

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Chapter 3701-19 Hospice Care Programs

Rule Number(s): 3701-19-01 through 3701-19-24

Date: August 5, 2019

**Rule Type:**

☒ New

☒ Amended

☒ 5-Year Review

☐ Rescinded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 regulations in plain language.**

Ohio Revised Code (“ORC”) section 3712.03 requires the Ohio Department of Health (“ODH”) to license and regulate hospice care programs in Ohio. A hospice care program is defined as: “a coordinated program of home, outpatient, and inpatient care and services that is operated by a person or public agency and that provides the following care and services to hospice patients, including services as indicated below to hospice patients' families, through a medically directed interdisciplinary team, under interdisciplinary plans of care established pursuant to section [3712.06](#) of the Revised Code, in order to meet the physical, psychological, social, spiritual, and other special needs that are experienced during the final stages of illness, dying, and bereavement:

- Nursing care by or under the supervision of a registered nurse;

- Physical, occupational, or speech or language therapy, unless waived by the department of health pursuant to rules adopted under division (A) of section [3712.03](#) of the Revised Code;
- Medical social services by a social worker under the direction of a physician;
- Services of a home health aide;
- Medical supplies, including drugs and biologicals, and the use of medical appliances;
- Physician's services;
- Short-term inpatient care, including both palliative and respite care and procedures;
- Counseling for hospice patients and hospice patients' families;
- Services of volunteers under the direction of the provider of the hospice care program;
- Bereavement services for hospice patients' families.

### **General:**

Grammatical and formatting changes have been made to the rules to improve the clarity and flow of the rules. As a result of House Bill (HB) 286 of the 133<sup>rd</sup> General Assembly, revisions have been made to incorporate language pertaining to the admission of non-hospice palliative care patients to hospice inpatient facilities for short term care.

### **ODH has drafted the following amendments:**

3701-19-01 - Sets forth the definitions for use throughout rules 3701-19-01 to 3701-19-24 including, but not limited to, “hospice patient”, “inpatient facility,” and “interdisciplinary care.” The rule is being revised to add new definitions for “palliative care consistent with the revision of the definition in section 3712.01 of the Ohio Revised Code made as a result of HB 286. The definition of a “follow up inspection” has been moved to this definitions rule from rule 3701-19-05 of the Ohio Administrative Code.

3701-19-02 - Sets forth the requirements pertaining to the applicability of licensure requirements for hospice care programs. The rule requires every person or public agency that proposes to provide a hospice care program to apply to the director for a license. The rule has been revised to correct citations in paragraphs (C) and (D)(3).

3701-19-03 - Sets forth the license application and fee requirements for initial, renewal, and change of ownership. These requirements include, but are not limited to, an application on a form prescribed by the director, a fee of \$600 for initial and renewal applications, and \$200 for change of ownership. The rule also requires documentation of the types of services that will be provided by the hospice care program and notification of the director of any changes that may affect the license. The rule is being revised to break down existing information into subparagraphs to improve the clarity and flow of the information. Additional revisions have been made to incorporate requirements for hospice care programs with hospice inpatient facilities or units that intend to admit non-hospice palliative care patients. The hospices will be required to submit an attestation that at least 51% of the program’s operations will be providing care to hospice patients and they will ensure the

availability of inpatient care for hospice patients. The rule is being revised to remove paragraph (B) which pertains to waiver and variances that are contained in rule 3701-19-23 of the Administrative Code. Finally, grammatical and formatting changes have been made to improve the clarity and flow of information in the rule.

3701-19-04 - The rule sets forth the requirements pertaining to the issuance, transfer, denial, suspension, and revocation of licenses. The rule requires the director to mail a written notice to an applicant within thirty days of receiving all necessary information to make a decision. Hospice care programs are required to post their license in a visible area. Furthermore, the rule authorizes the director to suspend a license for up to six months and charge a fine up to twenty thousand dollars for violations, depending on the severity and nature of the noncompliance with section 3712. Of the Revised Code and this Chapter. The rule is being revised make formatting changes to improve the clarity and flow of information in the rule.

3701-19-05 – The rule sets forth the requirements pertaining to inspections. The rule requires hospice care programs to be inspected prior to the issuance of a license and to be subject to periodic inspections (at least once every three years) to maintain their license and as a result of complaints. The fees for inspections are as follows:

- Licensure inspection: \$1625
- Complaint inspection: \$850
- Follow-up inspection: \$350
- Desk audit/compliance review: \$250

The rule is being revised to move the definition of ‘follow-up inspection’ to rule 3701-19-01 and make grammatical changes.

3701-19-06 –The rule sets forth the requirements for a governing body and a quality assessment and performance improvement program for each hospice care program. These requirements include, but are not limited to, the governing body must arrange for a physician medical director for the hospice care program; establish policies for the management, operation, and evaluation of the hospice care program; and conduct an ongoing quality assessment program. The appointed director of the hospice care program or the director’s designee is responsible for the implementation of the investigation and reporting requirements of section 3712.062 of the ORC. The rule is being revised to include exploitation in paragraph (C) in accordance with section 3721.23 of the Ohio Revised Code and make grammatical and formatting changes throughout the rule to improve the clarity and flow of information.

3701-19-07 – The rule sets forth the general requirements for hospice care programs. These include, but are not limited to, establishing an interdisciplinary plan of care for every patient that includes a list of all services to be provided by or arranged for by the hospice care program; ensuring that care is available twenty-four hours a day at the facility; and maintaining a clinical record for every patient. The rule is being revised to include grammatical changes to improve the clarity of the rule.

3701-19-08 – The rule sets forth the standards for inpatient hospice facilities. These standards include, but are not limited to, maintaining a home like environment, meeting all applicable Ohio building and occupancy codes for the facility type, and providing a meal service. The rule is being revised to include grammatical changes to improve the clarity of the rule.

3701-19-09 – The rule sets forth the general requirements for hospice care program personnel. These requirements include, but are not limited to, providing personnel with a job description and orientation; ensuring personnel act within the scope of their license, and that all personnel, including volunteers and contracted staff, are subject to a criminal records check as required by ORC section 3712.09. The rule is being revised to include exploitation in paragraph (C) in accordance with section 3721.23 of the Ohio Revised Code.

3701-19-10 – The rule sets forth the requirements for the medical director of a hospice care program. These requirements include, but are not limited to, the medical director reviewing patient eligibility for services, ensuring the continuity of medical services, and participation in interdisciplinary teams. The rule is being revised to add language clarifying that the hospice care program medical director maintains authority over other physician staff employed by the program.

3701-19-11 – The rule sets forth the requirements pertaining to interdisciplinary plans of care and interdisciplinary teams. Each hospice care program shall have an interdisciplinary team or teams that provides or supervises the provision of hospice care and services and is coordinated by a registered nurse. An interdisciplinary plan of care must be written for each patient that must be reviewed periodically by the patient's attending physician, if any. The rule is being revised to require the documentation of the date that a copy of a patient's plan of care is sent to their attending physician.

3701-19-13 – The rule sets forth the requirements pertaining to volunteers for hospice care programs. Hospice care programs are required to utilize volunteers and must provide the volunteers with an orientation and training, conduct a criminal records background check, and ensure that volunteers are supervised by appropriately qualified program staff. The rule is being revised to include grammatical changes to improve the clarity of the rule.

3701-19-15 – The rule sets forth the requirements for medical social services in hospice care programs. Medical social services must be provided by a social worker in a timely manner in accordance with the hospice care program's policies. The rule is being revised to include grammatical changes to improve the clarity of the rule.

3701-19-16 – The rule sets forth the requirements pertaining to home care services for hospice care programs. These requirements include, but are not limited to, services being available in the cope and frequency to meet the needs of hospice care program patients and their families and that a registered nurse must prepare and provide home health aides and hospice aides with written instructions for the care of each patient. The rule is being revised make formatting changes to improve the clarity and flow of information in the rule.

3701-19-17 – The rule sets forth the requirements for medical services in hospice care programs. Patient's may utilize their own physician or designate the program's medical director as their attending physician and the hospice care program must provide effective palliation and management of terminal illnesses and medical services to meet the needs of the patient that are not otherwise met by the attending physician. The rule is being revised to make grammatical changes throughout out and authorize patients to identify other hospice physician staff members as their attending physician.

3701-19-18 – The rule sets forth the requirements pertaining to counseling and bereavement services. Hospice care programs shall make available counseling services to the hospice care patient and the hospice care patient's family including dietary, spiritual, bereavement and any other necessary counseling services. Services are to be provided as part of the interdisciplinary plan of care. The rule is being revised to change the formatting of paragraphs (B)(2) and (C) to include existing language regarding arranging visits of clergy and religious organization with the counseling services and make the dietary counseling a stand-alone requirement.

3701-19-19 – The rule sets forth the requirements pertaining to physical, occupational, and speech therapy services. Hospice care programs are required to provide or arrange for the provision of these services by a licensed professional unless otherwise granted a waiver by the Director of Health. The rule is being revised to correct a citation in paragraph (A).

3701-19-20 – The rule sets forth the requirements pertaining to the admission of patients to a hospice care program. These requirements include, but are not limited to, meeting the diagnosis and life expectancy requirements of the hospice care patient definition provided in rule 3701-19-01; obtaining an informed consent from each patient or patient's representative prior to admission explaining the nature of the program's care; and obtaining confirmation of the patient's terminal status from the patient's physician or the medical director. The rule is being revised to make formatting changes to improve the flow of information within the rule.

3701-19-22 – The rule sets forth the requirements for short-term inpatient care and services provided or arranged by the hospice care program for pain control, symptom management, or respite care. These requirements include, but are not limited to, nursing care must be available twenty-four hours a day at a level to meet the needs of all hospice patients residing in the facility used by the hospice; inpatient care for pain control may only be provided in a certified or accredited hospice facility, hospital, or skilled nursing facility; and inpatient care for respite purposes may only be provided in a certified hospice facility, hospital, or skilled nursing facility or in a nursing home or residential care facility licensed under Chapter 3721. of the Revised Code. The rule is being revised to change the formatting to improve the clarity and flow of information in the rule and to provide a date for a citation in paragraph (D).

3701-19-23 – The rule sets forth the requirement for each hospice care program to maintain a clinical record for each patient. These requirements include, but are not limited to, inclusion of the interdisciplinary plan of care; notes from all services provided by the program and contractors, and to maintain all records to ensure confidentiality, protect from

theft, damage, or destruction. The rule is being revised to change the formatting to improve the clarity and flow of information in the rule.

**ODH has drafted the following new rule:**

3701-19-22.1 – This new rule sets forth the requirements for hospice care program inpatient facilities and units that admit non-hospice palliative care patients for short term care in accordance with section 3712.10 of the Revised Code. These requirements include, but are not limited to, the hospice medical director or their designee must determine the appropriateness of the admission of the non-hospice palliative care patient to the facility or unit, the facility must have the services and care available to treat the non-hospice palliative care patient's needs, the care must be for a short term basis only, clinical records, nursing, and medical social services must be provided in accordance with the rules of this Chapter, and staff must be trained in the philosophies, goals and issues associated with palliative care. Furthermore, non-hospice palliative care patients must be treated by an interdisciplinary team under the direction of a registered nurse and a clinical record must be maintained for each patient. All patient records, staff, and facilities must be made available for inspection as part of the standard survey process or complaints.

**ODH recommends the following rules without changes:**

3701-19-12 -The rule sets forth the requirements pertaining to the provision of a component or components of the hospice care program by written contract with another entity. These requirements include, but are not limited to, the hospice care program must provide the contractor with a copy of the patient's interdisciplinary plan of care; all care must be in compliance with the interdisciplinary plan of care; and all services provided by the contractor must be documented in the hospice care patient's clinical record.

3701-19-14 – The rule sets forth the requirement for nursing services in hospice care programs. These requirements include, but are not limited to, staffing nursing services to meet the needs of all patients and supervision and oversight by a registered nurse.

3701-19-21 – The rule sets forth the requirements that hospice care programs provide or arrange for medical supplies, appliances, drugs, and biologicals for hospice care patients. All medications and treatments must be administered by the appropriate staff member acting within their scope of practice. The rule additionally requires that the program's written policy regarding controlled substances containing opioids established under section 3712.062 of the ORC must account for medications that were prescribed to a patient as part of the patients hospice plan of care that are in the possession of the patient at the time of death or when no longer needed must be accounted for and destroyed by or the destruction must be witnessed by a program employee.

3701-19-24 – The rule sets forth the requirements for applying for a variance or waiver from any of the hospice care program rules. The rule allows the director to grant variances or waivers 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 any patient.

**2. Please list the Ohio statute authorizing the Agency to adopt these regulations.**

Ohio Revised Code sections 3712.03; 3712.04; 3712.05; and 3712.06; 3712.07; 3712.08; 3712.09

**3. Do the regulations implement a federal requirement? Are the proposed regulations 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?**

There are no federal requirements mandating these rules.

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

Not applicable to these rules.

**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)?**

As required by ORC sections 3712.03, 3712.04, 3712.05, and 3712.06, and 3712.09; rules 3701-19-01 through 3701-19-24 provide the necessary framework for ODH to ensure the quality of care provided by hospice care programs for the safety Ohio's health care consumers.

**6. How will the Agency measure the success of these regulations in terms of outputs and/or outcomes?**

Successful outcomes are measured through a standard survey (inspection) process approximately once every thirty-six months; successful outcomes would indicate compliance with the standards and requirements set forth in Chapter 3701-19. 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 regulations.**

Initial e-mail notifications and a request for informal comments were sent to stakeholders to share with their membership in August 2018 and stakeholder meetings were held in September 2018, November 2018, January 2019, and June 2019. Throughout this process, the drafts were repeatedly shared with stakeholders and revisions were made

based on stakeholder input, most notably in new rule 3701-19-22.1 pertaining to the admission of non-hospice palliative care patients to hospice inpatient facilities and units. Stakeholders involved include the following:

Community Hospice  
 Ohio Council for Homecare and Hospice  
 Hospice of Western Reserve  
 Mount Carmel Health Systems  
 LeadingAge Ohio  
 Hospice of Dayton  
 Sincera Care  
 Ohio Association of Community Health Professionals  
 National Hospice Cooperative  
 Hospice of Miami County  
 Hospice of NW Reserve  
 LifeCare Alliance  
 Hospice of Cincinnati  
 State of the Heart Care  
 Icare Solutions  
 Montefiore Home Care  
 Ohio Health  
 Akron Children's Hospital  
 Cincinnati Children's Hospital  
 Mercy Health System  
 My Hospice  
 Hospice of Central Ohio  
 Stein Hospice  
 Tri Health System

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

Stakeholders provided direct input throughout the rule review process. The group utilized existing national resources in developing the regulatory requirements set forth in new rule 3701-19-22.1, such as the following:

National Consensus Project for Quality Palliative Care – 3<sup>rd</sup> edition Clinical Practice Guidelines for Quality Palliative Care

American Hospital Association & Center to Advance Palliative Care – Palliative Care Services; Solutions for Better Patient Care and Today's Health Care Delivery Challenges



- 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?**

Not applicable to these rules.

- 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?**

The Ohio Department of Health is required to implement and monitor compliance with the licensing provisions mandated by ORC section 3712.04. Alternative regulations were not considered. The rules reflect ODH's experience with regulating hospice care programs and the direct past input of stakeholders regarding the expectations for hospice care programs and the licensing process.

- 11. Did the Agency specifically consider performance-based regulations? Please explain.**

Performance-based regulations were not deemed appropriate for these regulations. ODH rules contain both structural (process) and performance (outcome) based requirements. When there is a bad outcome, ODH can then look to ensure that the requirements of the rule were implemented properly and can identify break-downs in the process through surveys to provide opportunities for the program to correct their identified deficiencies and meet the quality and safety standards required by statute.

- 12. What measures did the Agency take to ensure that these regulations do not duplicate an existing Ohio regulation?**

The agency conducted a thorough review of the Revised Code and Administrative Code to ensure there are no other regulations in place pertaining to these specific requirements.

- 13. Please describe the Agency's plan for implementation of these regulations, including any measures to ensure that the regulations are applied consistently and predictably for the regulated community.**

Hospice care programs are surveyed approximately every thirty-six months. Surveys will also be conducted as necessary as the result of complaints to determine compliance. Surveys will be conducted by specially trained program staff utilizing a standard survey document and protocols specific to the type of service.

### **Adverse Impact to Business**

- 14. Provide a summary of the estimated cost of compliance with these rules. Specifically, please do the following:**

- a. Identify the scope of the impacted business community:**

All persons, government and private entities that seek licensure as a hospice care program.

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

License fees  
 Inspection fees  
 Time for compliance

**c. Quantify the expected adverse impact from the regulation:**

License fees

- Initial and renewal: \$600 every three years
- Change of Ownership license: \$200

Inspection fees as follows:

- Licensure inspection: \$1625 (At least every three years)
- Complaint inspection: \$850 (Conducted as the result of a complaint; no way to determine frequency.)
- Follow-up inspection: \$350 (Conducted as determined necessary to ensure that a plan of correction has been appropriately implemented as the result of a validated complaint investigation; no way to determine frequency.)
- Desk audit/compliance review: \$250 (Conducted as needed, when no on-site follow-up is required to determine compliance as the result of an inspection deficiency, to ensure compliance with rule requirements; no way to determine frequency.)

Time for compliance:

- 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 interdisciplinary plan of care for each hospice care program patient;
- Time and manpower necessary to develop policy and procedures pertaining to complaints.

All costs associated with records, interdisciplinary plan 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 \$102.00 per hour\*.

Registered Nurse:

\$0.00 to an average of \$32.13 per hour. \*

Other Healthcare Practitioners:

\$33.62 per hour\*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2018, using the codes for all health care practitioners and technical occupations (29-9099) physicians and surgeons, all others (29-1069), registered nurse (29-1141).

**15. 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 3712.04 by establishing licensing requirements for hospice care programs. The costs represented by the specific license and service standards set forth in rules 3701-19-01 through 3701-19-24 represent a general standard cost in terms of the administrative, personnel, and facility based requirements for the operation of a hospice care program 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**

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

Alternative means of compliance may be achieved through waiver or variance. Variances or waivers may be granted for any of the requirements of this 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 any patient. The requirements for a waiver or variance are set forth in rule 3701-19-24 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:

<https://odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/Office-of-General-Counsel/Statement-on-Paperwork-Violations/>

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

The requirements set forth in rules 3701-19-01 to 3701-19-24 of the Ohio Administrative Code are applicable to all hospice care programs. The Ohio Department of Health, Bureau of Regulatory Operations and Bureau of Survey and Certification staff provide information and assistance to providers. Information may be obtained via the ODH website at:

<https://odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/>