



Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*

Joseph Baker, *Director*

MEMORANDUM

TO: Olivia Igel, Ohio Department of Health

FROM: Jacob Ritzenthaler, Business Advocate

DATE: June 21, 2024

RE: **CSI Review – Chapter 3701-22 Hospital Licensure (OAC 3701-22-01, 3701-22-02, 3701-22-03, 3701-22-04, 3701-22-05, 3701-22-06, 3701-22-07 3701-22-08, 3701-22-09, 3701-22-10, 3701-22-11, 3701-22-12, 3701-22-13, 3701-22-14, and 3701-22-19)**

On behalf of Lt. Governor Jon Husted, 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 Department as provided for in ORC 107.54.

Analysis

This rule package consists of fourteen new rules proposed by the Ohio Department of Health (ODH). This rule package was initially submitted to the CSI Office on July 25, 2023, and the public comment period was held open through August 24, 2023. The rule package was first withdrawn for further discussion and resubmitted to the CSI Office on November 29, 2023, and a second public comment period was held open through December 14, 2023. Following that comment period, the rule package was again withdrawn and resubmitted on February 13, 2024, and a third public comment period was held open through March 5, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on February 13, 2024.

Ohio Administrative Code Chapter 3701-22 is a new chapter that establishes licensing requirements for hospitals. Beginning on September 10, 2024, Ohio law will require hospitals to be licensed by ODH, prompting the creation of new rules to provide guidelines for application, inspections, and specific hospital types. OAC 3701-22-01 lists definitions used throughout the chapter. OAC 3701-22-02 sets forth the applicability of the chapter to hospitals. OAC 3701-22-03 establishes

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requirements for the application for initial licensure, as well as the renewal and transfer of licenses. The rule lists the application fees, which are based on the number of beds within a hospital, fees for additional health care services, and additional required information. OAC 3701-22-04 concerns hospitals found to be operating without a license and prohibits interfering with an inspection. OAC 3701-22-05 sets forth requirements regarding hospital inspections and compliance actions, including the actions that may be taken by ODH in response to violations. OAC 3701-22-06 requires hospitals to provide effective administration of hospital functions, including compliance, governance, patient rights, and emergency preparedness. OAC 3701-22-07 lists basic functions that hospitals must provide, including requirements for medical staff, services for nursing, pharmacies, radiology, labs, and others. OAC 3701-22-08 lists optional functions available to hospitals, including surgical, anesthesia, nuclear medicine, outpatient, emergency, rehabilitation, and respiratory services.

OAC 3701-22-09 and 3701-22-10 establish requirements specific to critical access hospitals and rural emergency hospitals, including participation in quality assessment and performance improvement projects, regional hospital zones, and infestation control and waterborne pathogen provisions. OAC 3701-22-11 states that reporting requirements are to be developed with industry input to assure quality and patient health and safety. OAC 3701-22-12 requires hospitals to continue current annual reporting procedures until September 30, 2024. OAC 3701-22-13 provides requirements to develop data collection policies. OAC 3701-22-15 establishes the processes for a hospital to request a waiver or variance for any regulatory requirement.

During early stakeholder outreach, ODH sent the proposed rules to industry stakeholders and conducted two virtual meetings. ODH states that stakeholder feedback collected during that time was implemented in nearly every rule. During the CSI public comment period, ODH received comments from the Ohio Hospital Association (OHA), OhioHealth, MetroHealth, the Wexner Medical Center, University Hospitals, the Center for Community Solutions, and the Hospital Council of Northwest Ohio, as well as the Ohio Public Health Advisory Board.

OHA submitted comments that requested clarification of numerous definitions, as well as the removal of several definitions that were deemed unnecessary and needlessly confusing. In response, ODH removed definitions where appropriate and made clarifying adjustments to the rule language. Stakeholders, including OHA, also suggested reductions for licensing fees, but ODH did not make changes, noting that the cost is representative of the actual cost of administering hospital licensure. ODH also noted that the fee structure as presented in the rules was the requested method among several presented to stakeholders. Stakeholders also suggested shortening the timeline for notifying ODH of upcoming construction projects from thirty days to seven days. Following discussions with OHA, ODH reduced the notification timeline by 50% from the original 30-day proposal to allow hospitals to more quickly implement construction or significant alteration plans.

Stakeholders also submitted comments concerning the water management requirements, stating that the standards for testing water systems were excessively burdensome and costly and requesting that ODH align these requirements with federal standards. In response, the agency made a variety of changes to the original proposal, including referencing cost/benefit-based Centers for Disease Control standards for water management plans, reducing the testing requirements to reduce testing frequency to annual testing after having established a baseline through two successful tests during a hospital's first twelve months of licensure, and clarifying that the water management plan requirements apply to in-patient facilities. ODH also made changes to the proposed rules in response to stakeholder feedback by removing language that allows local health departments or ODH to initiate an investigation based on a single legionellosis-associated case. Stakeholders further stated that rule language concerning ODH's ability to assess penalties could result in harsh penalties for minor violations. ODH responded that the rule language is reflective of statute and that the language allows for the ODH to use discretion in determining penalties. Finally, following additional conversations with OHA, ODH provided additional clarification that information collected regarding emergency service beds will not count towards the hospital's bed count and license fee, deleted unnecessary language surrounding changes in ownership, and corrected typographical errors.

The business community impacted by the rules includes all hospitals operating in Ohio. The adverse impacts created by the rules include fees for applications and services, as well as requirements for administrative tasks, such as policy development and reporting, quality assurance, and performance improvement. ODH estimates approximately 4-8 hours of staff time for filing initial or renewal license applications, approximately 1 hour of time necessary to read and understand the rules, and that wage rates for a professional in the industry capable of performing these tasks is approximately \$62 per hour. ODH notes that many of the licensing requirements imposed in the rules are already implemented as standard practices in the industry and are unlikely to require a significant increase in time or costs. Application fees are calculated by the hospital's number of beds and range in cost from \$4,425 for hospitals with between 1 and 50 beds to \$61,850 for hospitals with more than 1,500 beds.

Hospitals must also pay a service fee of \$3,000 for each newborn care nursery, maternity unit, or health care service. Licenses are renewed on a triennial basis. ODH notes that the fee structure imposed by the rules was preferred by industry representatives and stakeholders for budgetary certainty reasons. There are also potential adverse impacts related to the imposition of penalties related to licensure actions, including suspension, denial, revocation, or civil money penalties. Water management costs and testing requirements are estimated by ODH to range from several hundred to several thousand dollars, depending on the characteristics and size of the hospital being evaluated. ODH also notes that the rules in question were aligned with federal hospital requirements to minimize duplication and unnecessary burdens for the regulated parties and notes that the hospital water management requirements are necessary to prevent Legionella outbreaks, such as one that took place in 2019. ODH states that the adverse impacts are necessary to comply with statutory requirements to

license hospitals and ensure that hospitals maintain standards for patient health and safety.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that ODH should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.