Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

TO: Alicyn Carrel, Ohio Department of Health

FROM: Joseph Baker, Director

DATE: November 23, 2022

RE: **CSI Review – Chapter 3701-84 Health Care Services (OAC 3701-84-02 to 3701-84-14, 3701-84-16 to 3701-84-21, 3701-84-21 to 3701-84-27, 3701-84-30, 3701-84-31 to 3701-84-34.2, 3701-84-37 to 3701-84-40, 3701-84-60 to 3701-84-65, 3701-84-67 to 3701-84-73, 3701-84-76 to 3701-84-85)**

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This rule package consists of thirty-six amended, ten new, nineteen rescinded, and two no-change rules proposed by the Ohio Department of Health (Department). This rule package was submitted to the CSI Office on September 13, 2022, and the public comment period was held open through October 12, 2022. After conclusion of the comment period, the Department withdrew OAC 3701-84-01, 3701-84-30.1, 3701-84-30.2, 3701-84-30.3, 3701-84-30.4, and 3701-84-36 from the original collection of rules submitted to CSI to conduct an additional second comment period and collect additional stakeholder feedback, after receiving several comments specific to these rules. Otherwise, unless noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on September 13, 2022.

The rules in this package set forth quality standards for health care services, including solid organ transplant services, blood and bone marrow transplant services, adult cardiac catheterization services,

open heart surgery services, pediatric intensive care units, pediatric cardiac catheterization services, and pediatric cardiovascular surgery services. These standards include personnel and staffing requirements, records retention and data management, ongoing training and operational performance evaluations, equipment access and maintenance requirements, facility requirements, and others. Many of the rules are amended to streamline language or adopt clarifying language. Substantive amendments are discussed below.

OAC 3701-84-02 sets forth the applicability of the chapter. OAC 3701-84-03 prohibits any person from operating a Health Care Service (HCS) that does not comply with the chapter and from interfering with investigations or misrepresenting information. The rule has been amended to remove an outdated prohibition on smoking inside HCS facilities. OAC 3701-84-04 requires each HCS to notify the Director of the Department (Director) prior to reinitiating a discontinued or suspended service and has been amended to clarify that the HCS service manager and medical director must attest compliance and to clarify the deadline for each HCS to reply to requests for additional information from the Director. OAC 3701-84-05 and 3701-84-06 authorize the Director to impose civil penalties or direct a HCS to cease operations, conduct inspections and audits, and establish criteria for determining appropriate discipline.

OAC 3701-84-07 requires each HCS to adopt patient care policies while OAC 3701-84-08 requires each HCS to comply with personnel and staffing requirements, including maintaining sufficient qualified personnel to meet patient needs, maintaining records documenting the qualifications of employed individuals, and other related responsibilities. OAC 3701-84-08 has been amended to authorize a HCS to request a waiver for physicians who are certified by a foreign board but not eligible to take an equivalent American examination, and to require a HCS to adopt an ongoing training program for all staff. OAC 3701-84-09 sets forth general service standards for each HCS, including infection control procedures, instruction and education to patients, documentation of medical services, and others. OAC 3701-84-10 requires a HCS to be certified for use by a local building department or the Ohio Department of Commerce, comply with the Ohio Fire Code, and dispose of hazardous wastes appropriately, among other requirements.

OAC 3701-84-11 requires each HCS to maintain and secure personal medical records for six years after the discharge of a patient, prohibits disclosing information unless authorized by the patient, and requires a HCS to systematically review records to ensure compliance. OAC 3701-84-12 requires each HCS to establish a quality assessment and improvement program to monitor patient care quality, improve patient care, and resolve problems. OAC 3701-84-13 requires each HCS to establish policies and procedures for resolving and reporting complaints regarding service quality. OAC 3701-84-14 authorizes the Director to grant certain waivers or variances upon request and authorizes a HCS to request reconsideration if the waiver or variance request is denied.

OAC 3701-84-16 specifies standards for transplanting solid organs. The Department reports that amendments to this section have been made to this rule to reflect current Center for Medicare & Medicaid Services (CMS) Conditions of Participation. OAC 3701-84-17, 3701-84-18, and 3701-84-19 are slated

for recission, as the requirements in those sections are included in federal law. The Department is proposing to rescind and replace OAC 3701-84-20, which will now require solid organ transplant services to use written patient selection criteria in determining a patient's placement on the waiting list or suitability for transplantation. Similarly, OAC 3701-84-21 is rescinded and replaced with a new rule of the same number requiring solid organ transplant services to achieve volume goals specified in federal law.

OAC 3701-84-24 requires blood and bone marrow transplant service providers to be located in a hospital, meet certain administrative requirements, and report certain information to the Director prior to initiating transplantation services. OAC 3701-84-25 requires blood and bone marrow transplant services to maintain personnel and staffing, including a medical director, another primary transplantation physician, and a multidisciplinary team of individuals with appropriate training. OAC 3701-84-26 requires blood and bone marrow transplant services to comply with various facility and safety standards, including adequate intensive care facilities, modern radiotherapy capabilities, laboratories, and others. The Department proposes to rescind existing 3701-84-27 and replace with a rule of the same number that requires transplantation services to apply prospective patient selection and specifies a review process for transplants performed on individuals who do not meet the selection criteria. The rule also sets forth volume goals for various types of services to ensure efficiency and a minimum floor of competency.

OAC 3701-84-30 requires adult cardiac catheterization service providers to report various information to the Director regarding the services it intends to provide, to establish a written protocol for emergency care, and to implement a quality assessment review process, in addition to specifying other related operational requirements. The rule has been amended to update the definition of major bleeding.

OAC 3701-84-31 specifies personnel and staffing requirements for adult cardiac catheterization services, including maintaining a qualified medical director, at least two credential physicians with appropriate training, and qualified support staff. OAC 3701-84-32 specifies facility and equipment requirements for adult cardiac catheterization services and has been amended to modify floor space and clearance requirements, which the Department reports reflect Facilities Guidelines Institute recommendations. OAC 3701-84-33 requires cardiac catheterization services to establish safety guidelines, implement electrical safety policies, and perform surveys and routine maintenance on equipment. The Department proposes to rescind OAC 3701-84-34 and replace with a rule of the same number requiring cardiac catheterization services to maintain a volume of procedures sufficient to ensure safety, quality, and cardiologist proficiency (but does not specify a minimum volume) and advises that the Director may require an independent third-party review of the service to have a high rate of complications, emergency transfers, or mortality. The rule differs from the previous version, which required cardiac catheterization services to perform at least three hundred procedures by the second year of operation.

OAC 3701-84-34.1 requires the Director to inspect an adult cardiac catheterization service once every three years and specifies criteria to be considered as indicators of quality. OAC 3701-84-34.2 authorizes the Director to order a cardiac catheterization service to cease operations if it determines that the entity

poses an imminent threat of serious physical or life-threatening danger. OAC 3701-84-37 requires open heart surgery services to comply with staffing and personnel standards, including maintaining a qualified medical director, two qualified thoracic surgeons, as well as certain support staff. The rule is amended to require that the medical director be certified by the American Board of Thoracic Surgery or otherwise approved by the Department through waiver.

OAC 3701-84-38 requires operating rooms for open heart surgery to meet minimum floor area requirements, clearance standards, have appropriate oxygen access, vacuum access, and lighting, and be equipped with certain technical devices relevant to surgery processes. The rule is amended to reflect Facilities Institute Guidelines for room size requirements. OAC 3701-84-39 requires open heart surgery services to engage in quality assessment and performance improvement efforts, including convening a regular morbidity and mortality conference, utilizing quality performance measures outcomes data, and conducting period reviews and evaluations. OAC 3701-84-40 requires open heart surgery services to maintain a volume goal sufficient to ensure safety and quality procedures and is amended to remove specific numerical requirements for such facilities. The rule also authorizes the Director to engage in a review and impose a probationary period based on the presence of safety or quality issues at the facility.

OAC 3701-84-61 specifies patient care standards for pediatric intensive care units (PICU). The rule requires a PICU to maintain a pediatric intensivist at all times and ensure that various physicians can be available within sixty minutes at all times, and that certain other physicians be available by teleconference within sixty minutes at all times. The rule has been amended to allow certain physicians to be available by teleconference and to allow PICUs without an onsite pediatric radiologist or radiologist, or those without a hemodialysis service, to instead maintain a written transfer agreement with an alternate provider that can be accessed within sixty minutes at all times. OAC 3701-84-62 sets forth personnel and staffing standards for PICUs, including maintaining a qualified medical director, a pediatric intensivist, another licensed physician, a nurse manager, appropriate nurse-to-patient ratios, and other required staff. Additionally, the PICU must implement a continuing education program that involves staff participation at regional pediatric critical care education programs, regular resuscitation practice sessions. OAC 3701-84-63 requires PICUs to have controlled access, be located in close proximity to the physician-on-call office and family waiting area, and be available by gurney, in addition to specifying room and area requirements.

OAC 3701-84-64 requires PICUs to maintain appropriate drug supplies, equipment, respiratory equipment, and bedside monitors and to have the capacity to continuously monitor various patient health factors. The rule is amended to remove a requirement that the PICU be capable of continuously monitoring pulmonary artery pressure. OAC 3701-84-65 requires PICUs to engage in a multidisciplinary quality assessment and performance improvement program reviewing various factors related to patient outcomes. The Department proposes to rescind existing OAC 3701-84-67 and replace the rule with a new version that requires radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery services to comply with rules specified in OAC 3748, OAC 3701-4 and the statutory requirements for the Ohio cancer incidence surveillance system. The Department proposes to rescind OAC 3701-84-69, 3701-84-70, 3701-

84-72, and 3701-84-73 as the contents of these rules are reflected in the cross-referenced requirements in OAC 3701-84-67.

OAC 3701-84-75 defines pediatric cardiac catheterization service standards, including that each service maintains an onsite pediatric cardiovascular surgery service, an experienced surgical team available within sixty minutes at all times, access to various technical abilities, and others. The rule is amended to require pediatric cardiac catheterization service providers who perform same-day services to establish written criteria for same-day catheterization and discharge. OAC 3701-84-76 defines personnel and staffing requirements for pediatric cardiac catheterization services, including a qualified medical director, two licensed physicians qualified to provide cardiac catheterization services, support staff skilled in various medical specialties, and others. The rule is amended to require that the medical director have additional education or experience in pediatric cardiac catheterization and intervention, in addition to being board-certified in pediatric cardiology.

The Department proposes to rescind and replace OAC 3701-84-77 with a new rule of the same number that sets forth facility requirements for pediatric cardiac catheterization facilities, such as room size, clearances, and equipment access. OAC 3701-84-78 requires pediatric catheterization services to establish safety guidelines, implement electrical safety policies, and perform surveys and routine maintenance on equipment. The Department proposes to rescind and replace 3701-84-79 with a new rule that requires pediatric cardiac catheterization services to maintain a volume of cardiac catheterization procedures sufficient to ensure the quality and safety of procedures performed at the service, and differs from the previous version by no longer specifying a minimum of at least one hundred procedures per year per provider.

OAC 3701-84-80 requires pediatric cardiac catheterization services to engage in quality assessment and performance improvement efforts, such as holding conferences, reviewing procedures for quality, and maintaining a database to support the review process. The rule is amended to increase the frequency of conference requirements to at least every sixty days instead of every ninety days. OAC 3701-84-81 sets forth pediatric cardiovascular surgery service standards, including that each provider maintain access to cardiac operating rooms, pediatric intensive care facilities, and a cardiac catheterization service at all times, have the capability to perform open heart procedures at all times, and have access to various specialists and resources. The rule is amended to remove a requirement to participate in the Society for Thoracic Surgeons Congenital Heart Surgery and instead to require participation in a data registry.

OAC 3701-84-82 defines personnel requirements for pediatric cardiovascular surgery services, including a qualified medical director, two thoracic surgeons with appropriate credentials, and support staff requirements. The Department proposes to rescind existing 3701-84-83 to replace with a rule of the same number setting forth facility standards for pediatric cardiovascular surgery services, including minimum floor size requirements, clearances, surgery-related resources such as vacuum and oxygen access, and related equipment. Additionally, the Department is rescinding OAC 3701-84-84 to replace the rule with a new iteration that requires pediatric cardiovascular surgery services to maintain a volume of

cardiovascular procedures sufficient to ensure the safety and quality of procedures, but no longer requiring a minimum of at least one hundred procedures annually (as the current version requires). Finally, OAC 3701-84-85 requires pediatric cardiovascular surgery services to engage in quality assessment and performance improvement efforts including utilizing outcomes data from participating in a registry, period reviews, and regular conferences.

During early stakeholder outreach, the Department held stakeholder meetings and shared numerous drafts of the rules with various hospital systems, the Ohio Children's Hospital Association, Ohio Hospital Association, Ohio Hemopoietic Therapy and Transplant Consortium, and others. Based on feedback from stakeholders concerning adult cardiac catheterization, revisions were made to the reporting requirements for all levels of services. The Department also reports that input received from solid organ transplant services resulted in the removal of redundant committee reviews of transplant candidates and the alignment of the services with national standards. Finally, the Department states that feedback from physicians, nurses, and surgeons ensured that the clinical components of the rules reflect current practices, technology, and quality standards within the industry.

During the CSI public comment period, the Department received comments from Blanchard Valley Hospital, Knox Community Hospital, Ohio State University Medical Center, Wooster Community Hospital, University Hospitals (UH), and Mercy Health. UH shared concerns about the interpretation of the terms "emotional health" or "emotional security" used in OAC 3701-84-05. In response, the Department noted that these terms have been in use for fifteen years and have not created any complaints to date. However, the Department determined to replace the term "emotional health" with "psychosocial health," which is defined in OAC 3701-84-01 and is a term commonly used by the CMS. UH also shared concerns about volume goals for autologous transplants for children, to which the Department noted that the volume thresholds are goals rather than requirements and that the rules as proposed note that volume will not be used as a sole indicator of service performance. UH also recommended that proposed changes to reduce the volume goal of at least 150 open heart procedures per year be retained and that reporting requirements for the Society for Thoracic Surgeons be kept as well. The Department responded that the rules do not specify a certain volume of procedures but do require each facility to maintain a volume sufficient to ensure the safety and quality of procedures. Additionally, the Department noted that it will retain the authority to access reports, including data registry reports. Finally, UH recommended allowing for medical directors of open-heart surgery services to be certified by a foreign equivalent board—a change agreed to by the Department. In response to the other remaining comments as well as additional feedback from UH, the Department withdrew OAC 3701-84-01, 3701-84-30.1, 3701-84-30.2, 3701-84-30.3, 3701-84-30.4, 3701-84-36 from the original collection of rules submitted to CSI in order to propose changes and conduct a second public comment period for the purpose of collecting additional stakeholder feedback on these rules.

According to the Department, the business community impacted by the rules includes general health care service providers, solid organ transplant services, bone marrow transplant services, stem cell harvesting and reinfusion services, adult cardiac catheterization services, open heart surgery services, pediatric

intensive care services, radiation therapy and stereotactic radiosurgery services, pediatric cardiac catheterization services, and pediatric cardiovascular surgery services. The adverse impacts to business include administrative time and costs associated with complying with service delivery or operational standards outlined in the rules, potential fines for non-compliance, and reporting requirements. Adverse impacts also include expenses connected to policy development and implementation of quality assessment standards, as well as performance improvement requirements. The Department states that the adverse impacts created in these rules are generally required of health care services due to CMS Conditions of Participation and other accrediting organizations. Penalties for noncompliance range from $1,000 to $250,000 depending on the severity of the violation. Additionally, the Department is authorized to order a health care service to cease operations if a violation poses an imminent threat of serious physical or life-threatening dangers. The Department states that the rules are necessary to comply with its statutory responsibility to establish safety and quality of care standards for health care service providers and to monitor and ensure the safety of Ohio's health care consumers.

Recommendations

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

Conclusion

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

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Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

TO: Alicyn Carrel, Ohio Department of Health

FROM: Joseph Baker, Director

DATE: December 27. 2022

RE: **CSI Review – Chapter 3701-84 Health Care Services (OAC 3701-84-01, 3701-84-30.1, 3701-84-30.2, 3701-84-30.3, 3701-84-30.4, and 3701-84-36)**

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 four amended rules and two new rules proposed by the Ohio Department of Health (Department). This rule package was originally submitted to the CSI Office on September 13, 2022, and the public comment period was held open through October 12, 2022. Based on receiving multiple comments regarding the rules in this package, the Department held a second comment period between November 8 and November 21, 2022. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on November 8, 2022.

Ohio Administrative Code (OAC) 3701-84-01 specifies definitions relating to health care services, and has been amended to establish several new definitions, clarify that children's hospitals are not prohibited from providing care up to a patient's twenty-second birthday, and make other related changes. OAC 3701-84-30.1 (amended), 3701-84-30.2 (amended), and 3701-84-30.3 (rescinded and replaced) specify requirements specific to Level I, Level II, and Level III cardiac catheterization services. Changes have been made to these rules to require Level I, II, and III cardiac catheterization services to report revised data regarding procedures performed beginning in 2025 and to specify reporting requirements for 2023

and 2024, to remove a requirement that Level II facilities operate twenty-four hours a day, and to remove a prohibition on Level II facilities performing atrial fibrillation ablation. New OAC 3701-84-30.4 defines standards regarding adult electrophysiology procedure rooms, including minimum floor area and patient table clearances, airflow and lighting, emergency power, and required equipment. Finally, OAC 3701-84-36 sets forth open heart surgery standards for providers, including the ability to perform procedures at all times, access to certain technical abilities, and requires open heart surgery services to report certain operations-related information to the Department. The rule is amended to require access to blood banking services and to remove a reporting requirement.

During early stakeholder outreach, the Department held stakeholder meetings and shared numerous drafts of the rules with various hospital systems, the Ohio Children's Hospital Association, Ohio Hospital Association, Ohio Hemopoietic Therapy and Transplant Consortium, and others. Based on feedback from stakeholders concerning adult cardiac catheterization, revisions were made to the reporting requirements for all levels of services. The Department also reports that input received from solid organ transplant services resulted in the removal of redundant committee reviews of transplant candidates and aligned the services with national standards. Finally, the Department states that feedback from physicians, nurses, and surgeons ensured that the clinical components of the rules reflect current practices, technology, and quality standards within the industry.

During the first CSI public comment period, the Department received comments from Blanchard Valley Hospital, Knox Community Hospital, Ohio State University Medical Center, Wooster Community Hospital, University Hospitals (UH), and Mercy Health. The Department proposed a variety of changes to the six rules in this package in response to those comments before revising and resending them to stakeholders for a second CSI public comment period. During the second CSI Public comment period, comments were received from Upper Valley Medical Center, UH, and Cleveland Clinic. UH raised concerns over the ambiguous nature of the term "psychosocial health," which was proposed by the Department as an alternative to the previous term, "emotional health" after UH raised concerns regarding that term in the first comment period. The Department responded that the term "psychosocial health" is included throughout Centers for Medicare and Medicaid Services (CMS) regulations and accounts for the complexity of both physical and mental patient well-being. Upper Valley Medical Center sought clarification regarding various definitions used with respect to certain medical procedures, which the Department provided. Finally, Cleveland Clinic shared some additional feedback regarding the definition of "major bleeding," which the Department noted was previously addressed following the first public comment period.

According to the Department, the business community impacted by the rules includes general health care service providers, solid organ transplant services, bone marrow transplant services, stem cell harvesting and reinfusion services, adult cardiac catheterization services, open heart surgery services, pediatric intensive care services, radiation therapy and stereotactic radiosurgery services, pediatric cardiac catheterization services, and pediatric cardiovascular surgery services. The adverse impacts to business include administrative time and costs associated with complying with service delivery or operational

standards outlined in the rules, potential fines for non-compliance, and reporting requirements. Adverse impacts also include expenses connected to policy development and implementation of quality assessment standards, as well as performance improvement requirements. The Department states that the adverse impacts created in these rules are generally required of health care services due to CMS Conditions of Participation and other accrediting organizations. Penalties for noncompliance range from $1,000 to $250,000 depending on the severity of the violation. Additionally, the Department is authorized to order a health care service to cease operations if a violation poses an imminent threat of serious physical or life-threatening dangers. The Department states that the rules are necessary to comply with its statutory responsibility to establish safety and quality of care standards for health care service providers and to monitor and ensure the safety of Ohio's health care consumers.

Recommendations

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

Conclusion

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