

CSI - Ohio

The Common Sense Initiative

MEMORANDUM

TO: Kaye Norton, Ohio Department of Health

FROM: Whitney Sullinger, Regulatory Policy Advocate

DATE: March 23, 2012

RE: **CSI Review – ODH 3701-84 Health Care Services**

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. This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

The rules submitted (Ohio Administrative Code Chapter 3701-84) were reviewed as required by the 5-year rule review process. The rules are needed to establish safety and quality of care standards for providers of Health Care Services (HCS) in Ohio, according to the Ohio Department of Health (ODH). The quality rules set minimum standards that a provider of the service must meet in order to offer the service. 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 a cobalt radiation therapy unit

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

Twenty-one of the fifty-six rules in this package were "No Change" rules. Thirty-five were revised for various reasons, including the following:

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 provider
4. Increase the annual HCS inspection fee to \$1,750
5. Provide updated access information for clinical consensus and guidelines from the American College of Cardiology
6. Correct minor grammatical and citation errors
7. Remove all references to obstetric and newborn services, and
8. Update patient selection criteria to reflect current industry standards

Stakeholder involvement on this package began with initial e-mail notifications and a request for informal comments sent to interested parties on August 15, 2011. Official posting to the ODH website and a public notification followed on November 4, 2011. Comments were received from various industry representatives and updates and revisions were made by ODH to service specific guidelines, patient selection criteria, and protocols as a direct result of this stakeholder input. ODH submitted the rules to CSI on February 8, 2012 and sent an additional electronic notification to stakeholders. No additional comments were received from this second posting.

After reviewing the BIA, the CSI Office has determined not to suggest any changes with respect to the rule or the BIA for the following reasons:

- Stakeholders were involved in the process, their comments were reviewed by ODH, and changes were made where appropriate.
- No comments were received from the public during the CSI public comment period.
- The BIA submitted by ODH was accurate and complete and did not raise any ongoing issues. Generally, the rule package satisfactorily meets the standards espoused by the CSI Office, and the purpose of the rules justifies the adverse impact identified in the BIA.

Recommendations

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

Conclusion

Based on the above comments, the CSI Office concludes that the Agency 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