

MEMORANDUM

Date: July 19, 2019

To: Interested Parties

From: Selina G. Jackson, MPA, Bureau of Regulatory Operations, Ohio
Department of Health

Subject: Draft Amendments to Chapter 3701-19 of the Ohio Administrative Code (“Hospice Care Programs”)

In accordance with Ohio Revised Code Section 119.04, the five-year rule review of the rules set forth in Ohio Administrative Code Chapter 3701-19 (“Hospice Care Programs”) must be completed by November 1, 2019. Amendments have been made to numerous rules in Chapter 3701-19 as a result of this five-year review and House Bill (HB) 286 of the 133rd General Assembly.

Revisions related to the five-year review include clarifying that a hospice care program medical director maintains authority over all other hospice physician staff, including physician staff at satellite locations and allows other hospice physician staff to be designated by a patient as their attending physician. Furthermore, revisions have been made to include exploitation in the abuse, neglect, and misappropriation protections provided in accordance with section 3721.23 of the Ohio Revised Code. Finally, the majority of the rules in this Chapter have been revised to make grammatical and formatting changes to improve the clarity and flow of the rules.

In addition to the five-year review, HB 286 resulted in revisions to section 3712. of the Ohio Revised Code that allow for the admission of non-hospice palliative care patients to hospice care program inpatient facilities and units and revised the statutory definition of palliative care. The revised definition of palliative care was made to include patients of any age with a serious or life-threatening illness and establish that palliative care is aimed at relieving symptoms of stress and suffering in patients to improve the patient’s quality of life. Hospice care programs with inpatient facilities or units will now be able to provide care on a short-term basis to non-hospice palliative care patients. The requirements for this inpatient care are established in new rule 3701-19-22.1 and include, but are not limited to, the following:

- A hospice care program that intends to provide short term inpatient care to non-hospice palliative care patients must provide a written attestation to the Director of Health that the hospice care program will ensure that at least fifty-one percent of all services will be provided to hospice patients and the program will ensure the availability of inpatient care for hospice patients;
- 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 staff necessary to meet the needs of the non-hospice palliative care patient;

- Staff must be trained in the philosophies, goals and issues associated with palliative care; and
- All care must be provided by an interdisciplinary team and documented in the patient's clinical record.

Please review the draft amended rules and provide any comments you may have by **August 19, 2019** to the address below. Please include the words "Hospice" in the subject line of all comments sent via regular mail or e-mail. ODH will review and consider the comments received before the rule is submitted for formal rule proposal and adoption proceedings. Thank you.

Office of the General Counsel [Hospice Rules]
Ohio Department of Health
246 N. High St.
Columbus, Ohio 43215
ODHRules@odh.ohio.gov

*****DRAFT - NOT FOR FILING*****

3701-19-01 Definitions.

As used in this chapter:

- (A) "Advanced Practice Nurse" means a registered nurse authorized to practice as a certified nurse specialist, certified registered nurse anesthetist, certified nurse midwife or certified nurse practitioner in accordance with section 4723.41 of the Revised Code;
- (B) "Applicant" means a person or public agency that submits an application for a license to provide a hospice care program under rule 3701-19-03 of the Administrative Code.
- (C) "Attending physician" means the physician identified by the hospice patient or the hospice patient's family as having primary responsibility for the hospice patient's medical care.
- (D) "Dietitian" means an individual licensed under Chapter 4759. of the Revised Code to practice dietetics.
- (E) "Director" means the director of health or any official or employee of the department of health designated by the director of health.
- (F) For purposes of this chapter, "follow-up inspection" means an inspection, which may include on-site and off-site activities, conducted by the department to determine whether the hospice care program has corrected a violation or violations cited on a previous inspection.
- ~~(F)~~ (G) "Governing body" means the entity that has ultimate responsibility and authority for the overall operation of a hospice care program, as specified in rule 3701-19-06 of the Administrative Code.
- ~~(G)~~ (H) "Home health aide" means an individual who, in accordance with rule 3701-19-16 of the Administrative Code, provides home care services for hospice patients and their families.
- ~~(H)~~ (I) "Hospice aide," for the purpose of this chapter, means a home health aide who has successfully completed a training and competency evaluation program approved by the director under division (A) of section 3721.31 of the Revised Code and Chapter 3701-18 of the Administrative Code, is currently listed in good standing on the state nurse aide registry, and is employed by a hospice care program.
- ~~(I)~~ (J) "Hospice care program" or "program" means 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 and rule 3701-19-11 of the Administrative 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:
 - (1) Nursing care by or under the supervision of a registered nurse;
 - (2) Physical, occupational, or speech or language therapy, unless waived by the department of health pursuant to paragraph (B) of rule 3701-19-19 of the Administrative Code;
 - (3) Medical social services by a social worker under the direction of a physician;
 - (4) Services of a home health aide;
 - (5) Medical supplies, including drugs and biologicals, and the use of medical appliances;

*****DRAFT - NOT FOR FILING*****

(6) Physician's services which include medical services provided by a physician or an advanced practice nurse acting within his or her scope of practice, as defined in section 4723.01 of the Revised Code, or a physician assistant acting within his or her scope of practice under the supervision, control, and direction of one or more physicians as defined in section 4730.01 of the Revised Code.

(7) Short-term inpatient care, including both palliative and respite care and procedures;

(8) Counseling for hospice patients and hospice patients' families;

(9) Services of volunteers under the direction of the provider of the hospice care program;

(10) Bereavement services for hospice patients' families.

~~(J)~~ (K) "Hospice patient" or "patient" means a patient who has been diagnosed as terminally ill, has an anticipated life expectancy of six months or less, and has voluntarily requested and is receiving care from a person or public agency licensed under Chapter 3712. of the Revised Code and this chapter to provide a hospice care program.

~~(K)~~ (L) "Hospice patient's family" or "family" means a hospice patient's immediate family members, including a spouse, brother, sister, child, or parent, and any other relative or individual who has significant personal ties to the patient and who is designated as a member of the patient's family by mutual agreement of the patient, the relative or individual, and the patient's interdisciplinary team.

~~(L)~~ (M) "Inpatient facility" means a facility that either is operated by or under contract with a hospice care program for the purpose of providing inpatient care to the hospice care program's patients.

~~(M)~~ (N) "Inpatient hospice facility" means a building or leased unit operated by a hospice care program that is separate and distinct from another licensed or certified facility where the hospice program directly provides accommodations and hospice services for its hospice patients.

~~(N)~~ (O) "Interdisciplinary plan of care" or "plan of care" means the interdisciplinary plan for care of a hospice patient and his or her family prepared under rule 3701-19-11 of the Administrative Code.

~~(O)~~ (P) "Interdisciplinary team" means a working unit composed of professional and lay persons that includes at least a physician, a registered nurse, a social worker, a member of the clergy or a counselor, and a volunteer.

~~(P)~~ (Q) "Licensed practical nurse" means a person licensed under Chapter 4723. of the Revised Code to practice nursing as a licensed practical nurse.

~~(Q)~~ (R) "Nurse" means a registered nurse or licensed practical nurse.

~~(R)~~ (S) "Palliative care" means ~~treatment~~ specialized care for a patient of any age who has been diagnosed with a serious or life-threatening illness ~~directed at controlling pain, relieving other symptoms, and enhancing the quality of life of the patient and the patient's family rather than treatment for the purpose of cure~~ that is provided at any stage of the illness by an interdisciplinary team working in consultation with other health care professionals, including those who may be seeking to cure the illness and that aims to do all of the following: ~~Nothing in this section shall be interpreted to mean that palliative care can be provided only as a component of a hospice care program.~~

(1) Relieve the symptoms, stress, and suffering resulting from the illness;

*****DRAFT - NOT FOR FILING*****

(2) Improve the quality of life of the patient and the patient's family;

(3) Address the patient's physical, emotional, social, and spiritual needs; and

(4) Facilitate patient autonomy, access to information, and medical decision making.

Nothing in this chapter shall be interpreted to mean that palliative care can be provided only as a component of a hospice care program or pediatric respite care program.

~~(S)~~(T) "Person" means an individual, corporation, business trust, estate, trust, partnership, and association.

~~(T)~~(U) "Physician" means a person authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

~~(U)~~(V) "Physician assistant" means a person who holds a certificate of authority to practice as a physician assistant issued under Chapter 4730. of the Revised Code.

~~(V)~~(W) "Respite care" means hospice care program services provided by the program in a patient's home or in an inpatient facility to give temporary relief to a hospice patient's family or other caregivers when the patient's family or other caregiver needs relief from the daily demands of caring for the patient.

~~(W)~~(X) "Registered nurse" means a person registered under Chapter 4723. of the Revised Code to practice professional nursing.

~~(X)~~(Y) "Social worker" means a person licensed under Chapter 4757. of the Revised Code to practice as a social worker or independent social worker.

~~(Y)~~(Z) "Staff member" or "staff" means an individual working for a hospice care program including the owner; the administrator; a full-time, part-time or temporary paid employee; or an individual working on contract.

~~(Z)~~(AA) "Volunteer" means a lay or professional person who offers and provides his or her services to a hospice care program without compensation.

*****DRAFT - NOT FOR FILING*****

3701-19-02 Applicability of licensure requirements.

- (A) Every person or public agency that proposes to provide a hospice care program shall apply to the director for a license in accordance with rule 3701-19-02 of the Administrative Code.
- (B) A hospital, nursing home, home for the aged, county medical care facility, or other health facility or agency that provides a hospice care program shall be licensed to provide a hospice care program under Chapter 3712. of the Revised Code and this chapter.
- (C) A nursing home licensed under Chapter 3721. of the Revised Code that does not hold itself out to be a hospice, does not hold itself out as providing a hospice care program, does not use the term "hospice" to describe or refer to its activities or facilities, and that does not provide all of the services enumerated in division (A) of section 3712.01 of the Revised Code and paragraph ~~(H)~~(J) of rule 3701-19-01 of the Administrative Code is not subject to the licensing provisions of Chapter 3712. of the Revised Code and this chapter.
- (D) No person or public agency, other than a person or public agency licensed under section 3712.04 of the Revised Code and this chapter, shall hold itself out as providing a hospice care program, or provide a hospice care program, or use the term "hospice" or any term containing "hospice" to describe or refer to a health program, facility, or agency.
- (1) A hospital, a home providing nursing care, or a home health agency that provides services under contract with a person or public agency providing a hospice care program that is licensed under section 3712.04 of the Revised Code and this chapter shall not be considered as providing a hospice care program in violation of paragraph (D) of this rule.
- (2) Paragraph (D) of this rule does not apply to the activities of regional, state, or national nonprofit organizations of which providers of hospice care programs, individuals interested in hospice care programs, or both are members and that do not provide or represent that they provide hospice care programs.
- (3) As used in paragraph (D) of this rule, "person" does not include a member of an interdisciplinary team, as defined in paragraph ~~(O)~~(P) of rule 3701-19-01 of the Administrative Code, or any individual who is employed by a person or public agency licensed under section 3712.04 of the Revised Code and this chapter.

*****DRAFT - NOT FOR FILING*****

3701-19-03 Initial license application process; renewal of license; and change of ownership license.

- (A) Application for a hospice care program license shall: ~~be made on forms prescribed by the director, shall include such information as the director requires, including the information prescribed by paragraph (C) of this rule, and shall be accompanied by a non-refundable license fee of six hundred dollars in the form of a cashier's check or a postal money order payable to the "Treasurer, State of Ohio."~~
- (1) Be made on forms prescribed by the director;
- (2) Include such information as the director requires, including the information prescribed in paragraph (C) of this rule; and
- (3) Be accompanied by a non-refundable license fee of six hundred dollars in the form of a cashier's check or a postal money order payable to the "Treasurer, State of Ohio."
- (B) Any person or public agency seeking to be licensed to provide a hospice care program shall submit an application for licensure at least sixty days prior to the requested date for the inspection required by paragraph (A) of rule 3701-19-05 of the Administrative Code.
- (C) An application for a license to provide a hospice care program shall include:
- (1) The name, address, and business telephone number of the hospice care program. A hospice care program that operates from multiple locations shall include the addresses and telephone numbers for all locations on the application for license. The application shall indicate which location is to be issued the license;
 - (2) The names and addresses of the persons having an ownership or ~~control~~ a controlling interest in the hospice care program and other information pertaining to ownership or control of the program;
 - (3) The corporate name of the hospice care program, if any, and the names, titles, addresses, and telephone numbers of its officers and statutory agent;
 - (4) A list of the services which are or will be provided by the hospice care program either directly or indirectly through written contracts, the identities of any contractors and the services they will provide, and the date the program will be operational;
 - (5) A description of the geographic area in which the hospice care program will provide services;
 - (6) If the applicant is requesting a waiver of the requirement for providing physical therapy, occupational therapy, or speech or language therapy services pursuant to paragraph (B) of rule 3701-19-19 of the Administrative Code, the documentation required by that paragraph;
 - (7) If the program provides hospice care and services in a hospice patient's home, a written attestation that the applicant is in compliance with section 3712.062 of the Revised Code; and
 - (8) If a hospice care program operates an inpatient hospice facility; ~~documentation of compliance with the building code standards required by paragraph (C) of rule 3701-19-08 of the Administrative Code.~~

(a) Documentation of compliance with the building code standards required by paragraph (C) of rule 3701-19-08 of the Administrative Code;

*****DRAFT - NOT FOR FILING*****

(b) If the hospice intends to admit non-hospice palliative care patients to the hospice inpatient unit in accordance with section 3712.10 of the Revised Code, a written attestation that the hospice care program will:

(i) Continue to be primarily engaged as a hospice care program and at least fifty-one per cent of all services provided by the hospice care program will be to hospice patients; and

(ii) Ensure the availability of hospice inpatient care to hospice care program patients through admission to the hospice care program's inpatient facility or through contract with an inpatient facility that meets the requirements of rule 3701-19-22 of the Administrative Code.

(D) The applicant or an authorized representative shall sign an affidavit included in the application certifying that, to the best of ~~his or her~~the applicant's knowledge, the information in the application and any accompanying material is true and accurate. If a representative signs the affidavit, ~~he or she~~the application shall include documentation that ~~he or she~~they is are the applicant's authorized representative.

(E) When reviewing a license application, the director may request, in writing, that an applicant furnish any additional information that the director determines to be necessary to assess compliance with Chapter 3712. of the Revised Code and this chapter. The applicant shall furnish any requested information within fourteen days after the mailing of the director's request.

(F) Licensure of a hospice care program providing services from multiple locations in Ohio.

(1) Except as prohibited by section 3712.08 of the Revised Code, the director may grant a license to a hospice care program which provides services from multiple locations in Ohio, if the applicant complies with all the following:

(a) Each location provides the same full range of services that is required of the hospice care program location issued the license;

(b) Each location is responsible to the same governing body and central administration that governs the hospice care program location issued the license, and the governing body and central administration is able to adequately manage each location;

(c) The hospice care program maintains clinical records for all patients served by the hospice care program regardless of where services are provided; and

(d) All hospice patients' clinical records requested by the director during an inspection are available at the hospice care program location issued the license.

(2) A hospice location that does not comply with the requirements of paragraph (F)(1) of this rule is operating as a separate hospice care program and shall obtain a separate license and pay the appropriate license fee.

(G) A hospice care program operating in another state seeking to provide services to patients in Ohio shall establish an administrative office in Ohio and comply with the rules of Chapter 3701-19 of the Administrative Code in order to obtain a license. All Ohio hospice patients' clinical records shall be maintained at the Ohio administrative office.

(H) Application for renewal of a hospice care program license shall be made at least ninety days prior to the

*****DRAFT - NOT FOR FILING*****

expiration of the license. The application shall be made and a renewal fee paid in accordance with paragraph (A) of this rule in the same manner as for an initial license.

- (1) In addition to the application and fee requirements of this paragraph, a hospice care program that operates an inpatient hospice facility shall:
 - (a) Submit documentation of continued compliance with the Ohio fire code required by paragraph (B) of rule 3701-19-08 of the Administrative Code;
 - (b) A certificate of use and occupancy required by paragraph (C) of rule 3701-19-08 of the Administrative Code only if it is different than the one previously submitted to the director; and
 - (c) If the program provides hospice care and services in a hospice patient's home, the application for renewal shall include a written attestation that the applicant is in compliance with section 3712.062 of the Revised Code.
 - (2) The director shall renew the license if the program continues to meet the requirements of Chapter 3712. of the Revised Code and Chapters 3701-19 and 3701-13 of the Administrative Code. If the program does not meet the requirements, the director may deny renewal of the license, in accordance with Chapter 119. of the Revised Code.
- (I) In addition to submitting the application and renewal fee required by paragraph (A) of this rule, an applicant applying for a license renewal pursuant to paragraph (J) of this rule shall also submit:
- (1) Evidence of the program's current medicare certification pursuant to Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981), with its expiration date noted; and
 - (2) If the program is certified or accredited by an entity other than the secretary of the United States department of health and human services (under Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981), a copy of the most recent accreditation decision report.
- (J) The director shall renew licenses to persons or public agencies to provide hospice care programs that are accredited or certified to provide such programs by an entity whose standards for accreditation or certification equal or exceed those provided for licensure set forth in Chapter 3712. of the Revised Code and this chapter.
- (1) For purposes of this paragraph, the standards for medicare certification set forth in Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981), shall be considered to equal or exceed the requirements for licensure set forth in Chapter 3712. of the Revised Code and this chapter. If an applicant seeks license renewal pursuant to this paragraph on the basis of accreditation or certification by another entity, the director shall review the entity's certification or accreditation standards and shall determine whether they equal or exceed the standards set forth in Chapter 3712. of the Revised Code and this chapter.
 - (2) If the certification or accreditation of a person or public agency providing a hospice care program that was granted a license renewal pursuant to paragraph (J) of this rule is terminated or expires and is not renewed:
 - (a) The hospice care program shall send written notification of the termination or expiration to the director prior to the effective date of the termination, expiration, or non-renewal of the certification or accreditation or within five business days after receipt of such notice of termination, expiration,

*****DRAFT - NOT FOR FILING*****

or non-renewal, which ever is sooner; and

(b) The director shall inspect the program to determine whether it otherwise meets the requirements of Chapter 3712. of the Revised Code and this chapter. After conducting the inspection, the director may take whatever action concerning the program's license that the director considers appropriate.

(K) Each licensed hospice care program shall notify the director, in writing, of any of the following:

- (1) Any change in any of the information specified in the license application under paragraphs (C)(1) to (C)(5) and (C)(8) of this rule no later than fifteen days after the change;
 - (a) A change of ownership shall require the submission of a change of ownership application on forms prescribed and provided by the director; and
 - (b) A non-refundable fee of two hundred dollars in the form of a check or money order payable to the "Treasurer, State of Ohio."
- (2) Any other change that would render the information submitted in the license application inaccurate at least twenty-one days prior to the effective date of the change.

*****DRAFT - NOT FOR FILING*****

3701-19-04 Issuance, denial, transfer, suspension, and revocation of licenses.

(A) The director shall grant a license for provision of a hospice care program to an applicant that complies with Chapter 3712. of the Revised Code and this chapter.

~~(B) Upon written request, the director may grant a variance from any requirement of this chapter, that is not a statutory requirement, if the person or public agency requesting the variance establishes that because of practical difficulties or other special conditions, strict application of the requirement will cause unusual or unnecessary hardship and that the variance will not jeopardize the health, safety, or welfare of any hospice patient or hospice patient's family.~~

~~(C)~~ (B) The director shall mail written notice to the applicant either granting or proposing to deny a license within thirty days after receiving all information necessary to determine compliance with Chapter 3712. of the Revised Code and this chapter, including the reports of the inspection conducted pursuant to paragraph (A) of rule 3701-19-05 of the Administrative Code. This thirty-day period shall be extended if the director has received a complaint concerning an applicant. In such a case, the director shall conduct a complaint investigation within thirty days after receipt of the complaint and shall mail written notice of the determination regarding the license application within thirty days after completion of the complaint investigation.

~~(D)~~ (C) If the applicant meets the requirements for licensure prescribed in paragraph (A) of this rule, the director shall issue a license to the applicant which shall:

(1) Indicate the name and address of the hospice care program location to which the applicant requested the license be issued. The names and addresses of additional locations operating under the same license shall be maintained on file;

(2) Be valid for three years only for the hospice care program at the address and additional locations indicated in the application except as provided for in paragraph (F) of this rule; and

(3) Be posted in a conspicuous place in the hospice care program location issued the license.

~~(E)~~ (D) Subject to Chapter 119. of the Revised Code, the director may deny, suspend, or revoke a license if the licensee:

(1) Made any material misrepresentation in the application for licensure; or

(2) No longer meets the requirements of Chapter 3712. of the Revised Code or this chapter.

~~(3) If, after a review of an application for license renewal in accordance with paragraph (H) of rule 3701-19-03 of the Administrative Code, the department determines that the program is not in compliance with section 3712.062 of the Revised Code, the department may suspend the hospice care program's license for not more than six months and impose a fine not to exceed twenty thousand dollars.~~

(E) If, after a review of an application for license renewal in accordance with paragraph (H) of rule 3701-19-03 of the Administrative Code, the department determines that the program is not in compliance with section 3712.062 of the Revised Code, the department may suspend the hospice care program's license for not more than six months and impose a fine not to exceed twenty thousand dollars.

(F) A hospice care program that seeks to transfer its license to another or new location shall submit a written request to the director of health to transfer its license. The request shall indicate the name and address of the

DRAFT - NOT FOR FILING

hospice care location issued the license and the address to which the hospice seeks to transfer the license. The request must be received by the director no later than ninety days prior to the current license expiration date or thirty days prior to the proposed transfer or relocation, whichever occurs sooner.

- (1) When reviewing a request for transfer of a license, the director may request any additional written information he or she determines necessary to assess whether the criteria in paragraph (F)(2) of this rule are met.
- (2) The director shall allow a license to be transferred if the following criteria are met:
 - (a) The hospice care program currently meets all of the licensing requirements and there are no pending complaints under investigation. Any pending complaints shall be investigated within thirty days of the request for transfer;
 - (b) The hospice care program is not undergoing any enforcement action at the time of the transfer or relocation or proposed transfer or relocation;
 - (c) The transfer or relocation is not due to a change in ownership or control;
 - (d) The transfer or relocation does not diminish the current geographic area being served by the hospice care program;
 - (e) The hospice care program continues to provide the same full range of services at the new location that was required of the hospice care program location that was issued the license;
 - (f) All hospice patients' clinical records are available, upon request of the director, at the new location to which the hospice license is to be transferred;
 - (g) If the hospice care program provides inpatient care directly, the transfer of the license does not involve either the establishment of an inpatient facility, or relocation of an existing inpatient facility, where the hospice care program provides inpatient care directly;
 - (h) The approval to transfer the license may be granted with no less than sixty-one days remaining prior to the expiration of the current license; and
 - (i) If the hospice care program obtained its license pursuant to paragraph (J) of rule 3701-19-03 of the Administrative Code, the hospice care program is currently in compliance with the applicable accreditation or certification standards
- (3) The director shall notify the hospice care program of whether or not the license may be transferred. If the director determines that the license is not transferable, the director shall provide the hospice care program with an opportunity for a reconsideration:
 - (a) The hospice care program shall request a reconsideration in writing within thirty days of the mailing of the notice of determination~~;~~;
 - (b) The request shall include any written documentation or other information not previously submitted to the director that the hospice care program wishes to refute the determination~~;~~;
 - (c) The director's final determination is not appealable under Chapter 119. of the Revised Code~~;~~ and

*****DRAFT - NOT FOR FILING*****

- (d) The hospice care program shall obtain a license for the new location prior to commencing services at the new location.

*****DRAFT - NOT FOR FILING*****

3701-19-05 Inspections.

- (A) Prior to issuing an initial license for a hospice care program, the director shall conduct an announced inspection of the applicant's facilities and services.
- (B) The director shall conduct an unannounced inspection of each licensed hospice care program at a minimum frequency of once every three years. The director may conduct additional inspections of any licensed hospice care program at any other time the director considers necessary including, but not limited to, ~~investigating~~ investigation of complaints.
- (C) The fees for inspections conducted by the director pursuant to section 3712.03 of the Revised Code and paragraphs (A) and (B) of this rule shall be as follows:
- (1) Licensure inspection fee of one thousand six hundred twenty five dollars;
 - (2) Complaint inspection fee of eight hundred fifty dollars;
 - (3) Follow-up inspection fee of three hundred fifty dollars; and
- ~~For purposes of this paragraph, "follow-up inspection" means an inspection, which may include on-site and off-site activities, conducted by the department to determine whether the hospice care program has corrected a violation or violations cited on a previous inspection.~~
- (4) Desk audit or compliance review inspection fee of two hundred fifty dollars.
- (D) For purposes of inspections by the director, each hospice care program shall provide access to its premises and staff at all times and to pertinent records upon request. The program shall ensure that the director has access to all parts of its facilities, services, and records, including the inpatient facilities operated by or under contract with the program. The inspections may include visits to hospice patients' homes and direct interaction with patients and their families, with the patients' or families' consent.
- (E) If an inspection of an applicant's hospice care program or of a licensed hospice care program reveals a violation or violations of Chapter 3712. of the Revised Code or of Chapter 3701-19 or 3701-13 of the Administrative Code, the director, ~~in at their~~ his or her discretion, may require submission of a plan of correction for each violation. The hospice care program shall submit the plan within ten calendar days after receiving the director's notification that a plan of correction is required.
- (F) When a hospice care program provides services at more than one location under one license, a violation found at any location shall constitute a violation for the entire hospice care program.

*****DRAFT - NOT FOR FILING*****

3701-19-06 Governing body; quality assessment and performance improvement.

- (A) The overall conduct and operation of the hospice care program, including the quality of care and the provision of services, shall be the full legal responsibility of a clearly defined, organized governing body.
- (B) The governing body of a licensed hospice care program may also provide governance for a pediatric respite care program if the programs are dually-licensed and meet all requirements set forth in this rule and chapter.
- (C) The governing body shall:
- (1) Establish and review policies for the management, operation, and evaluation of the hospice care program, including, but not limited to:
 - (a) Qualifications of employees and independent contractors; and
 - (b) Policies and procedures to receive and respond to patient grievances regarding medical treatment, quality of care, the lack of respect for person or property, mistreatment, neglect, exploitation, verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by any individual furnishing services on behalf of the hospice care program. The policies and procedures developed by the governing body shall, at a minimum, include:
 - (i) Notification procedures for hospice patients, employees and contracted staff to report alleged violations to the hospice program administration;
 - (ii) Documentation requirements for reported alleged violations, including time frames for response;
 - (iii) Reporting procedures for verified violations to the appropriate state licensing authority, local authorities, or both where appropriate; and
 - (iv) Requirements for timely corrective actions for all verified violations.
 - (2) Arrange for a physician to serve as medical director for the hospice care program who:
 - (a) Shall be knowledgeable about the psychological, social, and medical aspects of hospice care as the result of training, experience, and interest;
 - (b) May also serve as the physician representative on an interdisciplinary team or teams or as an attending physician; ~~and~~
 - (c) Maintain ultimate responsibility for physicians designated to act on behalf of the medical director; and
 - ~~(e)~~ (d) Shall designate a physician to act in ~~his or her~~ their absence.
 - (3) Appoint a qualified individual to serve as the ~~director~~ administrator of the hospice care program who shall perform the following duties:
 - (a) Be responsible for the day-to-day management of the program and for assuring compliance with Chapter 3712. of the Revised Code, Chapter 3701-13, and this chapter of the Administrative Code;
 - (b) Implement the hospice care program's policies and procedures regarding all activities and services provided by the hospice care program;

*****DRAFT - NOT FOR FILING*****

- (c) Designate an individual to act in ~~his or her~~their absence;
- (d) Implement the hospice care program's quality assessment and performance improvement program under paragraph (D) of this rule;
- (e) Implement the hospice care program's patient grievance program established under paragraph (C)(1) of this rule;
- (f) Implement the drug diversion investigation and reporting program required by section 3712.062 of the Revised Code. The hospice ~~director~~administrator or the ~~director's~~administrator's designee, must:
 - (i) Receive reports of suspected drug diversion from hospice staff;
 - (ii) Within twenty four hours of receipt, investigate reports of suspected drug diversion; and
 - (iii) No later than ten days after receipt of a report of suspected drug diversion or upon conclusion of an investigation, report to the law enforcement agency with jurisdiction over the territory in which the hospice patient's home is located the results of the hospice program's investigation when the investigation substantiates that drug diversion has occurred or when the results of the investigation are inconclusive. Nothing in this rule prohibits a hospice care program from reporting the result of any other drug diversion investigation to law enforcement.

(g) Designate a registered nurse that is a member of an interdisciplinary team to coordinate the overall functioning of the interdisciplinary team.

~~(4) Designate a registered nurse that is a member of an interdisciplinary team to coordinate the overall functioning of the team; and~~

~~(5)~~(4) Ensure that all services provided are consistent with accepted standards of practice for hospice care.

- (D) Each hospice care program governing body shall ensure that an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided by the program, including inpatient care, home care, and care provided under contracts with other persons or public agencies is conducted. The assessment shall include all services that were indicated and provided to the hospice care patients and their families and the patients' and caregivers' responses or outcomes to those services.
- (E) The hospice care program governing body shall ensure the use of the findings of the quality assessment and performance improvement program to correct identified problems and to revise hospice care program policies if necessary.
- (F) The hospice care program governing body shall ensure that an evaluation of the hospice care program's quality assessment and performance improvement program is conducted on an annual basis.

(G) If the hospice care program operates an inpatient hospice unit and admits non-hospice palliative care patients in accordance with section 3712.10 of the Revised Code, the hospice care program shall ensure that non-hospice palliative care patients and their families or caregivers are included in the requirements of paragraphs (D), (E), and (F).

*****DRAFT - NOT FOR FILING*****

3701-19-07 General requirements for hospice care programs after licensure.

- (A) Any person or public agency licensed under section 3712.04 of the Revised Code and this chapter to provide a hospice care program shall:
- (1) Provide a planned and continuous hospice care program, the medical components of which shall be under the direction of a physician;
 - (2) Ensure that care is available twenty-four hours a day and seven days a week;
 - (3) Establish an interdisciplinary plan of care for each hospice patient and the patient's family that:
 - (a) Is coordinated by one designated individual who shall ensure that all components of the plan of care are addressed and implemented;
 - (b) Addresses maintenance of patient-family participation in decision making;
 - (c) Is periodically reviewed by the patient's attending physician and by the patient's interdisciplinary team; and
 - (d) Provides a list of services that will be provided by or arranged for by the hospice care program.
 - (4) Have an interdisciplinary team or teams that provide or supervise the provision of care and establish the policies governing the provision of the care;
 - (5) Provide bereavement counseling for hospice patients' families~~;~~ [and](#)
 - (6) Not discontinue care because of a hospice patient's inability to pay for the care;
 - (7) Maintain central clinical records on all hospice patients under its care~~;~~ [and](#)
 - (8) Provide care in individual's homes, on an outpatient basis, and on a short-term inpatient basis~~;~~ [and](#)
- (B) A component or components of the care provided by a hospice care program may be provided under a written contract with another person or public agency, pursuant to rule 3701-19-12 of the Administrative Code.
- (C) After receiving a license, a hospice care program shall comply with all requirements of Chapter 3712. of the Revised Code and Chapters 3701-13 and 3701-19 of the Administrative Code.
- (D) Each licensed hospice care program shall notify the director, in writing, of any of the following:
- (1) Any change in any of the information specified in the license application under paragraphs (C)(1) to (C)(3) of rule 3701-19-03 of the Administrative Code no later than fifteen days after the change;
 - (2) Any other change that would render the information submitted in the license application inaccurate at least twenty-one days prior to the effective date of the change; [and](#)
 - (3) Any intent to cease operation at least sixty days prior to ceasing operation. This notification shall include a plan for assuring continuity of care for the program's patients and their families after the program ceases operation~~;~~ [and](#)

*****DRAFT - NOT FOR FILING*****

- (4) Each hospice care program that intends to cease operation shall do the following to assure the continuity of care of hospice program patients and their families by:
- (a) Providing a written notice of the proposed closure of the program, at least sixty days prior to ceasing operation, to each patient or patient's family;
 - (b) Developing a written discharge plan to be placed in each patient's record to assist the person or public agency that will be responsible for care of the patient and ~~his or her~~the patient's family after the program ceases operation; and
 - (c) Obtaining from each patient or ~~his or her~~their authorized representative a written approval of any transfer to another licensed hospice care program and a written authorization to release pertinent clinical records information to such a program or another person or public agency that will assume responsibility for the patient's and family's care.

*****DRAFT - NOT FOR FILING*****

3701-19-08 Standards for inpatient hospice facilities.

- (A) Each new inpatient hospice facility shall be inspected by the director to determine compliance with provisions of rules 3701-19-01 to 3701-19-24 of the Administrative Code. The new inpatient hospice facility shall not admit patients until the director has determined that the facility is in compliance with the requirements of this chapter of the Administrative Code.
- (B) The inpatient hospice facility shall meet all applicable provisions of the Ohio fire code, adopted pursuant to section 3737.82 of the Revised Code.
- (C) The building or buildings in which an inpatient hospice facility is located shall comply with the applicable provisions of the Ohio building code adopted by the board of building standards pursuant to Chapters 3781., 3783., and 3791. of the Revised Code, and have a certificate of use and occupancy issued by the appropriate building authority.
- (D) Each new inpatient hospice facility shall be connected to one of the following dependent upon the location and size of the facility:
 - (1) A public sewer system permitted under Chapter 6111. of the Revised Code;
 - (2) A small flow on site sewage treatment system permitted by a local health district under Chapter 3718. of the Revised Code; or
 - (3) A household sewage treatment system permitted by a local health district under Chapter 3718. of the Revised Code.
- (E) Each new inpatient hospice facility shall comply with the following requirements by:
 - (1) Maintaining appropriate space providing optimal comfort and privacy for patients and family members designed and equipped for the comfort and privacy of each patient and family members by:
 - (a) Providing decor which is homelike in design and function;
 - (b) Providing accommodations for family members to remain with the patient; [and](#)
 - (c) Ensuring physical space for private patient and family visiting and allowing patients to receive visitors, including small children, at any hour⁵.
 - (2) Maintaining appropriate patient rooms designed and equipped for adequate nursing care, comfort, and privacy of patients. Each room must:
 - (a) Be equipped with or conveniently located near toilet and bathing facilities;
 - (b) Be at or above grade level;
 - (c) Contain an appropriate bed and other appropriate furniture;
 - (d) Have closet space providing security and privacy for clothing and personal belongings;
 - (e) Contain no more than four beds;
 - (f) Measure at least one hundred square feet for a single patient room or eighty square feet for each

*****DRAFT - NOT FOR FILING*****

patient for a multipatient room; [and](#)

(g) Be equipped for calling the staff member on duty.

(3) Maintaining appropriate bathroom facilities and plumbing and provide:

(a) An adequate supply of hot water at all times for patient use; and

(b) Plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(4) Each facility shall provide appropriate linens at all times in a quantity for the proper care and comfort of patients. Linens must be handled stored, processed, and transported in a manner that prevents the spread of infection.

(5) Each facility shall have provisions for isolating patients with infectious diseases.

(6) Each facility must provide meal service. A hospice facility providing its own meal service must:

(a) Obtain an appropriate food service license, unless exempt in accordance with section 3717.42 of the Revised Code, or contracting with another licensed food service provider;

(b) Serve at least three meals or their equivalent each day at regular times, with not more than fourteen hours between a substantial evening meal and breakfast;

(c) Procure, store, prepare, distribute and serve all food under sanitary conditions; [and](#)

(d) Have a staff member trained or experienced in food management or nutrition who is responsible for:

(i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the dietary allowances recommended by the national academy of sciences; [and](#)

(ii) Supervising the meal preparation and service to ensure that the menu plan is followed;.

(7) Each facility must provide pharmaceutical services and must:

(a) Provide appropriate methods and procedures for dispensing, administering and disposing of drugs and biologicals;

(i) The facility is responsible for drugs and biologicals for its patients, whether drugs or biologicals are obtained from community or institutional pharmacists or stocked by the facility; [and](#)

(ii) The facility must ensure that pharmaceutical services are provided in accordance with accepted professional principles and appropriate federal, state and local laws;.

(b) Employ a pharmacist or have a formal agreement with a licensed pharmacist to advise the facility on ordering, storage, administration, disposal and recordkeeping of drugs and biologicals; [and](#)

(c) Ensure that orders for medications are given by a physician, physician assistant, or an advanced

*****DRAFT - NOT FOR FILING*****

practice registered nurse acting within ~~his or her~~their scope of practice;

- (i) If the medication order is verbal, the physician, physician assistant, or advanced practice registered nurse must give it only to a licensed nurse, pharmacist, or another physician; and
- (ii) The individual receiving the order must record and sign it immediately and have the prescribing physician, physician assistant, or advanced practice registered nurse sign it in a manner consistent with good medical practice.

*****DRAFT - NOT FOR FILING*****

3701-19-09 General requirements for hospice care program personnel.

- (A) Each hospice care program shall utilize personnel that have appropriate training and qualifications for the services that they provide. Any staff member, including a volunteer, who functions in a professional capacity shall meet the standards applicable to that profession, including but not limited to, possessing current Ohio licensure, registration, or certification, if required by law, and practicing within the applicable scope of practice.
- (B) The hospice care program shall provide each staff member, including volunteer and contracted staff members, with a written job description delineating his or her responsibilities. The program shall assure that the services provided by staff members, including volunteers and contracted staff, are provided:
- (1) In accordance with the patients' plans of care;
 - (2) In accordance with the policies and procedures developed by the interdisciplinary team;
 - (3) In accordance with current and accepted standards of practice;
 - (4) By staff members who comply with the program's employee health policies;
 - (a) The hospice care program shall have written employee health policies which include the following requirements for any staff, including volunteers, temporary agency employees, or paid consultants used by the hospice program who has direct patient contact;
 - (b) The hospice care program shall have a written plan to ensure the health and safety of hospice patients that includes policies and procedures regarding screening of staff, including volunteers, for communicable diseases;
 - (c) The hospice care program shall have written policies and procedures regarding measures taken to prevent staff, including volunteers, with direct hospice patient contact who have been diagnosed with a communicable disease from transmitting this disease to patients, care givers or other staff. The policies shall indicate when infected or ill staff must not render direct patient care; and
 - (d) The hospice care program shall document, as applicable, compliance with United States department of labor's occupational safety and health administration, United States centers for disease control and prevention, and applicable Ohio department of health standards concerning health requirements for staff provision of services in health care settings, including requirements for maintaining tuberculosis control.
 - (5) Documented in the patient's central clinical record.
- (C) Each hospice care program shall ensure that all personnel treat each patient and each patient's property with respect, do not abuse, exploit, or neglect patients, and do not misappropriate a patient's property in accordance with section 3721.23 of the Ohio Revised Code.
- (D) Each hospice care program shall employ personnel without discrimination on the basis of sex, age, race, creed, national origin, or handicap.
- (E) Each hospice care program shall provide both orientation and ongoing training program for its personnel,

*****DRAFT - NOT FOR FILING*****

including volunteers.

- (1) The orientation shall be appropriate to the tasks each member will be expected to perform; and
 - (2) The continuing training shall be designed to assure maintenance of appropriate skill levels and ensure that all personnel are informed of changes in techniques, philosophies, and goals of the hospice care program.
- (F) Each hospice care program shall evaluate the performance of each staff member regularly.
- (G) Except as provided in Chapter 3701-13 of the Administrative Code, no hospice care program shall employ a person who applies on or after January 27, 1997, for a position that involves the provision of direct care to an older adult, if the person:
- (1) Has been convicted of or pleaded guilty to an offense listed in division (C)(1) of section 3712.09 of the Revised Code; or
 - (2) Fails to complete the form(s) or provide fingerprint impressions as required by division (B)(3) of section 3712.09 of the Revised Code.

*****DRAFT - NOT FOR FILING*****

3701-19-10 Medical director.

- (A) The medical director of a hospice care program shall be a physician and have overall responsibility for the medical components of the program. The medical director shall be either a paid or contractual staff member or a volunteer.
- (B) The duties of the medical director shall include:
- (1) Participating as a member of the interdisciplinary team or teams in the development of individual plans of care or assuring that one or more other qualified physicians participate on the team or teams;
 - (2) Reviewing patient medical eligibility for hospice care services;
 - (3) Maintaining responsibility and authority over all other physicians employed by the hospice care program;
 - ~~(3)~~(4) Consulting with attending physicians, when appropriate, regarding pain and symptom management;
 - ~~(4)~~(5) Assuring overall continuity of the hospice care program's medical services, including availability of physician services for both routine and emergency situations;
 - ~~(5)~~(6) Acting as liaison between patients' attending physicians and the interdisciplinary team or teams;
 - ~~(6)~~(7) Establishing health policies for employees of the hospice care program; and
 - ~~(7)~~(8) Serving as liaison with community physicians, medical schools, healthcare facilities, and hospitals.

*****DRAFT - NOT FOR FILING*****

3701-19-11 Interdisciplinary team and interdisciplinary plan of care.

- (A) Each hospice care program shall have an interdisciplinary team or teams that provides or supervises the provision of hospice care and services. The registered nurse designated to coordinate each interdisciplinary team shall ensure all of the following for that team:
- (1) There is ongoing assessment of the hospice patient's and family's needs;
 - (2) That all components of the plan of care are addressed by the interdisciplinary team; and
 - (3) The plan of care is implemented in accordance with its terms.
- (B) If the hospice care program has more than one interdisciplinary team, it shall designate which team is to be responsible for establishing the policies and procedures or it shall specify particular areas for which each team is to establish policies and procedures.
- (C) The interdisciplinary team or teams shall perform the following functions:
- (1) Establish policies and procedures governing the provision of care;
 - (2) Ensure that all of its policies and procedures are available and accessible to all personnel;
 - (3) Establish an interdisciplinary plan of care for each patient and family;
 - (4) Review the interdisciplinary plan of care on a periodic basis no less frequently than every fifteen days;
 - (5) Encourage and foster active involvement of the patient and family in the development and implementation of the interdisciplinary plan of care; and
 - (6) Evaluate the hospice care and services provided and monitor the continuity of care across all settings for the hospice care program's patients and their families.
- (D) As part of a hospice patient's interdisciplinary plan of care required by paragraph (A) of rule 3701-19-07 of the Administrative Code, each hospice care program that provides hospice care and services in the patient's home shall do all of the following:
- (1) Before providing hospice care and services:
 - (a) Distribute a copy of the written policy established under division (A) of section 3712.062 of the Revised Code and paragraph (C) of rule 3701-19-21 of the Administrative Code, to the patient and patient's family and discuss the procedures included in the policy with the patient and patient's family; and
 - (b) Inform the patient and the patient's family that the hospice care program will dispose of any controlled substances containing opioids that are no longer needed by the patient and were included in the patient's interdisciplinary plan of care.
 - (2) Assess the patient, the patient's family, and the care environment for any risk factors associated with diversion;
 - (3) Maintain records of controlled substances containing opioids prescribed to the patient and included in the patient's interdisciplinary plan of care, including accurate counts of the numbers dispensed and used;

*****DRAFT - NOT FOR FILING*****

- (4) Monitor the use and consumption of controlled substances containing opioids prescribed to the patient and included in the patient's interdisciplinary plan of care, including prescription refills, for signs of diversion; [and](#)
- (5) After the patient's death or when no longer needed by the patient, request, in writing, that the patient or patient's family relinquish ~~to the hospice care program for disposal~~ any remaining controlled substances containing opioids that were included in the patient's interdisciplinary plan of care to the [hospice care program](#) ~~for disposal~~.
- (E) A hospice care program shall ensure that each patient's attending physician, if any, [is](#) periodically ~~reviews~~ [sent a copy of](#) the patient's plan of care. [The hospice care program shall document the date that the copy of the patient's plan of care is sent to the attending physician in the patient's clinical record.](#)

*****DRAFT - NOT FOR FILING*****

3701-19-12 Contracted services.

- (A) A provider of a hospice care program may arrange for another person or public agency to furnish a component or components of the hospice care program pursuant to a written contract in compliance with 42 C.F.R. 418.64 (2008).
- (B) Any contract executed under paragraph (A) of this rule, including a contract to which paragraph (C) of this rule applies, shall be legally binding on both parties and shall do all of the following:
- (1) Identify the services that may be provided;
 - (2) Stipulate that services may be provided only with the express authorization of the hospice care program;
 - (3) Describe the manner in which the contracted services are coordinated, supervised, and evaluated by the hospice care program;
 - (4) Delineate the role or roles of the hospice care program and the contractor in the admission process, patient and family assessment, and the interdisciplinary team reviews;
 - (5) Stipulate the requirements for documenting that services are furnished in accordance with the contract and the requirements of Chapter 3712. of the Revised Code, Chapter 3701-13, and this chapter of the Administrative Code;
 - (6) Set forth the qualifications of the personnel providing the services; and
 - (7) Stipulate that the hospice care program shall provide hospice care orientation and training, in accordance with paragraph (E) of rule 3701-19-09 of the Administrative Code, to the contractor's personnel who provide the care under the contract.
- (C) When a provider of a hospice care program arranges for a hospital, a home providing nursing care, or home health agency to furnish a component or components of the hospice care program to its patient, the care shall be provided by a licensed, certified, or accredited hospital, home providing nursing care, or home health agency pursuant to a written contract under which:
- (1) The provider of hospice care program furnishes to the contractor a copy of the hospice patient's interdisciplinary plan of care that is established under division (C) of section 3712.06 of the Revised Code and rule 3701-19-11 of the Administrative Code and specifies the care that is to be furnished by the contractor;
 - (2) The regimen described in the established plan of care is continued while the hospice patient receives care from the contractor, subject to the patient's needs, and with approval of the coordinator of the interdisciplinary team designated pursuant to division (C)(1) of section 3712.06 of the Revised Code and paragraph (A) of rule 3701-19-11 of the Administrative Code;
 - (3) All care, treatment, and services furnished by the contractor are entered into the hospice patient's medical record;
 - (4) The designated coordinator of the interdisciplinary team ensures conformance with the established plan of care;
 - (5) A copy of the contractor's medical record and discharge summary is retained as part of the hospice

*****DRAFT - NOT FOR FILING*****

patient's medical record; and

- (6) The contractor complies with the requirements of Chapter 3712. of the Revised Code, and this chapter as applicable to the contracted service.
- (D) The hospice care program shall encourage any hospital contracting for inpatient care to offer temporary limited privileges to the hospice patient's attending physician while the hospice patient is receiving inpatient care from the hospital.
- (E) The hospice care program shall assure the continuity of patient and family care in the home, outpatient, and inpatient settings.
- (F) The hospice care program shall retain professional management responsibility for contracted services and shall ensure that those services are furnished in a safe and effective manner, by persons meeting the qualifications prescribed by Chapter 3701-13 and this chapter of the Administrative Code, and in accordance with the patient's plan of care and the other requirements of this chapter.
- (G) The hospice care program shall retain responsibility for payment for services provided by a contractor which are related to the palliation and management of the terminal illness, arranged for by the hospice care program, and included in the patient's plan of care.
- (H) The hospice care program may contract with a durable medical equipment supplier, only if that supplier meets the medicare supplier quality and accreditation standards at 42 C.F.R. 424.57 (2011) and, as applicable, the requirements of Chapter 4752. of the Revised Code.

*****DRAFT - NOT FOR FILING*****

3701-19-13 Volunteer services.

- (A) Each hospice care program shall use trained volunteers to assist with the provision of administrative or direct patient care services and shall have trained volunteers available to [provide services to](#) hospice patients and ~~hospice~~ [the](#) patients' families as needed. Volunteers shall provide services under the supervision of a designated qualified and experienced hospice staff member.
- (B) Each hospice care program shall provide orientation and training to the volunteers it uses that is consistent with acceptable standards of hospice practice. The orientation and training shall include:
- (1) The hospice care program's goals and services;
 - (2) Confidentiality and the protection of patient and [the patient's](#) ~~family~~ [family's](#) rights;
 - (3) The volunteer's specific duties and responsibilities and the person or persons to contact if the volunteer needs assistance or instructions regarding the performance of the designated duties and responsibilities;
 - (4) Procedures for responding to medical emergencies or deaths;
 - (5) The physiological and psychological aspects of terminal illness;
 - (6) Family dynamics, coping mechanisms, and psychosocial issues surrounding terminal illness, death, and bereavement;
 - (7) Safety policies and procedures; and
 - (8) General communication skills.
- (C) The hospice care program shall document active and ongoing efforts to recruit and retain volunteers.

*****DRAFT - NOT FOR FILING*****

3701-19-14 Nursing services.

- (A) Each hospice care program shall provide nursing care and services by or under the supervision of a registered nurse. The program shall direct and staff nursing services to meet the nursing needs of all of the hospice care program's patients. The program shall specify the patient care responsibilities of nursing personnel.
- (B) A registered nurse shall be responsible for the supervision and oversight of all nursing services.
- (C) As used in this rule, "supervision" means monitoring and directing the provision of nursing care and services by record review, written or verbal instructions, review of interdisciplinary care plans, or direct observation.
- (D) The hospice care program shall ensure that nursing care is available twenty-four hours a day and seven days a week:
 - (1) To provide services to hospice care program patient's; and
 - (2) In each inpatient facility used to provide inpatient care to its patients.
- (E) The registered nurse who provides or supervises the provision of nursing services also may serve as the interdisciplinary team coordinator or team member.

*****DRAFT - NOT FOR FILING*****

3701-19-15 Medical social services.

- (A) Each hospice care program shall make medical social services available to each patient and ~~his or her~~the patient's family as needed. Medical social services shall be provided by a social worker under the direction of a physician. For the purposes of this rule, a physician's approval of a patient's interdisciplinary plan of care shall constitute direction.
- (B) The medical social service needs of each hospice patient and ~~his or her~~the patient's family shall be considered in conjunction with other services when the interdisciplinary team reviews the patient's and family's status.
- (C) Medical social services shall be provided in a timely manner in accordance with hospice care program's policy.

*****DRAFT - NOT FOR FILING*****

3701-19-16 Home care services.

- (A) Each hospice care program shall provide or make available home care services in the scope and frequency required to meet the needs of the hospice care program's patients and their families. Home care services include assistance with activities of daily living, personal care, ambulation and passive exercise, household services essential to health care at home, assistance with self-administration of medications, and preparation of meals. ~~The patient and family shall be informed of any limitations on home care services as required by paragraph (E) of rule 3701-19-20 of the Administrative Code.~~
- (B) The patient and family shall be informed of any limitations on home care services as required by paragraph (E) of rule 3701-19-20 of the Administrative Code.
- ~~(B)~~ (C) Home care services shall be provided by home health aides or hospice aides who have been selected on the basis of such factors as a sympathetic attitude toward patients and their families, ability to read, write, ~~and~~ carry out instructions, ~~and~~ maturity, and ability to cope with the demands of the job.
- ~~(C)~~ (D) The hospice care program shall ensure that home health aides or hospice aides providing home care services have been trained in the following: ~~methods of assisting patients to achieve maximum self-reliance, principles of nutrition and meal preparation, the aging process and emotional problems of illness, procedures for maintaining a clean, healthful, and pleasant environment, changes in a patient's condition that should be reported, the philosophy of hospice care and of the hospice care program, ethics, confidentiality, and recordkeeping.~~
- (1) Methods of assisting patients to achieve maximum self-reliance;
- (2) Principles of nutrition and meal preparation;
- (3) The aging process and emotional problems of illness;
- (4) Procedures for maintaining a clean, healthful, and pleasant environment;
- (5) Changes in a patient's condition that should be reported;
- (6) The philosophy of hospice care and of the hospice care program;
- (7) Ethics;
- (8) Confidentiality; and
- (9) Record Keeping.
- ~~(D)~~ (E) A registered nurse from the patient's interdisciplinary team shall prepare for each home health aide or hospice aide written instructions for patient care which are consistent with the interdisciplinary plan of care.
- ~~(E)~~ (F) The registered nurse responsible for preparing written instructions for home health aides and hospice aides shall make and document a supervisory visit to the patient's residence at least every two weeks when home health aide or hospice aide services are being provided to assess the provision of the home health aide or hospice aide services. The supervisory visit:

*****DRAFT - NOT FOR FILING*****

- (1) ~~The supervisory visit may~~ May be made either when the home health aide or hospice aide is present or when the aide is absent; and
- (2) ~~The purpose of the visit shall~~ Shall serve the purpose of observing and assisting ~~be to observe and assist~~ the home health aide or hospice aide, if present; ~~to assess~~ assessing the patient's and family's relationship with the home health aide or hospice aide, and ~~to determine~~ determining whether the patient's and family's needs and goals are being met; and
- (3) ~~The supervisory visit may~~ May be conducted in conjunction with a visit for other purposes.

*****DRAFT - NOT FOR FILING*****

3701-19-17 Medical services.

- (A) A hospice care patient may identify their own attending physician or may designate the hospice care program medical director [or another hospice care program physician](#) to be their attending physician.
- (B) Each hospice care program shall provide:
- (1) Effective palliation and management of terminal illness and related conditions; and
 - (2) Medical services which meet the medical needs of the patient that are not otherwise met by the patient's:
 - (a) Attending physician;
 - (b) A physician assistant, who is acting within ~~his or her~~[their](#) scope of practice under the supervision, control, and direction of a physician; or
 - (c) An advanced practice [registered](#) nurse, who is acting within ~~his or her~~[their](#) scope of practice and who is working in collaboration with a physician.
- (C) All medical orders for treatment, procedures, tests, and medications shall be signed by:
- (1) A physician;
 - (2) A physician assistant, who is acting within ~~his or her~~[their](#) scope of practice under the supervision, direction, and control of a physician; or
 - (3) An advanced practice [registered](#) nurse, who is acting within ~~his or her~~[their](#) scope of practice and who is working in collaboration with a physician.

*****DRAFT - NOT FOR FILING*****

3701-19-18 Counseling and bereavement services.

- (A) Each hospice care program shall make available counseling services to the hospice patient and the hospice patient's family. Counseling services shall include dietary, spiritual, bereavement and any other necessary counseling services while the patient is enrolled in the hospice care program. Counseling services shall be provided by a qualified interdisciplinary team member or one or more other qualified individuals, as determined by the hospice care program.
- (B) Counseling services shall be organized to meet the needs of the hospice patients and their families.
- (1) The hospice care program shall assess the needs of patients and families for spiritual counseling, in accordance with their religious preferences.
- (2) The hospice care program shall make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request visits and shall apprise patients of this opportunity.~~The hospice care program shall provide dietary counseling. Dietary counseling shall include use of food and mealtime to promote quality of life for hospice patients and to meet their needs for symptom control. Dietary counseling shall be planned and provided by or under the supervision of a dietitian or, if the program is unable to obtain the services of a dietitian, by a nurse.~~
- (C) ~~The hospice care program shall make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request visits and shall apprise patients of this opportunity.~~The hospice care program shall provide dietary counseling. Dietary counseling shall include use of food and mealtime to promote quality of life for hospice patients and to meet their needs for symptom control. Dietary counseling shall be planned and provided by or under the supervision of a dietitian or, if the program is unable to obtain the services of a dietitian, by a nurse.
- (D) Each hospice care program shall provide bereavement services, as needed, for hospice patients' families. These services shall be provided for up to one year after the patient's death. Bereavement services shall be provided under the supervision of a designated qualified professional.
- (1) The professional designated to supervise bereavement services shall have education or experience or both in providing those services.
- (2) Bereavement services shall be based on an assessment of the family's needs and its ability to cope with grief.
- (3) The plan of care for bereavement services shall reflect family needs and shall specify the frequency services are to be delivered and the persons furnishing the services.

*****DRAFT - NOT FOR FILING*****

3701-19-19 Physical therapy, occupational therapy, and speech therapy services.

- (A) Each hospice care program shall provide or arrange for the provision of physical therapy, occupational therapy, or speech or language therapy unless the provision of those services is waived by the director pursuant to division (A)(4) of section 3712.03 of the Revised Code and paragraph ~~(B)~~(C) of this rule. The services shall be adequate in frequency to meet the needs of the hospice patients.
- (B) Physical therapy services, occupational therapy services and speech or language therapy services must be offered in a manner consistent with accepted standards of practice for the provision of service to hospice patients.
- (C) The director may waive the requirement for providing physical therapy, occupational therapy, or speech or language therapy when the requirement would create a hardship because the therapy is not readily available in the geographic area served by the provider of the hospice care program. A request for a waiver under this paragraph shall be submitted to the director in writing and shall be accompanied by documentation of the number and location of therapists in the area served by the program and of the efforts that the program has made to engage those therapists and to encourage other therapists to serve the area.
- (D) Physical therapy shall be provided by a person who is licensed as a physical therapist under Chapter 4755. of the Revised Code and who meets the requirements under Chapter 3701-13 of the Administrative Code.
- (E) Occupational therapy shall be provided by a person who is licensed as an occupational therapist under Chapter 4755. of the Revised Code and who meets the requirements under Chapter 3701-13 of the Administrative Code.
- (F) Speech or language therapy shall be provided by a person who is licensed as a speech pathologist or audiologist under Chapter 4753. of the Revised Code and who meets the requirements under Chapter 3701-13 of the Administrative Code.

*****DRAFT - NOT FOR FILING*****

3701-19-20 Admission of patients to the hospice care program.

- (A) A hospice care program shall not admit any individual who does not meet the diagnosis and life expectancy requirements of a hospice patient defined in paragraph (J) of rule 3701-19-01 of the Administrative Code.
- (B) A hospice care program shall admit patients, provide care and services, and discharge or transfer patients without discrimination on the basis of sex, age, race, creed, national origin, or handicap.
- (C) A hospice care program shall require that the patient, or the patient's authorized representative, sign an informed consent form. This form shall include an acknowledgment by signature of the patient or patient's representative, that they have been: ~~given a full explanation of the palliative rather than curative nature of hospice care as it relates to the patient's terminal illness and have been informed that the patient may withdraw consent at any time.~~
- (1) Given a full explanation of the palliative rather than curative nature of hospice care as it relates to the patient's terminal illness; and
- (2) Informed that the patient may withdraw consent at any time.
- (D) A hospice care program shall permit a hospice patient to withdraw consent for hospice care at any time.
- (E) A hospice care program shall provide a patient or the patient's representative with information regarding the scope of services provided by the hospice care program, including any limitations of the hospice care program and charges for the services.
- (F) A hospice care program shall distribute a copy of the written policy established under division (A) of section 3712.062 of the Revised Code and paragraph ~~(C)~~(D) of rule 3701-19-21 of the Administrative Code, to the patient and patient's family and discuss the procedures included in the policy with the patient and patient's family before providing hospice care and services;
- (G) Prior to or within forty-eight hours after admission of each patient, a hospice care program shall obtain an oral statement from the patient's attending physician, if any, and the medical director of the hospice care program or the physician member of the interdisciplinary team, certifying that the patient is terminally ill. The program shall obtain written confirmation of the oral statement after admission. The written certification statement shall be signed by the patient's attending physician, if any, and the medical director of the hospice care program or the physician member of the interdisciplinary team.
- (1) The program should obtain from each patient's attending physician, if any, designation of an alternate physician to contact for emergency care of the patient or review of the patient's plan of care when the attending physician is not available; and
- (2) The hospice care program should obtain written confirmation of the oral statement certifying that the patient is terminally ill within a reasonable period of time after admission, ~~which is recommended to be not more than twenty-one days or within other acceptable written standards of practice guidelines.~~

*****DRAFT - NOT FOR FILING*****

3701-19-21 Medical supplies, drugs, and biologicals.

- (A) Each hospice care program shall arrange for provision of medical supplies, appliances, drugs, and biologicals to hospice patients as needed for the palliation and management of the patient's terminal illness and related conditions. The program shall ensure that drugs and biologicals are available at all times.
- (B) Each hospice care program shall ensure that drugs and biologicals are administered only by the following individuals:
 - (1) A registered nurse, a licensed practical nurse, or a physician;
 - (2) A patient or a family member if approved by the attending physician; or
 - (3) Any other individual authorized by the Revised Code to perform this task.
- (C) The individuals authorized to administer drugs or biologicals under paragraphs (B)(2) and (B)(3) of this rule and the drugs or biologicals they are authorized to administer shall be specified in the patient's plan of care.
- (D) Each hospice care program licensed under this chapter that provides hospice care and services in a hospice patient's home shall establish a written policy establishing procedures to be followed in preventing the diversion of controlled substances containing opioids that are prescribed to its hospice patients. The policy shall include procedures for the disposal of any such drugs prescribed to a hospice patient as part of the patient's interdisciplinary plan of care that are relinquished to the program after the patient's death or that otherwise are no longer needed by the patient. The policy shall require that the disposal be documented by a program employee and conducted in any of the following ways:
 - (1) Performed by a program employee and witnessed by the patient or patient's family member;
 - (2) Performed by the patient or patient's family member and witnessed by a program employee; or
 - (3) Performed by a program employee and witnessed by another program employee.
- (E) Each hospice care program shall ensure that the patient, patient's representative, and the patient's family receive a copy of the hospice care program's written policies and procedures along with education on the management and disposal of controlled drugs when a controlled substance is ordered; and document such actions in the patient's clinical record.

*****DRAFT - NOT FOR FILING*****

3701-19-22 Short-term inpatient care; standards and services.

- (A) Each hospice care program shall provide or arrange for the provision of short-term inpatient care to patients who require it for pain control, symptom management, or respite care. ~~The program may operate its own inpatient facility or may contract with one or more other persons or public agencies that operate inpatient facilities for provision of inpatient care. The inpatient facility or facilities that the program uses to provide inpatient care shall be licensed, certified, or accredited in accordance with applicable Ohio law and this rule.~~
- (1) The program may operate its own inpatient facility or may contract with one or more other persons or public agencies that operate inpatient facilities for provision of inpatient care; and
- (2) The inpatient facility or facilities that the program uses to provide inpatient care shall be licensed, certified, or accredited in accordance with applicable Ohio law and this rule.
- (B) The type of inpatient setting selected for a particular episode shall be based upon the needs of the patient. The program shall not place patients in an inpatient facility for the convenience of the program.
- (C) Each inpatient facility used by a hospice care program to provide inpatient care to its patients shall provide nursing services twenty-four hours a day or the hospice care program shall provide or arrange for nursing services twenty-four hours a day.
- (D) Inpatient care for pain control and symptom management shall be provided only in a hospice inpatient facility, hospital or a skilled nursing facility. Any such facility used by a hospice care program shall be certified under Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301(1981), as amended, or accredited by an organization that the United States centers for medicare and medicaid services has given deeming authority. Each inpatient facility used by the hospice care program to provide pain control and symptom management shall:
- (1) Have a registered nurse on staff and available at all times on each shift to render hands-on direct care; and
- (2) Ensure that nursing services are sufficient to meet the total nursing needs of the hospice patients residing in the facility.
- (E) Inpatient care for respite purposes shall be provided only:
- (1) In a hospice inpatient facility, a hospital, a skilled nursing facility or nursing facility certified under Title XVIII or XIX of the Social Security Act, or a nursing home or residential care facility licensed under Chapter 3721. of the Revised Code that provides nursing services twenty-four hours a day or the hospice care program shall provide or arrange for nursing services twenty-four hours a day. Nursing services shall be sufficient to meet the needs of the hospice patients residing in the facility; and
- (2) On an occasional basis and not for more than seven consecutive days unless further limited by payor.
- (F) Each inpatient facility used by a hospice care program to provide inpatient care to its patients shall ensure that sufficient personnel are available to:
- (1) Provide each patient's treatments, medications, and diets as prescribed;
- (2) Keep each patient comfortable, clean, well-groomed;

*****DRAFT - NOT FOR FILING*****

- (3) Assure that each patient's routine, special, and emergency needs are met at all times;
 - (4) Promptly respond to patient calls; and
 - (5) Protect each patient from accident, injury, and infection through the use of appropriate safety and infection control measures.
- (G) Each inpatient facility used by a hospice care program to provide inpatient care to its patients shall:
- (1) Have patient areas that are designed and equipped for the comfort and privacy of patients and their family members by:
 - (a) Maintaining adequate lighting levels in patient areas and designing patient areas that are devoid of glare and reflecting surfaces that produce discomfort;
 - (b) Minimizing sound level;
 - (c) Maintaining a comfortable temperature; and
 - (d) Providing adequate ventilation.
 - (2) Have physical space for private patient and family visiting;
 - (3) Provide accommodations for family members to remain with the patient throughout the night;
 - (4) Provide accommodations for family privacy after a patient's death;
 - (5) Have decor which is homelike in design and function;
 - (6) Permit patients to bring personal items into patient areas; and
 - (7) Permit patients to receive visitors at all times, including small children.

*****DRAFT - NOT FOR FILING*****

3701-19-22.1 Admission of non-hospice palliative care patients to hospice inpatient facilities.

- (A) A hospice care program that operates an inpatient hospice facility or unit may admit non-hospice palliative care patients to the inpatient hospice facility or unit for medically necessary care on a short-term basis in accordance with section 3712.10 of the Revised Code.
- (B) A hospice care program that operates an inpatient hospice facility or unit that admits non-hospice palliative care patients shall admit patients, provide care and services, and discharge or transfer patients without discrimination on the basis of sex, age, race, creed, national origin, or handicap.
- (C) A hospice care program that operates an inpatient hospice facility or unit that admits non-hospice palliative care patients shall require that the non-hospice palliative care patient, or the patient's authorized representative, sign an informed consent form. This form shall include an acknowledgment by signature of the patient or patient's representative, that they have been given a full explanation of the palliative nature of the care they will receive while admitted to the facility or unit and have been informed that the patient may withdraw consent at any time.
- (D) A hospice care program that operates an inpatient hospice facility or unit that admits non-hospice palliative care patients shall permit a patient to withdraw consent for inpatient care at any time.
- (E) A hospice care program that operates an inpatient hospice facility or unit that admits non-hospice palliative care patients shall provide a patient or the patient's representative with information regarding the scope of services provided by the hospice inpatient facility or unit, including any limitations of services and charges for the services.
- (F) Each hospice care program that operates an inpatient hospice facility or unit that has admitted non-hospice palliative care patients under section 3712.10 of the Revised Code or intends to admit non-hospice palliative care patients under this Chapter, shall provide a written attestation in accordance with paragraph (C)(8)(b) of rule 3701-19-03 of the Administrative Code by April 1, 2020.
- (G) Each hospice care program that operates an inpatient hospice facility or unit that admits non-hospice palliative care patients in accordance with section 3712.10 of the Revised Code and this Chapter, shall ensure:
- (1) The director has access to all facilities, services, and records for non-hospice palliative care patients for the purpose of inspections conducted pursuant to rule 3701-19-05 of the Administrative Code; and
 - (2) All non-hospice palliative care patients and their families or caregivers are included in the quality assurance and performance improvement requirements set forth in paragraphs (D), (E), and (F) of rule 3701-19-06 of the Administrative Code.
 - (a) The records associated with the quality assurance and performance improvement program for non-hospice palliative care patients and their families or caregivers may be maintained and reviewed separate from the hospice care program quality assessment and performance improvement program; and
 - (b) Beginning January 30, 2021, a report of the findings of the quality assessment and performance improvement program review required by this paragraph and the actions taken by the hospice care program to correct identified problems, shall be submitted to the department of health in a manner prescribed by the director.

*****DRAFT - NOT FOR FILING*****

(H) In addition to the notification requirements set forth in paragraph (D) of rule 3701-19-07 of the Administrative Code, a hospice care program that operates a hospice inpatient facility or unit that admits non-hospice palliative care patients shall notify the director, in writing, of any intent to cease the admission of non-hospice palliative care patients within thirty days of the discontinuation of the service.

(I) In addition to the orientation and training requirements set forth in rules 3701-19-09 and 3701-19-13 of the Administrative Code, all hospice care program personnel and volunteers that provide care to non-hospice palliative care patients in a hospice care program inpatient facility or unit shall be provided additional training in:

- (1) The philosophy of palliative care;
- (2) The goals of palliative care; and
- (3) Physiological and psychosocial issues associated with palliative care.

(J) In addition to the duties prescribed to the medical director of a hospice care program in rule 3701-19-10 of the Administrative Code, the hospice care program medical director, or the medical director's designee, for a hospice care program that admits non-hospice palliative care patients to the hospice's inpatient facility or unit shall:

- (1) Review all referrals for admission of a non-hospice palliative care patient;
- (2) Ensure that an assessment of the medical and psychosocial needs of the non-hospice palliative care patient is conducted to determine whether the patient's needs can be met by the hospice inpatient facility or unit. This assessment may include, but is not limited to, a review of the patient's medical records from the referring provider, a physical exam, assessment tools designed to determine the patient's psychosocial needs, or other tools the medical director deems appropriate; and
- (3) Document the determination as follows:
 - (a) If a determination is made to admit the non-hospice palliative care patient and the patient accepts, written documentation of the decision and the assessments conducted shall be included in the patient's clinical record for a period of no less than six years;
 - (b) If a determination is made to not admit the non-hospice palliative care patient, the following information shall be maintained in a manner that can be made available to the director upon request, for a period of no less than six years:
 - (i) Date of referral;
 - (ii) Diagnosis and reason for the referral;
 - (iii) The assessments conducted, if any; and
 - (iv) The reason the non-hospice palliative care patient was not admitted.

(K) Non-hospice palliative care patients admitted to a hospice care program inpatient facility or unit, shall have an interdisciplinary team or teams that provide or supervise the provision of care and services to non-hospice palliative care patients.

- (1) The hospice care program shall designate an interdisciplinary team to be responsible for establishing the

*****DRAFT - NOT FOR FILING*****

policies and procedures related to caring for non-hospice palliative care patients admitted to the hospice care program inpatient facility or unit. The team shall ensure that all policies and procedures are available and accessible to all hospice care program inpatient facility or unit personnel.

- (2) A registered nurse shall be designated to coordinate each interdisciplinary team and ensure the following:
 - (a) A clinical record is created and maintained in accordance with rule 3701-19-23 of the Administrative Code for each non-hospice palliative care patient admitted to a hospice care program inpatient facility or unit;
 - (b) There is ongoing assessment of the non-hospice palliative care patient's and patient's family's needs;
 - (c) That all components of the plan of care are addressed by the interdisciplinary team; and
 - (d) The plan of care is implemented in accordance with its terms.
- (3) Each interdisciplinary team shall perform the following functions:
 - (a) Establish an interdisciplinary plan of care for each non-hospice palliative care patient and their family that is coordinated by one individual who shall ensure:
 - (i) All components of the plan are addressed and implemented; and
 - (ii) The non-hospice palliative care patient and their family are encouraged to be actively involved in the development of the plan of care.
 - (b) Review the interdisciplinary plan of care on a periodic basis, but no less frequently than every three days; and
 - (c) Provide an ongoing evaluation of the palliative care and services provided to the non-hospice palliative care patient and their family.
- (4) As part of each non-hospice palliative care patient's interdisciplinary plan of care, the hospice care program inpatient facility or unit shall ensure:
 - (a) That the medical components of care are provided under the direction of a physician or a physician's designee prior to providing care and services to the non-hospice palliative care patient;
 - (b) A list of services that will be provided by or arranged for by the hospice care program is provided to the non-hospice palliative care patient;
 - (c) Nursing care is available to the non-hospice palliative care patient twenty-four hours a day seven days a week in accordance with rule 3701-19-14 of the Administrative Code;
 - (d) The non-hospice palliative care patient's plan of care is reviewed by the patient's attending physician and by the interdisciplinary team; and
 - (e) That each non-hospice palliative care patient's attending physician, if any, is sent a copy of the patient's plan of care. The date that the copy of the plan of care was sent to the attending physician shall be documented in the patient's clinical record.

*****DRAFT - NOT FOR FILING*****

- (L) All medical social services provided to non-hospice palliative care patients in a hospice care program inpatient facility or unit shall be provided in accordance with rule 3701-19-15 of the Administrative Code.
- (M) All medical services provided to non-hospice palliative care patients in a hospice care program inpatient facility or unit shall be provided in accordance with rule 3701-19-17 of the Administrative Code.
- (N) All counseling services provided to non-hospice palliative care patients in a hospice care program inpatient facility or unit shall be provided in accordance with paragraphs (A), (B) and (C) of rule 3701-19-18 of the Administrative Code. If indicated, the hospice care program may provide bereavement counseling for the non-hospice palliative care patient and the patient's family
- (O) All necessary physical therapy, occupational therapy, and speech therapy services provided to non-hospice palliative care patients in a hospice care program inpatient facility or unit shall be provided in accordance with rule 3701-19-19 of the Administrative Code.
- (P) Each hospice care program shall arrange for provision of medical supplies, appliances, drugs, and biologicals to all non-hospice palliative care patients as needed for the palliation and management of the patient's illness and related conditions. The program shall ensure that drugs and biologicals are available at all times. Each hospice care program shall ensure that drugs and biologicals are administered only by a registered nurse, a licensed practical nurse, a physician assistant, an advanced practice registered nurse, or a physician.

*****DRAFT - NOT FOR FILING*****

3701-19-23 Central clinical record.

- (A) Each hospice care program shall establish and maintain a central clinical record for each hospice patient receiving care and services from the program and his or her family. The record shall be established and maintained in accordance with accepted standards of practice.
- (B) The clinical record shall be a comprehensive compilation of information that is documented promptly for all services provided. The record shall be organized systematically to facilitate retrieval of information- and meet the following requirements: ~~Entries to the clinical record shall be made and signed by the person providing the service. All services, whether furnished by employees, persons under contract, or volunteers, shall be documented in the clinical record. Entries in the clinical record shall be dated and shall be made within a responsible period of time after the services were provided.~~
- (1) Documentation of all services provided, whether furnished by employees, persons under contract, or volunteers;
- (2) Documentation shall be dated and be made within a responsible period of time after the services were provided; and
- (3) Entries to the clinical record shall be made and signed by the person providing the service.
- (C) Each clinical record shall contain at least the following information:
- (1) Identification data;
 - (2) Pertinent medical history, including the physician's diagnosis of terminal illness;
 - (3) Consent and authorization forms;
 - (4) Initial and subsequent assessments that include evaluations of physical, psychosocial, nutritional, and spiritual needs, if any, and the need for volunteer or bereavement services;
 - (5) The interdisciplinary plan of care;
 - (6) Documentation of all services and events, such as evaluations, treatments, and progress notes;
 - (7) A statement of whether or not the patient, if an adult, has prepared an advanced directive. "Advanced directive" has the same meaning as "declaration" as defined in section 2133.01 of the Revised Code; and
 - (8) Transfer and discharge summaries.
- (D) The hospice care program shall provide for storage of the central clinical records to protect them against loss, destruction, and unauthorized use. The program also shall have policies and procedures to ensure the confidentiality of records.
- (E) A hospice care program which maintains a patient's clinical record electronically shall use an electronic signature system that meets the requirements specified under division (B) of section 3701.75 of the Revised Code. Electronic patient clinical records shall be accessible to the director during inspections.

*****DRAFT - NOT FOR FILING*****

3701-19-24 Variances; waivers.

- (A) The director may grant a variance or waiver from any requirement established by Chapter 3701-19 of the Administrative Code, unless the requirement is mandated by statute.
- (B) A hospice care program seeking a variance or waiver must submit a written request to the director. Such written request must include the following information:
 - (1) The rule requirement for which the variance or waiver is requested, with a reference to the relevant Administrative Code provision;
 - (2) The specific nature of the request, and the rationale for the request;
 - (3) The time period for which the variance or waiver is requested;
 - (4) If the request is for a variance, a statement of how the hospice care program will meet the intent of the requirement in an alternative manner; and
 - (5) If the request is for a waiver, a statement regarding why application of the requirement will cause undue hardship to the hospice care program and why granting the waiver will not jeopardize the health and safety of any patient.
- (C) The decision regarding a variance or waiver is a discretionary act by the director and an informal procedure not subject to Chapter 119. of the Revised Code. Upon written request by a hospice care program, the director may grant:
 - (1) A variance if the director determines that the requirement has been met in an alternative manner; or
 - (2) A waiver if the director determines that the strict application of the license requirement would cause an undue hardship to the hospice care program and that granting the waiver would not jeopardize the health and safety of any patient.
- (D) The director may stipulate a time period for which a variance or a waiver is to be effective and may establish conditions that the hospice care program must meet for the variance or waiver to be operative. Such time period may be different than the time period sought by the hospice care program in the written variance or waiver request.
- (E) The director may establish conditions that the hospice care program must meet for the variance or waiver to be operative. The director may, in his discretion, rescind the waiver or variance at any time upon determining that the hospice care program is not meeting such conditions.
- (F) The granting of a variance or waiver by the director shall not be construed as constituting precedence for the granting of any other variance or waiver. All variance and waiver requests shall be considered on a case-by-case basis.
- (G) The provider whose request for a waiver or variance under this rule is denied may request reconsideration of the decision by the director. A request for reconsideration must:
 - (1) Be received in writing by the director within thirty days of receipt of the director's denial of a waiver or variance request;
 - (2) Present significant, relevant information not previously submitted to the director by the provider because

*****DRAFT - NOT FOR FILING*****

it was not available to the provider at the time the waiver or variance request was filed; or

- (3) Demonstrate that there have been significant changes in factors or circumstances relied upon by the director in reaching the initial decision.
- (H) A decision on an appropriately filed request for reconsideration shall be issued within forty-five days of the director's receipt of the request for reconsideration and all information determined necessary by the director to make a decision.
- (I) The reconsideration process is an informal procedure not subject to Chapter 119. of the Revised Code. The director's decision on reconsideration is final.

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

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 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 133rd 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 – 3rd 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/>