

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Department of Health

Regulation/Package Title: Residential Care Facility Licensure Rules

Rule Number(s): 3701-17-50 to 3701-17-68-to be rescinded; Proposed as new 3701-16-01 to 3701-16-18

Date: April 19, 2017

Rule Type:

☒ New

☒ 5-Year Review

☒ Amended

☒ Rescinded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.

Rules 3701-17-50 to 3701-17-68, collectively, serve to regulate residential care facilities ("RCF"). Such facilities provide care and services to adults who, by reason of age and/or

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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.

ODH is proposing to rescind the current RCF licensure rules in their entirety and replace them with new rules in Chapter 3701-16 of the Administrative Code. This move is designed to eliminate confusion between the RCF rules and the nursing home rules (rules 3701-17-01 to 3701-17-28) that currently share the same chapter of the Administrative Code. To help Interested Parties read the rules, they are posted showing both amendments ([blue underlining](#) and ~~red strikethrough~~, for informational purposes only and may not show all amendments) and as new rules (all [blue underlining](#)). For ease of reading, in this memorandum though they will be proposed as new rules, the rules will be discussed as if they are amended.

After a series of meetings with stakeholders, ODH is proposing some amendment to the rules as follows:

Current 3701-17-50 (rescind)

New 3701-16-01

The rule lists the definitions of terms used in rules 3701-16-01 to 3701-16-68 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.”

Current 3701-17-51 (rescind)

New 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.

The rule has been amended to update cross-references and dietary terminology.

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Current 3701-17-52 (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.

The rule has been amended to require an attestation of financial solvency, rather than requiring a statement of financial solvency on a form prescribed by the director.

Current 3701-17-52.1 (rescind)

New Rule 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.

Current 3701-17-53 (rescind)

New Rule 3701-16-04

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

No changes have been made to this rule.

Current 3701-17-54 (rescind)

New Rule 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.

The rule has been amended update dietary terminology.

Current 3701-17-55 (rescind)

New Rule 3701-16-06

The rule summarizes the qualifications and requirements for personnel working in residential care facilities, including those pertaining to tuberculosis testing.

The rule has been reorganized in some areas to clarify training requirements. Additionally, the rule has been amended to require homes check the nurse aide registry and professional registries, of both Ohio and states in which an applicant is known or suspected to have lived, for findings of abuse, neglect or misappropriation.

Current 3701-17-57 (rescind)

New Rule 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.

The rule has been amended to reflect the requirements of section 3721.122 of the Revised Code that requires the home to check the Ohio Sex Offender Registry prior to admitting residents, to clarify that the acting administrator may sign resident agreements on behalf of the facility, and to update cross citations.

Current 3701-17-58 (rescind)

New Rule 3701-16-08

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

The rule has been amended to clarify what both the initial health assessment and the periodic health assessment must cover.

Current 3701-17-59 (rescind)

New Rule 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.

The rule has been amended to reflect current dietary standards.

Current 3701-17-59.1 (rescind)

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New Rule 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.

The rule has been amended to reflect current dietary standards.

Current 3701-17-60 (rescind)

New Rule 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 amended to reflect current dietary standards, to remove surplus language, and to clarify the difference between supervising therapeutic diets and preparing special diets.

Current 3701-17-61 (rescind)

New Rule 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.

The rule has been re-organized to be resident-centered. The rule has also been amended to require the home to make a final accounting of resident accounts and to convey any resident monies to the resident upon transfer or discharge, or to the resident's estate when opened.

Current 3701-17-62 (rescind)

New Rule 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 amended to require each RCF to designate an infection control person, and submit that individual's name and e-mail address to the ODH. ODH will use this information to communicate with the individual when there is an outbreak and to provide educational opportunities in infection control.

Current 3701-17-63 (rescind)

New Rule 3701-16-13

The rule sets forth building and fire safety requirements for residential care facilities.

The rule has been amended to require homes with fuel-burning appliances to install and maintain, in accordance with manufacturer's instructions, carbon monoxide ("CO") alarms or detectors (if licensed prior to the effective date of the rules) within twelve months of the effective date of the rules. Homes licensed on or after the effective date of the rules must to install and maintain, in accordance with manufacturer's instructions, CO detectors. The rule also defines the terms "carbon monoxide alarm," "carbon monoxide detector," "carbon monoxide detection system," and "fuel-burning appliance."

Current 3701-17-64 (rescind)

New Rule 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.

The rule has been amended to replace the term "call signal system" with "resident call system," to allow the window in resident rooms to open outside or to an atrium, and to clarify requirements for public toilet rooms.

Current 3701-17-65 (rescind)

New Rule 3701-16-15

The rule sets forth requirements for building maintenance, equipment and supplies.

This rule has been amended to include the effective date of a provision of the rule and to only require emergency numbers placed at phones maintained by the facility (e.g., pay phones or lobby phones).

Current 3701-17-66 (rescind)

New Rule 3701-16-16

The rule sets forth requirements for temperature regulation in residential care facilities.

No changes have been made to this rule.

Current 3701-17-67 (rescind)

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New Rule 3701-16-17

The rule sets forth requirements for residential care facilities in keeping records and reports.

This rule has been amended to specify records retention dates.

Current 3701-17-68 (rescind)

New Rule 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.

The rule has been amended to remove requirements for informal reconsideration and appeal rights under Chapter 119. Of the Revised Code to be consistent with all other ODH variance rules.

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

3721.04

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.

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

Not Applicable.

- 3. 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 Department of Health is required (RC § 3721.04) to set forth regulations governing residential care facilities. 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

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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.

4. 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 3701-17 (now Chapter 3701-16). Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

Development of the Regulation

5. 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.

- LeadingAge Ohio
- Ohio Academy of Senior Health Sciences
- State Long Term Care Ombudsman
- Ohio Health Care Association
- Ohio Department of Aging
- Ohio Dietetics Association
- State Fire Marshal
- Department of Medicaid

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

Stakeholders input was vital to the rules as they are posted. Stakeholder meetings were held on January 11 and February 15, 2017.

Stakeholders suggested reorganizing rule 3701-17-55 (proposed 3701-16-06) so that the requirements would be better understood by licensees. Additionally, stakeholders input was instrumental in drafting rule 3701-17-60 (proposed 3701-16-10) to conform current industry standards and to better differentiate between supervision of therapeutic diets and preparation of special diets.

Informal comments ODH received as part of this process are attached.

7. 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.

8. 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 3721.04 of the Revised Code. The rules reflect the current statutory requirement.

9. 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.*

Rules 3701-17-50 to 3701-17-68 (proposed 3701-16-01 to 3701-16-08) 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 break-downs in the processes that lead to those poor outcomes.

10. 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. Where there is limited overlap with building and fire safety standards, this generally applies to the use of existing regulatory language in ODH rules to prevent confusion, not to implement duplicative regulations.

Rule 3701-17-59 (proposed 3701-16-09)

While this rule is not duplicative of Board of Pharmacy rules pertaining to storage and dispensing of medications, ODH worked with the Board of Pharmacy and providers to implement some language from the Board of Pharmacy rules in these areas to allow ODH to act when there is a deficient practice or a threat to the health and safety of residents.

Rule 3701-17-63 (proposed 3701-16-13)

Pursuant to ODH's authority under RC §§ 3721.032 and 3721.04, ODH worked with the State Fire Marshal and providers to implement some language consistent with the Ohio

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Fire Code to allow ODH to act when there is a deficient practice or a threat to the health and safety of residents.

11. 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 regulation.

Adverse Impact to Business

12. 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;

The impacted business community consists of licensed RCFs. As of March 1, 2017, there are 690 licensed RCFs in Ohio.

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

The adverse impact of rules 3701-17-50 to 3701-17-68 (proposed new 3701-16-01 to 3701-16-18) include fees for licensing, staff time for reporting, record review and transcription, as well as time completing and submitting required forms to ODH.

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 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.

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.

Fees, as authorized in section 3721.02 of the Ohio Revised Code of \$320.00 for every 50 persons or part thereof.

Time and manpower necessary to develop tuberculosis control plan and infection control policies and provide training.

Time and manpower necessary to adopt and follow disaster preparedness and fire evacuation plans.

Cost for carbon monoxide alarms or detectors. While many homes have this as part of their fire alarm system, a home that does not could spend \$100.00 per alarm or up to approximately \$250.00 per smoke detector, plus installation.

Time and manpower necessary to prepare a waiver or variance request; both will be determined by the nature and complexity of the requirement.

The costs borne by the RCF are those generally associated with the provision of services within the industry including, but not limited to resident assessment, written policies, and employee training and development. All costs associated with 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 the administrator, physician or registered nurse would be responsible for this requirement, while training may be conducted by other health care practitioners.

Administrator: \$0.00 to an average of \$46.47 per hour; Physician: \$0.00 to an average of \$92.26 per hour; Registered Nurse: \$0.00 to an average of \$34.14 per hour; Other Healthcare Practitioners: \$40.92 per hour. *

*Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2015, using the codes for Medical and Health Services Managers (11-9111), Family and General Practitioners (29-1062), Registered Nurses (29-1141), and All Health Care Practitioners and Technical Occupations (29-1199).

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

Section 3721.04 requires ODH to establish rules for the licensure of residential care facilities. These rules establish the licensure structure for Ohio residential care facilities.

Regulatory Flexibility

14. 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 any of the requirements of the Chapter if the Director determines: that the requirement has been met in an alternative manner, that the strict application of the requirement would result in undue hardship, and that the granting of the waiver or variance would not jeopardize the health or safety of a resident. The requirements for a waiver or variance are set forth in rule 3701-17-68 and are determined on a case-by-case basis.

15. 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 is committed to the goal of ensuring that regulated customers can achieve compliance with ODH's procedural requirements. Therefore, when it is feasible, appropriate, and permitted by law, ODH will provide one (1) warning letter to a regulated customer who commits a first time or isolated violation of a "minor" paperwork or procedural requirement, such as failing to submit a timely and complete license renewal application or other required documentation to ODH. If permitted by law, ODH will not impose a civil monetary penalty for such a violation, and will give the customer a reasonable amount of time to correct the violation in accordance with section 119.14 of the Revised Code, unless:

- (1) The Director of Health determines the violation has the potential to cause serious harm to the public interest;
- (2) The violation involves a small business knowingly or willfully engaging in conduct that may result in a felony conviction;
- (3) Failure to impose an administrative fine or civil penalty for the violation would impede or interfere with the detection of criminal activity;

- (4) The violation is of a law concerning the assessment or collection of any tax, debt, revenue, or receipt;
- (5) The violation presents a direct danger to the public health or safety, results in a financial loss to an employee, or the Director of Health determines the violation presents the risk of severe environmental harm;
- (6) The violation is a failure to comply with a federal requirement for a program that has been delegated from the federal government to the Department of Health and includes a requirement to impose a fine.

This Policy Statement should not be construed as a waiver of ODH's authority to enforce any law or regulation requiring a person or entity to obtain a valid permit or license before engaging in regulated activity, or enforce any other state or federal law.

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

ODH's mission is to protect the health of Ohioans. However, we also recognize the challenges we face as a state in attracting and retaining businesses to maintain a strong economy for Ohio. To help meet both goals we strive for timely licensure, certification and permit application reviews that meet business timeframes whenever possible, while continuing our main mission of protecting the health and safety of all Ohioans.

ODH is working to continuously improve the accessibility, flexibility, responsiveness and problem solving involved in our daily activities. Thus, we've made several changes to improve the efficiency of our licensure, certification and permit process are continually reviewing our business practices for other areas of improvement.

The agency maintains program staff that can assist and provide guidance to licensee to improve their survey outcomes and maintain compliance through the Bureau Long Term Care Quality:

<https://www.odh.ohio.gov/odhprograms/ltc/Residential%20Care%20Facilities/Main%20Page.aspx>.