

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, 3701-17-52, 3701-17-53, 3701-17-54, 3701-17-55, 3701-17-57, 3701-17-58, 3701-17-59, 3701-17-59.1, 3701-17-60, 3701-17-61, 3701-17-62, 3701-17-63, 3701-17-64, 3701-17-65, 3701-17-66, 3701-17-67, 3701-17-68

Date: April 10, 2012

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☐ Rescinded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 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;

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(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. Descriptions of each rule and proposed amendments, if any, are set forth, below.

General

References to “home for the aging” and “community alternative homes” have been removed as ODH no longer licenses such homes. Additionally, the phrase “licensed health care professional acting within their applicable scope of practice” has been added throughout the rules to allow for the inclusion of certified nurse practitioners and physician assistants, among others. Finally, requirements for facilities that “hold themselves out” as serving special populations have been altered or removed.

Rule 3701-17-50

The rule lists the definitions of terms used in rules 3701-17-50 to 3701-17-68 of the Administrative Code.

Various grammatical and cross citation corrections have been made to the definitions. Additionally, “special care unit” has been defined.

Rule 3701-17-51

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.

Provisions of this rule pertaining to the license and operation or closure of a facility have been relocated to rule 3701-17-52. Provisions related to requirements for facilities that “hold themselves out” as serving a special population that are no longer in the rules have been stricken.

Rule 3701-17-52

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.

This rule has been amended to clarify: the difference between *initial* applications and *renewal* applications; the criteria for license *denial* and license *revocation*; and what must be included in a written notice of closure. Additionally, ODH intends to collect more data regarding the ownership of the operator and to set forth notification requirements when a facility alters its physical facilities or proposes to relocate beds to an unlicensed portion of the facility. Further, previous provisions of rule 3701-17-51 that pertain to the licensing and operation of a facility have been relocated to this rule. Finally, the requirement for facilities that “hold themselves out” as serving

a special population has been stricken, while the requirement for a policy for care of certain residents has been moved to rules 3701-17-57 and 3701-17-58.

Rule 3701-17-53

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.

Rule 3701-17-54

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 requirement relating to an on-staff physician or psychologist has been amended to reflect the removal of special population language from rule 3701-17-52. Language regarding when a dietitian is necessary has been updated to reflect the industry standard of “complex therapeutic diets,” rather than “special diets.” Finally, the rule has been amended to allow for shared staffing among an RCF, a nursing home, or an adult day care program located in the same building or on the same lot.

Rule 3701-17-55

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 for clarity. The requirement relating to the activities director has been amended to reflect the removal of special population language from rule 3701-17-52. Additionally, the first aid training is now required within sixty days of hire, and the American Heart Association’s Heartsaver First Aid course is now a recognized first aid course. Finally, language regarding when staff training by a dietitian is necessary, has been updated to reflect the industry standard of “complex therapeutic diets,” rather than “special diets.”

Rule 3701-17-57

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 term “pressure ulcers” has been defined and includes staging consistent with the *Updated Staging System* issued by the *National Pressure Ulcer Advisory Panel*. Language pertaining to the facility policy for care on a special care unit has moved from rule 3701-17-52 and information previously required to be presented that is no longer applicable, has been removed. Finally, the rule clarifies that a resident agreement cannot contain a waiver of a resident’s statutory rights.

Rule 3701-17-58

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, and to update “activities of daily living” to reflect current standards. Portions of previous requirements for care of special populations have been moved from rule 3701-17-52. Additionally, assessments for care on a special care unit have been clarified, as have tuberculosis testing requirements in the case of resident transfer or discharge and subsequent readmission.

Rule 3701-17-59

The rule sets forth who may perform personal care services and who may perform medication administration, application of dressings and supervise special diets.

Cross cites have been corrected and the rule has been clarified with regards to: topical medications; telephone orders; Ohio Board of Pharmacy and federal Drug Enforcement Administration requirements; over-the-counter medications; and admission of residents to a special care unit.

Rule 3701-17-59.1

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.

This rule has been amended to allow for the provision of skilled care to residents whose physicians have determined such care is routine if the facility enters into a written agreement with the individual, the individual’s physician or the provider of the skilled care. The written agreement must include a signed statement acknowledging the individual’s needs can be met at the facility, that periodic re-determinations are made, and that the individual has been given the choice of skilled nursing care providers, if applicable.

Rule 3701-17-60

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.

This rule has been amended to clarify the timeframes for meals and to remove language that does not rise to the level of a regulation. Additionally, the rule has been amended to reflect current dietary standards.

Rule 3701-17-61

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.

This rule has been amended to require facilities to consider resident preferences when planning activities, and to add language regarding the RCF's responsibility with regard to conveyance of funds and management of resident finances. Additionally, the amendments clarify what must be included in the RCF pet policy and disallow RCF staff from acting as the attorney-in-fact for a resident unless related by blood, marriage, or adoption.

Rule 3701-17-62

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.

This rule has been amended to conform to Legislative Services Commission rule-drafting requirements.

Rule 3701-17-63

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

Cross cites have been updated and language pertaining to missing persons has been amended to include notification of local law enforcement. Additionally, language pertaining to fire exit drills has been clarified. The rule has been further amended to require a home that permits outdoor smoking to make accommodations for residents during adverse weather conditions.

Rule 3701-17-64

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

This rule has been amended to change "toilet rooms" to "bathrooms" to match the definition provided within the rule. Additionally, language requiring the provision of a "toilet room directly accessible from and exclusively for each resident sleeping room or apartment" has been removed as this is inconsistent with statutory language passed in HB 153.

Rule 3701-17-65

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

This rule has been amended to clarify that emergency telephone numbers are only required to be displayed on phones provided by the facility.

Rule 3701-17-66

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

This rule has been amended to allow notification to an “other licensed health professional acting within the applicable scope of practice” when the temperature of the building is outside the acceptable range.

Rule 3701-17-67

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

This rule has been amended to allow for the documentation of the “other licensed health professional acting within the applicable scope of practice,” in addition to the attending physician, on the resident medical record, and to remove a reference to an annual report that ODH no longer collects.

Rule 3701-17-68

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.

No changes have been made to this rule.

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

RC § 3721.04

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

No.

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

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The 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

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with acceptable standards; that dietary services are provided to ensure residents are offered the appropriate nutritional intake; the personal and social services provided each RCF are appropriate for the population served; 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; that each RCF follow accepted standards and procedures when admitting and retaining a resident who requires the application of dressings, including requirements for charting and evaluating on a weekly basis; and, that RCFs conduct weekly evaluations of residents receiving skilled nursing care in residential care facilities, unless the resident is receiving routine skilled nursing care or is a hospice resident, in which case, the evaluations are no more than every 30 days, and no more than every 15 days, respectively.

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

Successful outcomes would be evidenced by compliance measured through a standard survey process approximately every fifteen months. Further evidence of success would be represented by the number of complaints regarding alleged violations of rules 3701-17-50 to 3701-17-68 received and the number of validated complaint surveys.

Development of the Regulation

7. 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.

Stakeholders were asked to provide comment on the existing rules in September, 2011 in preparation for ad hoc stakeholder meetings. Stakeholder meetings were held November 15, 2011 and December 12, 2011 and included representatives from:

- Ohio Assisted Living Association
- LeadingAge
- Ohio Council on Assisted Living
- The Academy of Senior Health Sciences
- Midwest Care Alliance
- Ohio State Long Term Care Ombudsman
- Ohio Association of Regional Long Term Care Ombudsman
- Ohio Department of Aging

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

Stakeholders were asked to give written comments on the current version of the rules prior to the stakeholder meetings. ODH took these comments, as well as discussion surrounding the rules during stakeholder meetings, into account while drafting amendments to the rule for the public comment posting. A listing of comments received is provided as an attachment.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Rule 3701-17-57

The *Updated Staging System* issued by the *National Pressure Ulcer Advisory Panel* has been updated and now prevents “back-staging” of pressure ulcers. “Back-staging” came about as a response to the required staging of ulcer in clinical practice, however, experts noted that this practice is anatomically incorrect because a healing skin defect is not filled by normal tissue, but rather is replaced by scar tissue.

Rule 3701-17-58

The *Lawton Instrumental Activities of Daily Living Scale* is the industry standard for evaluations and is used in the rule to inform what should be evaluated.

- Lawton, M.P., and Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. The Gerontologist, 9, 179-186.
- Buurman BM, et al (2011). Variability in measuring (instrumental) activities of daily living functioning and functional decline in hospitalized older medical patients: a systematic review. J Clin Epidemiol. 64, 619-27.
- Alosco ML, et al (2012). Cognitive Impairment Is Independently Associated With Reduced Instrumental Activities of Daily Living in Persons With Heart Failure. J Cardiovasc Nurs. 27, 44-50.

Rule 3701-17-62

Various recommendations by the United State Centers for Disease Control and Prevention were used in the creation of this rule.

- Rutala WA, Weber DJ, the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
- Siegel JD, Rhinehart E, Jackson M, et al. the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007

- CDC. Boyce JM, Pittet D. the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Hand Hygiene in Healthcare Settings. MMWR 2002;51
- CDC. the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Infection Control in Healthcare Personnel, 1998.

Rule 3701-17-63

The Life Safety Code, a publication of the National Fire Protection Association.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

ODH did not consider alternative regulations in this area. Generally, the rules reflect a national consensus that residential care facilities (or assisted living in some jurisdictions) meet minimum requirements to ensure the health and safety of residents.

11. 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 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.

12. 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 Revised Code and the Administrative Code to check for duplication of existing regulations. There are two areas where some overlap occurs, however, these generally apply to the use of existing regulatory language in ODH rules to prevent confusion, not to implement duplicative regulations.

Rule 3701-17-59

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 take action where there is a deficient practice or a threat to the health and safety of residents.

Rule 3701-17-63

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 Fire Code to allow ODH to take action where there is a deficient practice or a threat to the health and safety of residents.

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13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Providers will be surveyed at least once every 15 months to determine compliance with this regulation. The survey will be done by health care facility 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

14. 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;**
- b. Identify the nature of the adverse impact (e.g., license 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.

a. The scope of the impacted business community consists of (1) licensed residential care facilities, (2) facilities desiring to be licensed as residential care facilities, and (3) unlicensed facilities that should be licensed as residential care facilities under the law.

b. ORC 3721.03 requires revocation of the license for non-compliance with the rules.

c. Adverse impacts are set forth by rule, below:

Rule 3701-17-52

Compliance with this rule may require from one (1) to six (6) hours of one-time work by administrative personnel. The work required is the filing of initial/renewal license applications with ODH.

Costs for implementation are between an average of \$15.37 to an average of \$32.16 per hour. United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, codes for Office and Administrative Support Occupations (43-0000) and Healthcare Practitioner and Technical Occupations (29-0000).

Additionally, facilities are required to pay the license application fee specified in ORC 3721.02, which is currently \$300.00.

3701-17-54

If the facility serves an identified special population:

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Psychiatrist

\$0.00 to an average of \$83.29 per hour*.

Physician:

\$0.00 to an average of \$78.53 per hour*.

* The cost of compliance may be zero if the residents' mental health needs are being met by their private psychologists or physicians.

Note. Nurse coverage is only required where the facility provides skilled nursing care beyond those that are exempted by law.

Registered Nurse:

\$0.00 to an average of \$29.13 per hour.

Other Nurses:

An average of \$19.37 per hour to an average of \$29.13 per hour.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for psychiatrists (29-1066), general practitioners (29-1062), registered nurse (29-1111) and licensed practical nurses (29-2061).

3701-17-55

Training costs borne by the facility:

Personnel providing training

\$0.00 to an average of \$32.16 per hour of training session.

Coverage of personnel attending training

\$0.00 to an average of \$11.58 per hour of training session.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for all health care practitioners and technical occupations (29-0000) and nursing aides (31-1013).

3701-17-57

Though most residential care facilities already have policies and procedures in place, the development of policies and procedures could average \$32.16 per hour.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the code for all health care practitioners and technical occupations (29-0000).

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3701-17-57

Though residential care facilities already conduct initial and periodic assessments as residents are in the facility due to age or infirmity, the cost of conducting an could average \$32.16 per hour. When conducting an assessment for placement in a special care unit, the cost could be between \$40.27 and \$78.53 per hour.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for all health care practitioners and technical occupations (29-0000), physician assistants (29-1071) and general practitioners (29-1062).

3701-17-60

Cost for a dietitian and/or physician involvement in the provision of special and/or complex therapeutic diets could average \$23.51 to \$78.53 per hour, respectively.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for dietitians and nutritionists (29-1031) for general practitioners (29-1062).

3701-17-61

Cost for the development of a pet policy, if the facility elects to allow pets, would be \$42.50 per hour, for the involvement of a veterinarian and \$78.53 per hour, for the involvement of the facility medical director.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for veterinarians (29-1131) for general practitioners (29-1062).

3701-17-62

While all residential care facilities currently have infection control policies, the development of a policy could cost an average of \$32.16 per hour.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the code for Healthcare Practitioners and Technical Occupations (29-0000).

3701-17-68

Costs in this rule would be related to the preparation of a variance request. This could average from \$12.02 per hour to \$32.16 per hour.

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for all health care practitioners and technical occupations (29-0000), and healthcare support occupations (31-0000).

Other costs in these rules are generally associated with the provision of services in a building where personal care and/or skilled nursing care is provided to residents.

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

RC § 3721.04 requires ODH to establish rules for homes, including residential care facilities. Rules 3701-17-50 to 3701-17-68 establish minimum standards to ensure quality of care and help ensure the health and safety of residents of these homes, who, by way of age or infirmity, elect to receive or require those services provided by the home. This care includes personal care, or skilled nursing care, or both.

Regulatory Flexibility

16. 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.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

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: <http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx>.

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

ODH staff is available by phone and email during regular business hours. Additional guidance is posted to the ODH website: <http://www.odh.ohio.gov/odhPrograms/lrc/rcfacal/rcfac1.aspx>.