

NOTICE OF PUBLIC RULES HEARING

DATE: Friday, December 13, 2019
TIME: 11:00 a.m.
LOCATION: Ohio Department of Health
35 E. Chestnut Street
Columbus, Ohio 43215
ROOM: ODH Basement Training Room A

In accordance with *Chapter 119* of the Revised Code (R.C.), the Director of the Ohio Department of Health announces a Public Hearing at the date and time listed above to hear comments regarding the following action:

Ohio Revised Code (O.A.C.) Chapter 3701-19 – Hospice Care.

The proposed rules are under review as required by Ohio Revised Code 119, these rules concern Ohio's hospice care programs. Amendments to the rules include grammatical and formatting updates to enhance clarity, the addition of language regarding the admission of non-hospice palliative care patients to hospice inpatient facilities for short term care to satisfy requirements of H.B. 286 of the 133rd General Assembly, technical updates, requirements that hospices attest that at least 51% of the programs operations are focused on providing care and ensure the availability of inpatient care. The proposed changes also include additions to mention protections against exploitation of patients and their property in accordance with ORC 3721.23, requirements of documentation of the date a patient's plan of care is sent to the attending physician, the inclusion of language regarding arranging clergy and religious visits, and the designation of dietary counseling as a stand-alone requirement.

Information regarding rule package proposed:

This Ohio Department of Health (Department) rule package consists of 25 rules (20 amended, 4 no change, 1 new). This rule package was submitted to the CSI Office on August 5, 2019, as part of a statutory five-year review process, with the public comment period open through September 4, 2019.

During the period of early stakeholder outreach, the Department shared the proposed rules with stakeholders seeking comment. The request for comments was followed by four stakeholder meetings throughout late 2018 and early 2019. The department states that this process led to revisions of the draft rules, notably in the proposed new rule 3701-19-22.1, setting requirements for hospice care program inpatient facilities that admit non-hospice palliative care patients for short term care. Stakeholders include industry associations, professional associations, healthcare and hospice organizations, health systems, and regional hospitals.

During the public comment period, one comment was received from the Cleveland Clinic. The comment prompted clarification regarding percentage of services provided to hospice patients by a hospice care program, the use of the term "palliative care," informed consent, scope of services, medical directors access to records, medical directors and physicians delegation of responsibilities, and requirements of hospice care program inpatient facilities and units. Changes resulting from the comment include the addition of training in distinguishing features between palliative and hospice care for hospice care program personnel and volunteers.

Impacted communities include all entities seeking licensure as a hospice care program. Adverse impacts include licensure fees of \$600 for initial application and renewal, a \$200 change-of-ownership license fee; inspection fees of \$1,625 for licensure inspection at least every three years, \$850 for a complaint inspection, \$350 for a follow-up inspection to ensure a plan of correction has been properly implemented resulting from a validated complaint inspection, and \$250 for a desk audit/compliance review. Additional impacts include the administrative costs associated with compliance with the rules, which

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include developing plans for quality assessment and performance improvement programs, development of clinical records and interdisciplinary plans of care for patients and developing policies to correct complaints. The Department is required by ORC 3712.04 to establish licensing requirements for hospice care programs.

Ohio Revised Code (O.A.C.) Chapter 3701-84-27 Appendix A – Patient selection/utilization – bone marrow transplantation service.

The proposed rules are under review as required by Ohio Revised Code 3702.11, these rules provide the necessary state-based framework for the Department of Health to ensure the safety and quality of care of health care services for Ohio's health care consumers. The rules provide a means by which the Department of Health identifies health care service providers and may determine and enforce patient safety standards. Furthermore, the rules reduce negative health care service outcomes through required actions such as, but not limited to, reporting to the Director any of misadministration and medical events related to radioactive materials, requiring regular morbidity and mortality conferences, and reporting failure to meet nationally recognized quality standards for specified metrics.

Information regarding rule package proposed:

This Ohio Department of Health (Department) rule package consists of one amended Appendix. The rule package was submitted to the CSI Office on August 5, 2019, and the public comment period was open through September 4, 2019.

The rules reduce negative health care service outcomes through required actions such as, but not limited to, reporting to the Director any of misadministration and medical events related to radioactive materials, requiring regular morbidity and mortality conferences, and reporting failure to meet nationally recognized quality standards for specified metrics. Ohio does not license or certify health care services directly; however, the Department of Health performs its roles and functions related to Medicare survey and certification as an agent of the federal government's Center for Medicare and Medicaid Services (CMS) under the authority of section 1864 of the Social Security Act. Although health care services are certified through CMS and accredited through independent accrediting organizations, these organizations do not provide a direct or 'local' access point for the health care consumers of Ohio. These state rules provide that point of access and a mechanism through which health care consumers may have their concerns addressed through complaint investigations.

Revisions to the rule are based upon comments from the Ohio Hematopoietic Stem Cell Transplant Consortium. The Ohio Hematopoietic Stem Cell Transplant Consortium is viewed as an industry expert; the recommendations of the Consortium are based upon the most current and appropriate medical, technological, and psychological studies and the resultant guidelines established within this industry. The rule directly reflects those recommendations. The Ohio Hematopoietic Stem Cell Transplant Consortium has requested changes to Appendix A to rule 3701-84-27 of the Ohio Administrative Code. The Ohio Department of Health (ODH) recognizes the expertise of the Consortium and the need for Ohio's "Patient selection Criteria" to reflect current industry standards and practices. The Consortium establishes the criteria for bone marrow transplantation for Ohio's bone marrow transplantation providers.

Ohio Revised Code (O.A.C.) Chapter 3701-84-61 and -62 – Pediatric intensive care service standards/Personnel and staffing standards – pediatric intensive care service.

The proposed rules are under review as required by Ohio Revised Code 3702.11, these rules provide the necessary state-based framework for the Department of Health to ensure the safety and quality of care of health care services for Ohio's health care consumers. The rules provide a means by which the Department of Health identifies health care service providers and may determine and enforce patient safety standards.

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Information regarding rule package proposed:

This Ohio Department of Health (Department) rule package consists of two amended rules. The rule package was submitted to the CSI Office on August 5, 2019, and the public comment period was open through September 4, 2019.

The rules set forth the standards for pediatric intensive care services. These requirements include the service having a pediatric intensivist or their designee available within thirty minutes and other staff including, but not limited to, anesthesiologist, gastroenterologist, pulmonologist, and an infectious disease specialist available within sixty minutes on a twenty-four-hour basis. PICUs must also provide laboratory, nursing, pharmacy, and other pediatric critical care services. Based upon industry request and current industry practices, revisions have been made to update the type of pediatric and surgical subspecialties that must be available to PICUs and allow PICUs without pediatric cardiovascular surgery services and pediatric cardiac catheterization services to maintain written transfer agreements to transport patients with these urgent/emergent needs within sixty minutes to other PICU services to provide the necessary cardiac care. Finally, the rule has been revised to allow PICUs without the aforementioned cardiac services to have a cardiovascular surgeon available through contract or other arrangement instead of requiring those physicians to be on staff, as well as set forth the personnel and staffing standards required in PICU services. Staffing requirements include, but are not limited to, a medical director board certified in pediatrics, anesthesiology limited to infants and children, or pediatric surgery; an additional licensed physician, sufficient nursing staff, and a social worker. The rule has been revised to current an erroneous citation in paragraph (E).

A stakeholder meeting was held on May 21, 2019, and as well attended by PICU representatives from across the state including PICU physicians, medical directors, nurse managers, hospital government liaisons, and service administrators. The input of these stakeholders is represented in the proposed revisions. Stakeholders from the services and the industry provided professional opinions, updates to practice standards and guidelines, as well as acknowledgement and acceptance of agency recommended content revisions.

Ohio Revised Code (O.A.C.) Chapter 3701-59 – Hospitals.

The proposed rules are under review as required by Ohio Revised Code 3701.07, these rules establish hospital reporting requirements and include definitions, federal certification or national accreditation requirements to operate a hospital, reporting enforcement, and hospital registration requirements. The Department is amending the rules to align the definition of cardiac catheterization with other Department rules.

Information regarding rule package proposed:

This Ohio Department of Health (Department) rule package contains two amended and two no change rules being proposed by the Ohio Department of Health (Department) pursuant to statutory five-year rule review. The draft rules were submitted to the CSI Office on August 6, 2019, and the public comment period was open through September 5, 2019. The proposed rules impact all Ohio hospitals. Specific impacts include administrative costs associated with compliance and reporting requirements. Direct costs will vary based on hospital size and the personnel needed to prepare reports. The rules are required by ORC 3701.07 to provide the public with accurate and up-to-date information regarding the availability of hospital services. These rules provide the necessary state-based framework for the Department of Health ensure that the Department and general public receive accurate and up to date information pertaining to hospital facilities and services.

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The rules establish the registration requirements for all hospitals in Ohio. Ohio Department of Health program staff is responsible for monitoring the submission of the required reports and initiating enforcement action if hospitals fail to submit the statutorily required information.

Hearing and Contact Information:

At the hearing, people affected by the proposed action may appear and be heard in person or accompanied by an attorney. They may present their positions, arguments, or contentions orally or in writing; may offer witnesses; and may present evidence showing that the proposed rule, if adopted or effectuated, will be unreasonable or unlawful.

To aid in getting visitors through building security, any persons intending to testify at the hearing or planning to observe are encouraged to pre-register by writing to the Office of the General Counsel, Ohio Department of Health, 246 North High Street, 7th Floor, Columbus, Ohio 43215, or by phone to (614) 466-4882, or send an e-mail to odhrules@odh.ohio.gov.

Copies of the proposed rules will be available on the Register of Ohio website: <http://www.registerofohio.state.oh.us/rules/search> approximately one day after the rule is filed, or from the Office of the General Counsel, Ohio Department of Health (<https://odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/Office-of-General-Counsel/laws-and-rules/>).

Please e-mail any written comments to ODHrules@odh.ohio.gov by 5:00 p.m. on November 6, 2019.