CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Chapter 3701-84 – Health Care Services

Rule Number(s): 3701-84-01 through 3701-84-85

Date: September 30, 2016; Revised December 1, 2016; Additional Change January 19, 2017

Rule Type:

X New

X Amended

X 5-Year Review

X Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulations in plain language.**
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

No changes have been made to the following rules:

3701-84-30: The rule sets forth the general cardiac catheterization service standards including, but not limited to access to clinical and allied support services such as hematology and diagnostic radiology; providing notice to the Director of the service level classification provided; and maintaining a written transfer protocol for the transfer and care of patients in the event of an emergency.

3701-84-34: The rule sets forth the service performance measures for adult cardiac catheterization services, including the minimum number of procedures that should be performed at each established level.

3701-84-34.1: The rule sets forth the inspection and review standards for adult cardiac catheterization services, such as cardiac catheterization services will be inspected at least once every three years. The number of procedures performed are not the sole indicator of performance, but that failure to perform at established levels may result in further actions such as an extended review or annual inspections.

The following rules are being rescinded due to the fifty percent change restriction in Legislative Service Commission (LSC) rule drafting requirements. Each rule has been replaced with a new rule.

3701-84-17
3701-84-19
3701-84-25
3701-84-36
3701-84-39
3701-84-40
3701-84-75
3701-84-81
3701-84-85

The following new rules replace the rescinded rules listed above:

3701-84-17: New rule due to fifty percent change restriction in LSC rule drafting requirements. 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 patents. The rule has been revised to reflect the current CMS-COPs for a transplant multidisciplinary team and to break out existing paragraphs to improve the clarity and flow of information in the rule.

3701-84-19: New rule due to fifty percent change restriction in LSC rule drafting requirements. 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.

3701-84-25: New rule due to fifty percent change restriction in LSC rule drafting guidelines. The rule includes the previous personnel and staffing requirements in existing/rescinded rule 3701-84-25 and the recommendations of the FACT (Foundation for the Accreditation of Cellular Transplantation) relating to the medical director of a Bone Marrow Transplantation service.

3701-84-36: New rule due to fifty percent change restriction in LSC rule drafting guidelines. 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. Patient selection and utilization requirements from current rule 3701-84-40 have been moved to this rule. Services will be required to obtain/maintain enrollment in the Society for Thoracic Surgeons cardiac surgery database and provide an annual report to the director by July 1st of each year based upon the data submitted to the STS for the preceding calendar year. Additionally, similar to the adult cardiac catheterization services, open heart services will be required to provide notice to the director within thirty days of receipt of any STS report in which the service falls below the 10th percentile for specified National Quality Forum (NQS) measures for coronary artery bypass grafting surgeries. The revisions also reflect the current industry practice of a coordinated multidisciplinary approach to patient care, including meetings to develop care plans to meet the needs of complex medical cases. Finally, the revision require that patient selection be based upon American College of Cardiology guidance pertaining to coronary artery bypass graft surgery and management (including surgery) of adults with congenital heart disease.

3701-84-39: New rule due to fifty percent change restriction in LSC rule drafting guidelines. 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 incorporate the outcome data received from participation in the Society for Thoracic Surgeons database and the review and evaluation of the multidisciplinary meetings required in rule 3701-84-36. These revisions are reflective of current industry practices.

3701-84-40: New rule due to fifty percent change restriction in LSC rule drafting guidelines. The patient selection and utilization requirements have been moved from this rule to new rule 3701-84-36. The rule sets forth the performance measures for open heart surgery services, including a reduction in the volume goal for the service from 250 to 150. This reduction is based upon the American College of Cardiology recommendations and current analysis of Ohio's open heart services volume trends. Furthermore, the rule clarifies that the number of procedures performed will not be used as the sole indicator of performance, but that failure to perform at established levels may result in further actions such as an extended review or annual inspections. The corrective actions are the same as the adult cardiac catheterization services and provide the director with greater flexibility when working with open heart services to ensure compliance with the safety and quality standards in this Chapter

3701-84-75: New rule due to fifty percent change restriction in LSC rule drafting guidelines. 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 require participation in the American College of Cardiology National Cardiovascular Data Registry IMPACT registry as supported by the providers of pediatric cardiac catheterization services as part of the services overall quality assessment and performance improvement efforts. Services will also be required to document internal reviews conducted by the service of physicians with a combination of high mortality and low volume of procedures; this will assist the director during state surveys in determining the efforts of the service to improve the service's quality and safety. Each service must also have established criteria for the privileging of physicians to perform procedures in the service; this requirement is reflective of current industry practices and standards. Finally, the written emergency transfer agreement requirements in pervious paragraph (C) for services without an on-site cardiovascular surgery services has been removed. Existing pediatric cardiac catheterization services in Ohio are all located within hospitals with a pediatric cardiovascular surgery service and the industry supports ensuring that any future pediatric cardiac catheterization services maintain the same standards.

3701-84-81: New rule due to fifty percent change restriction in LSC rule drafting guidelines. 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 services should be provided in a coordinated multidisciplinary approach, including meetings to determine patient treatment plans and all services must participate in the Society for Thoracic Surgeons Congenial Heart Surgery Database. Services are also required to provide onsite or by arrangement, extracorporeal membrane oxygenation and ventricular assist device services. These revisions were recommended by the industry.

3701-84-85: New rule due to fifty percent change restriction in LSC rule drafting guidelines. 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 incorporate the outcome data received from participation in the Society for Thoracic Surgeons Congenital Heart Surgery database and the review and evaluation of the multidisciplinary meetings required in rule 3701-84-81. These revisions are reflective of current industry practices.

New Rule:

3701-84-80: This new rule clarifies the QAPI program requirements for pediatric cardiac catheterization services in addition to the general QAPI requirements in rule 3701-84-12. The rule includes requirements previously included in rule 3701-84-75 that are more appropriate for this standalone QAPI rule, as is the standard for other health care services as well as morbidity and mortality specific considerations that are reflective of current American College of Cardiology guidelines.

Revision have been made to the following rules:

3701-84-01: The rule sets forth the definitions used throughout the Chapter. Revisions have been made to paragraph (G) in accordance with current bone marrow transplantation guidelines. The four year reference in paragraph (OO) has been removed to clarify the requirements of a radiation oncologist and the definition of radiation therapy in paragraph (PP) has been updated to cite the corresponding Chapters of the Administrative Code. Finally, paragraph (YY) has been added to the definition section from existing rule 3701-84- 06.

3701-84-02: The rule delineates the service types under the authority of the Chapter and has been revised to update the reference to the adult cardiac catheterization rule set, up to rule 3701-84-34.2 and the "annual" review requirement in paragraph (B) has been changed to periodic review to accommodate the statutory required every five-years and reviews based on need, such as consultation with the industry or changes in technology.

3701-84-03: The rule sets forth the general provisions and prohibitions for all HCSs and has been revised to make grammatical corrections in accordance with LSC rule drafting guidelines.

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 for clarification.

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 for clarity.

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 for clarification.

3701-84-07: The rule requires HCSs to have patient care policies. The rule has been revised to clarify that the HCS must inform the patient of the HCS's policy pertaining to Do Not Resuscitate (DNR) orders.

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 record keeping requirements for the license/registration/certification of staff to align with similar record keeping requirements in other rule sets. Additional revision have been made for clarity and to improve the ease of use of the rule.

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 throughout.

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 for clarification.

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 for clarification.

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 for clarification.

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 for clarification.

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 for clarification.

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) to clarify that treatment must be through a multidisciplinary approach and that plans must be provided for living donors if living donations are performed.

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. The rule has been revised to make general grammatical changes.

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 has been revised based on industry standards and provider request, to provide an alternative determinant for pediatric renal function deterioration by use of glomerular filtration rate (GFR). The rule has been further revised to update and clarify the membership requirements for the chemical disorder committee that determines eligibility for patients with a history of alcohol or substance dependency. Appendices A and B have been revised at the request of the Solid Organ Transplant Consortium to reflect current standards.

3701-84-21: The rule sets forth the utilization/volume requirements for SOT services; these requirements are reflective of current CMS-COPs. The rule has been revised to clarify that pediatric transplant services, are not subject to volume goals. Pediatric only services are evaluated by CMS based upon outcomes.

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.

3701-84-26: 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 based upon industry practices and provider request, to allow for the provision of full body irradiation either on-site or through a contract or agreement with another hospital.

3701-84-27: The rule sets forth the patient selection/utilization requirements for BMT services. The appendix to the rule provides detailed exclusion criteria and disease specific requirements, while the rule provides a process for patient review and selection for patients who do not meet the standard criteria. BMT services volume goals remain unchanged and reflect current CMS COPs for stem cell transplantation. The rule has been revised to improve the clarity and flow of information in the rule and make grammatical changes.

3701-84-30.1: The rule sets forth the service standards for Level I adult cardiac catheterization services. This rule became effective in April of 2016 and limits Level I services to only diagnostic procedures. Based upon provider request, the rule has been revised to increase the number of days from 45 to 120 after the first of each year, for the service to provide the required annual report to the director. This expansion of the timeframe corresponds to the same increase for Level II and Level III services that allows for the inclusion of information from the National Cardiovascular Data Registry fourth quarter reports.

3701-84-30.2: The rule sets forth the service standards for Level II adult cardiac catheterization services. This rule became effective in April of 2016; Level II services may provide diagnostic and specified therapeutic procedures without on-site surgical backup. Based upon provider request, the rule has been revised to increase the number of days from 45 to 120 after the first of each year, for the service to provide the required annual report to the director. This expansion of the timeframe corresponds to the same increase for Level I and Level III services that allows for the inclusion of information from the National Cardiovascular Data Registry fourth quarter reports.

3701-84-30.3: The rule sets forth the service standards for Level III adult cardiac catheterization services. This rule became effective in April of 2016; Level III services maintain an open heart surgery service and provide the full spectrum of cardiovascular procedures. Based upon provider request, the rule has been revised to increase the number of days from 45 to 120 after the first of each year, for the service to provide the required annual report to the director. This expansion of the timeframe corresponds to the same increase

for Level I and Level II services that allows for the inclusion of information from the National Cardiovascular Data Registry fourth quarter reports.

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 clarify the medical director at a Level II or III service must be board certified in interventional cardiology and have either five years of experience or have performed at least five hundred percutaneous coronary interventions.

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 add language to the rule title.

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 add language to the title.

3701-84-34.2: The rule establishes the criteria for which the Department may issue an order to cease operations to an adult cardiac catheterization service for failure to comply with standards. The rule has been revised to make grammatical changes.

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 that medical directors must be board certified in thoracic surgery, nursing staff must be advanced cardiac life support certified and to update the education and training requirements for perfusionists to accurately reflect the current industry education/training program terminology. These changes reflect current industry standards and are supported by the providers. Finally, based upon provider requests and current practices, the revisions clarify that at least one nurse and one scrub nurse or technician must be present for each procedure.

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 make grammatical changes, to allow for the use of percutaneous mechanical circulatory assist devices, and to remove an outdated reference to accrediting entity standards in paragraph (D).

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 also been revised to breakout existing requirements for laboratory tests into subparagraphs to improve the clarity and flow of information. Additionally, the rule has been revised to update the type of pediatric and surgical subspecialties that must be available to PICUs to reflect current industry standards. Based upon industry request and current industry practices, revisions have been made to allow for radiation therapy, allergist, neonatologist, and geneticist services to be provided either on site or by arrangement with another facility. Finally, authorization for a temporary expansion of a PICU service due to seasonal illness or an outbreak is authorized as long as the area of expansion meets all of the requirements for a PICU.

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 update the education, training, and experience requirements of physician, nursing, and respiratory therapy staff to be reflective of current industry standards and practices. These revisions are based upon the American Academy of Pediatrics recommendations.

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. The rule has been revised to make grammatical changes and to break out existing information in the rule into subparagraphs to improve the clarity and flow of information throughout the rule.

3701-84-64: The rule sets forth the equipment and supplies requirements for PICUs. These requirements include the service having life-saving, therapeutic and monitoring equipment such as a defibrillator and crash cart. The rule has been revised to make grammatical changes and to update the required equipment list to reflect current American Academy of Pediatrics recommendations, which is the industry standard.

3701-84-65: The rule sets forth the QAPI requirements for PICUs. These requirements include the service conducting regular morbidity and mortality reviews. The rule has been revised to clarify that the PICU must have a multidisciplinary collaborative QAPI program; this is reflective of the industry practice and standards.

3701-84-67: The rule sets forth the service standards for radiation therapy and/or stereostatic radiosurgery services. These requirements include the service conducting an evaluation of each patient and assessing each tumor, having policies and procedures for the follow-up for patients treated for curative and palliative reasons, and compliance with the Ohio cancer incidence surveillance system. The rule has been revised to correct a citation in paragraph (F) to reflect a change in the statute.

3701-84-68: The rule sets forth the personnel and staffing requirements for radiation therapy and/or stereostatic radiosurgery services. These requirement include the service having a medical director that is either a radiation oncologist or a board certified neurosurgeon depending on the type of service provided. The rule has been revised to provide reference to the current certification/training/licensing requirements for medical physicists in Ohio set forth in Chapters 3701:1-67 and 3701:1-58 of the Administrative Code and to clarify that responses to urgent requests should be available twenty-four hours per day seven days a week.

3701-84-69: The rule sets forth the facilities, equipment, and supplies requirements for radiation therapy and/or stereostatic radiosurgery services. These requirements include the facility having an adequate number of exam rooms and having a preventive maintenance plan for all equipment. The rule has been revised to make grammatical changes and to break out information from the existing rule into subparagraphs to improve the clarity and flow of information in the rule.

3701-84-70: The rule sets forth the treatment standards for radiation therapy and/or stereostatic radiosurgery services. These requirements include, but are not limited to, the service providing accurate calculations of dosages and distributions and providing positioning devices to aid in immobilizing the patient during treatment. The rule has been revised to break out existing portions of the rule into new paragraphs to improve the clarity and flow of the information within the rule.

3701-84-71: The rule sets forth the radiation safety standards for radiation therapy and/or stereostatic radiosurgery services. These requirements include the service documenting and reporting of all misadministrations of radiation. The rule has been revised to make a change to the title.

3701-84-72: The rule sets forth the QAPI program requirements for radiation therapy and/or stereostatic radiosurgery services. These requirements include that the service evaluate the provision of its services. The rule has been revised to break out information from the existing rule into subparagraphs to improve the clarity and flow of information in the rule.

3701-84-73: The rule sets forth the medical records requirements for radiation therapy and/or stereostatic radiosurgery services. These requirements include that the service document services provided and maintain radiographic images. The rule has been revised to make a grammatical change.

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 he needs of the patients. The rule has been revised to require the medical director's board certification to be in pediatric cardiology and not cardiovascular disease. Board certification in pediatric cardiology is the current industry standard and is well supported by Ohio's existing pediatric cardiac catheterization services. The rule is also revised to require staff working with patients to be skilled in pediatric cardiopulmonary resuscitation. Finally, the rule has been revised to improve the clarity and flow of information throughout.

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 is equipped with high quality imaging and physiological monitoring equipment. The rule has been revised to make general grammatical changes and to incorporate an equipment list reflective of American College of Cardiology and American Academy of Pediatrics recommendations for pediatric cardiac catheterization services.

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 add language to the title and make grammatical changes.

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 revised to increase the procedural volume goal from seventy-five to one hundred consistent with the 2012 American college of cardiology foundation/society for cardiovascular angiography and interventions expert consensus document on cardiac catheterization laboratory standards update. This change has been supported by the existing services. Grammatical changes have been made to the rule and the title has been changed.

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 clarify that medical directors must be board certified in thoracic surgery, nursing staff must be pediatric life support certified and to update the education and training requirements for perfusionists to accurately reflect the current industry education/training program terminology. These changes reflect current industry standards and are supported by the providers.

3701-84-83: The rule sets forth the facilities, equipment, and supply requirements for pediatric cardiovascular services. These requirements include the service having appropriate oxygen and vacuum outlets and having proper operating room lighting. The rule has been revised to include a list of required equipment that reflects the current American Academy of Pediatrics and the American College of Cardiology requirements for pediatric cardiovascular surgery services. These revisions are supported by the providers.

3701-84-84: The rule sets forth the patient selection and utilization requirements for pediatric cardiovascular services. These requirements include that the service attain a volume goal of at least one hundred pediatric procedures per year. The rule has been revised to make general grammatical changes.

2. Please list the Ohio statute authorizing the Agency to adopt these regulations.

Ohio Revised Code sections 3702.11, 3702.13, and 3701.31

3. Do the regulations implement a federal requirement? Are the proposed regulations being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

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

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

Not applicable to these rules.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

As required by 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 heath 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.

6. **How will the Agency measure the success of these regulations in terms of outputs and/or outcomes?**

Successful outcomes are measured through a standard survey (inspection) process approximately once every thirty-six months; successful outcomes would indicate compliance with the standards and requirements set forth in Chapter 3701-84. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulations.**

Initial e-mail notifications and a request for informal comments were sent to interested parties – April 4, 2016 and stakeholder meetings were schedule May 25th, June 15th, and June 28, 2016. These meetings were well attended by representatives from across the state including pediatric cardiovascular surgeons and cardiologists, nurse managers, hospital government liaisons, and service administrators. Numerous comments were received as a result of these meetings and mailings and have had a direct impact on the revisions made to the Chapter as a whole. Those services contacted/participating included:

Ohio Hematopoietic Stem Cell Transplant Consortium
Ohio Solid Organ Transplant Consortium
Nationwide Children's Hospital
Cincinnati Children's Hospital
Akron Children's Hospital
Dayton Children's Hospital
Rainbow Babies
University Hospitals
Cleveland Clinic
Mercy Hospital
Ohio Chapter of the American College of Cardiology
Ohio Hospital Association
Metrohealth
Genesis Health Care
Atrium Medical Center
Riverside Methodist
Mt. Carmel Hospitals
Elyria Medical Center
Fairfield Medical Center
Grandview Medical Center
Grant Medical Center
Southern Ohio Medical Center
Adena Health Systems
Firelands Regional Medical Center

UC Health
Aultman Hospital
University of Toledo
Ohio State Wexner Medical Center
Summa Health Systems
Lifeline Ohio
OSU James Cancer Hospital

Official posting to ODH website, Governor's e-notification website, and direct e-mails to interested parties – October 2016

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

Stakeholders from the services and the industry provided professional opinions, updates to practice standards and guidelines, as well as acknowledgement and acceptance of agency recommended grammatical, formatting, and content revisions. Updates and revisions to service specific guidelines, patient selection criteria, and protocols were made as a direct result of stakeholder input.

Specifically:

3701-84-01 – Removed being over the age of forty as a high risk factor for allogeneic BMT from paragraph (G) – recommendation of the Ohio Hematopoietic Stem Cell Transplant Consortium.

3701-84-20 – The inclusion of new criteria for determining pediatric renal function deterioration is based upon input from Nationwide Children's Hospital Renal Transplant Service. Revisions to the Chemical Disorder Committee criteria and Appendices A and B patient selection criteria are the result of input from the Ohio Solid Organ Transplant Consortium.

3701-84-26 and 3701-84-27 - Revisions to the rule allowing for full body irradiation either on site or by agreement with another facility and changes to the patient selection criteria in Appendix A are based upon comments from the Ohio Hematopoietic Stem Cell Transplant Consortium, The Ohio State University Comprehensive Cancer Center, and the Cleveland Clinic.

3701-84-36 and 3701-84-37 – Revisions are based upon comments provided by Ohio Health, Summa Health, Nationwide Children's Hospital, the Cleveland Clinic, and Aultman Hospital.

3701-84- 60, 3701-84-62, and 3701-84-65 – Input was received from Akron Children's Hospital and Dayton Children's Hospital that resulted in the allowance for the provision of radiation therapy, allergist, neonatologist, and geneticist services either onsite or by arrangement with another facility; clarification of board certification requirements for the medical director; and the requirement that PICUS maintain a coordinated multidisciplinary QAPI program.

3701-84-75 to 3701-84-85 - Input was received from the Ohio Chapter of the American College of Cardiology, Nationwide Children's Hospital, Akron Children's Hospital and Cincinnati Children's Hospital and the recommendations are directly reflected in the rules. These recommendations resulted in revisions including: the requirement for participation in the National Cardiovascular Data Registry (NCDR) IMPACT registry; requiring a coordinated multidisciplinary approach to care with meetings to determine

appropriate patient treatment planning; inclusion of extracorporeal membrane oxygenation (ECMO) and ventricular assist device (VAD) services onsite or by arrangement as necessary services; participation in the Society for Thoracic Surgeons Congenital Heart Surgery database; and QAPI program review requirements.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The most current scientific, medical, and professional information was used in the development of these rules. The specific rules which incorporate scientific data are as follows:

3701-84-20 - The Centers for Medicare and Medicaid (CMS) and the Solid Organ Transplant Consortium is viewed as an industry experts; the recommendations of CMS by way of the Conditions of Participation (COP) for solid organ transplant centers and the Consortium are based upon the most current and appropriate medical, technological, and psychological studies and the resultant guidelines established within this industry. The rule directly reflects those recommendations.

3701-84-25; 27 - The Ohio Hematopoietic Stem Cell Transplant Consortium is viewed as an industry expert; the recommendations of the Consortium are based upon the most current and appropriate medical, technological, and psychological studies and the resultant guidelines established within this industry. The rule directly reflects those recommendations.

3701-84-30 through 3701-84-40 – The rules have incorporated the recommendations and guidelines of the American College of Cardiology, the Society for Thoracic Surgeons, The American Heart Association, and the Society for Cardiovascular Angiography and Interventions as they relate to performance measures/metrics for determining quality and safety in cardiac catheterization and open heart surgery services. The metrics referenced in these rules are reflective of the current national standards established by these entities.

3701-84-61 to 3701-84-65 – The rules have incorporated the American Academy of Pediatrics "Guidelines and Levels of Care for Pediatric Intensive Care Units" pertaining to facility, equipment, personnel, and management of PICUs.

3701-84-75 through 3701-84-85 - Due to the specialized nature of the pediatric cardiac catheterization rules, the providers of pediatric cardiac catheterization and cardiovascular surgery services are considered experts in this field. The recommendations of these organizations are based upon the most current and appropriate medical, technological, and psychological studies and the resultant guidelines established within this industry from organizations such as the American College of Cardiology, the American Academy of Pediatrics, the Society for Cardiovascular Angiography and Interventions, and the American Heart Association.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The Ohio Department of Health is required to 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.

11. Did the Agency specifically consider performance-based regulations? 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.

12. What measures did the Agency take to ensure that these regulations do not duplicate an existing Ohio regulation?

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

13. Please describe the Agency's plan for implementation of these regulations, including any measures to ensure that the regulations are applied consistently and predictably for the regulated community.

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

14. Provide a summary of the estimated cost of compliance with these rules. Specifically, please do the following:

a. Identify the scope of the impacted business community:

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;

Rules3701-84-67 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 the adverse impact (e.g., license fees, fines, employer time for compliance); and

Fines, time for compliance, and reporting requirements.

An adverse impact was not identified for every rule in Chapter 3701-84. 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.

Adult Cardiac Catheterization Services required participation in the American College of Cardiology National Cardiovascular Data Registry (NCDR) for Level II and Level III services; the services are already participating in this registry; the cost for the NCDR is $5000. The additional report required to be submitted to ODH is based upon data submitted to the registry and represents only minimal additional efforts on the part of a staff member to compile the data. This time is estimated to be approximately one hour.

Adult Open Heart Services required participation in the Society for Thoracic Surgeons cardiac surgery database; existing services indicated that their surgeons are already participating in the data registry so this state requirement does not represent an additional direct cost or indirect cost through time. The individual membership is $750 per year. The additional report required to be submitted to ODH is based upon data submitted to the STS registry and represents only minimal additional efforts on the part of a staff member to compile the data. This time is estimated to be approximately one hour.

Pediatric Cardiac Catheterization Service participation in the National Cardiovascular Data Registry (NCDR) IMPACT registry; existing services indicated that they are already participating in the registry so this state requirement does not represent an additional direct cost or indirect cost through time. The additional report required to be submitted to ODH is based upon data submitted to the registry and represents only minimal additional efforts on the part of a staff member to compile the data. This time is estimated to be approximately one hour.

Pediatric Cardiovascular Surgery Services required participation in the Society for Thoracic Surgeons cardiac surgery database; existing services indicated that their surgeons are already participating in the data registry so this state requirement does not represent an additional direct cost or indirect cost through time. The individual membership is $750 per year. The additional report required to be submitted to ODH is based upon data submitted to the STS registry and represents only minimal additional efforts on the part of a staff member to compile the data. This time is estimated to be approximately one hour.

c. Quantify the expected adverse impact from the regulation:

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:

Inspection Fee - $1750
Complaint Inspection Fee- $650
Follow-up Inspection Fee- $650
Desk Audit or Compliance Review Fee- $250

Time necessary for radiation therapy and radiostatic surgery centers to prepare and submit documentation of misadministration and medical events to the Director depends on the number of incidents and the severity of the incident.

Time and manpower necessary to prepare a waiver or variance request; both will be determined by the nature and complexity of the requirement.

Time and manpower necessary to develop policy and procedures pertaining to complaints.

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:
$0.00 to an average of $95.05 per hour*.
Registered Nurse:
$0.00 to an average of $34.14 per hour.*
Other Healthcare Practitioners:
$40.92 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2015, using the codes for all health care practitioners and technical occupations (29-1199) physicians and surgeons, all others (29-1069), registered nurse (29-1141).

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

ODH is required to implement section 3702.11of 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

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

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.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The agency maintains program staff to assist and provide guidance to health care service providers to improve their survey outcomes and maintain compliance. Additionally, as stated in rule 3701-84-05 of the OAC, "if any provider of a HCS fails to comply with any requirements of section 3702.14 of the Revised Code and Chapter 3701-84 of the Administrative Code, the Director shall provide the HCS a reasonable

and appropriate amount of time to correct the violation." The compliance and enforcement actions established by these rules are imposed based upon the severity of the violation and a number of factors including, but not limited to, the potential for physical harm and the duration of violation, which typically do not include "paperwork" violations.

18. 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:

http://www.odh.ohio.gov/odhPrograms/dspc/hcserv/HCserv1.aspx