

# 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): 3701-84-30 through 3701-84-34

Date: June 16, 2015: Revised filing September 11, 2015

**Rule Type:**

☒ New

☐ 5-Year Review

☒ Amended

☐ Rescinded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 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 rules subject to revisions at this time are specific to the adult cardiac catheterization standards set forth in rules 3701-84-30 through 3701-84-34 of the Administrative Code.

Revisions to the existing rules and creation of new rules are as follows:

3701-84-30 – New Rule replaces existing rule: The rule establishes the general cardiac catheterization service standards. The new rule incorporates much of the existing rule language including the service having access to clinical and allied support service such as hematology and diagnostic radiology.

Some of the service standards include, but are not limited to: cardiac catheterization services will be required to provide notice to the Director of the service level classification it provides or intends to provide; maintain a written transfer protocol for the transfer and care of patients in the event of an emergency; establish and maintain a quality assessment review process; criteria for granting privileges to the physicians perform catheterizations; and the service must be provided in a fully permanent setting. Finally, the rule provides definitions for use throughout the chapter such as ‘major bleeding’ and a detailing of the professional and clinical guidelines referenced in the rules.

3701-84-30.1 – New Rule: The rule establishes the standards for Level I services. Level I services will be restricted to providing only diagnostic procedures in a fully permanent setting on a regular basis. In addition to the general service standards, Level I services will be required to maintain a written transfer protocol for medical and surgical management with a registered hospital that provides open heart surgery and complete a drill of the protocol annually; review emergency transfers and complications at least every ninety days; and provide specific information related to procedures and services to the Director annually including adverse outcomes and the number of procedures performed. Level I services will not be prohibited from providing emergency care, including emergent PCI, when it is clinically indicated and must report such occurrences to the Department within forty-eight hours.

3701-84-30.2 – New Rule: The rule establishes the standards for Level II services. Level II services will be required to have provided diagnostic services for at least one year prior to requesting a Level II designation unless they submit a request for an accelerated designation and receive approval of that request from the Director. Level II services will be authorized to perform diagnostic and therapeutic procedures provided in a setting without an open-heart surgical service and be required to provide primary PCI on a twenty-four hour a day seven day a week basis. Level II services will be restricted from performing a number of procedures which are delineated by the rule including, but not limited to, transcatheter aortic valve replacement, cardiac biopsies, and mitral valve clips. In addition to the general service standards, Level II services will be required to maintain a written transfer protocol for medical and surgical management with a registered hospital and complete a drill of the protocol annually; maintain a formal written agreement with a ground/air ambulance that can commit to service within thirty minutes; review emergency transfers and complications at least every ninety days; and obtain/maintain enrollment in the National Cardiovascular Data Registry (NCDR) Cath/PCI Registry and provide an annual report to the director that includes information submitted to NCDR. Level II services will be required to provide notice to the director within thirty days any quarter in which the service fails to meet specified quality metrics established by the NCDR. Level II services will not be prohibited from providing emergency care, including emergent PCI, when it is clinically indicated and must report such occurrences to the Department within forty-eight hours.

3701-84-30.3 – New Rule: The rule establishes the standards for Level III services. The new rule incorporates many requirements from existing rule 3701-84-30 including, but not limited to having an experienced cardiovascular surgical team readily available in less than sixty minutes twenty-four hours a day and having one or more surgical suites equipped to accommodate thoracic and cardiac surgery. Level III services will provide the full spectrum of diagnostic and therapeutic catheterization services in a setting with an open-heart surgical service on a twenty-four hour a day seven day a week basis. New requirements include the Level III service obtaining/maintaining enrollment in the National Cardiovascular Data Registry (NCDR) Cath/PCI Registry and provide an annual report to the director that includes information submitted to NCDR. Level III services will be required to provide notice to the director within thirty days any quarter in which the service fails to meet specific quality metrics established by the NCDR.

3701-84-31 - Revised Rule: The rule establishes the general personnel/staffing requirements for cardiac catheterization services. The rule is being revised to make general LCS rule drafting formatting changes and to update references/citations to professional guidelines; clarify that nurses employed by the facility be advanced cardiac life support qualified; update a reference to the American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions 2007 to the American College of Cardiology/American Heart Association/American College of Physicians task force 2013 update of clinical competence statement on coronary artery interventional procedures in assessing clinical competence; and to clarify that physicians performing percutaneous coronary interventions (PCI) at the service must have completed a fellowship training program in interventional cardiology unless they were performing PCI prior to March 20, 1997.

3701-84-32 – Revised Rule: The rule establishes the general facilities, equipment, and supplies standards for all service levels. These requirements include procedure room space requirements and a listing of minimum equipment to be maintained by the service. The rule is being revised to make general formatting changes in accordance with Legislative Service Commission rule drafting requirements and to include updated equipment requirements consistent with industry practices. These updates include appropriate digital imaging equipment and an intra-aortic balloon pump or other percutaneous mechanical circulatory assistance device of superior capability.

3701-84-33 – Revised Rule: The rule establishes the basic building and equipment safety standards for cardiac catheterization services. These requirements include survey and maintenance of equipment in accordance with manufacturer's guidelines and maintaining electrical safety policies and practices. The rule is being revised to make general formatting changes in accordance with Legislative Service Commission rule drafting requirements.

3701-84-34 – New Rule replaces existing rule: The rule establishes the service performance measures for adult cardiac catheterization services, including the minimum number of procedures that should be performed at each established level. The new rule incorporates language from existing rule 3701-84-34 and new language clarifying the type of review requirements that may be set in the event of failure to meet the minimum procedure levels.

3701-84-34.1 – New Rule: The rule establishes 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 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.

3701-84-34.2 – New Rule: The rule establishes the conditions for termination of a cardiac catheterization service. A service's operations may be terminated for failure to comply with the Administrative code, failure of the service to meet designated quality outcomes, or if a determination of serious or life threatening harm is made regarding the facility's clinical outcomes and operations.

## **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.

**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 adverse events, and requiring regular morbidity and mortality conferences. While, Ohio does not license or certify health care services directly; the Department of Health is statutorily required to enforce quality standards within these services. Furthermore, although entities operating cardiac catheterization services may be certified through the Centers for Medicare and Medicaid Services 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 these specific rules. 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.**

In response to changes in the industry and the need for greater structural flexibility in cardiac cauterization service operation, approximately two years ago the then Division of Quality Assurance, now known as the Office of Health Assurance and Licensing, convened selected practitioners and organizational representatives from the cardiac services industry. The Interventional Cardiology Advisory Group (ICAG) worked directly with the agency on developing the rules identified in this BIA. These members include:

UC College of Medicine and American College of Physicians

OSU Wexner Medical Center (OSU College of Medicine)  
Case Western Reserve University School of Medicine  
Ohio Hospital Association  
Ohio State Medical Association  
American College of Cardiology (Ohio) and UT  
Society of Thoracic Surgeons and OSU  
American Heart Association (Ohio)  
Mission Lifeline  
Cleveland Clinic  
Ohio Health  
Lakeside Heart & Lung Center

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

The input by the aforementioned ICAG was significant and the rules reflect the direct input of the numerous participants. The inclusion of the specified guidance documents for both physicians and cardiac catheterization services, clinical standards, equipment, and procedures authorized at each level are the result of the ongoing and diligent cooperative effort between the ICAG and the Office of Health Assurance and Licensing.

Subsequent to the initial publishing of these draft rules for public comment in June 2015, the Department received comments which resulted in substantive changes to the draft rules. The ICAG membership worked with ODH staff in July and August 2015 to make additional revisions to the draft rules, which included, but was not limited to, refining the list of prohibited procedures for Level II services and additional actions that may be taken by the Director in the event that a service fails to meet established performance measures.

**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 rules have implemented many of the existing industry standards and guidelines that are based upon ongoing research and expert input, such as:

2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

2014 Society for Cardiovascular Angiography and Interventions/American College of Cardiology/American Heart Association Expert Consensus Document Update on Percutaneous Coronary Intervention without On-site Surgical Backup

American College of Cardiology/American Heart Association/American College of Physicians Task Force 2013 Update of Clinical Competence Statement on Coronary Artery Interventional Procedures in Assessing Clinical Competency

**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. These new rules reflect the current industry standards and emerging trends in cardiac catheterization services.

**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 cardiac catheterization 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, including cardiac catheterization 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 3701-84-30 to 3701-84-34 impact adult cardiac catheterization services;

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

In general, these rules do not represent costs that are independent of those already obligated to the cardiac catheterization service by virtue of their participation in the Centers for Medicare and Medicaid Services Conditions of Participation or Accreditation for Cardiovascular Excellence 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.

Adverse impacts identified include:

Fines, time for compliance, and reporting requirements.

A new requirement creating an identified adverse impact is participation in the National Cardiovascular Data Registry (NCDR) for Level II and Level III services; however, the majority of services that will be applying for Level II designation services are already participating in this registry as a condition of participation in the Cardiovascular Patient Outcomes Research Team (C-PORT) study of elective PCI at hospitals without on-site open heart surgical services. For those not currently participating, the cost for the NCDR is \$5000.

Although these rules represent a new approach to cardiac catheterization service regulation in Ohio that may result in direct or indirect cost to providers, the new structure also alleviates a significant adverse impact on current providers. The new three level structures of cardiac catheterization services will allow for the operation of Level II services, which will not be required to have an open-heart surgery service on-site. This eliminates the significant costs of maintaining an open-heart surgery service that likely is not cost effective or routinely utilized in the past.

**c. Quantify the expected adverse impact from the regulation:**

Costs specific to the state rules:

(1) As set forth in 3701-84-30.2 and 3701-84-30.3, participation in the National Cardiovascular Data Registry (NCDR): annual cost is \$5000 unless the service is already participating in one of the American College of Cardiology - Quality Improvement for Institution's other registries.

(2) 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.

(3) 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

(4) Time necessary for services to prepare and submit annual reports and sentinel adverse events to the Director depends on the number of incidents and the severity of the incident.

(5) Volume goals of 300 procedures for Level I services and 300 total procedures including at least 200 PCI for Level II and Level III services.

(6) Time and manpower necessary to prepare a waiver or variance request or a request for accelerated designation of a level; all will be determined by the nature and complexity of the requirement.

(7) Time and manpower necessary to develop policy and procedures.

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

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

(10) Payment of any fees associated with the independent third party review to the provider of the review. Costs will be dependent on the number of cases and type of procedures reviewed; typically provided by another licensed physician or team of physicians.

The costs borne by the cardiac catheterization 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.

Surgeon:  
\$113.61

Physician and surgeon, all other:  
\$0.00 to an average of \$87.58 per hour\*.

Registered Nurse:  
\$0.00 to an average of \$30.04 per hour.\*

Figures from May 2014, United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, using the codes for all health care practitioners and technical occupations (29-0000) surgeons (29-1067), 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 these rules 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 cardiac catheterization 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 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.

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: <http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx>.

### **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 Assurance and Licensing, Bureau of Health Care Services provides information and assistance to Health Care Service providers, including cardiac catheterization services. Additional information is available at:

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

