regarding the review of patient information available through OARRS when opioid analgesics or benzodiazepines are prescribed. The amendments also clarify and simplify the current standards for the review of patient information available through OARRS when prescribing controlled substances that are not opioid analgesics or benzodiazepines. The rule facilitates the goals of both the executive agencies and the legislature for wider utilization of OARRS by Ohio physicians in the prescribing of controlled substances in Ohio.

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

   Success will be measured by the increase in the utilization of OARRS by dentists. Statistics on OARRS usage are available to the Board.

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 changes to Rule 4715-6-01 reflect the mandates of Section 4715.302 of the Revised Code, effective April 1, 2015, the need to harmonize the requirements of Section 4715.302 with those in the current version of the rule, and the need to clarify the expectations for dentists who prescribe controlled substances. The Board drafted the language of the proposed rule and worked with the staffs of the medical and nursing boards so that the requirements for each set of licensees would be similar or the same. Additionally, the Board's Law and Rules Review Committee (Committee), holds open meetings throughout the rule review year. The Committee is comprised of eleven (11) members including representatives of the Board, the Ohio Dental Association and the Ohio Dental Hygienists' Association. Additionally, the Board sends public notices and proposed Rule Review agendas to the Board mailing list, a listing of parties interested in all Board proceedings. The Committee met with the opportunity to discuss this rule in May, June, July, September, and October 2015.

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

   The Committee concluded that the QUIP program was working as intended by the legislature and that the only change needed at this time was in statutory reference.

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 Board researched similar programs offered by the State Medical Board of Ohio and the Ohio Board of Nursing and formulated this rule based on that research.

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?**

    No alternative regulations were considered by the agency. The rule was drafted to facilitate the state policy of encouraging use of OARRS, therefore, rule 4715-6-01 that requires the dentist to run an OARRS check when prescribing a controlled substance.

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 rule is performance based to the extent possible. The rule requires the dentist to take into account various factors as part of the decision whether to prescribe a controlled substance that is reported to OARRS, but does not dictate the weight to be attributed to the various factors. While the rule specifies that OARRS must be checked in certain situations, it does not specify whether the dentist must personally check OARRS or might delegate the check to an employee who is properly registered with the Board of Pharmacy. The rule does not

prohibit the prescribing of controlled substances, but instead requires the dentist to document the reasons for the prescribing decision.

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

    The five-year rule review process is conducted with a focus on eliminating obsolete, unnecessary, and redundant rules and avoiding duplication. In addition, the Committee meetings involved interested parties to help ensure that these rules do not duplicate any existing Ohio regulation.

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 Board has had success with issuing guidance documents and will continue to update the guidance documents as necessary.

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;**
       Licensed dentists and employees of licensed dentists who are registered with the Ohio Board of Pharmacy to access the OARRS database.
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
       Adverse impact of the regulation would be in the time and effort for application to become registered and in access/use of the OARRS database.
    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 cost of the adverse impact of the regulation would be in the salary and/or wages of the dentist or employee to register and access OARRS.

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

    In enacting O.R.C. 4715.302, the General Assembly and Governor agreed that the use of OARRS should be mandatory when prescribing opioid analgesics and benzodiazepines. The regulatory intent of the rule justifies the adverse impact because of the state policy to encourage the use of OARRS by dentist who prescribe controlled substances. According to

the Governor's Opioid Action Team website, prescription drugs are involved in most unintentional drug overdoses and have largely driven a rise in overdose deaths. Prescription pain medications (opioids) and multiple drug use are the largest contributors to the epidemic.

Regulatory Flexibility

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

The proposed rules do not provide any exemptions of alternative means of compliance for small businesses. The benefit of checking OARRS in the battle against drug diversion and prescription drug abuse is required of all practices regardless of size.

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?

O.R.C. 4715 does not allow for the implementation of fines or penalties. Therefore, this is not applicable.

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

Resources available to assist small businesses/stakeholders with compliance are the Board's law, rules, and policies, which are available online at the Boards website. Additionally, Board staff regularly respond to inquiries from interested parties.

REVIEW OF OHIO AUTOMATED RX REPORTING SYSTEM

4715-6-01 STANDARDS AND PROCEDURES FOR REVIEW OF OHIO AUTOMATED RX REPORTING SYSTEM (OARRS).

(A) For purposes of this rule and division (A)(13) of section 4715.30 and section 4715.302 of the Revised Code:

(1) "OARRS" means Ohio automated prescription reporting system;

(2) "OARRS report" means a report of information related to a specific patient generated by the drug database established and maintained by the State board of pharmacy pursuant to section 4729.75 of the Revised Code.

(3) "Personally furnishing" does not include the administration of a drug.

(4) "Reported drugs" includes the following:

(a) All controlled substances in scheduled II, III, IV, and V; and

(b) All dangerous drug products containing carisoprodol or tramadol.

(5) "Diversion" includes but is not limited to the following:

(a) Selling drugs;

(b) Borrowing drugs;

(c) Sharing drugs.

(6) "Protracted basis" means for a period in excess of twelve continuous weeks, and for no more than twenty-four weeks over a period of one year.

(B) If a dentist knows or has reason to believe that a patient may be abusing or diverting drugs, the dentist shall use sound clinical judgment in determining whether or not a reported drug should be prescribed or personally furnished to the patient under the circumstances. To assist in this determination, the dentist shall consider whether to access OARRS and document receipt and assessment of the information received if the patient exhibits signs of drug abuse or diversion. These signs may include, but are not limited to, the following:

(1) Engaging in or has a history of drug related criminal activity;

(2) Is receiving reported drugs from multiple prescribers;

(3) Has family members, friends, law enforcement officers, or health care professionals express concern related to the patient's use of illegal or reported drug;

(4) Has a known history of chemical abuse or dependency;

(5) Is requesting reported drugs by street name, color, or identifying marks;

(6) Frequently requesting early refills of reported drugs;

(7) Frequently losing prescriptions for reported drugs.

(C) Following review of OARRS report information, the dentist shall document receipt of the information in the patient's record.

(D) A dentist licensed under this chapter who prescribes or personally furnishes reported drugs to treat a patient on a protracted basis shall, at a minimum, document receipt and assessment of an OARRS report in the following circumstances:

(1) Once the dentist has reason to believe that treatment will be required on a protracted basis;

(2) At least once annually thereafter.

(E) In requesting OARRS reports according to this rule:

~~(1) Reports requested should cover a time period of at least one year;~~

~~(2) In the event an OARRS report is not immediately available prior to writing a prescription for, or personally furnishing, a reported drug, the dentist shall document in the patient record why the OARRS report was not available.~~

~~(F) Paragraph (D) of this rule does not apply to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code.~~

~~*Effective: 01/10/2012*~~

4715-6-01 STANDARDS AND PROCEDURES FOR REVIEW OF "OHIO AUTOMATED RX REPORTING SYSTEM" (OARRS).

(A) Definitions: for purposes of this rule:

(1) "Delegate" means an authorized representative who is registered with the Ohio board of pharmacy to obtain an OARRS report on behalf of a dentist;

(2) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(3) "OARRS report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(4) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. Personally furnish does not include the administration of a drug, as set forth in 4715-3-01(B)(1) of the Administrative Code.

(5) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including controlled substances in schedules II, III, IV, and V.

(B) Standards of care: the accepted and prevailing minimal standards of care require that when prescribing or personally furnishing a reported drug, a dentist shall take into account all of the following:

(1) The potential for abuse of the reported drug;

(2) The possibility that use of the reported drug may lead to dependence;

(3) The possibility the patient will obtain the reported drug for a nontherapeutic use or distribute it to other persons; and

(4) The potential existence of an illicit market for the reported drug.

(5) In considering whether a prescription for or the personally furnishing of a reported drug is appropriate for the patient, the dentist shall use sound clinical judgment and obtain and review an OARRS report consistent with the provisions of this rule.

(C) OARRS Review: a dentist shall obtain and review an OARRS report to help determine if it is appropriate to prescribe or personally furnish an opioid analgesic, benzodiazepine, or reported drug to a patient as provided in this paragraph and paragraph (F) of this rule:

(1) A dentist shall obtain and review an OARRS report before prescribing or personally furnishing an opiate analgesic or benzodiazepine to a patient, unless an exception listed in paragraph (G) of this rule is applicable.

(2) A dentist shall obtain and review an OARRS report when a patient's course of treatment with a reported drug other than an opioid analgesic or benzodiazepine has lasted more than ninety days, unless an exception listed in paragraph (G) of this rule is applicable.

(3) A dentist shall obtain and review an OARRS report when any of the following red flags pertain to the patient:

(a) Selling prescription drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Suffering an overdose, intentional or unintentional;

(f) Having a drug screen result that is inconsistent with the treatment plan or

(g) Having been arrested, convicted, or received diversion or intervention in lieu of conviction for a drug related offense while under the dentist's care;

(h) Receiving reported drugs from multiple prescribers, without clinical basis;

(i) Traveling with a group of other patients to the dentist's office where all or most of the patients request controlled substance prescriptions;

(j) Traveling an extended distance or from out of state to the dentist's office;

(k) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs;

(l) A known history of chemical abuse or dependency;

(m) Appearing impaired or overly sedated during an office visit or exam;

(n) Requesting reported drugs by street name, color, or identifying marks;

(o) Frequently requesting early refills of reported drugs;

(p) Frequently losing prescriptions for reported drugs;

(q) A history of illegal drug use;

(r) Sharing reported drugs with another person; or

(s) Recurring visits to non-coordinated sites of care, such as emergency departments, urgent care facilities, or walk-in clinics to obtain reported drugs.

(D) Patient Care Documentation: a dentist who decides to utilize an opioid analgesic, benzodiazepine, or other reported drug in any of the circumstances within paragraphs (C)(2) and (C)(3) of this rule, shall take the following steps prior to issuing a prescription for or personally furnishing the opioid analgesic, benzodiazepine, or other reported drug:

(1) Review and document in the patient record the reasons why the dentist believes or has reason to believe that the patient may be abusing or diverting drugs;

(2) Review and document in the patient's record the patient's progress toward treatment objectives over the course of treatment;

(3) Review and document in the patient record the functional status of the patient, including activities for daily living, adverse effects, analgesia, and aberrant behavior over the course of treatment;

(4) Consider using a patient treatment agreement including more frequent and periodic reviews of OARRS reports and that may also include more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription or personally furnishing of reported drugs, and consequences for non-compliance with the terms of the agreement. The patient treatment agreement shall be maintained as part of the patient record; and

(5) Consider consulting with or referring the patient to a substance abuse specialist.

(E) Follow-up OARRS Reports; Frequency:

(1) For a patient whose treatment with an opioid analgesic or benzodiazepine lasts more than ninety days, a dentist shall obtain and review and OARRS report for the patient at least every ninety days during the course of treatment, unless an exception listed in paragraph (G) of this rule is applicable.

(2) For a patient who is treated with a reported drug other than an opioid analgesic or benzodiazepine for a period lasting more than ninety days, the dentist shall obtain and review and OARRS report for the patient at least annually following the initial OARRS report obtained and reviewed pursuant to paragraph (C)(2) of this rule until the course of treatment utilizing the reported drug has ended, unless an exception in paragraph (G) is applicable.

(F) OARRS Reports; Time Periods; Adjoining States: for purposes of paragraphs (C), (D) and (E) of this rule, when a dentist or their delegate requests an OARRS report in compliance with this rule, a dentist shall review and document receipt of the OARRS report in the patient record, as follows:

(1) Initial reports requested shall cover at least the twelve months immediately preceding the date of the request;

(2) Subsequent reports requested shall, at a minimum, cover the period from the date of the last report to present;

(3) If the dentist practices primarily in a county of this state that adjoins another state, the dentist or their delegate shall also request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county; and

(4) If an OARRS report regarding the patient is not available, the dentist shall document in the patient's record the reason that the report is not available and any efforts made in follow-up to obtain the requested information.

(G) Exceptions: a dentist shall not be required to review and assess an OARRS report when prescribing or personally furnishing an opioid analgesic, benzodiazepine, or other reported drug under the following circumstances, unless the dentist believes or has reason to believe that a patient may be abusing or diverting reported drugs:

(1) The reported drug is prescribed or personally furnished to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code, or any other patient diagnosed as terminally ill;

(2) The reported drug is prescribed for administration in a hospital, nursing home, or residential care facility;

(3) The reported drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days;

(4) The reported drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer; and

(5) The reported drug is prescribed or personally furnished to treat acute pain resulting from a surgical or other invasive procedure or a delivery.