MEMORANDUM

TO: Selina Jackson, Ohio Department of Health

FROM: Tess Eckstein, Regulatory Policy Advocate

DATE: January 23, 2017

RE: **CSI Review – Health Care Services Standards (OAC 3701-84-01 through 3701-84-14, 3701-84-16 through 3701-84-21, 3701-84-24 through 3701-84-27, 3701-84-30, 3701-84-30.1, 3701-84-30.2, 3701-84-30.3, 3701-84-31 through 3701-84-34, 3701-84-34.1, 3701-84-34.2, 3701-84-36 through 3701-84-40, 3701-84-61 through 3701-84-65, 3701-84-67 through 3701-84-73, 3701-84-75 through 3701-84-85)**

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 62 rules—58 amended,[1] one new, and three no-change—being proposed by the Ohio Department of Health (ODH) for review under the statutory five-year rule review requirement. The rule package was submitted to the CSI Office on October 19, 2016, and the comment period remained open until November 19, 2016. A second comment period was opened for two rules, one of which was revised in response to comments submitted during the original public comment period, and the other of which was affected by an error with the original posting. This comment period opened on December 6, 2016 and closed on January 5, 2017. Revised BIAs for the rule package were submitted on October 21, December 6, and January 19.

These rules establish safety and quality of care standards for providers of Health Care Services (HCS). The quality rules set minimum standards that a provider must meet to be able to offer a

[1] OAC 3701-84-17, -19, -25, -36, -39, -40, -75, -81, and -85 are being amended by more than 50 percent. The Legislative Service Commission requires that the rules be rescinded and replaced with new rules with the same numbers.

particular service, including facilities, equipment, personnel, and patient selection criteria. Affected services include solid organ transplantation, bone marrow transplantation, adult cardiac catheterization, adult open heart surgery, pediatric intensive care, pediatric cardiac catheterization, pediatric cardiovascular surgery, and the use of radiation therapy and stereotactic radiosurgery. The one new rule clarifies the Quality Assurance and Performance Improvement (QAPI) program requirements for pediatric cardiac catheterization services. It includes requirements previously included in rule 3701-84-75 that are more appropriate in a standalone QAPI rule, as is the standard for other HCS.

Many of the amended rules propose changes to format and grammar, in order to improve language flow and clarity. Other proposed amendments are more substantive and are the direct result of changes in technology, new professional standards, and significant provider input during the early stakeholder outreach process. For instance, these substantive amendments include, but are not limited to, revisions to require documentation of internal reviews of individual physicians or surgeons who have combinations of high mortality and low volume of procedures; to clarify that the number of open heart surgery procedures performed will not be used as the sole indicator of performance; to update recordkeeping requirements to align with those in other rule sets; and to update education, training, and experience requirements for staff to be reflective of current industry standards and practices.

Some of the proposed rules impact all HCS providers, while others specifically impact the services mentioned above. Potential adverse impacts from the rules include fines, time for compliance, and reporting requirements. For example, costs are associated with things like the time and manpower necessary to develop and implement policy, train employees, obtain informed consent from patients, and meet QAPI requirements. It is important to note, however, that costs for these and other requirements are largely already covered by virtue of HCS participating in Centers for Medicare and Medicaid Services (CMS) and other programs. In addition, individual reports specific to each type of HCS are comprised of information that is readily available and already submitted to outside registries, therefore requiring minimal time and effort to compile. Finally, failure to comply with the rules in this chapter could result in civil monetary penalties, each of which would be based on the severity of a particular violation. The BIA explains that these rules are necessary because they ensure safety and quality of care of HCS for Ohio's health care consumers. They reduce negative HCS outcomes and provide a mechanism through which consumers can have their concerns addressed through investigations. Furthermore, requirements such as reporting provide ODH with information that is necessary to monitor and ensure the health and safety of consumers.

ODH sent email notifications to interested stakeholders in April 2016 and conducted three stakeholder meetings in May and June. These meetings were attended by pediatric cardiovascular surgeons and cardiologists, nurse managers, hospital government liaisons, and service administrators. As a result of this outreach, ODH received significant feedback. Stakeholder input led to revisions being made to service specific guidelines, patient selection criteria, and protocols. For example, input from hospitals gave rise to a clarification of board certification requirements for each service's medical director.

During the initial CSI public comment period, four comments were submitted, each of which led to rule revisions. In total, six rules were revised as a result of comments received or the CSI review process. For the few suggestions that were not incorporated into the amended rules, ODH provided a thorough explanation for not revising the rules. One rule, 3701-84-36, underwent so many revisions—requirements were revised to more accurately reflect the Society for Thoracic Surgeons (STS) reporting elements, and to restrict the majority of reporting elements to Coronary Artery Bypass Grafting (CABG) procedures, to accommodate a lack of available data on other procedures—that ODH, in an effort to be transparent, chose to give stakeholders another chance to comment on the rule. By the close of a second formal comment period, only one comment had been submitted. In response, ODH provided necessary clarification but did not make any additional changes to the rule. In light of all revisions made to the rules, the CSI Office has determined the purpose of the rules to be justified.

Recommendations

For the reasons discussed above, the CSI Office does not have any recommendations for this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Ohio Department of Health 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