CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Chapter 3701-83 – Health Care Facilities

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

Date: October 7, 2015

Rule Type:

- ☐ New
- X Amended
- X 5-Year Review
- ☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulations 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 of the Ohio Revised Code

The rules are being revised as part of the mandatory five year review process and incorporate the required statutory revisions set forth in HB 59 (130th General Assembly) and HB 64 (131st General Assembly)

Revisions have been made to:

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. The rule is being amended to incorporate notice and documentation requirements for exempt birthing centers that are already in practice in the licensure program and the exempt birthing center communities.

3701-83-04 - This rule sets forth the license application and renewal procedures for HCFs. The rule is being amended to make formatting and grammatical changes.

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. The rule is being amended to remove an outdated item in paragraph (E)(3) and to make formatting changes in compliance with Legislative Service Commission rule drafting requirements.

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. The rule is being amended to remove an unnecessary reference to Chapter 119. of the Revised Code.

3701-83-07 - This 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 shall be allowed to withdraw their consent for treatment. The rule is being amended to include the HCF's policies relating to Do-Not-Resuscitate (DNR) orders as one of the policies that must be discussed with patients.

3701-83-08 - This 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 is being amended to incorporate language consistent with other ODH rule sets relating to record keeping systems to enable the Director to ascertain personnel license, certification, and registration requirements are met.

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. The rule is being amended to clarify that the documentation and review of adverse events and complications shall be part of the HCF's quality assessment and performance improvement program.

3701-83-10 - This rule sets forth the general building and site requirements for use throughout Chapter 3701-83. The rule is being amended to make minor grammatical changes and clarify that disaster preparedness plans should include emergencies in addition to fires.

3701-83-11 - This rule sets forth the general medical record keeping requirements for HCFs. The rule is being reformatted for clarity.

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. The rule is being amended to make a grammatical change.

3701-83-13 - This rule sets forth the requirement for HCFs to develop and follow procedures to receive, investigate, and resolve complaints. The rule is being to make grammatical changes for clarification.

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. The rule is being amended to make a grammatical change consistent with Legislative Service Commission 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 is being amended to make a grammatical change consistent with Legislative Service Commission rule drafting requirements.

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. The rule is being revised to require the designation of an individual trained in infection control to direct the facility's infection control program. This change is the result of statutory revisions in HB 59 in 2013.

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. The rule is being amended to make minor grammatical changes.

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. The rule is being amended to reformat the rule for clarity and to incorporate language consistent with other ODH rule sets relating to record keeping systems to enable the Director to ascertain personnel license, certification, and registration requirements are met.

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. The rule is being amended to make grammatical changes, be reformatted for clarity, and to incorporate statutory requirements from HB 59 (2013) for the biennial updating of written transfer agreements.

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. The rule is being amended to make minor grammatical changes and reference the medical records requirements established by rule 3701-83-11 of this Chapter.

3701-83-22 - This rule sets forth the specific requirements for ambulatory surgical facilities quality assessment and performance improvement programs. The rule is being amended to make minor changes to the rule title for clarity.

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. The rule is being amended to make grammatical and formatting changes for clarity and to clarify that dialysis centers operated by a hospital are exempt from freestanding licensure requirements only if they are located in the hospital or on the same grounds as the hospital, are included in the hospital's accreditation or certification, and are not providing routine chronic maintenance dialysis on an outpatient basis.

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. The rule is being amended to make grammatical and formatting changes for clarity and to include the HCF's policies relating to Do-Not-Resuscitate (DNR) orders as one of the policies that must be discussed with patients.

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. The rule is being

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. . The rule is being amended to include the HCF's policies relating to Do-Not-Resuscitate (DNR) orders as one of the policies that must be discussed with patients and to make grammatical and formatting changes.

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. The rule is being amended to make a minor change to the rule title for clarity.

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. The rule is being amended to make grammatical changes and to reformat the rule for clarity.

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. The rule is being amended to make grammatical changes and to reformat the rule for clarity.

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 plan 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. The rule is being amended to make grammatical changes and to reformat the rule for clarity.

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. The rule is being amended to make grammatical changes, to reformat the rule for clarity and to incorporate language consistent with other ODH rule sets relating to record keeping systems to enable the Director to ascertain personnel license, certification, and registration requirements are met.

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. The rule is being amended to make grammatical changes for clarity.

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. The rule is being amended to make grammatical changes for clarity.

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. The rule is being amended to make grammatical changes for clarity.

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. The rule is being amended to make grammatical changes for clarity.

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. The rule is being amended to make grammatical changes for clarity.

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. The rule is being amended to make grammatical changes for clarity.

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. The rule is being amended to make grammatical changes for clarity.

3701-83-37 - This 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 make grammatical and formatting changes for clarity.

3701-83-38 – 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. The rule is being amended to make grammatical and formatting changes for clarity and to incorporate language consistent with other ODH rule sets relating to record keeping systems to enable the Director to ascertain personnel license, certification, and registration requirements are met.

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. The rule is being amended to make grammatical and formatting changes for clarity.

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. The rule is being amended to make grammatical and formatting changes for clarity and to clarify equipment maintenance records retention requirements.

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. The rule is being amended to make grammatical and formatting changes for clarity and to clarify that medications and supplies shall be disposed of in accordance with industry standards and practices.

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. The rule is being amended to make grammatical and formatting changes for clarity.

3701-83-43 - This 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.

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 amended to make grammatical and formatting changes for clarity.

3701-83-45 – This 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 make a minor grammatical change.

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 is being amended to make grammatical changes for clarity.

3701-83-47 - This 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 make a grammatical change.

3701-83-48 - This 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 correct a citation to the calibration and operation requirements for equipment in Chapter 3701:1-67 of the Administrative Code and to make grammatical and formatting changes for clarity and to clarify equipment maintenance records retention requirements.

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 amended to make grammatical and formatting changes for clarity.

3701-83-50 - This rule sets forth the quality assessment and performance improvement requirements for freestanding radiation therapy centers. The rule is being amended to make grammatical and formatting changes for clarity.

3701-83-52 - This 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 make grammatical and formatting changes for clarity.

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 is being amended to make a change to the rule title for clarity.

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 is being amended to make grammatical and formatting changes for clarity.

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 make grammatical and formatting changes for clarity.

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. The rule is being amended to make grammatical changes.

New Rules

3701-83-23.2 - This new rule replaces existing rule 3701-83-23.2 due to the Legislative Rule Drafting requirement for the creation of a new rule when more than fifty percent of an existing rule's language is changed. The rule sets forth the personnel and staffing requirements specific to freestanding dialysis centers. These requirements include, but are not limited to, maintaining copies of current staff licenses, maintaining copies of staff schedules, and providing an ongoing staff training program. The rule is being amended to reformat the rule for clarity and to incorporate language consistent with other ODH rule sets relating to record keeping systems to enable the Director to ascertain personnel license, certification, and registration requirements are met and to reformat the rule for clarity.

No changes have been made to the following:

3701-83-01 - This rule sets forth the definitions for use throughout Chapter 3701-83. The rule is being filed without change.

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. The rule is being filed without change.

3701-83-05.2 - 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. The rule is being filed without change.

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. The rule is being filed without change.

3701-83-20 – This rule sets forth the building, site and equipment requirements for ambulatory surgical facilities. The rule is being filed without change.

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. The rule is being filed without change.

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 filed without change.

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". The rule is being filed without change.

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. The rule is being filed without change.

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. The rule is being filed without change.

2. Please list the Ohio statute authorizing the Agency to adopt these regulations.

Ohio Revised Code sections 3702.13, 3702.30, and 3702.31

3. Do the regulations implement a federal requirement? Are the proposed regulations 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.

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

Not applicable to these rules.

5. 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.

6. **How will the Agency measure the success of these regulations 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.

Development of the Regulation

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

Representatives of the HCF industry were made aware of the recommended revisions to the rules during regularly scheduled non-long-term care provider meetings and sent a copy of the draft revisions to the rules on July 1, 2015 and included the following identified parties:

Nationwide Childrens Hospital
Ohio Hospital Association
Beacon Orthopedics
Midwest Care Alliance
Ohio Department of Aging
Ohio Department of Medicaid
Ohio Council for Home Care and Hospice
Mercy Hospital Systems
DaVita Healthcare Partners
Ohio Association of Ambulatory Surgical Centers
Middlefield Care Center
Mahoning Valley Birth Center
Blessed Beginnings (exempt birthing center)
New Bedford Care Center (exempt birthing center)
Mt. Eaton Care Center (exempt birthing center)

A stakeholder meeting was held on August 12, 2015 without additional comments or revisions.

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

Several non-substantive comments were received from stakeholders that resulted in grammatical changes and staff providing clarification for requested rules. The substantive revisions that were made to the rules were the result of statutory changes from the 2013 and 2015 State Budget Bills. Many of the other changes were minor grammar and formatting changes to improve the readability and flow of information in the rules.

9. **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. Alternative regulations to the four rules being amended were not considered. 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.

10. Did the Agency specifically consider performance-based regulations? 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.

11. What measures did the Agency take to ensure that these regulations do 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 HCFs.

12. Please describe the Agency's plan for implementation of these regulations, including any measures to ensure that the regulations are 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

13. Provide a summary of the estimated cost of compliance with these rules. Specifically, please do the following:

a. Identify the scope of the impacted business community:

All HCFs

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.

Adverse impacts identified include fines for violations, 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. There exists the possibility for an increase in costs for those hospital based dialysis units that are determined require a freestanding dialysis center license due to the clarification of the definition of freestanding dialysis center in rule 3701-83-23(D). If the unit is determined to be providing non-emergency chronic maintenance dialysis services they will be required to apply for licensure and pay the associated license fees as described in section (C)(2) of this paragraph below.

c. Quantify the expected adverse impact from the regulation:

(1) 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 will remain at $300 and the cost for an amended license will remain at $150.

(2) 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 will remain 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

Freestanding Radiation Therapy Centers/Diagnostic or Mobile Imaging Centers:

Inspection Fee - $950
Follow-up Inspection Fee - $475
Complaint Inspection Fee - $475
Desk Audit or Compliance Review Fee - $250

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

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

(5) 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.

(6) 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 $87.58 per hour*.

Registered Nurse:
$0.00 to an average of $30.04 per hour.*

Other Healthcare Practitioners:
$23.74 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2014, using the codes for all health care practitioners and technical occupations (29-9099) physicians and surgeons, all others (29-1069), registered nurse (29-1111).

(7) Civil monetary penalties may be charged in accordance with Chapter 119. of the Ohio Revised Code, to an HCF for failure to meet licensing or safety requirements. These penalties are based upon the severity of the violation and range from one thousand to two hundred and fifty thousand dollars. A cease operation order may be obtained in the event of a second or subsequent violation or if the Director determines a first violation poses an imminent threat of serious physical or life-threatening danger.

14. 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

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

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.

16. 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?

The agency maintains program staff to assist and provide guidance to HCF providers to improve their survey outcomes and maintain compliance. Additionally, as stated in rule 3701-8.3-05.1 of the OAC, the Director may provide the HCF a reasonable and appropriate amount of time to correct a violation. The compliance and enforcement actions established by these rules are imposed based upon the severity of the violation and a number of factors including, but not limited to, the potential for physical harm and the duration of violation, which typically do not include "paperwork" violations.

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: http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx.

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

The Ohio Department of Health, Office of Health Assurance and Licensing, Bureau of Community Health Care provides information and assistance to HCF providers. Additional information is available at:

http://www.odh.ohio.gov/odhprograms/chcf/comhfs/chcfs1.aspx