

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: February 8, 2012

Rule Type:

☐ New

☒ Amended

☒ 5-Year Review

☐ Rescinded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. These requirements include, but are not limited to, 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
- Operation of a gamma knife
- Operation of cobalt radiation therapy unit

Revisions have been made to: 3701-84-01, 3701-84-02, 3701-84-06, 3701-84-08 to 3701-84-12, 3701-84-14 to 3701-84-18, 3701-84-24 to 3701-84-31, 37-1-84-34, 3701-84-36, 3701-84-39, 3701-84-40, 3701-84-61, 3701-84-64, 3701-84-65, 3701-84-69, 3701-84-72, 3701-84-75 to 3701-84-77, 3701-84-81 to 3701-84-83, and 370184-85. The recommended revisions: 1) remove exception language from the existing bone marrow transplantation service protocol requirements; 2) remove the requirement for an external committee review of exceptions to the bone marrow transplantation protocol; 3) add a desk audit fee of \$250 to the inspection fees that may be charged to an HCS; 4) increase the annual HCS inspection fee to \$1750 as authorized in section 3702.31 of the Ohio Revised Code; 5) provide updated access information for clinical consensus and guidelines from the American College of Cardiology; and 6) correct minor grammatical, citation, and formatting errors throughout the rules to comply with Legislative Service Commission drafting requirements. Furthermore, as a result of the enactment of the new rules pertaining to the licensure of maternity units, newborn care nurseries, and maternity homes set forth in Chapter 3701-7 of the Ohio Administrative Code, all references to obstetric and newborn services are being removed throughout the HCS rules. Finally, Appendices A and B to rule 3701-84-20 have been updated to reflect current industry patient selection criteria.

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 requirements such as, but not limited to, Conditions of Participation for solid organ transplantation contained within 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 and requiring regular morbidity and mortality conferences. 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.

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 - August 15, 2011

Official posting to ODH website, Governor's e-notification website, and direct e-mails to interested parties - November 4, 2011

Ohio Hematopoietic Stem Cell Transplant Consortium
Nationwide Children's Hospital
Cincinnati Children's Hospital
Ohio Chapter of the American College of Cardiology
Ohio Hospital Association
Ohio Nurses Association
Ohio Board of Nursing
Ohio Medical Board
Ohio Solid Organ Transplant Consortium
Ohio State Medical Association
Ohio Osteopathic Association
Strategic Health Care
Metrohealth

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

Various stakeholder industry representatives 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:

3701-84-20 - Input was received from the Solid Organ Transplant Consortium which led to the amendment of Appendices A and B to the rule. Numerous changes were made to the patient selection criteria, particularly in the areas of indications and contraindications. Lung and intestine transplant requirements were added to Appendix B and additional criteria were added to the chemical dependency evaluation criteria.

3701-84-21 - The recommendations of the Solid Organ Transplant Consortium are based upon the most current and appropriate medical, technological, and psychological studies and the resultant guidelines established within this industry. The rule reflects volume goals that are exceeded by all of Ohio's transplant centers on an annual basis.

3701-84-27 - Input was received from the Ohio Hematopoietic Stem Cell Transplant Consortium which led to the amendment of Appendix A to the rule. Numerous changes were made to the patient selection criteria, such as including language indicating the appropriateness of transplantation for other severe life-threatening immune deficiencies for which transplant has been shown to be effective. As a direct result of the Consortium's input, the requirement for an external committee review of exceptions to the bone marrow transplantation protocol was removed from the rule.

3701-84-75 to 3701-84-85 - Input was received from the Ohio Chapter of the American College of Cardiology, Nationwide Children's Hospital, and Cincinnati Children's Hospital. This input consisted of approval of the minor grammatical and formatting changes recommended by the agency and the stakeholders recommended the continuation of the existing standards set forth in rules 3701-84-75 to 3701-84-85 of the Administrative Code.

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 were used in the development of these rules. The specific rules which incorporate this scientific data are as follows:

3701-84-09 - Centers for Disease Control Guidelines for Infection Control in Health Care Facilities. The CDC is considered the nation's lead agency for disease prevention and control; its issued guidelines are the accepted standard for the healthcare industry.

3701-84-20 - The Solid Organ 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.

3701-84-27 - 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 - Appendix A to the rule contains “Selected Criteria for Identifying High Risk Conditions for Cardiac Catheterization” developed by the Ohio Chapter of the American College of Cardiology based upon the guidelines established by the American College of Cardiology, American Heart Association, and the Society for Cardiac Angiography and Interventions. These standards directly support and reflect the intent and purpose of the rule.

3701-84-34 - The rule is based upon the most recent scientific data available in the American College of Cardiology/American Heart Association/ Society for Cardiovascular Angiography and Interventions 2011 Guideline for Percutaneous Coronary Intervention and the 2001 Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards. These organizations are viewed as industry experts and the guidelines established by these organizations are directly reflected in the state rule.

3701-84-40 - The rule is based upon the most recent scientific data available in the American College of Cardiology/American Heart Association 2011 Guideline for Coronary Artery Bypass Graft Surgery. These organizations are viewed as industry experts and the guidelines established by these organizations are directly reflected in the state rule.

3701-84-75 through 3701-84-82 - Due to the specialized nature of the pediatric cardiac catheterization rules, the Ohio Chapter of the American College of Cardiology, Nationwide Children’s Hospital, and Cincinnati Children’s Hospital are viewed as industry experts. 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 Academy of Pediatrics 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 fifty-five 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 3710-84-03 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 impact adult cardiac catheterization services;

Rules 3701-84-36 to 3701-84-40 impact open heart surgery services;

Rules 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 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.

c. Quantify the expected adverse impact from the regulation:

Costs specific to the state rules:

(1) 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.

(2) 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

(3) 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.

(4) Volume goals of seventy-five procedures for pediatric cardiac catheterization and pediatric cardiovascular surgery services.

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

(6) Time and manpower necessary to develop policy and procedures pertaining to complaints.

- (7) Time and manpower necessary to develop written plans for a Quality Assessment and Performance Improvement (QAPI) program and conduct meetings.
- (8) Time and manpower necessary to develop tuberculosis control plan and infection control policies and provide training.
- (9) 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. 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 \$82.39 per hour*.

Registered Nurse:

\$0.00 to an average of \$29.13 per hour.*

Other Healthcare Practitioners:

\$32.16 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2010, using the codes for all health care practitioners and technical occupations (29-0000) physicians and surgeons, all others (29-1069), registered nurse (29-1111).

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 3702.11 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

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, Division of Quality Assurance, Health Care Services Section and the Division of 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>