



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Health

Rule Contact Name and Contact Information:

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

Chapter 3701-18 – Nurse Aide Training and Competency Evaluation Programs/ Train the Trainer Programs (“NATCEP/TTT”)

Rule Number(s): 3701-18-01 to 3701-18-27

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/ X rules

No Change/ X rules (FYR? Y)

Amended/ X rules (FYR? Y)

Rescinded/ X rules (FYR? Y)

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.

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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.

Nurse aides in Ohio work in a variety of settings. While the rules are necessarily geared toward nursing homes, state tested nurse aides also work in assisted living, home and community-based settings, hospitals, and other health care facilities. The rules in this package set forth minimum standards for (1) programs to train nurse aides; (2) the testing of nurse aides; (3) the training of trainers of nurse aide instructors; and (4) the testing of trainers of nurse aide instructors to ensure state tested nurse aides entering the workforce, whether in long term care or another capacity, have the same baseline knowledge and skills to help ensure the health and safety of residents and patients in Ohio's health care settings.

In general, the rules have been updated to better align with federal requirements in 42 CFR 483.152. Areas that have changed include:

- Allowing for online classroom instruction;

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- Making the program coordinator an administrative position and shifting the training/work experience requirements to the primary instructor, while continuing to allow a non-facility based NATCEP program coordinator who meets the requirements of a primary instructor to serve as a primary instructor;
- Allowing a NATCEP to request a variance to provide for clinical experiences in a laboratory setting; and
- Reducing the in-person hours of skills training (pre-clinical) to 4 hours for demonstration and sign-off by a registered nurse as to the student's competency.

The Ohio Department of Health is (ODH) proposing to amend the rules as follows:

Rule 3701-18-01

This rule contains the definitions for terms used in chapter 3701-18 of the Administrative Code.

ODH is proposing to file this rule without amendment ("no change").

Rule 3701-18-02

This rule allows for the Director of Health to enter into an agreement to allow another governmental entity to approve NATCEPs and TTTs.

The rule has been amended for clarity.

Rule 3701-18-03

This rule sets forth the Director's ability to inspect approved NATCEPs and TTTs, as well as situations where the Director may deny, suspend, or revoke approval of a program.

The rule has been amended for clarity and to allow for the information concerning NATCEPs published to the ODH website to meet its obligation to provide information regarding NATCEPs upon request.

3701-18-04

This rule sets for the requirements for an initial application for approval of a NATCEP, including forms and fees that must be submitted to ODH.

In accordance with Legislative Services Commission ("LSC") rule-drafting requirements, ODH is proposing to rescind this rule a replace it with a new rule. The rule has been redrafted for clarity.

3701-18-05

This rule sets for the requirements for an application for reapproval of a NATCEP, including forms and fees that must be submitted to ODH.

In accordance with LSC rule-drafting requirements, ODH is proposing to rescind this rule and replace it with a new rule. The rule has been redrafted for clarity.

Rule 3701-18-06

This rule contains criteria for approval of NATCEPs by the department, including requirements as to where a facility-based program can be provided.

ODH is proposing to file this rule without amendment (“no change”).

3701-18-06.1

This rule set forth general post-approval requirements for NATCEPs, including when the program must give ODH notice of change to the NATCEP.

The rule has been redrafted for clarity.

Rule 3701-18-08

This rule contains special requirements for NATCEPs, including requirements for the classroom and clinical portions of the program.

The rule has been redrafted for clarity and to allow for a program to request a variance to allow the clinical portion of the program to be conducted in a laboratory setting.

3701-18-09

This rule contains the personnel requirements for NATCEPs, including requirements related to the program coordinator, the primary instructor, and supplemental instructors.

The rule has been redrafted to better reflect and not conflict with federal regulations in 42 CFR 483.152. Additionally, the rule now makes the program coordinator an administrative position while shifting the training/work experience requirements to the primary instructor. The rule now allows a primary instructor to meet the applicable requirements through supervisory experience. Further, the rule clarifies who may supervise clinical experiences and allows for online instruction for the classroom portion of the NATCEP.

Rule 3701-18-10

This rule contains requirements related to the physical facilities that need to be provided by a NATCEP.

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The appendix to this rule has been amended to update the equipment to be provided by a NATCEP to include personal protective equipment such as gloves, gowns, and masks, as well as to include sanitizing wipes.

Rule 3701-18-11

This rule contains the recordkeeping requirements for NATCEPs, including records for both trainees and staff.

The rule has been amended to update the term “guest lecturer” to “supplemental instructor.”

Rule 3701-18-12

This rule contains the NATCEP curriculum criteria, including hours needed for various topics, as well as the pre-clinical instruction.

The rule has been updated to better cite the appendix to this rule and to reflect an allowed variance. Additionally, the appendix to this rule has been updated to include both the most recent infection control and oral health practices. The bibliography to the appendix has also been updated.

Rule 3701-18-13

This rule contains requirements on how a NATCEP is to evaluate its trainees taking the program, including skills testing and passing rates for tests and quizzes.

The rule has been amended to reflect an allowed variance and to update the term “guest lecturer” to “supplemental instructor.” The term “program coordinator” has been deleted and the passing score of tests and quizzes used in the classroom has been reduced to 70%.

3701-18-14

This rule sets for the requirements for an initial application for approval of a TTT, including forms and fees that must be submitted to ODH.

In accordance with LSC rule-drafting requirements, ODH is proposing to rescind this rule and replace it with a new rule. The rule has been redrafted for clarity.

3701-18-15

This rule sets for the requirements for an application for reapproval of a TTT, including forms and fees that must be submitted to ODH.

In accordance with LSC rule-drafting requirements, ODH is proposing to rescind this rule and replace it with a new rule. The rule has been redrafted for clarity.

Rule 3701-18-16

This rule contains criteria for approval of TTT by the department, including requirements as to when notice to the department is needed and timeframes for approval.

ODH is proposing to file this rule without amendment.

3701-18-17

This rule contains special requirements for TTTs, including requirements for to ensure only eligible participants are registered.

The rule has been amended to remove “program coordinator” and update a cross-cite.

3701-18-19

This rule contains the physical facilities requirements for TTT, including requirements related to space, lighting, and equipment.

The rule has been amended to require the provision of computers or similar technology in a classroom.

3701-18-20

This rule contains the recordkeeping requirements for TTTs, including records for both participants and faculty.

The rule has been amended to replace “guest lecturer” with “supplemental instructor.”

3701-18-20

This rule contains the recordkeeping requirements for TTTs, including records for both participants and faculty.

The rule has been amended to replace “guest lecturer” with “supplemental instructor.”

3701-18-21

This rule contains the curriculum for a TTT requirements on how a TTT is to evaluate its program participants, including requirements for successful completion of a TTT.

The rule has been amended for clarity and to reduce the passing percentage on the TTT’s written examination to 70%.

Rule 3701-18-23

This rule contains the eligibility requirements for an individual to sit for the state-administered competency exam (“state test”), which, when passed, allows the individual to be registered as a state-tested nurse aide.

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ODH is proposing to file this rule without amendment.

Rule 3701-18-24

This rule sets for the requirements for a eligible candidate to register for the state test.

ODH is proposing to file this rule without amendment.

Rule 3701-18-25

This rule sets for the required fees for the state test.

In accordance with LSC rule-drafting requirements, ODH is proposing to rescind this rule a replace it with a new rule. The rule has been redrafted to reflect changes to section 3701.044 of the Revised Code allowing ODH to publish fees to its website.

3701-18-26

This rule sets forth the requirements for scheduling candidates to take the state test, including requirements for proof of identity, as well as requirements related to interpreters for candidates with hearing impairments.

The rule has been amended to allow for a test registrant to use a visa issued by the United States Citizenship and Immigration Services Agency as a form of identification and for clarity.

3701-18-27

This rule sets forth how a candidate may pass the state test, as well as requirements related to candidates that fail the test or a portion of the test.

The rule has been amended reduce the passing score on the written portion of the state test to 70%.

- 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.**

ORC §§ 3721.30, 3721.31, 3721.32

- 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.

Yes. The federal Medicare and Medicaid programs pay for the training of nurse aides used by nursing homes that are certified for participation in those programs. As such, the Centers for Medicare and Medicaid Services, through 42 CFR 483.151, requires each state to either specify NATCEPs that meet the federal requirements set forth in 42 CFR 483.152 and/or 42 CFR or to offer a NATCEP. Ohio has chosen to specify those

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programs that meet the federal requirements though meeting the OAC 3701-18 regulations.

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

The training curriculum to rule 3701-18-12 exceeds the federal requirements found at 42 CFR 483.152 in one limited area, namely that Ohio requires training programs to teach bed-making techniques. This was implemented based on suggestions from providers that they were spending time teaching this skill at the facility where it took away from patient care and they would like to see students trained in this area before coming to the facility

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)?

In addition to the above-referenced federal requirements, this rule implements the statutory requirements set forth in section 3721.30 of the Revised Code, which requires ODH to issue rules regarding the approval of training programs. Further, these rules help to ensure: (1) nurse aides who care for older adults in nursing homes are properly trained to carry out their duties; and (2) individuals training nurse aides have the experience and ability to teach the subject matter.

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

Successful outcomes are measured through a standard survey (inspection) process. This process is generally conducted once every twelve months. Successful outcomes would be indicated by a finding of compliance with the Chapter 3701-18 requirements. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

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.

Not applicable.

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.

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Stakeholders were contacted by email on May 20, 2022 and a virtual stakeholder meeting was held on May 24, 2022

C-TEC OF LICKING COUNTY
LEADINGAGE OHIO
CLARK STATE COMMUNITY COLLEGE
APOLLO CAREER CENTER
WINDSOR HOUSE
PARADIGM HEALTH SERVICES
ARBORS AT GALLIPOLIS
COURTHOUSE MANOR
JAG HEALTH CARE
ARBORS AT POMEROY
INSPRIA HEALTH GROUP
ORAL HEALTH OHIO
ALIA HEALTH CARE
CINCINNATI STATE COMMUNITY COLLEGE
GREAT OAKS CAREER CAMPUSES
THE HEALTH COLLABORATIVE
OHIO HEALTH CARE ASSOCIATION
OHIO ACADEMY OF SENIOR HEALTH SCIENCES
CAPITAL HEALTH CARE NETWORK
OHIO DEPARTMENT OF AGING
STATE LONG-TERM CARE OMBUDSMAN

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

Stakeholders provided significant input to nearly every rule and these draft rules reflect the groups comments and suggestions.

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?

The curriculum was informed by best practices in the medical field. See the updated bibliography in the Appendix to rule 3701-18-12.

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?

ODH did not consider any alternatives to the proposed regulation. ODH is required to implement section 3721.30 of the Revised Code. These rules reflect the current statutory requirement for approval of NATCEP/TTT programs.

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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.

Performance-based regulations were not deemed appropriate for this rule set. ODH is required to implement section 3721.30 of the Revised Code. Rules 3701-18-01 to 3701-18-27 contain both structural (process) and performance (outcome) based requirements. When there is a poor outcome, ODH can then look to ensure that processes were implemented correctly and can identify breakdowns in the processes that lead to those poor outcomes.

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

The agency conducted a thorough review of the Ohio Revised Code and Ohio Administrative Code to ensure there are no other regulations in place pertaining to NATCEP/TTT programs.

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.

Programs will be surveyed approximately once every two years to determine compliance with the regulations. The survey will be done by long term care program staff using a standard survey tool. This staff will have been trained in the survey process, including understanding of the regulation(s).

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**

In general, these rules do not represent costs that are independent of those already obligated to the licensee by the virtue of their participation in the industry. Those costs include, but are not limited to, the costs associated with the purchase or lease of real estate, equipment, and personnel. There are also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assurance and performance improvement. The similar requirements set forth in Ohio's rules are unlikely to require a significant amount

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of time or costs in addition to that which is already expended by the service and the services will, more likely than not, already meet or exceed the state requirements.

The adverse impact of these rules as a whole consists of license suspension, denial, or revocation. Individual rules have additional adverse impacts; including application fee, reporting, recordkeeping, as well as time completing and submitting required forms to ODH.

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.

Compliance with these rules may require:

- (1) Application fees of \$300.00 (NATCEP) and \$600.00 (TTT).
- (2) Filing of initial/renewal license applications with ODH may require eight (8) to twelve (12) hours of work by a registered nurse.¹
- (3) Notice requirements to ODH require up to four (4) hours of time by a registered nurse.¹
- (4) Equipment costs. This generally requires a NATCEP to set-up a nursing home resident room in their building. While nearly all NATCEPs have this equipment, the cost for providing the equipment required by Appendix E to rule 3701-18-10 can range from \$0.00 to approximately \$10,000.00 if the program must buy a new long-term care bed (approximately \$3,000.00 to \$9,000.00).² The TTE equipment rule requires a TTT program to provide audio/visual equipment, computers or tablets, and teaching aides - not the full range of equipment required of NATCEPs. Provision of this equipment is estimated to be up to \$2,500.00.
- (5) Test taking fees for students as follow:
 - Exam: \$26.00
 - Oral exam: \$36.00
 - Performance demonstration (skills): \$78.00
- (6) Time to read the rules specific to the level of care provided; up to one (1) hour for applicable portions of the Chapter.¹

¹ Registered Nurse: An average of \$35.62 per hour.* ODH is using this occupation code the program director is generally a registered nurse.

² Figure compiled from discussions with stakeholders and internet searches. Bed price from www.hill-rom.com, a leading supplier of long-term care beds.

³ Fees are set through a competitive bidding process with testing companies.

*Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2021, using the code for Registered Nurse (29-1141) because the program coordinator is generally a registered nurse.

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

Section 3721.30 requires ODH to establish rules regarding the approval of training programs. These Chapter 3701-18 rules establish those approval requirements for programs to ensure the nurse aide workforce has a baseline of knowledge and skills when entering a long-term care facility to provide direct care to residents.

Regulatory Flexibility

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

Alternative means of compliance may be achieved through waiver or variance. Variances or waivers may be granted for the program coordinator or primary instructor requirements of the Chapter. The requirements for a waiver or variance are set forth in rule 3701-18-09 and are determined on a case-by-case basis.

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?

ODH's Office of General Counsel has set forth a policy for ODH to follow regarding the waiver of fines and penalties for paperwork violations and first-time offenders. ODH implements this policy as part of its business process. Information regarding this policy can be found online at:

<https://odh.ohio.gov/about-us/offices-bureaus-and-departments/ogc/Statement-on-Paperwork-Violations>.

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

The agency maintains program staff that can assist and provide guidance to licensee to improve their survey outcomes and maintain compliance through the Bureau of Survey and Certification, NATCEP/TTT Unit.

<https://odh.ohio.gov/know-our-programs/nurse-aide-training-and-competency-evaluation-program-NATCEP/natcep>.