Ohio | Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Health

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Chapter 3701-83 Health Care Facilities Licensure

Rule Number(s): 3701-83-01 to 3701-83-59

Date of Submission for CSI Review: 5/21/2021

Public Comment Period End Date: 6/31/2021

Rule Type/Number of Rules:

New/_1__ rules **No Change/_48_ rules (FYR? _X__)**

Amended/_16_ rules (FYR? _X__) **Rescinded/__1__ rules (FYR? X___)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

   The rules set forth in Chapter 3701-83 of the Ohio Administrative Code establish licensing requirements for providers of Health Care Facilities ("HCF") in Ohio. These requirements include, but are not limited to, facilities, equipment, personnel, and service standards. The standards and requirements established by these regulations are applicable to the following services:

   •Ambulatory surgical facilities
   •Freestanding dialysis centers
   •Freestanding inpatient rehabilitation facilities
   •Freestanding birthing centers
   •Freestanding radiation therapy centers
   •Freestanding or mobile diagnostic imaging centers
   •Freestanding birthing centers exempted from licensure under 3702.301 ORC

The following rules are being filed with amendments.

3701-83-04- The rule sets forth the license application and renewal procedures for HCFs. The rule is being amended to remove a typographical error.

3701-83-05.2 – The rule establishes the civil penalties the director may impose if an HCF is in violation of Chapter 3701-83 or the applicable sections of the Ohio Revised Code. The rule is being amended to remove a restriction pertaining to hearings for civil monetary penalties in paragraph (A)(4) and remove outdated language referring to waiver of rights to a hearing.

3701-83-07 - The rule establishes the requirement for patient care policies to be developed in all HCFs. These policies include, but are not limited to, the facilities must: patients must be informed of a facility's policies regarding advanced directives and that name of the physician or individual in charge of the patient's care and how they can be contacted; facilities must have a patient satisfaction survey; and patients are allowed to withdraw their consent for treatment. The rule has been amended to make grammatical changes in accordance with LSC rule drafting requirements.

3701-83-08 - The rule sets forth general staffing standards for HCFs. These include, but are not limited to, utilizing appropriately trained and licensed individuals; having a tuberculosis control plan; and providing ongoing staff training program. The rule has been amended to make grammatical changes in accordance with LSC rule drafting requirements.

3701-83-15 - This rule sets forth the definitions for use specifically in rules 3701-83-15 to 3701-83-22 of the Administrative code, pertaining to ambulatory surgical facilities. The rule has been amended to make grammatical changes in accordance with LSC rule drafting requirements.

3701-83-20 – This rule establishes the service standards for ambulatory surgical facilities. These standards include, but are not limited to the facility: ensuring anesthetics are administered by individuals acting within their scope of practice; that there is adequate equipment, space and staff to meet the needs of the patient; and maintaining a written transfer agreement with a hospital in the event of complications, emergencies, or if other needs arise. The rule has been amended to make grammatical changes in accordance with LSC rule drafting requirements.

3701-83-22 – The rule sets forth the specific requirements for ambulatory surgical facilities quality assessment and performance improvement programs. The title of the rule is being amended to remove a typographical error.

3701-83-37 - The rule sets forth the admission, discharge, and transfer requirements for freestanding birth centers. These requirements include, but are not limited to the facility: establishing policies and procedures for the assessment of expectant mothers; having a written

transfer agreement with a hospital or other appropriate healthcare facility; and establishing and following discharge criteria utilizing nationally recognized standards. The rule is being amended to clarify that expectant mothers experiencing complications at freestanding birthing centers must be transferred to a hospital.

3701-83-43 - The rule sets forth the definitions for use in rules 3701-83-43 through 3701-83-50 of the Administrative Code. The rule is being amended to make grammatical changes and to reference the radiation protection rule promulgated under Revised Code 3748 for consistency in the physician's qualifications as a radiation oncologist.

3701-83-44 - This rule establishes the general service standards for freestanding radiation therapy centers. These standards include, but are not limited to the facility: evaluating patients and assessing tumors; providing services necessary to meet the needs of patients; and providing radiation therapy only upon the written order of a radiation oncologist. The rule is being revised to update a citation in paragraph (E).

3701-83-45 – The rule establishes the personnel requirements and qualifications for freestanding radiation therapy centers. These requirements include, but are not limited to the facility must have: an administrator; a medical physicist or teletherapy physicist certified by an approved listed organization; and a sufficient number of staff as appropriate for the services being offered. The rule is being amended to reference the radiation protection rules promulgated under Revised Code 3748 for consistency in the qualifications of a medical physicist for radiation oncology.

3701-83-46 - This rule sets forth the treatment standards for freestanding radiation therapy centers. These standards include, but are not limited to, the facility providing accurate calculation of doses and dose distribution, devices to aid in the positioning an immobilizing of the patients, and a system for independent checking of initial dose calculations. The rule has been revised to make grammatical changes to improve the clarity and flow of information in the rule.

3701-83-47 - The rule sets forth radiation safety standards for freestanding radiation therapy centers, including the reporting of misadministration and adverse events to the Director. The rule is being amended to update terminology from misadministration to medical event, to identify that this medical event, and rule reference is for radiation treatment with radiation therapy equipment. Additionally, the rule is revised to identify to the reader that this medical event and rule reference is for radiation treatment with radioactive materials.

3701-83-48 – The rule establishes the equipment standards for freestanding radiation therapy centers. These standards include, but are not limited to the facility: having the necessary equipment to provide services; developing and implementing a program to monitor the calibration and measurement of the radiation beam; and developing and implementing a preventive maintenance and repair program. The rule is being amended to provide an updated citation to the calibration and operation of radiation therapy equipment in Chapter 3701:1-67 of the Ohio Administrative Code.

3701-83-49 - This rule sets forth the medical records requirements for freestanding radiation therapy centers. These requirements include, but are not limited to, for each patient, the facility must maintain documentation of services and radiographic images; dosimetry calculations; and the patient's treatment plan. The rule is being revised to make grammatical changes and reference the follow-up plan requirements of rule 3701-83-44.

3701-83-51 – This sets forth the definitions for use in rules 3701-83 -51 through 3701-83-55 of the Administrative Code pertaining to freestanding diagnostic imaging centers. The rule is being amended to include definitions of the types of licensed professionals mentioned in the freestanding diagnostic imaging center rules. The additions include "Certified Nurse Practitioner," "Certified Nurse Specialist," "Certified Nurse Midwife", and "physician assistant." A definition for "local anesthesia" has also been added for clarification.

3701-83-52 - The rule establishes the personnel requirements and qualifications for freestanding diagnostic imaging centers. These requirements include, but are not limited to the facility having: sufficient and qualified personnel as appropriate for the services being offered; a physician on site when sedation or contrast agents are being administered; and an appropriately certified medical physicist. The rule is being amended to reference the radiation protection rule promulgated under Revised Code 3748 for consistency in the qualifications of a medical physicist in diagnostic radiography.

3701-83-53 - This rule sets forth the service standards for freestanding diagnostic imaging centers. These standards include, but are not limited to, all equipment being certified for clinical use by the Food and Drug Administration, each facility establishing and maintaining safety guidelines, and each facility establishing and maintaining procedures for handling emergencies. The rule has been revised to make grammatical changes to improve the clarity and flow of information in the rule.

3701-83-54 – This rule establishes the medical records requirements for freestanding diagnostic imaging centers. Facilities must maintain a record for each patient that includes a diagnostic imaging radiology report and must be maintained for six years. The rule has been revised to make grammatical changes to improve the clarity and flow of information in the rule.

3701-83-55 – This rule establishes the quality assessment and performance improvement requirements for freestanding diagnostic imaging centers. These requirements include, but are not limited to the facility: establishing and maintaining a clinical image quality control program; monitoring and evaluating the accuracy of image interpretations; and reporting specific information to the director. The rule is being amended to improve the clarity and flow of information in the rule as it pertains to the monitoring and evaluation of image interpretation.

Rescinded rule.

3701-83-50 – The rule sets forth the quality assessment and performance improvement requirements for freestanding radiation therapy centers. The rule is being rescinded and replaced with a new rule in accordance with LSC rule drafting requirements for rules amended over fifty percent. The new rule includes the review and evaluation requirements for freestanding radiation therapy centers and removes redundant language.

New rule.

3701-83-50 – The rule sets forth the quality assessment and performance improvement requirements for freestanding radiation therapy centers. The rule is being rescinded and replaced with a new rule in accordance with LSC rule drafting requirements for rules amended over fifty percent. The new rule includes the review and evaluation requirements for freestanding radiation therapy centers and removes redundant language.

The following rules are being filed without change.

3701-83-01 - This rule sets forth the definitions for use throughout Chapter 3701-83.

3701-83-02 - This rule sets forth the applicability of the rules to the designated facility types, including: ambulatory surgical facilities, freestanding dialysis centers, freestanding inpatient rehabilitation facilities, freestanding birthing centers, freestanding radiation therapy centers, and freestanding mobile or diagnostic imaging centers. The rule exempts certain freestanding birthing centers from licensure.

3701-84-03 - The rule sets forth the general provisions and prohibitions for use throughout Chapter 3701-83; including, but not limited to: prohibiting facilities from operating as an HCF without a state issued license; requiring facilities to have a governing board; and maintaining documentation of liability insurance.

3701-83-05 – This rule sets forth the requirements for the maintenance of, issuance of, renewal of, and denial of a license to operate an HCF. These requirements include, but are not limited to, submission of documentation of accreditation status, a possible licensing inspection, and notification to the director if the facility's accreditation is terminated.

3701-83-05.1 - This rule establishes the compliance and revocation actions the director may take if an HCF is operating without a license or is in violation of Chapter 3701-83 or the applicable sections of the Ohio Revised Code. These actions include, but are not limited to, a written order to cease operations, civil penalties, court injunction, or revocation of a license.

3701-83-06 - This rule sets forth the requirements pertaining to inspections of HCFs. The director may make announced and unannounced inspections of facilities based on complaints, identified issues, or as part of the licensing process.

3701-83-09 - This rule sets forth the general service standards for HCFs. These standards include, but are not limited to, providing services in accordance with the clinical capabilities of the facility; establishing and following written infection control standards; and maintaining and operating equipment in accordance with manufacturer's instructions.

3701-83-10 - This rule sets forth the general building and site requirements for use throughout Chapter 3701-83 including, but not limited to, obtaining a certificate of occupancy, and adhering to fire and electrical building codes.

3701-83-11 - This rule sets forth the general medical record keeping requirements for HCFs. This includes, but is not limited to, ensuring the security of the records, and maintaining records for six years.

3701-83-12 - This rule sets forth the general quality assessment and performance improvement requirements for HCFs. These requirements include, but are not limited to, the development of a written plan, monitoring and evaluating all aspects of care, and the reporting of QAPI information to the director at designated intervals.

3701-83-13 - This rule sets forth the requirement for HCFs to develop and follow procedures to receive, investigate, and resolve complaints.

3701-83-14 - This rule sets forth the requirements for the granting of a waiver or variance from any of the building or safety requirements established by this Chapter. The director may grant a waiver if the standards are met in an alternative manner or if the requirement would create an undue hardship to the HCF and the granting would not jeopardize the health and safety of any patient.

3701-83-16 - This rule sets forth the governing board requirements for ambulatory surgical facilities. These requirements include, but are not limited to the review and approval of surgical procedures at least every twenty-four months and the granting or denial of clinical privileges to facility physicians and healthcare professionals based on established standards.

3701-83-17 - This rule sets forth the admission, transfer, and discharge requirements for ambulatory surgical facilities. The requirements include, but are not limited to: the admission of patients requiring care for less than twenty-four hours; ensuring each patient has a comprehensive medical history and physical exam prior to any procedure at the facility; and providing patients with verbal and written post-treatment care instructions.

3701-83-18 - This rule sets forth the personnel and staffing requirements specific to ambulatory surgical facilities. These requirements include, but are not limited to the facility must: have a medical director and a facility administrator; have a director of nursing; and provide an ongoing training program for staff.

3701-83-19 - This rule establishes the service standards for ambulatory surgical facilities. These standards include, but are not limited to the facility: ensuring anesthetics are

administered by individuals acting within their scope of practice; that there is adequate equipment, space and staff to meet the needs of the patient; and maintaining a written transfer agreement with a hospital in the event of complications, emergencies, or if other needs arise.

3701-83-21 - This rule sets forth the medical records requirements for ambulatory surgical facilities. Medical records must be maintained for each patient and include information such as admission date, medical history, treatment, and discharge data.

3701-83-23 - This rule sets forth the definitions for use in rules 3701-83-23 to 3701-83-24 pertaining to freestanding dialysis centers.

3701-83-23.1 – This rule sets forth the service standards specific to freestanding dialysis centers. These standards include, but are not limited to, maintaining an isolation room, developing, and following policies for documenting and responding to adverse events, and providing services in accordance with the clinical capabilities of the facility.

3701-83-23.3 - This rule sets forth the specific medical records requirements for freestanding dialysis centers. These requirements include, but are not limited to, treatment data, medication information, and a signed consent form.

3701-83-23.4 - This rule sets forth the specific infection control and prevention requirements for freestanding dialysis centers. These include, but are not limited to, establishing, and following a preventive maintenance schedule for equipment, water testing and treatment, and routine Hepatitis B surveillance.

3701-83-24 - This rule establishes the specific quality assessment and performance improvement (QAPI) requirements for freestanding dialysis centers. The requirements include a self-assessment and reviews as part of the QAPI and require the facility to designate individuals responsible for the program and to utilize the review results in their ongoing improvement of services.

3701-83-25 - This rule sets forth the definitions for use in rules 3701-83-25 through 3701-83-32 of the Administrative Code pertaining to inpatient rehabilitation facilities.

3701-83-26 - This rule sets forth the specific service standards for inpatient rehabilitation facilities. These standards include, but are not limited to the facility: developing and following current care protocols following accepted standards of care; providing each patient with the services of an interdisciplinary team; and providing each patient with information concerning the services to be provided.

3701-83-27 - This rule establishes the admission procedures and preliminary assessment requirements for inpatient rehabilitation facilities. These requirements include, but are not limited to the facility: developing a written criteria for admission to the facility; requiring a patient to be medically stable prior to admission; and evaluating and determining the

appropriateness of the patient's placement at the facility based on services available and the patient's needs.

3701-83-28 - This rule establishes the requirement for an inpatient rehabilitation facility to develop: 1) a comprehensive inpatient rehabilitation evaluation; 2) a treatment plan; and 3) discharge plans for each patient. These plans must include, but are not limited to, a summary of the patient's clinical condition; and a determination of the need for supportive services. Finally, the plan must be periodically reviewed by the interdisciplinary team assigned to the patient.

3701-83-29 – This rule sets forth the personnel and staffing requirements specific to inpatient rehabilitation facilities. These requirements include, but are not limited to, having a medical director, a director of nursing, and an ongoing training program for personnel.

3701-83-30 - This rule sets forth the building and site requirements specific to inpatient rehabilitation facilities. These requirements include, but are not limited to the facility having: sufficient floor space to allow maneuverability in a wheelchair; handrails on both sides of corridors; and adequate space designated for group recreation.

3701-83-31 - This rule establishes the equipment and supply requirements for inpatient rehabilitation facilities. These requirements include the facility: maintaining supplies and equipment in a quantity to meet the needs of patients; maintaining equipment in a safe and sanitary manner; and developing, maintaining and implementing a preventive maintenance plan in accordance with manufacturer's instructions.

3701-83-32 - This rule sets forth the quality assessment and performance improvement requirements for inpatient rehabilitation facilities. These requirements include, but are not limited to the facility collecting and maintaining data on the number of admissions; number of patient transfers; and the number of patients who achieved discharge goals.

3701-83-33 - This rule sets forth the definitions for use in rules 3701-83-33 through 3701-83-42 of the Administrative Code pertaining to freestanding birthing centers.

3701-83-34 - This rule sets forth the general provisions for freestanding birth centers. These provisions include, but are not limited to the facility: admitting and retaining only low-risk expectant mothers; providing a home-like environment with adequate space and furnishings; and establishing and enforcing written infection control policies.

3701-83-35 - This rule establishes the requirements for the governing board of a freestanding birthing center. These requirements include, but are not limited to the governing board: meeting regularly; establishing a quality assessment and performance improvement program; and approving qualifications for all staff.

3701-83-36 - This rule sets forth the service standards for freestanding birth centers. These standards include, but are not limited to the facility providing: services that meet the patient's needs in accordance with the patient's plan of care; intrapartum care that requires minimal intervention; and emergency response as necessary.

3701-83-38 – This rule establishes the personnel and staffing requirements for freestanding birth centers. These requirements include each facility having a director of patient services who is a physician or certified nurse midwife, maintenance of a personnel file for each employee, and maintaining a sufficient number of staff to meet the needs of patients.

3701-83-39 - This rule establishes the building and site requirements for freestanding birth centers. These requirements include, but are not limited to each facility having: at least two birth rooms; a system to provide emergency lighting; and hot and cold running water.

3701-83-40 - This rule establishes the equipment standards for freestanding birth centers. Each facility must: have readily accessible emergency carts for the mother and a newborn; designate an area for the emergency equipment; and develop and implement a preventive maintenance and repair program.

3701-83-41 - This rule establishes the supply and medication requirements for freestanding birth centers. These requirements include but are not limited to the facility: maintaining an inventory of supplies and medications sufficient to meet patient needs; monitoring the shelf life of all medications; and establishing written policies and procedures to ensure accountability of all medication and supplies.

3701-83-42 - This rule establishes the quality assessment and performance improvement requirements for freestanding birth centers. These requirements include, but are not limited to the facility, developing evaluation criteria for determining eligibility for admission to the facility and reviewing and evaluating the management of care and developing discharge criteria for the mother and newborn.

3701-83-56 - This rule sets forth the definitions for use in rules 3701-83-57 through 3701-83-59 of the Administrative Code pertaining to exempt freestanding birthing centers and include definitions for the terms such as "doula" and "lay midwife."

3701-83-57 - This rule sets forth the patient safety monitoring and evaluation requirements for exempt freestanding birthing centers. These include the requirement that policies and data must be reviewed "periodically", and facilities must have a plan and procedures for emergency situations requiring evacuation of patients.

3701-83-58 - This rule sets forth the quality assessment and performance improvement requirements for exempt freestanding birthing centers. These requirements include, but are not limited to the facility: monitoring and evaluating the provision of direct care to patients;

reporting specific data to the director; and ensuring that any data reported is reviewed by the facility's consulting physician.

3701-83-59 - This rule sets forth the compliance requirements for exempt freestanding birthing centers. The compliance actions the director may take include, but are not limited to: requiring the exempt center to come into compliance within a period specified in a written order, and if the facility fails to comply, issuing a second order requiring the center to cease operations until the center obtains a license as a freestanding birthing center.

3. **Please list the Ohio statute(s) that authorize the agency, board, or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Ohio Revised Code sections 3702.13, 3702.30, and 3702.31

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

   There are no federal requirements mandating these rules.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Not applicable to this rule.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   As required by Ohio Revised Code 3702.30, these rules provide the necessary state-based framework for the Department of Health to ensure the safety and quality of care of HCFs for Ohio's health care consumers. The rules provide a means by which the Department of Health identifies HCFs and may determine and enforce safety standards. Furthermore, the rules reduce negative health care outcomes through required actions such as, but not limited to, requiring adherence to industry standards, and establishing minimum safety requirements.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   Successful outcomes are measured through a standard survey (inspection) process approximately once every thirty-six months; successful outcomes would indicate compliance with the standards and requirements set forth in Chapter 3701-83. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

   Not applicable.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

   Representatives of the HCF industry were made aware of the recommended revisions to the rules during regularly scheduled non-long-term care provider meetings.

   State Medical Board of Ohio
   Ohio Board of Nursing
   Nationwide Children's Hospital
   Ohio Hospital Association
   Ohio Council for Home Care and Hospice
   DaVita Healthcare Partners
   Ohio Association of Ambulatory Surgical Centers
   New Bedford Care Center (exempt birthing center)
   Mt. Eaton Care Center (exempt birthing center)

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    The State Medical Board of Ohio and the Ohio Board of Nursing were instrumental in changes to the freestanding diagnostic imaging rules that are being revised to allow certain Advanced Practice Registered Nurse to administer contrast agents during imaging.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Not applicable.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    The Ohio Department of Health is required to monitor compliance with the licensing provisions mandated by section 3702.30 of the Revised Code. The rules reflect the current

industry standards pertaining to HCFs that providers are expected to meet for participation in accrediting organizations and participation in Centers for Medicare and Medicaid Services programs.

13. Did the Agency specifically consider a performance-based regulation? Please explain.

ODH rules contain both structural (process) and performance (outcome) based requirements. When there is a bad outcome, ODH can then look to ensure that the requirements of the rule were implemented properly and can identify break-downs in the process through surveys to provide opportunities for the services to correct their identified deficiencies and meet the quality and safety standards required by statute.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The agency conducted a thorough review of the Ohio Revised Code and Ohio Administrative Code to ensure there are no other regulations in place pertaining to these specific requirements.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

HCFs are surveyed approximately once every thirty-six months and are conducted as necessary as the result of complaints, to determine compliance. Surveys are conducted by specially trained HCF program staff utilizing a standard survey document and protocols specific to the type of service.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community:

All licensed Health Care Facilities as defined in rule 3701-83-01 of the Ohio Administrative Code and section 3702.30 of the Ohio Revised Code.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

In general, these rules do not represent costs that are independent of those already obligated to the HCF by virtue of their participation in the industry and the Centers for Medicare and

Medicaid Services Conditions of Participation for many of the HCF types. Those costs include, but are not limited to, the costs associated with the purchase or lease of real estate, equipment, and personnel. There are also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assessment and performance improvement. The similar requirements set forth in Ohio's rules are unlikely to require a significant amount of time or costs in addition to that which is already expended by the service and the services will, more likely than not, already meet or exceed the state requirements. Potential adverse impacts identified include fines for violations, license application fees, time for compliance, and reporting requirements. Those costs include, but are not limited to, the costs associated with equipment, personnel, and time and manpower costs associated with policy development/implementation.

c. Quantify the expected adverse impact from the regulation:

As authorized in section 3702.31 of the Ohio Revised Code and set forth in rule 3701-83-04 of the Ohio Administrative Code, the fee for an initial or renewal license is $300 and the cost for an amended license is $150.

Fees, as authorized in section 3702.31 of the Ohio Revised Code, associated with inspections approximately once every 36 months or as the result of a complaint are as follows:

General HCF Fees: Inspection Fee - $1750
Complaint Inspection Fee- $875
Follow-up Inspection Fee- $875
Validation Inspection Fee - $1750
Desk Audit or Compliance Review Fee- $250

(1) Time and manpower necessary to develop infection control policies, emergency plans, and provide training.

(2) Time and manpower necessary to develop a written transfer agreement with a local hospital.

(3) Time and manpower necessary to prepare a written request for a waiver or variance from the requirements of the Chapter; may include time to compile documentation and a cost analysis.

(4) Time to read the rules specific to the HCF type; estimated to be 30 minutes for the entire Chapter. The costs borne by the HCF are those generally associated with the provision of services within the industry. All costs associated with policy and procedure development and training would be based upon the nature and complexity of the requirement and the staff

chosen to perform the task. In most instances a physician or registered nurse would be responsible for this requirement, while training may be conducted by other health care practitioners.

Physician: $0.00 to an average of 107.67 per hour*

Registered Nurse: $0.00 to an average of 33.53 per hour*

Other Healthcare Practitioners: $32.13 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2020, using the codes for all health care practitioners and technical occupations (29-9098) physicians and surgeons, all others (29-1228), registered nurse (29-1141).

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

ODH is required to implement section 3702.30 of the Ohio Revised Code by establishing licensing requirements for HCFs. The costs represented by the specific license and service standards set forth in Chapter 3701-83 are considered to be acceptable and represent a general standard cost in terms of the administrative, personnel, and facility based requirements for the operation of a HCF within the industry. The minimal reporting requirements established in these rules provide information to the Department of Health that is necessary to monitor and ensure the health and safety of Ohio's health care consumers that cannot be obtained in a timely manner by other means.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Alternative means of compliance may be achieved through waiver or variance. Variances or waivers may be granted for any of the requirements of the Chapter if the Director determines: that the requirement has been met in an alternative manner, that the strict application of the requirement would result in undue hardship, and that the granting of the waiver or variance would not jeopardize the health or safety of any patient. The requirements for a waiver or variance are set forth in rule 3701-83-14 and are determined on a case-by-case basis.

Additionally, HCFs may submit an accreditation award letter from an approved accrediting agency (i.e.; Joint Commission, American Osteopathic Association) as evidence of compliance with the standards set forth in Chapter 3701-83.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

ODH's Regulatory Ombudsman has set forth a policy for ODH to follow regarding the waiver of fines and penalties for paperwork violations and first-time offenders. ODH implements this policy as part of its business process. Information regarding this policy can be found online at: https:// odh.ohio.gov/wps/portal/gov/odh/about-us/offices-bureaus-and-departments/Office-of-General- Counsel/Statement-on-Paperwork-Violations/

20. What resources are available to assist small businesses with compliance of the regulation?

The Ohio Department of Health, Bureau of Regulatory Operations provides information and assistance to HCF providers. Additional information is available at: https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/Health-Care-Facilities/HealthCareFacilities