CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Department of Health

Regulation/Package Title: Nursing Home Licensure Rules

Rule Number(s): 3701-17-01 to 3701-17-26

Date: January 17, 2017 **RESUBMITTED March 27, 2017**

Rule Type:

- X New
- X Amended
- X 5-Year Review
- X Rescinded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.

   The Ohio Department of Health (ODH) is responsible for licensing nursing homes in Ohio. These rules are the result of a year-long stakeholder process that began looking at the rules holistically to see how Ohio could better serve nursing home residents while

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attempting to keep changes as cost neutral for nursing homes as possible. ODH is proposing to amend the rules as follows:

ODH has made additional amendments to rules 3701-17-01, 3701-17-05 and 3701-25 after reviewing comments received after the first posting for comment. As such, ODH is re-posting those rules for a second comment period. Changes made for the second posting are highlighted in yellow.

3701-17-01

This rule lists the definitions of terms used in rules 3701-17-01 to 3701-17-26 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The term "call signal system" has been replaced by the term "resident call system."

3701-17-02

This rule states that rules 3701-17-01 to 3701-17-26 of the Administrative Code apply to all nursing homes.

This rule is being proposed without amendment.

3701-17-03

This rule states what the license fee is for nursing homes ($320.00 for every 50 persons or part thereof), the application process, conditions for issuance of a license, and circumstances in which a license can be revoked.

The rule has been amended to allow only one licensed nursing home on a "lot" of land.

3701-17-03.1

This rule states the fee ($2,250.00) for expedited initial inspections of a nursing homes.

This rule is being proposed without amendment.

3701-17-04

The rule sets forth the requirements for determining a nursing home's licensing capacity.

This rule is being proposed without amendment.

3701-17-05

This rule summarizes certain actions from which applicants, nursing homes, staff, and other individuals are prohibited.

The rule has been amended for clarity and to include a prohibition of allowing individuals who are not residents to stay in the home for more than 24 consecutive hours.

The rule has been further amended to clarify who is a transient guest for purposes of the rule and to provide exceptions to the definition of "transient guest," including individuals in the facility for short term respite stays, individuals helping a resident adjust to life in the home, and individuals staying with a resident at end-of-life.

3701-17-06

This rule outlines the responsibilities of the nursing home administrator and the operator, as well as requirements for quality assurance and performance improvement (QAPI).

The rule is being rescinded and replaced in accordance with Legislative Service Commission rule drafting requirements. Changes to the rule include amendments for clarity and requirements for a QAPI program consisting of at least a quality assurance committee and participation in a quality improvement program every two years. The rule also requires the quality assurance committee with tracking and monitoring the homes' infection control program, and to clarify that the QA records are not subject to disclosure but that the home must document the ongoing existence of an effective QA committee.

3701-17-07

This rule sets forth the qualifications for personnel working in nursing homes, to include licensed nursing home administrators, activities professionals, and food service managers.

The rule has been amended to track Food Code requirements; to include require training in person-centered care, and to prohibit employment individuals who have finding of abuse, neglect, or misappropriation on the nurse aide registry of Ohio or another state, or who has had a disciplinary taken against hem by a licensing board as a result of a finding of abuse, neglect, or misappropriation.

3701-17-07.1

This rule details the required training and competency evaluation for state tested nurse aides working in long term care facilities.

The rule has been amended to require training in and evaluation of principles of person-centered care. Additionally, a home that "holds itself out" as providing specialty care must provide additional annual training in that care to nurse aides.

3701-17-07.2

This rule sets forth the required training for, and how a dining assistant may be used in a nursing home. The rule also includes an appendix that has the dining assistant program curriculum.

The rule has been amended to reflect current dietary standards and the appendix to the rule has been amended to include principles of person-centered care, update practices to current professional standards, and to update the bibliography.

3701-17-07.3

This rule sets forth the training, testing, and work experience requirements that a nurse aide must meet to be placed and retained on the Nurse Aide Registry.

This rule is being filed without amendment.

3701-17-08

This rule establishes the minimum personnel requirements for nursing homes, including nursing, dietary, activities, and ancillary staff.

The rule has been amended to require homes to conduct an assessment of the staffing needs of the home, and to clarify sharing of staff between ODH–licensed facilities. Two paragraphs have been re-ordered for ease of reading.

3701-17-09

This rule establishes parameters and personnel requirements for ongoing activities programs, social services, chaplain services, mail, and access to technology.

The rule has been renamed "resident life enrichment" and re-written to be resident-centered and re-ordered for clarity.

3701-17-10

This rule details the requirements for resident medical assessments, both annual and periodic, as well as advanced care planning for residents.

The rule has been amended to be more resident-focused and to remove outdated language.

3701-17-11

This rule requires nursing homes to have and follow infection control procedures that limit the likelihood of transmission of disease and to have a tuberculosis control plan based on Centers for Disease Control guidelines.

This rule is being filed without amendment.

3701-17-12

This rule establishes notification and reporting requirements for nursing homes when residents have a change in health status.

The rule has been amended to change “attending physician” to “resident’s physician”

3701-17-13

This rule requires each nursing home to have a medical director and establishes the medical directors’ duties, including periodic evaluation of residents. The rule also requires each home to ensure that every resident is under the supervision of a physician.

The rule is being filed without amendment.

3701-17-14

This rule details the requirements for resident care plans, transfer and discharge responsibilities of the home, and coordination of care when the resident is receiving hospice services.

The rule has been amended to be more resident-centered and to allow for more participation in the care planning process. Additionally, the rule has been amended to require the home to account for the resident’s monies held by the home and return them to the resident immediately upon transfer or discharge, or, to the resident’s family with 30 days of the resident’s death.

3701-17-15

This rule outlines how restraint may be used in nursing homes, including the need for a physician’s order and periodic review of the restraint. The rule also bars transitional holds and prone restraints in homes.

The rule has been amended to define “attending physician” as it is used in this rule.

3701-17-16

This rule sets forth what equipment and supplies a nursing home must have to meet the needs of residents, including mattresses, dressers and other bedroom items not furnished by the residents.

This rule is being proposed without amendment.

3701-17-17

This rule sets forth what medicines and drugs the nursing home is required to obtain. The rule also details to whom the drug should be administered and how they should be labeled.

The rule is being proposed without amendment.

3701-17-18

This rule outlines the food and nutrition requirements in nursing homes, including what meals must be served. The rule also requires a nursing home to employ a dietician to oversee the dietary service of the home. This rule has been amended to reflect current dietary standards. Specifically, the terms “complex, therapeutic diet” has been replaced with “therapeutic diets,” along with updating appropriate professional requirements.

3701-17-19

This rule outlines what records are to be kept by a nursing home and for how long, requires the home to note the resident’s Medicare Part D plan, if any, in the resident’s admission record, and to require a photograph of the resident, if the resident consents.

The rule has been amended to change “attending physician” to “resident’s physician,” clarify that a resident or their sponsor is always entitled to their medical records, and to require the operator of a home who sells the home to a new operator to transfer all resident records to the new operator.

3701-17-20

This rule sets forth requirements for smoking and fire safety requirements for ashtrays and waste containers and to require a home that permits outdoor smoking to make accommodations for residents during adverse weather conditions.

This rule is being proposed without amendment.

3701-17-21

This rule outlines the space requirements for nursing home dining and activity areas. The rule also details the requirements for toilet rooms in nursing homes. This rule has been amended to clarify the timeframes for compliance with the dining and activity room requirements: (1) prior to December 22, 1964; (2) between December 22, 1964 and July 17, 2002; and (3) after July 17, 2002.

The rule has been amended to remove the requirement that each toilet room be for the exclusive use of a resident sleeping room to allow the sharing of toilet rooms between no more than two residents.

3701-17-22

This rule sets forth plumbing, building and sanitation requirements for nursing homes, and also bans the use of overhead paging.

This rule is being proposed without amendment.

3701-17-23

This rule establishes space and occupancy requirements for resident sleeping rooms with 3 square footage and room capacity requirements based on the date the home was licensed: (1) prior to December 22, 1964; (2) between December 22, 1964 and July 17, 2002; and (3) after July 17, 2002.

This rule is being proposed without amendment.

3701-17-24

This rule establishes the temperature range allowable in nursing homes, between 71 and 81 degrees Fahrenheit, requires the home to develop a plan for resident health and safety when the temperature in the home is outside of the range, and requires repairs to be made in less than 48 hours when the HVAC system in incapable of maintaining appropriate temperatures.

This rule is being proposed without amendment.

3701-17-25

This rule sets forth the disaster preparedness requirements in the event of fire or other emergency. The rule also requires emergency evacuation drills, a plan for protection of all persons in the event of fire, to include a fire watch, notice to the Ohio missing adult alert system when a resident is missing, and for staff fire training to be conducted by the state fire marshal or township, municipal, or local legally constituted fire department.

The rule has been amended to require nursing homes to have 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 and for nursing homes licensed on or after the effective date of the rules to have CO detectors. The rule specifies where CO detectors must be placed and also defines those terms.

The rule has been amended to clarify that the CO monitoring requirement is only applicable to homes that have fuel burning appliances. The term "fuel-burning appliances" has been defined.

3701-17-26

This rule sets forth the procedures for requesting and granting a variance to the requirements of Administrative Code Chapter 3701-17.

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.

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

   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.

   Generally, no. While nursing homes can also be certified for participation in the federal Medicare and/or Medicaid program(s), and be subject to similar federal regulations, this chapter sets forth the state licensure requirements for oversight of nursing homes.

   In the three areas these rules do implement federal requirements (namely, 3701-17-07.1, use of state tested nurse aides; 3701-17-07.2, use of dining assistants; and 3701-17-07.3, operation of a nurse aide registry).

   Federal law (Titles XVIII and XIX of the Social Security Act and the regulations at 42 CFR §§ 483.154, 483.160, 483.156) require homes certified for participation in the Medicare and/or Medicaid program to use state tested nurse aides, trained dining assistants, and nurse aides to be listed on a nurse aide registry maintained by the state.

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

The rules do not exceed the federal requirements for the use of state tested nurse aides, dining assistants or the operation of a nurse aide registry

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 nursing homes. These rules serve to protect the health and safety of Ohioans, who, by reason of age or infirmity, live in nursing homes. The rules serve to ensure: that NHs 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 personal and social services provided each NH are appropriate for the residents of the home; 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

6. **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. Further evidence of success would be represented by the number of complaints 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.

- LeadingAge Ohio
- Ohio Academy of Senior Health Sciences
- State Long Term Care Ombudsman
- Ohio Health Care Association
- Alzheimer's Association
- Ohio Department of Mental Health and Addiction Services

- National Assn. of Social Workers – Ohio
- NAMI Ohio
- Department of Developmental Disabilities
- Ohio AARP
- Ohio Medical Directors Assn.
- Ohio Board of Nursing
- Ohio Board of Dietetics
- Ohio Department of Aging
- Ohio Dietetics Association
- Advocates for Ohio's Future
- Ohio Nurses Association
- State Fire Marshal
- Department of Medicaid

8. **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 the rules as they are posted. ODH held a series of stakeholder meetings to brainstorm how to make the nursing homes rules more effective, while attempting to remain cost neutral for homes. Meetings were held on April 7 & 28, and May 12, 2016.

   All parties agreed that making the rules more resident-centered, where appropriate, would be one way to transform Ohio's regulations in this area. This can be seen in many rules, but particularly rules 3701-17-09 and 3701-17-14.

   Additionally, it was agreed that a functioning QAPI program could lead to reduced enforcement actions as future bad outcomes could be avoided.

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

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?**

   - Process for Care Planning and Resident Choice, The Hulda B. & Maurice L. Rothschild Foundation (February, 2015)
   - Helping Measure Person Centered Care, The Health Foundation UK (March, 2014)
   - The High Cost of Poor Care: The Financial Case for Prevention in American Nursing Homes, The National Consumer Voice for Quality Long-Term Care (April, 2011)
   - Patient-Centered Care is Associated with Decreased Health Care Utilization, Journal of the American Board of Family Medicine (May/June , 2011)
   - The Value of Resident-Centered Care, Herman Miller (2013)

- Occupancy and Revenue Gains from Culture Change in Nursing Homes: A Win-Win Innovation for a New Age of Long-Term Care, Seniors Housing & Care Journal, (November, 2010)

The above research regarding "person centered care" supports changes throughout the rules to have a greater focus on person centered care. As shown in the literature, "person centered care" provides for better health outcomes for residents and ultimately less cost to the health care systems. Homes that focus on providing person centered care have decreased staff turnover, which is a leading indicator for resident health outcomes.

"New Dining Practice Standards." (Pioneer Network: Food and Dining Clinical Standards Task Force. August, 2011.)

Hee-Jung Song, Judy Simon, and Dhruti Patel. "Food Preferences of Older Adults in Senior Nutrition Programs." Journal of Nutrition in Gerontology and Geriatrics. Mar 5, 2014. DOI: 10.1080/21551197.2013.875502

American Dietetic Association: Changes in Type of Foodservice and Dining Room Environment Preferentially Benefit Institutionalized Seniors with Low Body Mass Indexes: 2007

American Dietetic Association: Higher Dietary Variety is Associated with Better Nutritional Status in Frail Elderly People: 2002

Connections: New Dining Practice Standards: Spring 2014

American Dietetic Association: Standards of Practice and Standards of Professional Performance for Registered Dietitians (Competent, Proficient and Expert) in Extended Care Settings: 2011

American Dietetic Association: Education and Certification Influence the Nutrition and Management Knowledge of Long-Term Care Foodservice Managers: 1999

Connections: Using Evidence-Based Organizational Strategies to Prevent Weight Loss in Frail Elders: Spring 2014

American Medical Directors Association, Altered Nutritional Status: 2009

American Medical Directors Association, Synopsis of Food Regulations: 2009

American Dietetic Association, Position Paper Diet Liberalization: 2005

American Dietetic Association, Liberalization of Diet Improves Quality of Life: 2005

American Dietetic Association, Unintended Weight Loss Guideline: 2009

The above research regarding dining standards supports changes in the rules regarding dining, care plan, and assessments. While weight loss among the elderly is common, it is also a sign of significant adverse outcomes.

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 any alternatives to the proposed regulation. ODH is required to implement section 3721.04 of the Revised Code. The rule reflects the current statutory requirement.

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.***

A performance based regulation was not deemed appropriate for this standard and not authorized by statute.

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 Ohio Revised Code and Ohio Administrative Code to ensure there are no other regulations in place licensure of nursing homes. Where there is limited overlap with building and fire safety standards, these generally applies to the use of existing regulatory language in ODH rules to prevent confusion, not to implement duplicative regulations.

<u>Rule 3701-17-13</u>

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.

<u>Rule 3701-17-25</u>

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.

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.

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

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;

The impacted business community consists of licensed nursing homes. As of January 1, 2016, there are 952 licensed nursing homes 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 3701-17-01 to 3701-17-26 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, including Centers for Medicare and Medicaid Services requirements for nursing facilities and skilled nursing facilities. 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 written plans for a Quality Assessment and Performance Improvement (QAPI) program and conduct meetings.

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

If applicable, time and manpower necessary to provide dining assistant 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 health care service are those generally associated with the provision of services within the industry including, but not limited to patient care planning, 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).

15. 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 nursing homes. These rules establish the licensure structure for Ohio nursing homes.

Regulatory Flexibility

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

Yes. Nursing homes with 120 beds or fewer do not need to employ a full-time social worker.

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 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.

18. 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:

http://www.odh.ohio.gov/odhprograms/ltc/nurhome/nurhome1.aspx.