



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Health

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Regulation/Package Title (a general description of the rules' substantive content):

Health Care Services (HCS)/Hospital Licensure

Rule Number(s): New: 3701-22-30 through 3701-22-65 and Rescind: 3701-84-01 through 3701-84-14, 3701-84-16, 3701-84-20 through 3701-84-21, 3701-84-24 through 3701-84-27, 3701-84-30 through 3701-84-34.2, 3701-84-36 through 3701-84-40, 3701-84-61 through 3701-84-65, 3701-84-67, 3701-84-75 through 3701-84-85.

****MINIMAL CHANGES HIGHLIGHTED IN YELLOW BEFORE POSTING.****

NO OTHER CHANGES WERE MADE SINCE POSTING/NO COMMENTS RECEIVED DURING PUBLIC POSTING.

Date of Submission for CSI Review: 11/27/2024

Public Comment Period End Date: 12/27/2024

Rule Type/Number of Rules:

New/ X rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ X rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies

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should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

The rules set forth in Chapter 3701-84 of the Ohio Administrative Code (OAC) which establish the safety and quality of care standards for providers of Health Care Services (HCS) in Ohio are required by Section 3722.06 of the Ohio Revised Code (ORC) to be integrated into the Hospital Licensure rules set, Chapter 3701-22 of the Ohio Administrative Code. The existing Chapter 3701-84 of the OAC will be statutorily rescinded. Chapter 3701-84 of the OAC recently completed its five-year review in 2022/2023 and minimal changes were made when adding these rules to the Hospital Licensure Chapter 3701-22, as seen below.

These rules set minimum standards that a provider of a health care service must meet in order to offer the service including facilities, equipment, personnel, and patient selection criteria. The standards and requirements established by these regulations are applicable to the following services:

- Solid organ transplantation

- Bone marrow transplantation
- Adult cardiac catheterization
- Adult open-heart surgery
- Pediatric intensive care
- Pediatric cardiac catheterization
- Pediatric cardiovascular surgery
- Operation of a linear accelerator/gamma knife/cobalt radiation therapy unit

New Rules

3701-22-30 The rule sets forth the requirement for services to provide at least a 30-day notice to the Department prior to initiating or reactivating an HCS and what is to be included in such notice. An HCS service manager must sign an attestation of compliance in addition to the medical director of the service. And any information requested by ODH within 30 days of the mailing of the request.

Changes made:

- In paragraph (E), changes were made to align with current hospital licensure to the “scope of the HCS, the hospital” from “scope of the hospital, the HCS.” These changes were made now that the license falls under the hospital in Chapter 3701-22 and not the HCS unit in rescinded Chapter 3701-84.
- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-31 The rule sets forth the service standards for solid organ transplant (SOT) services including, but not limited to, location within a registered hospital, participation in a statewide transplant consortium, and have written patient policies and procedures. The rule further requires compliance with current Center for Medicare & Medicaid Services (CMS) Conditions of Participation (COPs).

3701-22-32 The rule sets forth the patient selection criteria for SOT services including participation in a statewide review process, adherence to identical selection criteria, and requirements pertaining to patients who do not meet the standard selection criteria. Furthermore, the rule provides general patient selection criteria as established by the Organ Procurement and Transplantation Network and the Centers for Medicare and Medicaid Services.

3701-22-33 The rule establishes the utilization level requirements for solid organ transplant services. These services should achieve volume goals consistent with Title 42 CFR 482.80 and 482.82 to ensure efficiency and minimum competency. Heart-lung, intestinal, pancreas, and pediatric transplants do not have utilization requirements.

3701-22-34 The rule sets forth the service license for Bone Marrow Transplantation (BMT) services including, but not limited to, in a licensed hospital, participate in national cancer treatment research, and have patient management planning and protocols consistent with national standards.

3701-22-35 The rule sets forth the personnel and staffing standards for blood and bone marrow transplant services including a board-certified medical director, at least one additional transplant physician, and a dedicated nursing staff.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-36 The rule sets forth the facilities and safety standards for BMT services including, but not limited to, having a designated BMT unit with beds to meet the patient demand, reverse isolation rooms, and multiple types of laboratory services.

3701-22-37 The rule requires bone BMT patient selection for blood and bone marrow transplantation services to be conducted in accordance with Title 42 Code of Federal Regulations Section 482.80 to 482.82.

Changes made:

- Changes made in (C) to “ensure efficiency and a minimum floor of competency.” This change came from the bureau staff to allow for more clear language.
- Removed unnecessary “or” in (C)(3).

3701-22-38 The rule sets forth the general service standards for adult cardiac catheterization services including having emergency transfer protocols, a quality assessment review process, morbidity and mortality reviews, and for physician credentialing requirements.

Changes made:

- Changes made in (I) from “registered hospital” to “licensed hospital” to match with current hospital licensure Chapter 3701-22.
- Changes made in (I)(2) from “registered” to “licensed” to match with current hospital licensure Chapter 3701-22.

3701-22-38.1 The rule sets forth the service standards for Level I adult cardiac catheterization services which provide only diagnostic catheterizations. These requirements include reporting, providing notice when procedures are performed on an emergency basis that are not within the scope of approved services, obtaining informed consent, and conducting a review of adverse outcomes every sixty days.

Changes made:

- Changes made in (G) from “registered hospital” to “licensed hospital” to match with current hospital licensure Chapter 3701-22.
- Changes made in (G)(5) from “surgeon” to “surgeon(s)” as program staff stated that often there are more than one.
- Changes made to (I)(1) from “March” to “June” as program staff stated that very few hospitals can meet the March deadline.
- Revised language in (I)(1)(ii) to clarify for providers.
- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-38.2 The rule sets forth the service standards for Level II adult cardiac catheterization services including providing diagnostic and specified therapeutic procedures without on-site surgical backup. The rule allows for membership in any appropriate data registry for cardiac catheterization procedures and annual reporting. Level II services must operate on a regular schedule.

Changes made:

- Changes made in (H) from “registered hospital” to “licensed hospital” to match with current hospital licensure Chapter 3701-22.
- Changes made in (H)(5) from “surgeon” to “surgeon(s)” as program staff stated that often there are more than one.
- Changes made in (I) to reference paragraph (H) not (I) as it’s paragraph (I).
- Changes made to (L) from “March” to “June” as program staff stated that very few hospitals can meet the March deadline.
- Revised language in (L)(2)(b) to clarify for providers.
- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-38.3 The rule establishes the Level III adult cardiac catheterization service standards. Level III services maintain an open-heart surgery service and provide the full spectrum of cardiovascular procedures. The rule allows for membership in any appropriate data registry and requires annual reporting.

Changes made:

- Changes made to (J) from “March” to “June” as program staff stated that very few hospitals can meet the March deadline.
- Revised language in (J)(2)(b) to clarify for providers.
- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-38.4 This rule establishes the standards for adult electrophysiology procedure rooms utilized by adult cardiac catheterization services. These requirements include a minimum floor area of three hundred and fifty square feet and that a clearance at the head of the bed be allocated for anesthesia equipment on either side and sterile access to jugular vein entry sites, if employed, while allowing for the free range of movement of a fluoroscopy C-arm. Furthermore, the rule sets forth the list of equipment that must be available in the electrophysiology room and the utilities required.

3701-22-39 The rule sets forth the personnel and staffing requirements for adult cardiac catheterization services including, but not limited to, the service medical director must actively perform procedures at the service, each service must have at least two physicians credentialed to perform catheterizations, and have support staff with the necessary skills, training, and experience in cardiac care in sufficient numbers to meet the needs of patients.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-40 The rule sets forth the facilities and equipment requirements for adult cardiac catheterization services including, but not limited to, having procedure and control rooms of specified dimensions, appropriate imaging equipment, and equipment for ventilator and circulatory support. Facility standards align with current Facilities Institute Guidelines recommendations.

3701-22-41 The rule sets forth the safety standards for adult cardiac catheterization services including compliance with applicable nuclear regulatory requirements, maintaining electrical safety, and maintenance of equipment.

3701-22-42 The rule establishes the performance measures for adult cardiac catheterization services that include maintaining a volume of procedures performed to ensure the safety and quality of procedures performed at the service. Adult cardiac catheterizations services and clinicians are heavily regulated by accrediting and certifying organizations, physician-level industry standards, and hospital credentialing requirements. ODH will rely on publicly available data, hospital reporting, complaints, and inspections to ensure the quality and safety of patients.

3701-22-42.1 The rule sets forth the requirements for inspections and review of adult cardiac catheterization services which includes maintaining a volume to ensure the safety and quality of cardiac catheterization procedures at the service. Cardiac services are heavily regulated by accrediting and certifying organizations, physician level industry standards, and hospital credentialing requirements. ODH will rely on publicly available data, hospital reporting, complaints, and inspections to ensure the quality and safety of patients.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-43 The rule sets forth the standards for open heart surgery services. These requirements include the service having equipment, personnel, and the ability to perform twenty-four-hour emergency open heart procedures and access to specified diagnostic, allied health, and supportive services. This rule removes membership in the Society for Thoracic Surgeons adult cardiac surgery database and allows for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report.

Changes made:

- Changes made to "building of a licensed hospital" in paragraph (E) to account for hospital licensure as part of Chapter 3701-22.
- Changes made to (G) from "March" to "June" as program staff stated that very few hospitals can meet the March deadline.

3701-22-44 The rule sets forth the personnel and staffing requirements for open heart surgery services. These requirements include having a board-certified medical director and a minimum of two perfusionists. The rule clarifies the requirements for the service medical director to be board certified in thoracic surgery or have an approved waiver from ODH for a medical director who is otherwise qualified for the position, such as foreign training and certification.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-45 The rule sets forth the facilities, equipment, and supplies requirements for open heart surgery services. These requirements include the service having an appropriate number of oxygen and vacuum outlets in each room, operational cardiopulmonary bypass machines, and a variety of specified monitoring, analyzing, emergency, and supportive equipment. The Facilities Guidelines Institute is a primary source for healthcare facilities standards in the United States, including the Centers for Medicare and Medicaid Services.

3701-22-46 The rule sets forth the quality assessment and performance improvement (QAPI) requirements for open heart surgery services. These requirements include regular morbidity and mortality conferences.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-47 The rule sets forth the performance measures for adult open-heart surgery services. The rule removes numerical volume requirement for adult open-heart services and replaces it with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Open-heart services are heavily regulated by accrediting and certifying organizations, physician-level industry standards, and hospital credentialing requirements. ODH will rely on publicly available data, hospital reporting, complaints, and inspections to ensure the quality and safety of patients.

3701-22-48 The rule sets forth the standards for pediatric intensive care services. These requirements include the service having an on a twenty-four-hour basis 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. The rule clarifies which staff need to be in-house and on-site in the facility to be available to the PICU twenty-four hours a day, seven days a week. Due to the staffing shortages exacerbated by the recent pandemic, numerous types of providers have been realigned to phone or teleconference availability within sixty minutes and within twenty-four hours and other services that can be provided by consultation as necessary. Allowances have been made for the provision of radiological procedures and hemodialysis by agreement with other facilities available by emergency transport.

Changes made:

- Changes made in paragraph (C) to reference (E) instead of (G).

3701-22-49 The rule sets forth the personnel and staffing requirements for PICUs including, but not limited to having a board-certified medical director, a pediatric intensivist, a licensed physician twenty-four hours a day assigned to the PICU, and nursing staff in number to meet the acuity level and needs of the patients served.

Changes made:

- Changes made to reference rule 3701-22-48 paragraph (D) to match renumbering of new rules in hospital licensure Chapter 3701-22.

3701-22-50 The rule sets forth the physical design and facilities requirements for PICUs including, but not limited to, the PICU having patient isolation rooms and having a rapid, reliable system for timely reporting of laboratory results.

3701-22-51 The rule sets forth the equipment and supplies requirements for PICUs. These requirements include the service having lifesaving, therapeutic and monitoring equipment such as a defibrillator and crash cart.

3701-22-52 The rule sets forth the QAPI requirements for PICUs. These requirements include the service conducting regular morbidity and mortality reviews.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-53 The rule establishes service standards for radiation therapy and stereotactic surgery services. The standards include compliance with Chapter 3748 of the Ohio Revised Code and reporting to the Ohio Cancer Incidence Surveillance System.

3701-22-54 The rule sets forth the service standards for pediatric cardiac catheterization services including, but not limited to, the service must have an onsite pediatric cardiovascular surgery service, established patient selection criteria, and immediate access to specified diagnostic services and staff.

Changes made:

- Changes made to “building of a licensed hospital” in paragraph (H) to account for hospital licensure as part of Chapter 3701-22.

3701-22-55 The rule sets forth the personnel and staffing requirements for pediatric cardiac catheterization services including, but not limited to, a medical director board certified in pediatric cardiology, at least two credentialed physicians to provide catheterizations, and support staff and nursing personnel with appropriate training/licensing in sufficient numbers to meet the needs of the patients.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-56 The rule sets forth the facilities, equipment, and supplies requirements for pediatric cardiac catheterization services including, but not limited to, procedure and control rooms must be of specified dimensions and the service must be equipped with high quality imaging and physiological monitoring equipment.

3701-22-57 The rule sets forth the safety standards for pediatric cardiac catheterization services including compliance with applicable nuclear regulatory requirements, maintaining electrical safety, and maintenance of equipment.

3701-22-58 The rule sets forth the performance measures for pediatric cardiac catheterization services including setting a volume goal and for the facility, but not for individual physicians.

3701-22-59 The rule sets forth the quality assessment and performance improvement requirements for pediatric cardiac catheterization services including maintaining a database for procedure information and outcomes and conducting morbidity and mortality reviews.

3701-22-60 The rule sets forth the service standards for pediatric cardiovascular services. These requirements include, but are not limited to, a board-certified medical director, two thoracic surgeons, access to diagnostic, emergency, radiology, and having a surgical team available within sixty minutes.

3701-22-61 The rule sets forth the personnel and staffing requirements for pediatric cardiovascular services. These requirements include, but not limited to, a board-certified medical director, two thoracic surgeons, and nursing staff with specialized training in pediatric cardiovascular surgery.

Changes made:

- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-62 This rule establishes the facilities, equipment, and supplies requirements for pediatric cardiovascular services. The rule has been rescinded and replaced with a new rule due to the Legislative Service Commission rule drafting requirements for rules revised more than fifty percent. The rule establishes room size requirements to align with current Facilities Institute Guidelines' recommendations. The changes reduce the required square footage of a standard operating room from five hundred to four hundred square feet and six hundred square feet for hybrid operating rooms. The control room's minimum square footage requirements have been removed and replaced with guidelines for equipment and personnel space. The Facilities Guidelines Institute is a primary source for healthcare facilities standards in the United States, including the Centers for Medicare and Medicaid Services.

3701-22-63 This rule establishes pediatric cardiovascular surgery service performance measures. The rule removed numerical volume requirements for pediatric cardiovascular surgery service and replaces it with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Pediatric cardiovascular surgery services and clinicians are heavily regulated by accrediting and certifying organizations, physician level industry standards, and hospital credentialing requirements. ODH will rely on publicly available data, hospital reporting, complaints, and inspections to ensure the quality and safety of patients.

3701-22-64 The rule sets forth the QAPI program requirements for pediatric cardiovascular services in addition to the general QAPI requirements in rule 3701-84-12. These requirements include a regular morbidity and mortality review.

Changes made:

- Changes made to (A)(2) to reference paragraph (C) of 3701-22-59.
- Changes made to rule to reference administrative rules in Chapter 3701-22. (3701-22-01 through 3701-22-14, and 3701-22-19).

3701-22-65 The rule sets forth the authority of ODH to issue an order to suspend operations to any health care service that fails to ensure the quality and safety of procedures performed.

Changes made:

- Removed duplicative "service" in paragraph (A).
- This new rule mimics current rule 3701-84-34.2, but the department changed the rule to allow for the suspension of operations for any health care service, not just adult cardiac catheterization services.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Ohio Revised Code section 3722.

Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

There are no federal requirements mandating these rules. Many of the rules, however, contain citations to or reflect current federal Conditions of Participation in the Code of Federal Regulations.

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

No applicable

- 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 Ohio Revised Code 3722., 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 of any 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. These rules will now be licensed under the hospital licensure Chapter 3701-22 per ORC 3722., and ODH will be rescinding Chapter 3701-84 as ODH will now survey and license health care services under one hospital license.

- 6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Successful outcomes are measured through a standard survey (inspection) process approximately once every thirty-six months; successful outcomes would indicate compliance with the standards and requirements set forth in the new Chapter 3701-22. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

- 7. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

Chapter 3701-84 underwent a five-year review a year ago (2023). The stakeholders below were contacted, and revisions were made based on those comments. Because of recent revisions, these rules are undergoing non-substantiative changes and correcting grammatical errors only as part of the rescinding of chapter 3701-84 and moving into the hospital chapter 3701-22.

University Hospitals
Mercy Health System
University of Cincinnati
Ohio State University Medical Center
Cincinnati Children's
Nationwide Children's
Akron Children
Rainbow Babies
Children's Dayton
Cleveland Clinic
Wright State University
Fairfield Medical Center
Lima Memorial Hospital
Kettering Health
Mount Carmel Health Systems
Southern Ohio Medical Center
Firelands
Adena Health Systems
Metro Health
Ohio Hospital Association
State Medical Board of Ohio
Genesis Health System
Summa Health System
The Christ Hospital
Case Western
Ohio Children's Hospital Association
Ohio Solid Organ Transplant Consortium
Promedica
Ohio Health
Ohio Hemopoietic Therapy and Transplant Consortium

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The rules received a five-year review with numerous revisions which were responsive to stakeholder requests in 2022/2023. These rules are statutorily required to be integrated into the forthcoming Chapter 3701-22 OAC, Hospital licensure and be in effect by October 1, 2024. The stakeholders support the integration of these previously licensed services into the new Hospital Licensure Chapter 3701-22 OAC.

11. 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?

Resources utilized during the 2022/2023 five-year review and/or cited within the rules.

Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards:

Process, Protocols, Equipment, Personnel, and Safety

SCAI Expert Consensus Statement Update on best Practices for Transradial Angiography and

Intervention

Calculating Risk for Poor Outcomes After Transcatheter Aortic Valve Replacement

Racial and Ethnic Disparities in Coronary, Vascular, Structural, and Congenital heart Disease

SCAI Position Statement on Adult Congenital Cardiac Interventional Training, Competencies and Organizational Recommendations

SCAI Expert Consensus Update on Best Practices in the Cardiac Catheterization Laboratory: Update to the 2012 and 2016 Consensus Documents

The IAC Standards and Guidelines For Cardiac Electrophysiology Accreditation

World Health Organization Guidance on Organ Transplantation

American Society of Transplantation Guidance Documents

Organ Procurement and Transplantation Network Guidance

Public Health Service Guidelines 2020

SCAI/CCAS/SPA Expert Consensus Statement for Anesthesia and Sedation Practice:

Recommendations for Patients Undergoing Diagnostic and Therapeutic Procedures in the Pediatric and Congenital Cardiac Catheterization Laboratory

SCAI expert consensus update on best practices in the cardiac catheterization laboratory

Extracorporeal Cardiopulmonary Resuscitation (E-CPR)

During Pediatric In-Hospital Cardiopulmonary Arrest Is Associated With Improved Survival to Discharge A Report from the American Heart Association's Get With The

Guidelines–Resuscitation (GWTG-R) Registry

The IAC Standards and Guidelines for Cardiovascular Catheterization Accreditation

Indications for Cardiac Catheterization and Intervention in Pediatric Cardiac Disease

A Scientific Statement From the American Heart Association

2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Criteria for Critical Care Infants and Children: PICU Admission, Discharge, and Triage

Practice Statement and Levels of Care Guidance

AMA Journal of Ethics

American Society of Extracorporeal Technology Standards and Guidelines for Pediatric and Congenital Perfusion Practice

12. 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 monitor compliance with the quality and safety standards mandated by section 3702.11 of the Revised Code. Alternative regulations to the rules set forth in the current Chapter 3701-22 of the Administrative Code were not considered. The rules reflect the current industry standards pertaining to Health Care Services that providers are expected to meet for participation in accrediting organizations and participation in Centers for Medicare and Medicaid Services programs.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

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

14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Health Care Services provide a self-attestation of compliance and are surveyed approximately once every thirty-six months. Surveys are also conducted as necessary as the result of complaints, to determine compliance. Surveys are conducted by specially trained health care service program staff utilizing a standard survey document and protocols specific to the type of service.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

- Rules 3701-22-31 to 3701-22-33 impact solid organ transplant services;
- Rules 3701-22-34 to 3701-22-37 impact bone marrow transplant services, including stem cell harvesting and reinfusion services;
- Rules 3701-22-38 to 3701-22-42.2 impact adult cardiac catheterization services;
- Rules 3701-22-43 to 3701-84-47 impact open heart surgery services;
- Rules 3701-22-48 to 3701-22-52 impact pediatric intensive care services;
- Rule 3701-22-53 impacts radiation therapy and stereotactic radiosurgery services;

- Rules 3701-22-54 to 3701-22-59 impact pediatric cardiac catheterization services; and
- Rules 3701-22-60 to 3701-22-64 impact pediatric cardiovascular surgery services.
- Rule 3701-22-65 impact all health care services as part of this chapter.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

Fines, time for compliance, and reporting requirements.

In general, these rules do not represent costs that are independent of those already obligated to the Health Care Service by virtue of their participation in the Centers for Medicare and Medicaid Services Conditions of Participation and other accrediting organization programs. Those costs include, but are not limited to, the costs associated with the purchase or lease of real estate, equipment, and personnel. There are also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assessment and performance improvement. The similar requirements set forth in Ohio's rules are unlikely to require a significant amount of time or costs in addition to that which is already expended by the service and the services will, more likely than not, already meet or exceed the state requirements.

Costs specific to the state rules:

As set forth in the current rule, 3701-22-05, of the Ohio Administrative Code, civil monetary penalties may be charged in accordance with Chapter 119. of the Ohio Revised Code, to a health care service for failure to meet safety and quality standards. The new rule should be placed as part of rule 3701-22-05 but is still under review. These penalties are based upon the severity of the violation and range from one thousand to two hundred and fifty thousand dollars. A cease operation order may be obtained in the event of a second or subsequent violation or if the Director determines a first violation poses an imminent threat of serious physical or life-threatening danger.

Fees, as authorized in section 3701-22-03 of the Ohio Revised Code, associated with the application for a license to operate a hospital, renewal of an existing license includes the following:

- A nonrefundable license application or renewal fee based on the number of beds within the hospital;
- A nonrefundable service fee in the form of a check or money order made payable to the "treasurer, state of Ohio" for each healthcare service at three thousand dollars.

Time and manpower necessary to develop policies and procedures.

Time and manpower necessary to develop written plans for a Quality Assessment and Performance Improvement (QAPI) program and conduct meetings.

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

Time and manpower necessary to adopt and follow disaster preparedness and fire evacuation plans.

The costs borne by the health care service are those generally associated with the provision of services within the industry including, but not limited to patient care planning, written policies, employee training and development, and obtaining informed consent from patients. All costs associated with policy and procedure development and training would be based upon the nature and complexity of the requirement and the staff chosen to perform the task. In most instances a physician or registered nurse would be responsible for this requirement, while training may be conducted by other health care practitioners.

Physician:

Average of \$130.31 per hour*

Registered Nurse:

Average of \$40.59 per hour. *

Other Healthcare Practitioners:

Average of \$45.36 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2023, using the codes for all health care practitioners and technical occupations (29-1299) physicians and surgeons, all others (29-1229), registered nurse (29-1141).

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

Regulatory restrictions have removed while under the five-year rule review process in 2022/2023 in accordance with SB 9 of the 134th General Assembly.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

ODH is required to implement section 3722. of the Ohio Revised Code by establishing safety and quality of care standards for providers of Health Care Services. The costs represented by the specific quality and safety requirements set forth in the current Chapter 3701-84 are considered to be acceptable and represent a general standard cost in terms of the administrative, personnel, and facility-based requirements for the operation of a health care service within the industry. The ODH specific inspection fees set forth in rule 3701-84-05 represent only a portion of the actual direct and indirect costs incurred by the Department during the survey process. The new rule should be placed as part of rule 3701-22-05 but is still under review. These costs include, but are not limited to, staff, salary, and administrative costs which average \$2584.31. Section 3701.31 of the Revised Code authorizes ODH to charge up to \$1750.00 for inspection purposes. Finally, the minimal reporting requirements established in these

rules provide information to the Department of Health that is necessary to monitor and ensure the health and safety of Ohio's health care consumers that cannot be obtained in a timely manner by other means.

Regulatory Flexibility

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

The Health Care Services covered by the regulations set forth in the current Chapter 3701-22 of the Ohio Administrative Code are not typically operated by 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 the 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 3701-84-19 and are determined on a case-by-case basis. The new rule should be placed as part of rule 3701-22-19 but is still under review.

Additionally, Health Care Services may submit an accreditation award letter from an approved accrediting agency (i.e., Joint Commission, American Osteopathic Association) as evidence of compliance with the standards set forth in the current Chapter 3701-22.

19. 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/>

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

The Health Care Services covered by the regulations set forth in the current Chapter 3701-22 of the Ohio Administrative Code are not typically operated by small businesses.

The Ohio Department of Health, Office of Health Assurance and Licensing, Health Care Services Section, and the Prevention/Radiologic Technology Section provide information and assistance to Health Care Service providers. Additional information is available at:

<https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/health-care-services/healthcareservices>