CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: **Ohio State Board of Optometry**

Regulation/Package Title: **5-Year Rule Review – Rules being amended**

Rule Number(s): **4725-1-01, 4725-5-01, 4725-15-01, 4725-15-06, 4725-16-04**

Date: **8/15/13**

Rule Type:

X New | **X 5-Year Review**

X Amended | **X Rescinded**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.**
   Basically, the above listed rules are being updated with very minor changes or being rescinded since they are no longer necessary.
   4725-1-01 – adding the wording "or by electronic means" so that email can be used to save the cost of postage for mailing.
   4725-5-01 – changing the word "surgeon" to "licensed physician" for consistency in the wording of this rule.
   4725-15-01 – Rescinding rule since it is no longer applicable.
   4725-15-06 - Rescinding rule since it is no longer applicable.
   4725-16-04 – Standards for OARRS (new)

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

   Ohio Revised Code (ORC) Section 4725.09 is the statutory authority for Ohio Administrative Code rules stating, "(A) The state board of optometry shall adopt rules as it considers necessary to govern the practice of optometry and to administer and enforce sections 4725.01 to 4725.34 of the Revised Code. All rules adopted under those sections shall be adopted in accordance with Chapter 119. 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?**
   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 listed rules are necessary to ensure safety to the public and acceptable business practices for all licensees. The two rules being rescinded (4725-15-01 and 4725-15-06) are no longer necessary due to neither being applicable any longer. The regulations being amended are required by the Ohio Revised Code and they allow the Board to consistently interpret the laws and rules providing the citizens of Ohio uniformity in these matters. The new rule, 4725-16-04 is required because House Bill 93 of the 129th General Assembly directed the Optometry Board to adopt a rule on the use of the Ohio Automated Rx Reporting System (OARRS).

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

   Success will be measured by licensee's compliance to the administrative rules.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   Those reviewing the listed rules for the 5-Year Rule Review including; 6 Board Members, which include 5 licensed optometrists and 1 public member, the Ohio Optometric Association, the Ohio State University College of Optometry, our assigned Assistant Attorney General, the Executive Director of the Board and our Program Administrator 2.

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

   An email was forwarded to the above listed stakeholders for an early review requesting comments. The Stakeholders contacted had no changes or comments to date to the proposed amendments, rescissions or the new rule proposed.

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?**

   N/A

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?**

    Upon review of this chapter, the agency assessed the relevancy of the rules, the appropriateness of the rules, and critically reviewed for any needed changes. The changes proposed do not change any meaning to that specific rule.

11. **Did the Agency specifically consider a performance-based regulation? Please explain.**
    N/A

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

    The Board reached out to Cameron McNamee, of the Ohio State Board of Pharmacy, regarding the language in the new rule OAC 4725-16-04. Mr. McNamee suggested adding "Other non-controlled dangerous drug products as listed in rule 4729-37-02 of the Administrative Code in the definitions as (A)(5)(b)" to the rule to avoid having to update the rule in the future. Mr. McNamee suggested the added wording to avoid having to update the rule in the future. I added the language to the rule as directed. Mr. McNamee also suggested removing the word "Carisoprodol" from Section (A)(5)(b) of this rule, "since it is already a schedule IV substance. It was recently reclassified by the DEA so no need to put it into your rule." This was also corrected per his direction.

    The rule was updated under Section (A)(5) with:

    <u>(a) Controlled substances in schedules II, III, IV, and V, and</u>

    <u>(b) All dangerous drug products containing tramadol.</u>

    <u>(c) **Other non-controlled dangerous drug products as listed in rule 4729-37-02 of the Administrative Code in the definitions as (A)(5)(b).**</u>

    Mr. McNamee reviewed the additional language and approved it for 4725-16-04.

Chapter 4725 does not duplicate any other existing Ohio regulations.

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 Members and Board Staff will continue to apply the listed rules fair and consistently, when confronted with a situation that would apply to that specific rule.

Adverse Impact to Business

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

There is no cost associated with the compliance of the listed rules.

a. **Identify the scope of the impacted business community;**
   The impacted business community includes over 2100 Ohio licensed optometrists and the professional and/or general corporations who offer services through authorized business entity.
b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);**
   The adverse impact for non-compliance by an Ohio licensed optometrist could result in license suspension, fines or other discipline deemed necessary by the Board.
c. **Quantify the expected adverse impact from the regulation.**
   There is no adverse impact to be quantified regarding the proposed minor changes and rescissions.

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

The two rules with minor amendments (4725-1-01 and 4725-5-01) have been in place for many years and their regulatory intent justifies the adverse impact to the regulated business community in a fair and consistent manner. By adding the wording "or by electronic means" to 4725-1-01, it is a cost-savings measure and has no adverse impact to the regulated business community. The change to 4725-5-01, changing the word "surgeon" to "licensed physician" is only to make the rule read uniformly and does not create any adverse impact to the regulated business community. The new rule, 4725-16-04 is required by legislation.

Regulatory Flexibility

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

The listed rules provide optometrist with the direction necessary to prevent them from violating our laws.

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?**

    The proposed rule changes do not necessarily impose fines or penalties. The Board generally applies the ORC section 119.14 waiver provision to all optometric programs, including those that meet the definition of "small business" as defined in paragraph (G)(1) of that section.

    The Board reviews any complaint or offense on a case-by-case basis and each is investigated fairly and consistently.

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

    The Board staff is always available to respond to inquiries without hesitation.

TO: Jeff Greene, Ohio State Board of Optometry

FROM: Paula Steele, Regulatory Policy Advocate

DATE: December 31, 2013

RE: CSI Review – Five-Year Review (OAC 4725-1-01, 4725-5-01, 4725-15-01, 4725-15-06 and 4725-16-04)

On behalf of Lt. Governor Mary Taylor, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis. This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This Ohio State Board of Optometry (Board) rule package contains five rules – two amended, two rescinded, and one new rule – submitted as a five-year rule review as required by ORC 119.032.

The amendments to the existing rules are minor and address public notices, and solicitors and agents. The *Solicitor, Agent, etc*. rule 4725-5-01, includes provisions which prohibit paying for or receiving anything of value for referrals. In addition, the rule articulates patient co-management requirements between a licensed physician and an optometrist.

According to the BIA submitted by the Board, the rescinded rules address outdated pharmacology education, and a certification to administer topical ocular pharmaceutical agents. The rescission of these rules will eliminate the adverse impacts contained within which include pharmacology examination requirements and fees for certification.

The new rule, OAC 4725-16-04, is intended to comply with ORC 4725.092, which was enacted in 2011 and requires the Board to establish standards and procedures for optometrists who hold a therapeutic pharmaceutical agent certificate regarding the review of patient information available through the drug database known as Ohio Automated Rx Reporting System (OARRS).

The BIA submitted by the Board states that these rules do not duplicate any other existing regulations, despite the fact that OARRS is maintained by the Ohio State Board of Pharmacy. Upon review of the BIA and the proposed rules, the CSI Office determined that the Optometry Board had not reach out to the Pharmacy Board for input on the new rule. The CSI Office reached out to Pharmacy Board staff who confirmed the proposed rule was accurate and did not conflict with Pharmacy Board rules. However, the Pharmacy Board suggested an addition to the rule language as new substances will require reporting in OARRS effective in 2014.

The BIA acknowledged that the lack of compliance with the proposed rules could lead to the loss of licensure. No other adverse impacts were identified and there were no comments submitted during the review period to suggest that the proposed rules were unduly burdensome. Therefore the CSI Office believes that the adverse impacts of the proposed rules are justified.

Recommendations

1. The Board should reach out to the Pharmacy Board to ensure the following suggested language is appropriate to include in the new rule OAC 4725-16-04: "Other non-controlled dangerous drug products as listed in rule 4729-37-02 of the Administrative Code" in the definitions as (A)(5)(b).

2. For future rule packages, the Board should more fully consider potential overlap with other regulating entities as it answers the BIA question, "What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?" This question is intended to help ensure that potential duplication, conflict, or inconsistencies in regulation – such as the one described in Recommendation #1 – are avoided.

Conclusion

Based on the above comments, the CSI Office concludes that the Board should not file the proposed rules with JCARR until it has consulted with the Pharmacy Board as described in Recommendation #1 above and made the appropriate amendments to the proposed rule pertaining to OARRS.

cc: Mark Hamlin, Lt. Governor's Office

State of Ohio - Ohio State Board of Optometry

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January 8, 2014

Paula Steele

Regulatory Policy Advocate

CSI – Ohio

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RE: Package 1 - Five-Year Review (OAC 4725-5-02 through 06, 4725-5-08 through 15, 4725-7-03 through 05)

Package 2 – Five-Year Review (OAC 4725-1-01, 4725-5-01, 4725-15-01, -06, and 4725-16-04)

Dear Ms. Steele,

This correspondence is to acknowledge receipt of your CSI memos of December 31, 2013, and January 6, 2014.

Based on your recommendation, the Board will proceed with the formal filing of Package 1 with the Joint Committee on Agency Rule Review.

In regards to your recommendation for Package 2, the Board reached out to Cameron McNamee, of the Ohio State Board of Pharmacy, regarding the language CSI suggested in the new rule OAC 4725-16-04, "Other non-controlled dangerous drug products as listed in rule 4729-37-02 of the Administrative Code in the definitions as (A)(5)(b)". Mr. McNamee suggested the added wording to avoid having to update the rule in the future. I added the language to the rule as directed.

Mr. McNamee also suggested removing the word “Carisoprodol” from Section (A)(5)(b) of this rule, “since it is already a schedule IV substance. It was recently reclassified by the DEA so no need to put it into your rule.” This was also corrected per his direction.

In the future, the Board will more fully consider potential overlap with other regulating entities when answering the question in the BIA which asks; “What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?”

Attached is an updated copy of the proposed new rule 4725-16-04 with the added language and an updated BIA for Package 2.

The Board will proceed with the formal filing of Package 2 with the Joint Committee on Agency Rule Review after completing CSI’s recommendation.

Thank you for your review of the Board’s rule packages. If you have any additional comments or questions, please do not hesitate to contact me.

Sincerely,

Jeffrey W. Greene

Executive Director

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