



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Nursing

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Board Organization & Records, Definitions, Continuing Education, Pre-licensure Nursing Education, and Nurse Licensure Compact Fees

Rule Number(s): 4723-1-01, 4723-1-02, 4723-1-03, 4723-1-04, 4723-1-05, 4723-1-06, 4723-1-07, 4723-1-08, 4723-1-09, 4723-1-10, 4723-1-11; 4723-3-01, 4723-3-02; 4723-14-01, 4723-14-03, 4723-14-04, 4723-14-05, 4723-14-06, 4723-14-07, 4723-14-08, 4723-14-09, 4723-14-10, 4723-14-11, 4723-14-12, 4723-14-13, 4723-14-14, 4723-14-15, 4723-14-16, 4723-14-17, 4723-14-18; 4723-5-04, 4723-5-23; 4723-11-02

Date of Submission for CSI Review: September 15, 2022

Public Comment Period End Date: September 23, 2022

Rule Type/Number of Rules:

New/ 1 rule

No Change/ 17 rules (FYR? 17)

Amended/ 15 rules (FYR? 13)

Rescinded/ 0 rules (FYR? 0)

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The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

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

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

See attached tracked rules and overview as to each rule here:

Chapter 4723-1 Board Organization and Records. Five Year Review.

This chapter addresses the board's organization and governance requirements including election of officers and a supervising member for disciplinary matters, as well as board documents and forms, and board records including records to be maintained by the board, authorization to access records and confidential information. It also addresses incorporated materials and notice of board meetings and notices required related to intended rulemaking.

4723-1-01 Board organization. No change.

4723-1-02 Personnel. No change.

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4723-1-03 Board records and documents. AMEND. *Amend (B) and delete (G)(35) because name change requests are now completed electronically through eLicense. Amend (G)(24), (25), (33), and (36)-(53) to reflect new dates on referenced forms and new numbering due to amendments.*

4723-1-04 Fees. No change.

4723-1-05 Notice of adoption, amendment, or rescission of rules. No change.

4723-1-06 Notice of board meetings. No change.

4723-1-07 Personal information system definitions. No change.

4723-1-08 Procedures for accessing confidential personal information. No change.

4723-1-09 Valid reasons for accessing confidential personal information. AMEND. *In (B)(4), delete “certificate of authority” and “certificate of prescriptive authority” as these terms are no longer in use.*

4723-1-10 Confidentiality statutes, regulations, and rules. AMEND. *In (C), delete “certificate of authority” as this term is no longer in use.*

4723-1-11 Restricting and logging access to confidential personal information in computerized personal information systems. No change.

Chapter 4723-3 Definitions. Five Year Review.

This chapter defines certain terms used throughout the rules.

4723-3-01 Definitions. No change.

4723-3-02 Definition of mental or physical impairment or disability. AMEND. *Revise to align with Sections 4723.28(B)(9)(10) and (11), Ohio Revised Code, which reference both nursing care and dialysis care.*

Chapter 4723-14 Continuing Education. Five Year Review.

This chapter establishes CE requirements for individual renewal applicants and other applicants (licensure reinstatement, licensure by endorsement). It also establishes requirements for CE approvers and providers.

4723-14-01 Definitions. AMEND.

In (D) add reference to enduring materials.

In (E), delete OBN, because OBN does not approve provider units.

Amend (F), (G), and (H), to conform language to that used by national entities.

Amend (I) to allow rounding to nearest quarter hour.

Amend (J)(3) to define enduring continuing education activity.

Renumber (J)(3) and (J)(4) due to amendment of (J)(3).

Amend (K) to correct typographical error.

Delete (O) because the term is not utilized in the rules.

Renumber (P)-(U) due to deletion of (O).

Delete (V) because the term is not utilized in the rules.

Renumber (W) due to deletion of (V).

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4723-14-03 Continuing education requirement for licensed practical and registered nurses. AMEND. *Delete (E)(2)(b)-(e). Move content of (E)(2)(a) into (E), allowing the applicant to select content of required CE hours, other than the two hours of category A. In (K)(2), correct typographical error.*

4723-14-04 Determining the continuing education credit. AMEND. *In (A), delete "which is sixty minutes" consistent with recommended amendment of 4723-14-01(I).*

4723-14-05 Educational activities that do and do not meet the continuing education requirement. AMEND. Amend (A)(5), (8), and (8)(b) to add references to "enduring continuing education activities" to clarify they are distinct from independent study continuing education activities. Add (A)(10) to reiterate the licensee's responsibility to retain proof of completion of continuing education to submit to the Board if audited or upon request. In (B)(2), add a reference to enduring activity.

4723-14-06 Proof of completion of continuing education. No change.

4723-14-07 Continuing education audit. No change.

4723-14-08 General requirements for an Ohio board of nursing (OBN) approver. No change.

4723-14-09 Process to obtain initial approval as an OBN approver. No change.

4723-14-10 Re-approval of an OBN approver. No change.

4723-14-11 Termination of OBN approver status. No change.

4723-14-12 OBN approver processes and statements. AMEND. In (A)(5), add a reference to enduring continuing education activity. Amend (A)(9), to conform language to that used by national entities. Amend (A)(11), to conform language to that used by national entities. Delete (C), to remove requirement for organizational chart; essential content is required elsewhere. Renumber (D), due to deletion of (C).

4723-14-13 Reports to the board by an OBN approver. AMEND. Amend (A) to clarify information required to be reported to the Board.

4723-14-14 Approval of a continuing education provider or approved provider unit. AMEND. In (A)(5), add a reference to enduring activity. In (F), change "pending" to "not yet determined" to clarify that whether the course will be approved has not been determined.

4723-14-15 Approval of a faculty-directed continuing education activity. AMEND. Amend title, and (A), (F), and (G) to clarify the distinction between independent study continuing education activities and others. Amend (A)(9) to conform language to that used by national entities. Add (A)(13) to require applications to include method used to determine number of contact hours to be awarded. In (B)(2), change "pending" to "not yet determined" to clarify this means whether the

course will be approved has not been determined.

In (D)(4), no longer require that a summary evaluation be maintained for each date the continuing education activity is offered.

4723-14-16 Approval of an independent study continuing education activity. No change.

4723-14-17 Approval of the continuing education system of a provider unit. AMEND. Delete typographical errors, (A)(5)(f)(i) and (ii), numbers without content.

Amend (A)(5)(g) to conform language to that used by national entities.

Amend (C)(2) to specify that the term key personnel includes both the registered nurse responsible for the planning and implementation of continuing education activities and the primary contact for the provider.

In (E)(2)(a), delete faculty directed.

4723-14-18 Voluntary termination of approval activities. No change.

Rules 4723-5-23 and 4723-5-04. Amendment.

Chapter 4723-5 addresses Board regulation of prelicensure nursing education programs. Every program is either on Conditional approval (every new program begins on conditional approval), Full approval, or Provisional approval. Currently, the Board is required to change a program's approval status from Full to Provisional if a program experiences four consecutive years of NCLEX (National Council Licensure Examination) scores that fall below an established benchmark.

Rule 4723-5-04 Procedure for board determination of a program's status. AMEND. *Change the reference in 4723-5-04(E)(4) from 4723-5-23(B)(4) to 4723-5-23(B). This is a technical change required by the recommended amendment of 4723-5-23(B), below.*

Rule 4723-5-23 Program NCLEX rates. AMEND. *Add paragraph (B)(5) to provide the Board discretion to refrain from changing a prelicensure nursing education program's approval status from Full to Provisional, during, or during a relevant time period following, a declared state or federal emergency, or a state or local disaster. The current rule requires the Board to change the approval status from Full to Provisional following four consecutive years of low NCLEX scores.*

Rule 4723-11-02, Multistate license to practice nursing; fee. New Rule.

Through Section 4723.11, ORC, the Nurse Licensure Compact was enacted into law effective January 1, 2023. Section 4723.112, ORC, *Multistate license to practice nursing; fee*, does not establish a fee for issuance of the multistate license but instead says in part, "The board of nursing may charge a fee in excess of the traditional license fee for issuance of a multistate license. The board shall not pass along to a traditional license applicant or holder any costs associated with entering into or administering the "Nurse Licensure Compact" under section 4723.11 of the Revised Code."

Rule 4723-11-02 Fees. NEW. As authorized by Section 4723.112, Ohio Revised Code, this rule establishes fees for multistate licensure consistent with the decision of the Board at its July 2022 Meeting.

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- 3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Ohio Revised Code Sections, 119.03; 121.22; 1347.; 1347.05, 1347.15, 4723., 4723.02, 4723.05, 4723.06, 4723.07, 4723.08, 4723.24, 4723.26, 4723.28, 4723.69, 4723.77, 4723.79, 4723.86, 4723.88, 4723.112, 4723.651, and 4723.652.

- 4. 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, these rules do not implement a federal requirement.

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

There are no federal requirements. The Ohio Board of Nursing is entirely a state-level regulatory program. All associated rules pertain to the authority from the Ohio Revised Code.

- 6. 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 mission of the Board of Nursing is to actively safeguard the health of the public through the effective regulation of nursing care. In this effort, the Board regulates prelicensure nursing education programs, continuing education, licensure, scope and standards of care, and other aspects of nursing regulation through enforcement of Chapter 4723, ORC. The Board adopted the referenced rules and is proposing the tracked changes to effectuate that mission.

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

Board staff interacts with stakeholders and others through public outreach functions, phone and email inquiries, Advisory Groups and Committees, and investigation of complaints filed with the Board. The Board will continue to engage in review of rules, seeking input from staff, stakeholders, and advisory group members, and review of the recommendations of the Advisory Group on Rules.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

N/A.

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Development of the Regulation

9. 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.

At its May 2022 Meeting the Board created its Advisory Group on Rules to review rules and make recommendations to the Board to adopt, amend, or rescind a rule. The Group is comprised of three Board members and two public members. Currently all five members of the Advisory Group are licensees.

On July 21, 2022, the Board sent notice to stakeholders by email, including all licensees and certificate holders (approximately 325,000 individuals), that the Board is conducting the required five-year review of Chapter 1, Board Organization and Records; Chapter 3, Definitions; and Chapter 14, Continuing Education; that the Board is proposing to amend Rule 4723-5-04, Procedure for board determination of a program's status, and Rule 4723-5-23, Program NCLEX rates; and that the Board is proposing to adopt Rule 4723-11-02, NLC Fees. The notice included a link to the rules.

On July 21, 2022, the same email notice was also sent to a list of 108 individuals and entities who have made a written request to receive a copy of any public notice issued by the Board of its intention to adopt, amend, or rescind a rule.

The July 21, 2022, emails requested comments about the referenced rules be sent to the Board by August 3, 2022. Nineteen individuals sent in forty-two comments, including several comments for no change. Comments received in response to the July 21, 2022, notice were summarized and provided, along with staff responses, to the Board's Advisory Group on Rules in advance of its August 12, 2022, meeting to review the rules. The comments received were reviewed by the Advisory Group in advance of its recommendations to the Board.

In addition, the Board received extensive input about Chapter 14 from the Advisory Group on Continuing Education (CE). The Advisory Group on CE is comprised of stakeholders including CE providers and CE approvers. The Advisory Group on CE met virtually on March 31, 2022, and again on June 15, 2022, and reviewed all rules in Chapter 4723-14. The Advisory Group on CE made recommendations as to amendments to Chapter 4723-14. Those recommendations were also shared with the Advisory Groups on Rules for its review at its August 12, 2022, meeting.

The recommendations of the Advisory Group on Rules were then reported to the Board at its September 14-15, 2022, meeting. At that time the Board adopted the recommendations of the Advisory Group on Rules except the recommendation as to

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Rule 4723-1-01. The Board proposes no change to Rule 4723-1-01. All changes proposed by the Board are reflected in the attached tracked rules.

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

Regarding Chapter 4723-14, the vast majority of proposed changes reflected in the attached tracked draft rules originated with members of the Advisory Group on CE which is comprised of stakeholders including CE providers and CE approvers, and recommendation of all changes were agreed upon by the Group. As reflected in item 2., above, many of the proposed changes were proposed to conform Ohio administrative rule language to that used by national organizations that approve and/or provide CE, to distinguish between enduring materials and independent study, or to otherwise clarify the rules. The proposed changes in Rules 4723-5-04, and 4723-5-23, providing the Board discretion to refrain from changing an education program's status from full to provisional, was originally proposed by a Board Member who has experience in prelicensure nursing education administration. Input received from eight stakeholders about Rules 4723-5-04, and 4723-5-23, in response to the July 21, 2022, emails supported the proposed changes to these two rules. Regarding new Rule 4723-11-02, Fees, two writers expressed support for the rule, two requested no fee for conversion of an existing traditional/single state license to a multistate license, and several others asked that license fees not be increased or stated this was not the right time to increase fees. Responses were sent explaining that the proposed rule would not increase any existing fee; that the Board is authorized by Section 4723.112, ORC, to establish fees for the new multistate license; and that the Board is prohibited from passing along costs of implementing the new multistate licensure to single state/traditional licensees and applicants. The comments received were reviewed by the Advisory Group on Rules at its August 12, 2022, meeting, in advance of its recommendations to the Board.

11. 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. The rules and proposed changes are based on the operational experiences regulating and operating the Board for the public health and safety of Ohioans.

12. 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 mission of the Board of Nursing is to actively safeguard the health of the public through the effective regulation of nursing care. In this effort, the Board regulates prelicensure nursing education programs, continuing education, licensure, and scope and standards of practice, among other aspects of nursing care. The Board adopted the referenced rules and is proposing the tracked changes in support of that mission.

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13. 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.

It was not necessary for the Board to consider performance-based regulations for these rules.

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

The mission of the Board of Nursing is to actively safeguard the health of the public through the effective regulation of nursing care. The Board is the only agency that regulates the Ohio professional practice scope and standards of nursing care in Ohio and the only agency that regulates nursing licensure in Ohio.

15. 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 publishes guidance on a variety of topics including, for example, licensure requirements, including required fees; CE requirements; and practice guidance, etc. This guidance is published on the Board website and in Momentum, the Board's quarterly magazine, and is also distributed to targeted groups via email. The Board also publishes a summary of rule changes in Momentum. It also hosts two free workshops each year for prelicensure nursing education program administrators and faculty which includes a full review of law and rule applicable to prelicensure nursing education programs. In addition, Board staff are trained on implementation of new rules as needed to ensure consistent and predictable regulation.

Adverse Impact to Business

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

Chapter 1, 3, no cost or impacted business community identified.

Chapter 14, Continuing Education. While the overall cost of compliance is difficult to quantify, Chapter 14 does include the following costs to identified communities: It requires individual licensees to obtain 24 hours of CE as a requirement of licensure renewal which is required every two years (and a numbers of CE hours for applicants

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seeking reinstatement of a license or seeking licensure by endorsement, see 4723-14-03(C) and (K)). CEs may range in cost from free to variable depending upon the provider and the course(s) selected. They also require licensee or applicant time to complete. Licensees are also required to report compliance with CE requirements on the Board's renewal application, to maintain CE completion records for a period of six years in case of audit, and to produce proof of compliance with CE requirements if audited. Chapter 14 also requires CE approvers and providers to meet certain standards with respect to conflicts of interest, marketing, etc., in order to ensure that CE offered to licensees meets quality standards. It also requires CE providers and approvers to collect, retain and report certain information to the Board to ensure the Board can exercise oversight as needed. In addition, Section 4723.08(A)(11), (12) and (13), ORC, require CE approvers to pay a fee to become a CE approver and a fee to renew CE approver status. The fees themselves, which range from \$150.00 to \$1,000.00, are established by Section 4723.08(A)(11), (12) and (13), ORC.

Rules 4723-5-04, Procedure for board determination of a program's status, and 4723-5-23 Program NCLEX rates. The impacted business community is prelicensure nursing education programs. While the overall cost of compliance is difficult to quantify, the costs of compliance for the affected community include: program time for compliance with reporting requirements, cooperation with a survey visit, and possible change of approval status from full to provisional.

Specifically, Rule 4723-5-23 requires that if a program's graduates experience an NCLEX (national licensure examination) pass rate below the established benchmark (less than 95% of the national average for its first-time candidates who took the exam within six months of program completion, within a calendar year) the following is required: (1) After the first year, the program must submit an action plan to the Board indicating steps to improve the NCLEX scores; (2) After two consecutive years, the program must prepare a report that evaluates the first year action plan and identifies additional steps; (3) After three consecutive years, a representative of the board must conduct a survey visit and the board may take action on the approval status of the program; and (4) After four consecutive years, a representative of the board may conduct a survey visit. In addition, after four consecutive years, the board is *currently required* to place a program that is on full approval status on provisional approval status, or, if the program is on conditional approval status, propose to withdraw conditional approval and deny full approval status following procedures in Chapter 119, ORC. The Board may restore a program to full approval status after it attains a pass rate for at least two consecutive years that meets or exceeds the benchmark.

The proposed change would give the Board discretion, during or following an emergency or disaster, to refrain from placing a program on provisional approval following four consecutive years of low scores.

Rule 4723-11-02, Fees. Pursuant to Section 4723.112, ORC, the Board set fees for individuals to obtain or renew a multistate license.

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

The mission of the Board of Nursing is to actively safeguard the health of the public through the effective regulation of nursing care. The Board regulates nursing care to ensure public safety through enforcement of Chapter 4723, ORC, and enforcement of the rules it has adopted, Chapter 4723, OAC.

Chapter 1 and 3. N/A.

Chapter 14. The rules in Chapter 14 are in place to ensure quality CE is available to licensees to provide them the opportunity to maintain current knowledge of safe nursing care. The adverse impact to businesses, such as CE approvers and providers meeting standards around conflicts of interest, and reporting limited operational information to the Board, is justified by the Board's obligation to approve CE approvers and to ensure that, at minimum, CE processes meet certain standards in order to ensure quality CE is available to licensees.

Rule 4723-5-04, 4723-5-23. The regulatory intent of the current rule is to ensure quality prelicensure nursing education by requiring the Board to change a program's approval status from full to provisional if the program has experienced four consecutive years NCLEX scores that are lower than a benchmark score. Prior to the 4th year, the rule requires programs with low NCLEX scores to submit a plan for improvement and report on implementation of the plan for improvement. Application of the rule ensures the program is aware of its students' collective performance on the NCLEX and has an opportunity to make changes to improve that performance. The proposed amendment provides the Board discretion, during or following an emergency or disaster, to refrain from changing the program's approval status from full to provisional after four consecutive years of low NCLEX scores.

Rule 4723-11-02. Section 4723.11, ORC, requires the Board to implement the National Licensure Compact. Section 4723.112, ORC, prohibits the Board from passing on costs of implementing the NLC/multistate license onto non-multistate licensees and authorizes the Board to establish fees to obtain or renew a multistate license. The Board was provided with information including information about other states' fees, and board staffing and infrastructure considerations prior to establishing the proposed NLC/multistate license fees.

Regulatory Flexibility

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

There are no exemptions or alternative means of compliance for small businesses. Regarding Rules 4723-5-23, the rule has a stepped approach to low NCLEX scores, allowing programs to develop and implement plans for improvement of scores prior to reaching the fourth consecutive year of low scores. Regarding CE Approver applications, Rule 4723-14-09(C), requires Board staff to notify applicants in writing of any additional information required to complete the application.

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19. 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 rules in issue do not impose administrative fines or civil penalties for paperwork violations. Regarding licensure specifically, licensure applications remain open for sufficient time to allow applicants to correct deficiencies to avoid forfeiture of fees paid. Regarding CE Approver applications, Rule 4723-14-09(C), requires Board staff to notify applicants in writing of any additional information required to complete the application. In addition, and more generally, Chapter 4723, ORC, does not require the board to act on minor violations of Chapter 4723, ORC, or the rules adopted under it, if the violations are committed by individuals licensed under Chapter 4723, ORC, and the board determines that the public is adequately protected by issuing a notice or warning to the alleged offender. See Section 4723.061, ORC.

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

Board staff are available to respond to questions about compliance with any Board regulation. Individuals may telephone the Customer Service Center to be routed to the appropriate staff, or may directly email the appropriate unit from the Board home page. Also, in addition to the Advisory Group on Rules, the Board has an Advisory Group on Education, an Advisory Group Community Health Workers, an Advisory Group on Dialysis, and a Committee on Advanced Practice Registered Nursing. Each of these groups meets several times a year and can raise or entertain issues raised by others, and can report recommendations to the Board. Typically, each group is also called upon to review and comment when rules relevant to their charge are up for five-year review. Recommendations and other information from the groups are routinely communicated to the Board through reports and shared minutes.

The Board publishes guidance on a variety of topics including, for example, requirements for licensure, CE requirements, scope and standards of care, nursing education, etc. This guidance is distributed by publication on the Board website; in Momentum, the Board's quarterly magazine; and distributed to targeted groups via email as well. The Board also hosts two free workshops each year for prelicensure nursing education program administrators and faculty which includes a full review of applicable law and rule.