



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Chapter 3701-84 Health Care Services

Rule Number(s): 3701-84-01 to 3701-84-14, 3701-84-16 to 3701-84-21, 3701-84-21 to 3701-84-27, 3701-84-30-3701-84-34, 3701-84-36 to 3701-84-40, 3701-84-60 to 3701-84-65, 3701-84-67 to 3701-84-73, 3701-84-76 to 3701-84-85

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/ X rules

No Change/ X rules (FYR?)

Amended/ X rules (FYR? X)

Rescinded/ X rules (FYR?)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 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.

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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.**

The rules set forth in Chapter 3701-84 of the Ohio Administrative Code establish safety and quality of care standards for providers of Health Care Services (“HCS”) in Ohio. The quality rules set minimum standards that a provider of the 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

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Revised Rules

3701-84-01 The rule sets forth the definitions used throughout the Chapter. Revisions have been made to update definitions to include current medical terminology (bone marrow risk levels), update the definition of “hospital” due to the passage of HB 110, 134th GA, and include new definitions for “pediatric intensivist” and “electrophysiology study.”

3701-84-02 The rule delineates the service types under the authority of the Chapter and has been revised to update reference to “blood and bone marrow” services to align with current terminology.

3701-84-03 The rule sets forth the general provisions and prohibitions for all HCSs and has been revised to remove an outdated reference to smoking prohibitions.

3701-84-04 The rule sets forth the requirement for services to provide at least a 30-day notice to the Department prior to initiating or reactivating a HCS and what shall be included in such notice. The rule has been revised to clarify that a HCS service manager must sign an attestation of compliance in addition to the medical director of the service. Additional revisions have been made to clarify that information requested by ODH must be received within 30 days of the mailing of the request.

3701-84-05 The rule sets forth the compliance actions that may be taken by the director in the event a HCS is determined to be non-compliant with statutory or administrative requirements. The rule has been revised to remove unnecessary language.

3701-84-06 The rule sets forth the requirement for inspection and audit of HCS providers, including investigation of alleged violations, the fees for the specific types of inspections, and the cap on fees changed to each HCS. The rule has been revised to make grammatical changes and clarify that patients’ personal information must be removed from any information submitted to ODH.

3701-84-07 The rule requires HCSs to have patient care policies. The rule has been revised to make grammatical changes.

3701-84-08 The rule sets forth the general personnel and staffing requirements for all HCSs, such as staffing to meet the needs of patients, staff must have appropriate training and qualifications, and that an ongoing training program must be provided by the HCS. The rule has been revised to update the tuberculosis screening guidelines, specify training and orientation requirements for staff, and remove unnecessary language.

3701-84-09 The rule sets forth the general service standards for all HCSs including, but not limited to, documentation of all services provided, a medical record for each patient, written infection control policy requirements, and the maintenance of equipment. The rule has been revised to make grammatical changes and clarify that post-care instructions must be provided prior to discharge.

3701-84-10 The rule sets forth the general building and site requirements for all HCSs including, but not limited to, certificates of occupancy and written emergency and disaster preparedness plans. The rule has been revised to make grammatical changes.

3701-84-11 The rule sets forth the requirement for a medical record for each patient served by a HCS. The rule has been revised to make grammatical changes.

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3701-84-12 The rule sets forth the general QAPI requirements for all HCS s to ensure the monitoring, documenting, and resolution of issues that impact the quality and safety of patient care. The rule has been revised to make grammatical changes.

3701-84-13 The rule sets forth the general complaint requirement for HCSs, including the HCS posting the Department's complaint number and having policies and procedures to address patient complaints. The rule has been revised to make grammatical changes.

3701-84-14 The rule sets forth the waiver and variance requirements for HCSs including, but not limited to, providing a written request for a waiver/variance to the director, providing supporting documentation, and the reconsideration options available in the event of a denial. The rule has been revised to make grammatical changes.

3701-84-16 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 written patient policies and procedures. The rule has been revised to reflect current Center for Medicare & Medicaid Services (CMS) Conditions of Participation (COPs) in preparation for upcoming Hospital Licensure and make grammatical changes.

3701-84-24 The rule sets forth the service standards for Bone Marrow Transplantation (BMT) services including, but not limited to, location in a registered hospital, participation in national cancer treatment research, and patient management planning and protocols consistent with national standards. The rule has been revised to improve the clarity and flow of information within the rule and to make grammatical changes.

3701-84-25 The rule sets forth the personnel and staffing standards for blood and bone marrow transplant services and has been revised to make grammatical changes.

3701-84-26 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. The rule has been revised to make grammatical changes.

3701-84-30 The rule sets forth the general service standards for adult cardiac catheterization services including emergency transfer protocols, a quality assessment review process, morbidity and mortality reviews, and physician credentialing requirements. The rule has been revised to clarify that an adult means an individual eighteen or older and to make grammatical changes.

3701-84-30.1 The rule sets forth the service standards for Level I adult cardiac catheterization services including Level I services only providing diagnostic catheterizations. The rule has been revised in preparation for the integration of these rules into the forthcoming hospital licensure rule set. Reporting requirements have been revised to require new reporting elements starting January 1, 2025, when all hospitals must be licensed in Ohio, clarify what an emergent transfer is, and make grammatical changes.

3701-84-30.2 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 has been revised to remove atrial fibrillation ablation from the prohibited procedures list, remove membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report. Additionally, the requirement to operate twenty-four-hours a day, seven days a week, has been replaced

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with the requirement to operate on a regular schedule. This change has been made in anticipation of the allowance for the performance of 17 diagnostic and 6 PCI procedures in ambulatory surgical facilities within the next year in Ohio. If the requirement for 24/7 were to remain in place, it would create an advantage for ambulatory surgical facilities and negatively impact Level II adult cardiac catheterization services providers.

3701-84-31 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 support staff with the necessary skills, training, and experience in cardiac care in sufficient numbers to meet the needs of patients. The rule has been revised to make formatting changes to include the clarity and flow of the rule as well as to remove the requirement for nursing personnel to have prior cardiac service training. Level II services will be allowed to provide nursing personnel with orientation and training applicable to the service.

3701-84-32 The rule sets forth the facilities and equipment requirements for adult cardiac catheterization services including, but not limited to, procedure and control rooms of specified dimensions, appropriate imaging equipment, and equipment for ventilator and circulatory support. The rule has been revised to update 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. Control room 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.

3701-84-33 The rule sets forth the safety standards for adult cardiac catheterization services including compliance with applicable nuclear regulatory requirements, electrical safety, and maintenance of equipment. The rule has been revised to make grammatical changes.

3701-84-34.1 The rule sets forth the requirements for inspections and review of adult cardiac catheterization services. The rule has been revised to remove numerical volume requirement for adult cardiac catheterization services and replace with a requirement to maintain 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.

3701-84-34.2 The rule sets forth the authority of ODH to issue an order to cease operations to services that fail to ensure the quality and safety of procedures performed. The rule has been revised to remove the requirement for membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry.

3701-84-36 The rule sets forth the standards for open heart surgery services. These requirements include the service having equipment, personnel, and capability to perform twenty-four-hour emergency open heart procedures and access to specified diagnostic, allied health, and supportive services. The rule has been revised to remove membership in the Society for Thoracic Surgeons adult cardiac surgery database and allow for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report. Citations to industry guidelines have been updated to their most current versions and access to blood banking services have been added as a requirement.

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3701-84-37 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 has been revised to clarify 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.

3701-84-38 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 rule has been revised to update 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. Control room 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.

3701-84-39 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. The rule has been revised to remove membership in the Society for Thoracic Surgeons adult cardiac surgery database and allow for membership in any appropriate data registry and require morbidity and mortality reviews at least once every sixty days, increase from thirty days, to align with the sixty-day review requirements in rule 3701-84-12.

3701-84-40 The rule sets forth the performance measures for adult open-heart surgery services. The rule has been revised to remove numerical volume requirement for adult open-heart services and replace with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Open-heart 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.

3701-84-61 The rule sets 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. The rule has been revised to clarify 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.

3701-84-62 The rule sets forth the personnel and staffing requirements for PICUs including, but not limited to, 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. The rule has been revised to make grammatical changes and to clarify that training and orientation must be documented in a nurse's personnel file.

3701-84-64 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. The rule has been revised to remove the requirement for continuous pulmonary arterial pressure which has been replaced by more modern technology and make grammatical changes.

3701-84-75 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. The rule has been revised to remove the requirement for participation in National Cardiovascular Data Registry IMPACT registry and replace with participation in an applicable data registry of choice. Furthermore, revisions add same day procedure discharge requirements, and clarify that an adult means an individual eighteen or older and that the pediatric service may provide care to an individual aged eighteen or older as determined appropriate by the clinicians.

3701-84-76 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 the appropriate training/licensing in sufficient numbers to meet the needs of the patients. The rule has been revised to make grammatical changes and clarify that the medical director should have experience in pediatric cardiac catheterization and intervention.

3701-84-78 The rule sets forth the safety standards for pediatric cardiac catheterization services including compliance with applicable nuclear regulatory requirements, electrical safety, and maintenance of equipment. The rule has been revised to make grammatical changes and clarify that preventive maintenance activities must be documented.

3701-84-80 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. The rule has been revised to make grammatical changes and to reduce the requirement for morbidity and mortality reviews from every ninety days to every sixty days to align with the general quality assessment requirements in rule 3701-84-12.

3701-84-81 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. The rule has been revised to clarify that an adult patient means aged eighteen and older and that an adult patient can be serviced by the pediatric cardiovascular surgery services when determined appropriate by the clinicians. Furthermore, the rule has been revised to remove the requirement for participation in the Society for Thoracic Surgeons congenital heart registry and replace with a data registry of the service's choice as appropriate and paragraphs have been reformatted to improve the flow of information in the rule and make grammatical changes.

3701-84-82 The rule sets forth the personnel and staffing requirements for pediatric cardiovascular services. These requirements including, but not limited to, a board-certified medical director, two thoracic surgeons, and nursing staff with specialized training in pediatric cardiovascular surgery. The rule has been revised to make grammatical changes.

3701-84-85 The rule sets forth the QAPI program requirements for pediatric cardiac catheterization services in addition to the general QAPI requirements in rule 3701-84-12. These requirements include a regular

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morbidity and mortality review. The rule has been revised to remove the requirement for participation in the Society for Thoracic Surgeons congenital heart registry and replace with a data registry of the service's choice as appropriate and make grammatical changes.

Rescinded Rules

3701-84-17 The rule sets forth the personnel and staffing requirements for SOT services, such as at least one primary transplant surgeon for each type of organ transplanted and a multidisciplinary care team comprised of appropriately qualified medical, nursing, and supportive service staff to meet the needs of patients. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-18 The rule sets forth the facilities requirements for SOT services including, but not limited to, operating rooms, laboratory, and diagnostic/treatment services. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-19 The rule sets forth the safety standards for SOT services and has been revised to improve the clarity and flow of information in the rule. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-20 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. The rule and its associated appendices A and B are being rescinded and replaced with new rule 3701-84-20 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-21 The rule sets forth the utilization/volume requirements for SOT services; these requirements are reflective of current CMS-COPs. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-27 The rule sets forth the patient selection/utilization requirements for BMT services. The rule is being rescinded and replaced with new rule 3701-84-27 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-30.3 The rule sets forth the service standards for Level III adult cardiac catheterization services. The rule is being rescinded and replaced with new rule 3701-84-30.3 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-34 The rule sets forth the performance measure requirements for adult cardiac catheterization services. The rule is being rescinded and replaced with new rule 3701-84-34 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-67 The rule sets forth the service standards for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded and replaced with new rule 3701-84-67 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

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3701-84-68 The rule sets forth the personnel and staffing requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-69 The rule sets forth the facilities, equipment, and supplies requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-70 The rule sets forth the treatment standards for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-71 The rule sets forth the radiation safety standards for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-72 The rule sets forth the QAPI program requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-73 The rule sets forth the medical records requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-77 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. The rule has been rescinded and replaced with new rule 3701-84-77 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-79 The rule sets forth the performance measures for pediatric cardiac catheterization services including a setting a volume goal and for the facility, but not for individual physicians. The rule has been rescinded and replaced with new rule 3701-84-79 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-83 The rule sets forth the facilities, equipment, and supply requirements for pediatric cardiovascular services. The rule has been rescinded and replaced with new rule 3701-84-83 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-84 The rule sets forth the patient selection and utilization requirements for pediatric cardiovascular services. The rule has been rescinded and replaced with new rule 3701-84-84 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

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New Rules

3701-84-20 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. The new rule replaces existing rule 3701-84-20 and removes the patient selection criteria requirements previously set forth in the rule and its associated appendices A and B. The previous requirements are being replaced with general patient selection criteria as established by Organ Procurement and Transplantation Network and the Centers for Medicare and Medicaid Services.

3701-84-21 The new rule replaces the existing rule 3701-84-21 and in preparation for the integration of these rules into the forthcoming hospital licensure rules, replaces the existing patient selection criteria for blood and bone marrow transplantation services with a citation to Title 42 Code of Federal Regulations Section 482.80 to 482.82.

3701-84-27 The new rule replaces existing rule 3701-84-27 and establishes the patient selection and utilization requirements for blood and bone marrow transplant services. The new rule requires the attainment of volume goals at single clinical sites, multiple clinical sites, allogeneic only, autologous only, and both allogeneic and autologous site consistent with current Foundation for the Accreditation of Cellular Therapy (FACT) standards.

3701-84-30.3 The new rule replaces existing rule 3701-84-30.3 and 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 has been revised to remove atrial fibrillation ablation from the prohibited procedures list, remove membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report.

3701-84-30.4 This new 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 clearance at the head of the bed should be allocated for anesthesia equipment on either side and sterile access to jugular vein entry sites, if employed, while allowing for 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.

3701-84-34 The new rule replaces existing rule 3701-84-34 and establishes the performance measures for adult cardiac catheterization services. The rule has been revised to remove numerical volume requirement for adult cardiac catheterization services and replaces them with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Adult cardiac catheterization 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.

3701-84-67 The new rule replaces existing rule 3701-84-67 and establishes the service standards for radiation therapy and stereotactic surgery services. The new standards include compliance with Chapter 3748 of the Ohio Revised Code and reporting to the Ohio Cancer Incidence Surveillance System.

3701-84-77 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

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dimensions and the service must have been equipped with high quality imaging and physiological monitoring equipment. The new rule replaces existing rule 3701-84-77 and updates 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. Control room 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.

3701-84-79 This new rule replaces existing rule 3701-84-79 and establishes the pediatric cardiac catheterization service performance measures. The rule has been revised to remove numerical volume requirement for pediatric cardiac catheterization services and replaces them with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Pediatric 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.

3701-84-84 This new rule replaces existing rule 3701-84-84 and establishes the pediatric cardiovascular surgery service performance measures. The rule has been revised to remove numerical volume requirement for pediatric cardiovascular surgery service and replaces them with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Pediatric cardiovascular surgery service 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.

No Change

3701-84-63 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.

3701-84-65 The rule sets forth the QAPI requirements for PICUs. These requirements include the service conducting regular morbidity and mortality reviews

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 sections 3702.11, 3702.13, and 3701.31

4. 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?

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.

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- 5. 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.

- 6. 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 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. 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.

- 7. 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 Chapter 3701-84. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

- 8. 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?**

No

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Development of the Regulation

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

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

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

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?

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

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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 Chapter 3701-84 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. Did the Agency specifically consider a performance-based regulation? Please explain.

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 services to correct their identified deficiencies and meet the quality and safety standards required by statute.

14. 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.

15. 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.

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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

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

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

- Rules 3710-84-01 to 3701-84-14 impact all health care service providers;
- Rules 3701-84-16 to 3701-84-21 impact solid organ transplant services;
- Rules 3701-84-24 to 3701-84-27 impact bone marrow transplant services, including stem cell harvesting and reinfusion services;
-
- Rules 3701-84-30 to 3701-84-34.2 impact adult cardiac catheterization services;
-
- Rules 3701-84-36 to 3701-84- 40 impact open heart surgery services;
- Rule 3701-84-61 to 3701-84-65 impact pediatric intensive care services;
- Rules 3701-84-67 to 3701-84-73 impact radiation therapy and stereotactic radiosurgery services;
- Rules 3701-84-75 to 3701-84-79 impact pediatric cardiac catheterization services; and
- Rules 3701-84-81 to 3701-84-85 impact pediatric cardiovascular surgery services.

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

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.

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c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

Costs specific to the state rules:

As set forth in rule 3701-84-05 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. 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 3702.31 of the Ohio Revised Code, associated with inspections approximately once every 36 months or as the result of a complaint:

Complaint Inspection Fee- \$650

Follow-up Inspection Fee- \$650

Desk Audit or Compliance Review Fee- \$250

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 \$97.08 per hour*

Registered Nurse:

Average of \$35.62 per hour. *

Other Healthcare Practitioners:

Average of \$42.88 per hour*

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Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2021, using the codes for all health care practitioners and technical occupations (29-1299) physicians and surgeons, all others (29-1229), registered nurse (29-1141).

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 3702.11 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 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 3701-84-06 represent only a portion of the actual direct and indirect costs incurred by the Department during the survey process. 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 Chapter 3701-84 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 3701-84-14 and are determined on a case-by-case basis.

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 Chapter 3701-84.

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

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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 Chapter 3701-84 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>



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Sean McCullough, Director

Business Impact Analysis

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

Rule Contact Name and Contact Information:

Selina Jackson, 614-420-5505

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

Chapter 3701-84 Health Care Services

Rule Number(s): 3701-84-01 to 3701-84-14, 3701-84-16 to 3701-84-21, 3701-84-21 to 3701-84-27, 3701-84-30-3701-84-34, 3701-84-36 to 3701-84-40, 3701-84-60 to 3701-84-65, 3701-84-67 to 3701-84-73, 3701-84-76 to 3701-84-85

Date of Submission for CSI Review: 9/13/22; revised 11/7/22

Public Comment Period End Date:

Rule Type/Number of Rules:

New/ X rules

No Change/ X rules (FYR?)

Amended/ X rules (FYR? X)

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 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.

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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.**

The rules set forth in Chapter 3701-84 of the Ohio Administrative Code establish safety and quality of care standards for providers of Health Care Services (“HCS”) in Ohio. The quality rules set minimum standards that a provider of the 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

Revised Rules

3701-84-01 The rule sets forth the definitions used throughout the Chapter. Revisions have been made to update definitions to include current medical terminology (bone marrow risk levels), update the definition of “hospital” due to the passage of HB 110, 134th GA, and include new definitions for “pediatric intensivist” and “electrophysiology study.”

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UPDATE 11/7/22: A definition for the term “psychosocial health” has been added to provide clarity in the rules by replacing the term “emotional health.”

3701-84-02 The rule delineates the service types under the authority of the Chapter and has been revised to update reference to “blood and bone marrow” services to align with current terminology.

3701-84-03 The rule sets forth the general provisions and prohibitions for all HCSs and has been revised to remove an outdated reference to smoking prohibitions.

3701-84-04 The rule sets forth the requirement for services to provide at least a 30-day notice to the Department prior to initiating or reactivating a HCS and what shall be included in such notice. The rule has been revised to clarify that a HCS service manager must sign an attestation of compliance in addition to the medical director of the service. Additional revisions have been made to clarify that information requested by ODH must be received within 30 days of the mailing of the request.

3701-84-05 The rule sets forth the compliance actions that may be taken by the director in the event a HCS is determined to be non-compliant with statutory or administrative requirements. The rule has been revised to remove unnecessary language.

3701-84-06 The rule sets forth the requirement for inspection and audit of HCS providers, including investigation of alleged violations, the fees for the specific types of inspections, and the cap on fees changed to each HCS. The rule has been revised to make grammatical changes and clarify that patients’ personal information must be removed from any information submitted to ODH.

3701-84-07 The rule requires HCSs to have patient care policies. The rule has been revised to make grammatical changes.

3701-84-08 The rule sets forth the general personnel and staffing requirements for all HCSs, such as staffing to meet the needs of patients, staff must have appropriate training and qualifications, and that an ongoing training program must be provided by the HCS. The rule has been revised to update the tuberculosis screening guidelines, specify training and orientation requirements for staff, and remove unnecessary language.

3701-84-09 The rule sets forth the general service standards for all HCSs including, but not limited to, documentation of all services provided, a medical record for each patient, written infection control policy requirements, and the maintenance of equipment. The rule has been revised to make grammatical changes and clarify that post-care instructions must be provided prior to discharge.

3701-84-10 The rule sets forth the general building and site requirements for all HCSs including, but not limited to, certificates of occupancy and written emergency and disaster preparedness plans. The rule has been revised to make grammatical changes.

3701-84-11 The rule sets forth the requirement for a medical record for each patient served by a HCS. The rule has been revised to make grammatical changes.

3701-84-12 The rule sets forth the general QAPI requirements for all HCS s to ensure the monitoring, documenting, and resolution of issues that impact the quality and safety of patient care. The rule has been revised to make grammatical changes.

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3701-84-13 The rule sets forth the general complaint requirement for HCSs, including the HCS posting the Department's complaint number and having policies and procedures to address patient complaints. The rule has been revised to make grammatical changes.

3701-84-14 The rule sets forth the waiver and variance requirements for HCSs including, but not limited to, providing a written request for a waiver/variance to the director, providing supporting documentation, and the reconsideration options available in the event of a denial. The rule has been revised to make grammatical changes.

3701-84-16 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 written patient policies and procedures. The rule has been revised to reflect current Center for Medicare & Medicaid Services (CMS) Conditions of Participation (COPs) in preparation for upcoming Hospital Licensure and make grammatical changes.

3701-84-24 The rule sets forth the service standards for Bone Marrow Transplantation (BMT) services including, but not limited to, location in a registered hospital, participation in national cancer treatment research, and patient management planning and protocols consistent with national standards. The rule has been revised to improve the clarity and flow of information within the rule and to make grammatical changes.

3701-84-25 The rule sets forth the personnel and staffing standards for blood and bone marrow transplant services and has been revised to make grammatical changes.

3701-84-26 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. The rule has been revised to make grammatical changes.

3701-84-30 The rule sets forth the general service standards for adult cardiac catheterization services including emergency transfer protocols, a quality assessment review process, morbidity and mortality reviews, and physician credentialing requirements. The rule has been revised to clarify that an adult means an individual eighteen or older and to make grammatical changes.

3701-84-30.1 The rule sets forth the service standards for Level I adult cardiac catheterization services including Level I services only providing diagnostic catheterizations. The rule has been revised in preparation for the integration of these rules into the forthcoming hospital licensure rule set. Reporting requirements have been revised to require new reporting elements starting January 1, 2025, when all hospitals must be licensed in Ohio, clarify what an emergent transfer is, and make grammatical changes.

UPDATE 11/7/22: A new reporting paragraph was added detailing the reporting requirements for the January 1, 2023, through December 31, 2024, timeframe.

3701-84-30.2 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 has been revised to remove atrial fibrillation ablation from the prohibited procedures list, remove membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report. Additionally, the requirement to operate twenty-four-hours a day, seven days a week, has been replaced

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with the requirement to operate on a regular schedule. This change has been made in anticipation of the allowance for the performance of 17 diagnostic and 6 PCI procedures in ambulatory surgical facilities within the next year in Ohio. If the requirement for 24/7 were to remain in place, it would create an advantage for ambulatory surgical facilities and negatively impact Level II adult cardiac catheterization services providers.

UPDATE 11/7/22: A new reporting paragraph was added detailing the reporting requirements for the January 1, 2023, through December 31, 2024, timeframe.

3701-84-31 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 support staff with the necessary skills, training, and experience in cardiac care in sufficient numbers to meet the needs of patients. The rule has been revised to make formatting changes to include the clarity and flow of the rule as well as to remove the requirement for nursing personnel to have prior cardiac service training. Level II services will be allowed to provide nursing personnel with orientation and training applicable to the service.

3701-84-32 The rule sets forth the facilities and equipment requirements for adult cardiac catheterization services including, but not limited to, procedure and control rooms of specified dimensions, appropriate imaging equipment, and equipment for ventilator and circulatory support. The rule has been revised to update 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. Control room 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.

3701-84-33 The rule sets forth the safety standards for adult cardiac catheterization services including compliance with applicable nuclear regulatory requirements, electrical safety, and maintenance of equipment. The rule has been revised to make grammatical changes.

3701-84-34.1 The rule sets forth the requirements for inspections and review of adult cardiac catheterization services. The rule has been revised to remove numerical volume requirement for adult cardiac catheterization services and replace with a requirement to maintain 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.

3701-84-34.2 The rule sets forth the authority of ODH to issue an order to cease operations to services that fail to ensure the quality and safety of procedures performed. The rule has been revised to remove the requirement for membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry.

3701-84-36 The rule sets forth the standards for open heart surgery services. These requirements include the service having equipment, personnel, and capability to perform twenty-four-hour emergency open heart procedures and access to specified diagnostic, allied health, and supportive services. The rule has been revised to remove membership in the Society for Thoracic Surgeons adult cardiac surgery database and

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allow for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report. Citations to industry guidelines have been updated to their most current versions and access to blood banking services have been added as a requirement.

UPDATE 11/7/22: A new reporting paragraph was added detailing the reporting requirements for the January 1, 2023, through December 31, 2024, timeframe.

3701-84-37 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 has been revised to clarify 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.

3701-84-38 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 rule has been revised to update 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. Control room 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.

3701-84-39 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. The rule has been revised to remove membership in the Society for Thoracic Surgeons adult cardiac surgery database and allow for membership in any appropriate data registry and require morbidity and mortality reviews at least once every sixty days, increase from thirty days, to align with the sixty-day review requirements in rule 3701-84-12.

3701-84-40 The rule sets forth the performance measures for adult open-heart surgery services. The rule has been revised to remove numerical volume requirement for adult open-heart services and replace with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Open-heart 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.

3701-84-61 The rule sets 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. The rule has been revised to clarify 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.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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3701-84-62 The rule sets forth the personnel and staffing requirements for PICUs including, but not limited to, 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. The rule has been revised to make grammatical changes and to clarify that training and orientation must be documented in a nurse's personnel file.

3701-84-64 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. The rule has been revised to remove the requirement for continuous pulmonary arterial pressure which has been replaced by more modern technology and make grammatical changes.

3701-84-75 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. The rule has been revised to remove the requirement for participation in National Cardiovascular Data Registry IMPACT registry and replace with participation in an applicable data registry of choice. Furthermore, revisions add same day procedure discharge requirements, and clarify that an adult means an individual eighteen or older and that the pediatric service may provide care to an individual aged eighteen or older as determined appropriate by the clinicians.

3701-84-76 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 the appropriate training/licensing in sufficient numbers to meet the needs of the patients. The rule has been revised to make grammatical changes and clarify that the medical director should have experience in pediatric cardiac catheterization and intervention.

3701-84-78 The rule sets forth the safety standards for pediatric cardiac catheterization services including compliance with applicable nuclear regulatory requirements, electrical safety, and maintenance of equipment. The rule has been revised to make grammatical changes and clarify that preventive maintenance activities must be documented.

3701-84-80 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. The rule has been revised to make grammatical changes and to reduce the requirement for morbidity and mortality reviews from every ninety days to every sixty days to align with the general quality assessment requirements in rule 3701-84-12.

3701-84-81 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. The rule has been revised to clarify that an adult patient means aged eighteen and older and that an adult patient can be serviced by the pediatric cardiovascular surgery services when determined appropriate by the clinicians. Furthermore, the rule has been revised to remove the requirement for participation in the Society for Thoracic Surgeons congenital heart registry and replace with a data registry of the service's choice as appropriate and paragraphs have been reformatted to improve the flow of information in the rule and make grammatical changes.

3701-84-82 The rule sets forth the personnel and staffing requirements for pediatric cardiovascular services. These requirements including, but not limited to, a board-certified medical director, two thoracic surgeons, and nursing staff with specialized training in pediatric cardiovascular surgery. The rule has been revised to make grammatical changes.

3701-84-85 The rule sets forth the QAPI program requirements for pediatric cardiac catheterization services in addition to the general QAPI requirements in rule 3701-84-12. These requirements include a regular morbidity and mortality review. The rule has been revised to remove the requirement for participation in the Society for Thoracic Surgeons congenital heart registry and replace with a data registry of the service's choice as appropriate and make grammatical changes.

Rescinded Rules

3701-84-17 The rule sets forth the personnel and staffing requirements for SOT services, such as at least one primary transplant surgeon for each type of organ transplanted and a multidisciplinary care team comprised of appropriately qualified medical, nursing, and supportive service staff to meet the needs of patients. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-18 The rule sets forth the facilities requirements for SOT services including, but not limited to, operating rooms, laboratory, and diagnostic/treatment services. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-19 The rule sets forth the safety standards for SOT services and has been revised to improve the clarity and flow of information in the rule. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-20 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. The rule and its associated appendices A and B are being rescinded and replaced with new rule 3701-84-20 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-21 The rule sets forth the utilization/volume requirements for SOT services; these requirements are reflective of current CMS-COPs. In preparation for the forthcoming hospital licensure rules and the integration of the HCS rules into the new Chapter, this rule has been rescinded. The requirements will be captured by the Code of Federal Regulations cited in rule 3701-84-16.

3701-84-27 The rule sets forth the patient selection/utilization requirements for BMT services. The rule is being rescinded and replaced with new rule 3701-84-27 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-30.3 The rule sets forth the service standards for Level III adult cardiac catheterization services. The rule is being rescinded and replaced with new rule 3701-84-30.3 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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3701-84-34 The rule sets forth the performance measure requirements for adult cardiac catheterization services. The rule is being rescinded and replaced with new rule 3701-84-34 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-67 The rule sets forth the service standards for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded and replaced with new rule 3701-84-67 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-68 The rule sets forth the personnel and staffing requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-69 The rule sets forth the facilities, equipment, and supplies requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-70 The rule sets forth the treatment standards for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-71 The rule sets forth the radiation safety standards for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-72 The rule sets forth the QAPI program requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-73 The rule sets forth the medical records requirements for radiation therapy and/or stereostatic radiosurgery services. The rule has been rescinded due to the consolidation of all radiation therapy and stereotactic surgery regulations being captured by reference to Chapter 3748. Of the Revised Code in rule 3701-84-67.

3701-84-77 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. The rule has been rescinded and replaced with new rule 3701-84-77 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-79 The rule sets forth the performance measures for pediatric cardiac catheterization services including a setting a volume goal and for the facility, but not for individual physicians. The rule has been rescinded and replaced with new rule 3701-84-79 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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3701-84-83 The rule sets forth the facilities, equipment, and supply requirements for pediatric cardiovascular services. The rule has been rescinded and replaced with new rule 3701-84-83 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent.

3701-84-84 The rule sets forth the patient selection and utilization requirements for pediatric cardiovascular services. The rule has been rescinded and replaced with new rule 3701-84-84 due to Legislative Service Commission rule drafting requirements for rules revised more than fifty percent

New Rules

3701-84-20 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. The new rule replaces existing rule 3701-84-20 and removes the patient selection criteria requirements previously set forth in the rule and its associated appendices A and B. The previous requirements are being replaced with general patient selection criteria as established by Organ Procurement and Transplantation Network and the Centers for Medicare and Medicaid Services.

3701-84-21 The new rule replaces the existing rule 3701-84-21 and in preparation for the integration of these rules into the forthcoming hospital licensure rules, replaces the existing patient selection criteria for blood and bone marrow transplantation services with a citation to Title 42 Code of Federal Regulations Section 482.80 to 482.82.

3701-84-27 The new rule replaces existing rule 3701-84-27 and establishes the patient selection and utilization requirements for blood and bone marrow transplant services. The new rule establishes the volume goals at single clinical sites, multiple clinical sites, allogeneic only, autologous only, and both allogeneic and autologous site consistent with current Foundation for the Accreditation of Cellular Therapy (FACT) standards.

3701-84-30.3 The new rule replaces existing rule 3701-84-30.3 and 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 has been revised to remove atrial fibrillation ablation from the prohibited procedures list, remove membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry, and to reduce the reporting elements required in the service's annual report.

UPDATE 11/7/22: A new reporting paragraph was added detailing the reporting requirements for the January 1, 2023, through December 31, 2024, timeframe.

3701-84-30.4 This new 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 clearance at the head of the bed should be allocated for anesthesia equipment on either side and sterile access to jugular vein entry sites, if employed, while allowing for 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.

UPDATE 11/7/22: The rule was revised to allow for the provision of electrophysiology 3D mapping services by arrangement or contract with another hospital.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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3701-84-34 The new rule replaces existing rule 3701-84-34 and establishes the performance measures for adult cardiac catheterization services. The rule has been revised to remove numerical volume requirement for adult cardiac catheterization services and replaces them with a requirement to maintain a volume 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.

3701-84-67 The new rule replaces existing rule 3701-84-67 and establishes the service standards for radiation therapy and stereotactic surgery services. The new standards include compliance with Chapter 3748 of the Ohio Revised Code and reporting to the Ohio Cancer Incidence Surveillance System.

3701-84-77 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 have been equipped with high quality imaging and physiological monitoring equipment. The new rule replaces existing rule 3701-84-77 and updates 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. Control room 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.

3701-84-79 This new rule replaces existing rule 3701-84-79 and establishes the pediatric cardiac catheterization service performance measures. The rule has been revised to remove numerical volume requirement for pediatric cardiac catheterization services and replaces them with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Pediatric 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.

3701-84-84 This new rule replaces existing rule 3701-84-84 and establishes the pediatric cardiovascular surgery service performance measures. The rule has been revised to remove numerical volume requirement for pediatric cardiovascular surgery service and replaces them with a requirement to maintain a volume to ensure the safety and quality of procedures performed at the service. Pediatric cardiovascular surgery service 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.

No Change

3701-84-63 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.

3701-84-65 The rule sets forth the QAPI requirements for PICUs. These requirements include the service conducting regular morbidity and mortality reviews

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- 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 sections 3702.11, 3702.13, and 3701.31

- 4. 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?**

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.

- 5. 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.

- 6. 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 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. 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.

- 7. 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 Chapter 3701-84. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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8. 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?

No

Development of the Regulation

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

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?

Stakeholder input was received from numerous clinicians which resulted in updates to the "prohibited procedures" list in rule 3701-84-30.2, revisions to the square footage requirements for all operating and procedure rooms throughout the rule set, and the allowance for the performance of 3D mapping studies for electrophysiology procedures to be obtained through agreement or contract with another hospital.

Input additionally resulted in the allowance for cardiac catheterization and open heart services to utilize a data registry of their choice, report data as raw numbers, reliance on CMS Conditions of Participation where appropriate, and a significant reduction in the number of reporting elements for those services required to report to ODH.

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?

Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards: Process, Protocols, Equipment, Personnel, and Safety

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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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 Chapter 3701-84 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. Did the Agency specifically consider a performance-based regulation? Please explain.

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

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services to correct their identified deficiencies and meet the quality and safety standards required by statute.

14. 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.

15. 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

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

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

- Rules 3710-84-01 to 3701-84-14 impact all health care service providers;
- Rules 3701-84-16 to 3701-84-21 impact solid organ transplant services;
- Rules 3701-84-24 to 3701-84-27 impact bone marrow transplant services, including stem cell harvesting and reinfusion services;
-
- Rules 3701-84-30 to 3701-84-34.2 impact adult cardiac catheterization services;
-
- Rules 3701-84-36 to 3701-84- 40 impact open heart surgery services;
- Rule 3701-84-61 to 3701-84-65 impact pediatric intensive care services;
- Rules 3701-84-67 to 3701-84-73 impact radiation therapy and stereotactic radiosurgery services;
- Rules 3701-84-75 to 3701-84-79 impact pediatric cardiac catheterization services; and
- Rules 3701-84-81 to 3701-84-85 impact pediatric cardiovascular surgery services.

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

Fines, time for compliance, and reporting requirements.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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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.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Costs specific to the state rules:

As set forth in rule 3701-84-05 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. 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 3702.31 of the Ohio Revised Code, associated with inspections approximately once every 36 months or as the result of a complaint:

Complaint Inspection Fee- \$650

Follow-up Inspection Fee- \$650

Desk Audit or Compliance Review Fee- \$250

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.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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Physician:
Average of \$97.08 per hour*

Registered Nurse:
Average of \$35.62 per hour. *

Other Healthcare Practitioners:
Average of \$42.88 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2021, using the codes for all health care practitioners and technical occupations (29-1299) physicians and surgeons, all others (29-1229), registered nurse (29-1141).

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 3702.11 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 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 3701-84-06 represent only a portion of the actual direct and indirect costs incurred by the Department during the survey process. 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 Chapter 3701-84 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 3701-84-14 and are determined on a case-by-case basis.

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 Chapter 3701-84.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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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 Chapter 3701-84 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>