

**MEMORANDUM**

TO: Kaye Norton, Ohio Department of Health

FROM: Sydney King, Regulatory Policy Advocate

DATE: November 30, 2015

RE: **CSI Review – Adult Cardiac Catheterization (OAC 3701-84-30 through 3701-84-34)**

On behalf of Lt. Governor Mary Taylor, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of six new and four amended¹ rules – along with one appendix – being proposed by the Ohio Department of Health (ODH). This chapter of the Ohio Administrative Code was reviewed by ODH pursuant to the statutory five-year review requirement. The rule package was submitted to the CSI Office on September 21, 2015, and the comment period for the rules closed on November 20, 2015. The rule package was previously filed June 22, 2015 but ODH requested the rule package be removed from CSI review because substantive amendments were needed based on stakeholder input.

The rule package establishes standards and procedures for adult cardiac catheterization services. ODH regulations categorize the service facilities as Level I, Level II, or Level III. Each level is regulated differently and the services provided differ based on the level categorization. For example, a Level I facility can only provide diagnostic cardiac catheterization procedures. The

¹ Rule 3701-84-34 is being amended by more than 50 percent. Therefore the Legislative Service Commission requires that the existing rule be rescinded and replaced by a new rule that has the same rule number.

rule package provides requirements for the type of services allowed for each level, the staff qualifications, written policies and procedures, agreements between Level I and Level II facilities with emergency hospital facilities and transportation, facility structure and layout, necessary supplies and equipment, safety standards, performance measures and reporting data, the process for ODH's inspection and review of the facility, and the process for termination by ODH of an adult cardiac catheterization facility.

The BIA states that the amendments to the regulations for adult cardiac catheterization services were a result of stakeholder feedback requesting greater structural flexibility in cardiac catheterization services. ODH worked with practitioners and organizational representatives to develop the regulatory framework reflected in the draft rules. Stakeholders included the Ohio Hospital Association, Ohio State Medical Association, American College of Cardiology (Ohio), American Heart Association (Ohio), Mission Lifeline, Cleveland Clinic, OhioHealth, Lakeside Heart & Lung Center and several university hospitals. Two comments were received during the CSI public comment period; resulting in the rules being amended based on suggestions. Additionally, ODH provided clarity and instruction to the stakeholders regarding the implementation of new requirements.

According to the BIA, the impacted stakeholders are providers of adult cardiac catheterization services. The BIA provides a detailed analysis of the costs associated with the adverse impacts. The adverse impacts include equipment and facility costs, the annual fee for participation in the National Cardiovascular Data Registry, inspection fees, complaint fees, and the administrative time necessary to comply with the reporting and written policy requirements. ODH states the adverse impacts are justified in order to ensure the quality of health care services for Ohio's health care consumers. Additionally, the reporting requirements are necessary to monitor the health and safety of Ohio's health care consumer.

After reviewing the proposed rules and the BIA, the CSI Office has determined that the rules satisfactorily meet the standards espoused by the CSI Office, and the purpose of the rule package is justified.

Recommendation

For the reasons explained above this office does not have any recommendations regarding this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Department should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.

cc: Mark Hamlin, Lt. Governor's Office