



Common Sense Initiative

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Business Impact Analysis

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

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

Residential Care Facility Licensure

Rule Number(s): 3701-16-01 and 3701-16-18

Date of Submission for CSI Review: 10/25/2023

Public Comment Period End Date: 11/27/2023

Rule Type/Number of Rules:

New/ X rules

No Change/ rules (FYR?)

Amended/ X rules (FYR? X)

Rescinded/ X rules (FYR? X)

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.

Rules 3701-16-01 to 3701-16-18, collectively, serve to regulate residential care facilities (“RCF”). Such facilities provide care and services to adults who, by reason of age and/or infirmity elect to receive or require the provision of such care. RCFs can provide skilled nursing care that, with some exception, is limited to 120 days in a 365 day period. Exceptions to this include the: (1) supervision of special diets; (2) application of dressings; and (3) medication administration. Additionally, there are limited exceptions regarding the type of skilled care provided. These include the provision of “routine” skilled nursing care to residents and the provision of skilled nursing care to residents receiving hospice services. All rules have been revised to remove regulatory restrictive language per SB 9 of the 134th Ohio General Assembly.

3701-16-01

The rule lists the definitions of terms used in rules 3701-16-01 to 3701-16-18 of the Administrative Code. Amendments include adding, modifying, and updating terms to meet current professional standards, including “complex therapeutic diets,” “special diets,” and “therapeutic diets.” Statutory citations have been amended to meet Legislative Service

Commission rule drafting standards. The term “call signal system” has been replaced by the term “resident call system.”

3701-16-02

The rule establishes general requirements and prohibitions for residential care facilities, including, but not limited to, those pertaining to the provision of skilled nursing care, the admission of residents, and compliance with statutory residents’ rights provisions.

Current 3701-16-03 (rescind)

New Rule 3701-16-03

The rule describes the licensure application and renewal procedures for RCFs, the conditions for issuance of licenses, and the circumstances in which a license can be revoked. Revisions have been made to clarify the requirements for a Change of Operator application, the requirement for a statement of financial solvency, and additional contact methods such as electronic email address and telephone number for the applicant and other parties to the business. Additional revisions include a listing of who must be notified of a closing of a facility, including residents and their sponsors or legal representatives and the state long-term care ombudsman.

3701-16-03.1

The rule sets forth the requirements for submitting a request for an expedited initial survey to ODH and a timeframe in which ODH must complete the inspection upon receipt of all the required documentation and fees.

3701-16-04

The rule sets forth requirements that RCFs must follow during inspections and investigations conducted by the Ohio Department of Health.

3701-16-05

The rule sets forth the personnel requirements for residential care facilities, including, but not limited to, those pertaining to nursing, dietary, activities, and ancillary staff. Paragraph (L) was added to not allow RCF’s to admit residents in excess without a proper amount of nursing coverage and other appropriate staffing levels.

3701-16-06

The rule summarizes the qualifications and requirements for personnel working in residential care facilities, including those pertaining to tuberculosis testing. Paragraph (E)(c) has been added to allow an LPN to work under the direction of an RN for first-aid training.

3701-16-07

The rule sets forth admission and discharge criteria for residents, as well as the types of information that must be included in a resident agreement.

3701-16-08

The rule sets forth what is required in a resident assessment, and the timeframes for such assessments.

3701-16-09

The rule sets forth who may perform personal care services and who may perform medication administration, application of dressings and supervise special diets. Revisions have been made to clarify when personal care services are considered provided and require the RCF to have policies and procedures to prevent the misappropriation or theft of controlled substances. The definition of “chemical restraint” for purposes of this rule, has been revised to clarify that it means any drug that is used for discipline or staff convenience and not prescribed to treat medical symptoms.

3701-16-09.1

The rule describes the types of part-time skilled nursing care that may be provided in residential care facilities, as well as what types of care are counted towards the 120-day skilled nursing care limit.

3701-16-10

The rule sets forth the dietary standards that must be met for facilities that choose to provide meals to residents. Also included in this rule are the requirements for the supervision of special diets. The rule has been revised to clarify that the RCF will ensure that food texture is appropriate to the individual needs of each resident, except that residential care facility staff are not allowed to perform syringe feedings.

3701-16-11

The rule sets forth a variety of RCF requirements, such as those pertaining to laundry services, resident activities, the regulation of pets, and accounting practices.

3701-16-12

The rule sets forth the responsibilities of a residential care facility with regards to changes in a resident's health status and other incidents, as well as infection control. The rule has been revised to provide detailed infection control requirements including having an infection, prevention, and control coordinator that works at least part-time in the facility, a TB control plan, communicable disease restrictions, and a water management plan to prevent the transmission of waterborne pathogens.

3701-16-13

The rule sets forth building, plumbing, fire, carbon monoxide safety, and disaster preparedness standards for residential care facilities. The rule has been revised to require the RCF to notify ODH when there is an interruption of normal business due to a disaster or emergency, integrate the restriction of vapor products with the smoking prohibitions, and maintain a copy of the facility disaster preparedness plan electronically or offsite to ensure access during emergencies.

3701-16-14

The rule sets forth the space requirements for areas of a residential care facility, including dining and activity areas, and resident sleeping rooms.

3701-16-15

The rule sets forth requirements for building maintenance, equipment, and supplies. Paragraph (C)(1) allows residents to choose an alternative piece of furniture, such as a recliner, to sleep in.

3701-16-16

The rule sets forth requirements for temperature regulation in residential care facilities. Paragraph (B) now states that a device such as hand held hygrometer or infrared thermometer should be on hand to check the ambient temperature of rooms.

3701-16-17

The rule sets forth requirements for residential care facilities in keeping records and reports. Paragraph (A)(1)(i) was added if applicable, that contact information of nearest relative or guardian information be updated every six months to ensure notification in case of an emergency.

3701-16-18

The rule sets forth procedures with which a residential care facility may request a variance for the requirements of rules 3701-17-50 to 3701-17-67.

- 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.**

3721.04, 3721.02

- 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.

There are no federal requirements to provide these rules.

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

No

- 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)?**

ODH is required by section 3721.04 of the Revised Code to develop rules for the licensure of Residential Care Facilities to ensure the health and safety of Ohio's long-term care consumers. These rules serve to protect the health and safety of Ohioans, who, by reason of age or infirmity, live in residential care facilities. The rules serve to ensure: that RCFs have minimum space requirements for occupants and equipping of the buildings in which homes are housed so that residents have healthful, safe, sanitary, and comfortable conditions; the number and qualifications of personnel, including management and nursing staff are appropriate for the population served; the medical, rehabilitative and recreational services are provided in accordance with acceptable standards; that dietary services are provided to ensure residents are offered the appropriate nutritional intake; the business and accounting practices followed are in accordance with accepted standards, and patient and business records are stored in accordance standards and kept for accepted timeframes.

- 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 fifteen months. Successful outcomes would be indicated by a finding of compliance with Chapter 3701-16. 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.

No

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.

Leading Age
OHCA
Ohio Academy of Senior Health Sciences
State Long-term Care Ombudsman
Department Aging
Attorney General
Elder Care Systems
Ohio Department of Medicaid
OALA

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

A stakeholder meeting was held, and multiple drafts and recommended revisions were included. This includes infection control, the ability for a resident to choose an alternate piece of furniture for sleeping, modifications to the definition of “chemical restraint,” and allowing an LPN to work under an RN for CPR training.

- 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?**

Scientific data was not used in this review.

- 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?**
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

ODH did not consider any alternatives to the proposed regulation. ODH is required to implement section 3721.04 of the Revised Code. The rules reflect the current statutory requirement. Regulatory language was added regarding infection control to assure a safe, sanitary, and comfortable environment.

13. 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 for the licensure of RCFs.

14. 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.

An on-site survey may be initiated to determine compliance with this rule. 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 regulations.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

All Residential Care Facilities – 794 facilities as of October 16, 2023.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

License Fee for initial or renewal - For each state fiscal year thereafter, three hundred twenty dollars for each fifty person or part thereof.

Expedited Inspection fee - \$2250

Increase or decrease of bed expedited inspection - \$2250

Time for compliance:

The costs borne by the RCF can be assumed to include:

- Time and manpower necessary to prepare a waiver or variance request; both will be determined by the nature and complexity of the requirement.
- Time and manpower necessary to develop written plans for a Quality Assessment and Performance Improvement (QAPI) program and conduct meetings.
- Time to develop a clinical record and plan of care for each resident.
- Time and manpower necessary to develop policy and procedures pertaining to complaints.
- Time and manpower to complete applications and submit information.
- Time and manpower to conduct resident assessments.
- If the facility allows pets, time and manpower for policies and vetting.
- Time and manpower for preparation of special diets, infection control, training of personnel

All costs associated with records, plans of care, and policy and procedure development and training would be based upon the nature and complexity of the requirement and the staff chosen to perform the task. In most instances a physician or registered nurse would be responsible for this requirement, while training may be conducted by other health care practitioners.

Physician:

\$0.00 to an average of \$103.33 per hour*.

Registered Nurse:

\$0.00 to an average of \$37.72 per hour.*

Other Healthcare Practitioners:

\$20.01 per hour*

Dietician

\$31.15 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2022, using the codes for all health care practitioners and technical occupations (31-9099) physicians and surgeons, all others (29-1229), registered nurse (29-1141), dietician (29-1031).

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden*)

may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).

Regulatory restrictions have been removed in accordance with SB9.

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

ODH is required to implement ORC section 3721.04 by establishing licensing requirements for residential care facilities. The costs represented by the specific license and service standards set forth in rules 3701-16-01 through 3701-16-18 represent a general standard cost in terms of the administrative, personnel, and facility based requirements for the operation of a residential care facility and are considered to be acceptable within the industry. The requirements established in these rules provide the necessary framework for ODH to effectively and efficiently monitor and ensure the health and safety of Ohio's health care consumers.

Regulatory Flexibility

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

No. The rules apply to all residential care facilities regardless of the size of the business.

In rule 3701-16-18, there is an allowance for waiver variances.

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 Regulatory Ombudsman 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/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/Office-of-General-Counsel/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 licensees through the Bureau of Regulatory Operations and the Bureau of Survey and Certification.

<https://odh.ohio.gov/know-our-programs/residential-care-facilities-assisted-living/residentialcarefacilitiesassistedliving>