

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 3701-84-27 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.

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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.

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 correct 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.

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

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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.