

MEMORANDUM

Date: July 25, 2023
To: Interested Parties
From: Jayson Rogers, Bureau of Regulatory Operations
Ohio Department of Health
Subject: New Chapter 3701-22 of the Ohio Administrative Code (“Hospital Licensing”)

The state biennium budget, [House Bill 110](#) of the 134th General Assembly, included new sections of the Revised Code (see, [3722.01 et seq.](#)) requiring the Department of Health (“ODH”) to license hospitals in the state beginning October 1, 2024. On that date, hospitals will be required to be licensed, and other areas within the hospital (maternity/newborn and health care services) that are currently licensed will be subsumed as part of the overall hospital license.

To develop these rules, ODH has worked with stakeholders and representatives of the industry to advance a rule set that both protects the health and safety of patients and minimizes the impact on regulated hospitals. Hospitals provide acute medical care to many Ohioans, yet they have not been subject to overall state licensing¹. This will change beginning September 30, 2024, when, pursuant to Substitute House Bill number 110, hospitals in Ohio will be required to be licensed by the Ohio Department of Health. As such, the Ohio Department of Health worked with hospitals and their industry representatives for over a year to develop rules to appropriately regulate hospitals in Ohio.

ODH’s recommended new rules are set forth as follows:

Rule 3701-22-01

This rule contains the definitions for terms used in chapter 3701-22 of the Administrative Code. These include definitions brought in from current Chapters 3701-07 (maternity/newborn), 3701-59 (hospital registration), and 3701-84 (health care services) of the Administrative Code, as well as rules developed from industry standards. These definitions are applicable to the entirety of Chapter 3701-22 of the Administrative Code.

Rule 3701-22-02

This rule sets forth the applicability of Chapter 3701-22. This rule, given that hospitals have until September 30, 2024, allows for hospitals to continue operating by meeting existing rules related to hospital registration, maternity/newborn units, and health care services, as applicable. Once the hospital licensing rules are in place, the rule provides hospitals with maternity/newborn units, and health care services, as applicable, must meet upon licensing as a hospital.

¹ Some specific parts of a hospital have had licensing for that specific part, such as maternity/newborn units and where health care services are provided. These licenses will now become part of the overall hospital license.

Rule 3701-22-03

This rule sets forth the requirements for initial, renewal, and transfer applications. The rule proposes a main licensing fee based on the number of beds within the hospital, and an additional fee(s) that is based on the number of maternity/newborn units and/or health care services provided by the hospital. The fees are structured so that ODH's work related to hospital licensing, including any required on-site inspection, is covered without the need to charge an additional inspection fee.

The rule requires the hospital to identify any additional locations of the hospital, but only to department of a hospital, a remote location of a hospital, and satellite facilities where certain services are provided that will be captured under the hospital's license. Additionally, the hospital is required to report the type and number of beds, and to identify and maternity/newborn units and/or health care services at the main hospital and any additional locations, if applicable.

The rule also requires notice to the Director of Health prior to when being used for patient care, opening a new location, adding a building(s), replacing a building(s), or expanding a building's patient care areas; when changing the layout of a patient care area of the hospital; and when converting non-patient care areas to patient care areas.

3701-22-04

This rule sets forth prohibitions against operating a hospital without a license, as well as interfering with an inspection of a hospital or material misrepresenting information to ODH.

3701-22-05

This rule allows for inspections of hospitals by ODH to address an incident that may impact public health, respond to a complaint submitted to the director, or otherwise ensure the safety of patients cared for by the hospital. This rule also sets forth ODH's ability to - when a violation of Chapter 3722. of the Revised Code has occurred - take enforcement action(s) against a hospital that is not in compliance. These actions include requiring a plan of correction to address the deficiency; imposition of civil money penalties based on the nature and seriousness of the deficiency; or suspension of a hospital's license. The rule contains requirements for the director to consider when choosing a civil money penalty, and allowance for a settlement when a civil money penalty is proposed.

Rule 3701-22-06

This rule contains requirements related to the effective administration of the hospital, including compliance with applicable federal, state, and local laws, that the hospital have a governing body, that the hospital be responsible for patients' rights, as well as emergency preparedness. In accordance with input from the regulated industry, these rules incorporate existing federal hospital requirements from 42 CFR 482.

Rule 3701-22-07

This rule establishes the basic hospital functions for all hospitals other than critical access and rural emergency hospitals. The rule requires hospitals to provide for a quality assessment and

performance improvement program; the establishment of regional hospital zones to respond to public health events and/or outbreaks or disease; and requirements related to various services within the hospital, such as the medical staff, the nursing staff, and pharmaceutical services, among others. In accordance with input from the regulated industry, these rules incorporate existing federal hospital requirements from 42 CFR 482; however, ODH has expanded the infection control and protection to require a tuberculosis plan, a surveillance plan for healthcare associated infections and multi-drug resistant organism, and a water management plan to help manage the risk and transmission of waterborne pathogens, such as *legionella* in the building water system(s).

Rule 3701-22-08

This rule establishes those services that a hospital can elect to provide, such as surgical, outpatient, and emergency services. Hospitals that elect to provide these optional services must then follow the applicable regulations for those services, which, at the request of the regulated industry, incorporates by reference applicable provisions of 42 CFR 482.

3701-22-09

This rule establishes requirements for critical access hospitals. Critical access hospitals are generally small (under 25 beds) hospitals in rural areas that are intended to provide short-term acute and emergency care to rural residents. There are currently 32 critical access hospitals in Ohio.

At the request of the regulated community, provisions for 42 CFR 482 applicable to critical access hospitals have been incorporated by reference, with expansion of requirements:

- To participate in quality assessment and performance improvement projects;
- Allows the director to establish regional hospital zones;
- Related to infection control and waterborne pathogens; and
- Cooperation with any public health investigation.

Rule 3701-22-10

This rule establishes requirements for rural emergency hospitals. Rural emergency hospitals are generally small hospitals in rural areas that are intended to provide care to patients for no more than 24 hours and emergency care to rural residents.

At the request of the regulated community, provisions for 42 CFR 482 applicable to critical access hospitals have been incorporated by reference, with expansion of requirements:

- To participate in quality assessment and performance improvement projects;
- Allows the director to establish regional hospital zones;
- Related to infection control and waterborne pathogens; and
- Cooperation with any public health investigation.

Rule 3701-22-11

This rule establishes ODH's intent to work with the regulated industry to develop reporting requirements related to patient care and safety to go into effect after October 1, 2024.

Rule 3701-22-12

This rule establishes ODH's intent to work with the regulated industry to develop annual reporting requirements to go into effect after October 1, 2024. The rule requires hospitals to continue reporting information under current chapter 3701-59 of the Administrative Code until new reporting requirements are developed.

Rule 3701-22-13

This rule establishes ODH's intent to work with the regulated industry to develop data reporting requirements in agreed-upon areas to determine areas within hospitals that can be assisted with a technical assistance program developed by ODH.

Rule 3701-22-15

This rule establishes the process through which a hospital may request a waiver or variance from a regulatory requirement.

Please review the rules and **provide any comments you may have by August 24, 2023**, to the address below. Please include the words "Hospital Licensure" in the subject line of all comments sent via regular mail or e-mail. ODH will review and consider the comments received before the rule is submitted for formal rule proposal and adoption proceedings. Thank you.

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3701-22-01

Definitions.

As used in this chapter:

(A) "Advanced practice registered nurse" means an individual who holds a valid license under Chapter 4723. of the Revised Code to practice nursing as a certified registered nurse anesthetist, clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(B) "Alcohol and drug hospital" means a hospital engaged primarily in providing specialized care to inpatients with alcoholism or chemical dependency rehabilitative service needs.

(C) "Alcohol or drug abuse rehabilitation bed" means a hospital bed that is staffed and equipped for care of inpatients whose primary diagnosis is alcoholism or other chemical dependency.

(D) "Anesthesiologist" means a physician who has completed a residency training program in anesthesiology accredited by the accreditation council for graduate medical education or the American osteopathic association.

(E) "Anesthesiologist assistant" means an individual who holds a valid certificate of registration under Chapter 4760. of the Revised Code to practice as a anesthesiologist assistant.

(F) "Average daily census" means total patient days for a given calendar year divided by the number of days in the year.

(G) "Average daily census" means total patient days for a given calendar year divided by the number of days in the year.

(H) "Beds in use" means the sum of the number of beds staffed and available for patient care on the last day of each month of the calendar year, divided by twelve.

(I) "Blood and bone marrow transplantation service" also known as "hematopoietic stem cell transplantation" or "(HSCT)" means the replacement or supplementation of a patient's bone marrow with autologous or allogeneic hematopoietic stem cells when the patient's own bone marrow has been ablated or partially ablated by disease or therapy for the purpose of achieving long-term management of certain hematologic, immunologic, oncologic or genetic conditions, or enzymatic deficiency disease. A bone marrow transplantation service includes a service in stem cell harvesting and reinfusion.

(J) "Burn care bed" means a hospital bed that is staffed and equipped for care of inpatients whose primary diagnosis is burn-related.

(K) "Burn care hospital" means a hospital engaged primarily in providing inpatient care to patients requiring specialized burn-related diagnostic or therapeutic services.

- (L) "Cancer hospital" means a hospital that is classified as a cancer hospital under 42 C.F.R. 412.23(f) (1985) and is organized primarily for treatment and research on cancer.
- (M) "Cardiac catheterization" means a procedure used to diagnose and treat various cardiac and circulatory diseases that involves inserting a thin, pliable catheter into a major blood vessel and manipulating the tip of the catheter through veins or arteries to the heart.
- (N) "Cardiac catheterization service" means the staff, equipment, physical space, and support services required to perform cardiac catheterization and percutaneous coronary interventions.
- (O) "Certified nurse-midwife" means a registered nurse who holds a valid license issued under Chapter 4723. of the Revised Code to practice as a certified nurse-midwife in accordance with section 4723.43 of the Revised Code and rules adopted by the board of nursing.
- (P) "Certified nurse practitioner" means a registered nurse who holds a valid license issued under Chapter 4723. of the Revised Code to practice as a certified nurse practitioner in accordance with section 4723.43 of the Revised Code and rules adopted by the board of nursing.
- (Q) "Children's hospital" means either of the following:
- (1) A hospital that provides general pediatric medical and surgical care in which at least seventy-five per cent of annual inpatient discharges for the preceding two calendar years were individuals less than eighteen years of age;
 - (2) A distinct portion of a hospital that provides general pediatric medical and surgical care, has a total of at least one hundred fifty pediatric special care and pediatric acute care beds, and in which at least seventy-five per cent of annual inpatient discharges for the preceding two calendar years were individuals less than eighteen years of age.
- (R) "Chiropractor" means a person licensed under Chapter 4734. of the Revised Code to practice chiropractic care.
- (S) "Cobalt service" means the structural unit of a hospital which provides radiation therapy using a cobalt teletherapy machine.
- (T) "Cobalt service" means the structural unit of a hospital which provides radiation therapy using a cobalt teletherapy machine.
- (U) "Consultation" means an individual is capable of rendering advice, opinions, recommendations, suggestions, and counsel in evaluating a patient upon notice by

the requesting physician and in accordance with the medical needs of the patient. This may be done by telemedicine or e-medicine in accordance with accepted professional standards.

(V) "Critical access hospital" means a hospital that is certified by the federal government as meeting the conditions of participation in the medicare program under 42 C.F.R. part 485, subpart F (1993).

(W) "Deceased patient" means a human body or part of a human body from the condition of which it reasonably may be concluded that death recently occurred.

(X) "Department" means the Ohio department of health.

(Y) "Director" means the director of health or his duly authorized representative.

(Z) "Direct care services" means any in-person patient contact where health care or personal care is provided in the hospital.

(AA) "Discharge" means a patient who is formally released from a hospital including deaths. Discharge does not include temporary transfers to other settings.

(BB) "Electrophysiology study" means a test performed to assess the heart's electrical system or activity and is used to diagnose abnormal heartbeats or arrhythmias. For the purpose of this chapter, the term also includes the implantation of permanent pacemakers and ICD devices and other electrophysiology procedures within the scope of procedures authorized at each level of a cardiac catheterization service.

(CC) "Emergency service bed" means a bed within the distinct portion of a hospital or a freestanding building that provides emergency services.

(DD) "Emergency services" means a distinct portion of a hospital or a freestanding building that provides care to individuals with emergency medical conditions.

(EE) "Fetal death" means death prior to the complete expulsion or extraction from its mother of a product of conception, which after such expulsion or extraction, does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

(FF) "Final disposition" means the interment, cremation, removal from the state, donation, or other authorized disposition of a dead body or a fetal death.

(GG) "Full-time equivalent" means at least one thousand eight hundred and twenty hours per calendar year.

(HH) "Gamma knife" means a dedicated device for stereotactic radiosurgery which employs multiple cobalt-60 sealed radiation sources aimed at a single isocenter. The gamma knife may also be used to perform stereotactic radiotherapy.

(II) "Gamma knife service" means the structural unit of a hospital which provides stereotactic radiosurgery or stereotactic radiotherapy using a gamma knife.

(JJ) "Health care service" or "HCS" means any of the following:

- (1) Pediatric intensive care;
- (2) Solid organ and bone marrow transplantation;
- (3) Stem cell harvesting and reinfusion;
- (4) Cardiac catheterization;
- (5) Open heart surgery;
- (6) Operation of linear accelerators;
- (7) Operation of cobalt radiation therapy units;
- (8) Operation of gamma knives.

(KK) "Heart hospital" means a hospital primarily engaged in providing inpatient care to patients requiring specialized cardiac diagnostic or therapeutic services.

(LL) "High-risk allogeneic bone marrow transplantation" is determined according to the combination of: hematopoietic cell transplant comorbidity index (HCT-CI), performance status of recipient, and disease-risk index (DRI) as defined by established criteria.

(MM) "Hospice beds" means the inpatient beds of a hospice care program as defined in division (A) of section 3712.01 of the Revised Code.

(NN) "Hospital" means an institution or facility that provides inpatient medical or surgical services for a continuous period longer than twenty-four hours. "Hospital" includes a children's hospital. "Hospital" does not include:

- (1) A hospital operated by the federal government;
- (2) An ambulatory surgical facility or other health care facility licensed as described in section 3702.30 of the Revised Code;
- (3) A nursing home or residential care facility licensed under Chapter 3721. of the Revised Code;
- (4) A hospital or inpatient unit licensed under section 5119.33 of the Revised Code;
- (5) A residential facility as defined in section 5119.34 of the Revised Code;

- (6) A residential facility as defined in section 5123.19 of the Revised Code;
- (7) A community addiction services provider as defined in section 5119.01 of the Revised Code;
- (8) A facility providing services under a contract with the department of developmental disabilities under section 5123.18 of the Revised Code;
- (9) A facility operated by a hospice care program licensed under section 3712.04 of the Revised Code and that is used exclusively for the care of hospice patients;
- (10) A facility operated by a pediatric respite care program licensed under section 3712.041 of the Revised Code and that is used exclusively for the care of pediatric respite care patients;
- (11) The site where a health care practice is operated, regardless of whether the practice is organized as an individual or group practice;
- (12) A clinic providing ambulatory patient services where patients are not regularly admitted as inpatients;
- (13) An institution for the sick that is operated exclusively for patients who use spiritual means for healing and for whom the acceptance of medical care is inconsistent with their religious beliefs, accredited by a national accrediting organization, exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986, 26 U.S.C. 1, and providing twenty-four-hour nursing care pursuant to the exemption from the licensing requirements of Chapter 4723. of the Revised Code described in division (E) of section 4723.32 of the Revised Code.
- (OO) "Hospital bed" or "bed" means a bed in a hospital with the attendant physical space, fixtures, and equipment for use in caring primarily for inpatients. "Hospital bed" includes beds used in caring for patients who stay for less than twenty-four hours, but the primary use of such beds is for care of inpatients.
- (PP) "Inpatient" means a patient who is admitted to the hospital.
- (QQ) "Inpatient surgical operating room" means a room in a hospital used to perform any operative or manual procedure undertaken for the diagnosis or treatment of a disease or other disorder.
- (RR) "Ionizing radiation" means gamma rays and x-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other atomic or nuclear particles or rays.
- (SS) "Licensee" or "license holder" means the individual, corporation, partnership, board,

association or entity licensed by the director under Chapter 3722. of the Revised Code and rule 3701-22-03 of the Administrative Code to maintain a hospital.

(TT) "Licensed capacity" means the maximum number of patients that the maternity unit, newborn care nursery, or maternity home is authorized to accommodate under its license.

(UU) "Licensed dietitian" means an individual licensed under Chapter 4759. of the Revised Code to practice as a licensed dietitian.

(VV) "Licensed practical nurse" means an individual licensed under Chapter 4723. of the Revised Code to practice nursing as a licensed practical nurse.

(WW) "Linear accelerator" means a medical linear accelerator which provides a collimated beam of electrons or electronically produced x-rays used for radiation therapy treatment.

(XX) "Linear accelerator service" means the structural unit of a hospital which provides radiation therapy or stereotactic radiosurgery using a linear accelerator.

(YY) "Long term acute care hospital", or LTACH, means a hospital that is classified as a long-term care hospital under 42 C.F.R. 412.23(e) (1985), that is engaged primarily in providing medically necessary specialized acute hospital care for medically complex patients who are critically ill or have multi-system complications or failures, and that has an average length of stay of forty-five days or less.

(ZZ) "Long term acute care hospital bed" means a bed in a long term acute care hospital.

(AAA) "Low-risk allogeneic bone marrow transplantation" means fully matched allogeneic sibling donor transplants without any of the high-risk features listed under paragraph (G) of this rule.

(BBB) "Maternity unit" means a distinct portion of a hospital in which inpatient care is provided to women during all or part of the maternity cycle.

(CCC) "Medical/surgical bed" means a hospital bed in a medical or surgical unit where general medical/surgical services are provided.

(DDD) "Neonatal care service" means a newborn care nursery.

(EEE) "Newborn care nursery" means a distinct portion of a hospital in which inpatient care is provided to infants. Newborn care nursery includes a distinct portion of a hospital in which intensive care is provided to infants.

(FFF) "Number of admissions" means the number of patients accepted for inpatient service of twenty-four hours or more, including transfers by a service within the hospital.

(GGG) "Nurse" means either a licensed practical nurse or a registered nurse.

(HHH) "Nursing staff" means registered nurses, licensed practical nurses, and other staff that render care under the supervision of a registered nurse.

(III) "Observation bed" means any other bed within a hospital that is used to evaluate and determine the condition of a patient for possible admission to the hospital as an inpatient.

(JJJ) "Obstetric service" means a maternity unit.

(KKK) "Occupational therapist" means a person licensed to practice occupational therapy pursuant to section 4755.07 of the Revised Code.

(LLL) "On-call" means an individual is capable of being reached by telephone or other electronic device and able to return to the maternity unit or newborn care nursery in accordance with facility policies.

(MMM) "On-duty" means in the maternity unit, newborn care nursery, or maternity home, alert and responsive to patient needs.

(NNN) "On-site" means in the building in which the maternity unit or newborn care nursery is located, or in the case of campus settings, in a nearby building and able to immediately respond to the maternity unit or newborn care nursery.

(OOO) "On-staff" means a member of the formal organization of physicians and other health professionals approved by the governing body with the delegated responsibility to provide for the quality of all medical care, and other health care as appropriate, provided to patients.

(PPP) "Outpatient" means a patient who is not admitted as an inpatient.

(QQQ) "Outpatient bed" means a bed used for the treatment of outpatients in an area of the hospital that provides outpatient services. This does not include beds in those areas listed in division (C) of section 3722.02 of the Revised Code.

(RRR) "Outpatient surgical operating room" means a room in a hospital designed to perform an operative or manual procedure undertaken for the diagnosis or treatment of a disease or other disorder on non-inpatients.

(SSS) "Patient" means any individual who receives care in a hospital, maternity unit, newborn care nursery, or in a health care service.

(TTT) "Patient days of care" means annual total number of inpatients in a hospital on a daily count at a specific uniform time of day.

(UUU) "Patient representative" means either a person acting on behalf of a patient with the consent of the patient or the patient's legal guardian.

(VVV) "Pediatric intensive care unit" or "PICU" or "pediatric intensive care service" means a separate and distinct unit in a hospital where pediatric patients, suffering from critical illness, receive care. "PICU" does not include a neonatal intensive care unit.

(WWW) "Pediatric intensive care beds" means beds located in a separate and distinct pediatric intensive care unit where pediatric patients suffering from critical illness receive care;

(XXX) "Pediatric patient" means any patient less than twenty-two years of age, unless otherwise specified in this chapter.

(YYY) "Pediatric intensivist" means a physician who is board eligible or board certified in pediatric critical care medicine after training in an ACGME-accredited program and participates in training to meet ongoing education and certification requirements for pediatric critical care medicine.

(ZZZ) "Percutaneous coronary interventions" or "PCI," commonly known as coronary angioplasty or simply angioplasty, is a non-surgical procedure used to treat the stenotic (narrowed) coronary arteries of the heart found in coronary heart disease.

(AAAA) "Percutaneous transluminal coronary angioplasty" or "PTCA" means the inflation of a balloon-tipped catheter at the site of a coronary artery stenosis to attempt to enlarge the diameter of the lumen.

(BBBB) "Pharmacist" means an individual registered under Chapter 4729. of the Revised Code to practice pharmacy.

(CCCC) "Physical rehabilitation bed" means a hospital bed that is staffed and equipped for care of inpatients requiring intensive, multi-disciplinary physical restorative services.

(DDDD) "Physical rehabilitation hospital" means a hospital engaged primarily in providing specialized care to inpatients with intensive, multi-disciplinary physical restorative service needs.

(EEEE) "Physical therapist" means a person licensed to practice physical therapy pursuant to section 4755.44 of the Revised Code.

(FFFF) "Physician" means an individual who is licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, or osteopathic medicine and surgery.

(GGGG) "Physician assistant" means a individual who holds a valid certificate to practice issued under Chapter 4730. of the Revised Code to provide services to patients as a physician assistant under the supervision, control, and direction of one or more physicians who are responsible for the physician assistant's performance.

(HHHH) "Political subdivision" means a county, township, municipal corporation, or other body corporate and politic responsible for governmental activities in a geographic area smaller than that of the state.

(IIII) "Provider of a health care service" means a person or governmental entity who assumes legal liability for purposes of compliance with this chapter.

(JJJJ) "Psychiatric care bed" means a hospital bed that is staffed and equipped for care of inpatients whose primary diagnosis in mental illness.

(KKKK) "Psychiatric hospital" means a hospital engaged primarily in providing specialized care to inpatients diagnosed with mental illness.

(LLLL) "Psychologist" means a person licensed to practice psychology pursuant to Chapter 4732. of the Revised Code.

(MMMM) "Radiation oncologist" means a physician who:

(1) Has satisfactorily completed a radiation oncology residency in an accreditation council for graduate medical education or American osteopathic association approved program;

(2) Is certified in radiology by the American board of radiology or the American osteopathic board of radiology and who has had a practice limited to radiation oncology for the ten year period prior to May 1, 1996; or

(3) Is certified in radiation oncology or therapeutic radiology by the American board of radiology, the American osteopathic board of radiology, the royal college of physicians and surgeons of Canada.

(NNNN) "Radiation therapy" means the use of ionizing radiation, including external beam radiation therapy (teletherapy), or intraoperative radiation therapy and radioactive materials for therapeutic administration as authorized on a radioactive materials license issued by the director pursuant to Chapter 3701:1-58 of the Administrative Code in the treatment of human illness.

(OOOO) "Radiation therapy service" means the structural unit of a hospital which provides radiation therapy.

(PPPP) "Registered nurse" means an individual who is licensed under section 4723.09 of the Revised Code to practice as a licensed registered nurse.

(OOOO) "Rural emergency hospital" means a hospital that is certified by the federal government as meeting the conditions of participation in the medicare program under 42 C.F.R. part 485, subpart E (2023).

(RRRR) "Serious harm" means an adverse outcome that results in or is likely to result in any of the following:

(1) Death;

(2) A significant decline in physical, mental, or psychosocial functioning that is not solely due to the normal progression of a disease or aging process;

(3) A loss of limb, or disfigurement;

(4) Avoidable pain that is excruciating, and more than transient; or

(5) Other serious harm that creates life-threatening complications/conditions.

(SSSS) "Social worker" means an individual licensed to practice social work under Chapter 4757. of the Revised Code.

(TTTT) "Special care bed" means a hospital bed in which special medical/surgical services, beyond general medical/surgical care and including intensive care or coronary care, are provided.

(UUUU) "Solid organ transplant service" means the transplantation of heart, lung, liver, kidney, pancreas, small bowel, islet cells, excluding autologous islet cell transplantation, and any and all combinations of such transplanted organs.

(VVVV) "Staff member" or "staff" means the administrator and individuals providing direct care to patients on a full-time, part-time, temporary, contract, or voluntary basis. Staff member or staff does not include volunteers who are family members of a patient.

(WWWW) "State university" has the same meaning as in section 3345.12 of the Revised Code.

(XXXX) "Stereotactic radiosurgery" means the closed-skull destruction of a precisely defined intracranial or extracranial target by beam(s) of ionizing radiation in which the total dose is administered during a single treatment session.

(YYYY) "Stereotactic radiosurgery service" means the structural unit of a hospital which provides stereotactic radiosurgery.

(ZZZZ) "Stereotactic radiotherapy" means the closed-skull destruction of a precisely defined intracranial target by beam(s) of ionizing radiation in which the total dose

of radiation is administered as fractions during multiple treatment sessions.

(AAAAA) "Stillbirth" means that an infant of at least twenty weeks of gestation suffered a fetal death.

(BBBBB) "Total number of beds" means the total number of beds in which patient care may be provided, whether or not the bed is staffed and available. Beds in temporarily closed units are included in the total. Beds that are temporarily unavailable as the result of building renovations are included in the total. A temporary increase in the number of beds in use that is caused by unusually high volumes of admissions is not included in the total, where "temporary increase" means the average daily census exceeds licensed capacity for less than forty-five days in any six month period.

3701-22-02

Applicability of rules.

(A) Until such time a hospital is licensed as a hospital, each hospital:

- (1) With a maternity unit, newborn care nursery, or both, complies with chapter 3701-7 of the Administrative Code;
- (2) With a pediatric intensive care unit complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (3) With a solid organ and bone marrow transplantation service complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (4) With a stem cell harvesting and reinfusion complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (5) With a cardiac catheterization service complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (6) With a open heart surgery service complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (7) That operates linear accelerators complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (8) With a cobalt radiation therapy unit complies with the applicable requirements of chapter 3701-84 of the Administrative Code;
- (9) That operates gamma knives complies with the applicable requirements of chapter 3701-84 of the Administrative Code;

(B) In the event that any chapters of the Administrative Code listed in paragraph (A) of this rule have not been incorporated into this chapter on or before September 30, 2024, each hospital continues to comply with the applicable rules of chapter 3701-7 or chapter 3701-84 of the Administrative Code, as applicable, until such time as the rules are incorporated into this chapter.

3701-22-03

Application for initial, renewal, or transfer licensure; notice to the director; sales, assignments, or transfers.

(A) Application for a license to operate a hospital, renewal of an existing license may be made either in writing on a form provided by the director and signed by the applicant or the applicant's agent, or using an electronic system prescribed by the director and affirmed by the applicant or the applicant's agent. A completed application the following:

(1) A nonrefundable license application or renewal fee based on the number of beds within the hospital as follows:

(a) One to fifty beds, four thousand four hundred twenty five dollars;

(b) Fifty one to one hundred beds, eight thousand eight hundred fifty dollars;

(c) One hundred one to one hundred fifty beds, thirteen thousand two hundred fifty dollars;

(d) One hundred fifty one to three hundred beds, seventeen thousand six hundred seventy five dollars;

(e) Three hundred one to five hundred beds, twenty six thousand five hundred dollars;

(f) Five hundred one to seven hundred fifty beds, thirty five thousand three hundred fifty dollars,

(g) Seven hundred fifty one to one thousand beds, forty four thousand one hundred seventy five dollars;

(h) One thousand one to one thousand five hundred beds, fifty three thousand dollars; or

(i) More than one thousand five hundred beds, sixty one thousand eight hundred fifty dollars;

Any fee paid pursuant to this section may be paid either in full at the time of application, renewal, or transfer, or in increments of one-third of the total amount annually.

(2) A nonrefundable service fee as follows:

(a) For each maternity unit, three thousand dollars;

(b) For each newborn care nursery, three thousand dollars; and

(c) For each health care service, three thousand dollars;

Any fee paid pursuant to this section may be paid either in full at the time of application, renewal, or transfer, or in increments of one-third of the total amount annually.

- (3) The name to appear on the license;
- (4) The address of the main hospital location and the address(es) of each "department of a provider," remote location of a hospital," and "satellite facility" as those terms are defined in 42 CFR 413.65, that provides basic hospital services, outpatient surgical services, or emergency services, to include a designation of any maternity unit, newborn care nursery, or health care service at each location. For purposes of this rule, "outpatient surgical services" does not include office-based surgical services provided at a health care practice to patients of that practice under chapter 4731-25 of the Administrative Code, regardless of whether the practice is organized as an individual or group practice.
 - (a) Entities listed pursuant to this section are operated under the license issued under Chapter 3722 to the hospital that is the "main provider" as that term is defined in 42 CFR 413.65. Only those entities are permitted to be operated under the main hospital's license;
 - (b) Hospitals are to maintain a current list of all provider-based locations and provide that list to the department at the department's request.
- (5) Proof of certification or accreditation, if applicable. For a newly-constructed hospital seeking licensure after October 1, 2024, provide complete an initial application after which the department will issue the hospital a letter of intent to license the hospital.
- (6) A listing of the beds within the hospital, under the following categories:
 - (a) Adult medical/surgical;
 - (b) Adult special care (ICU/CCU);
 - (c) Alcohol or drug abuse rehabilitation;
 - (d) Burn care;
 - (e) Emergency service;
 - (f) Hospice;
 - (g) Long term acute care;

(h) Long term, reported in the following categories:

(i) Skilled nursing facility beds certified under Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981) and which are not licensed under Chapter 3721. of the Revised Code;

(ii) Nursing facility beds certified under Title XIX of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981) and which are not licensed under Chapter 3721. of the Revised Code;

(iii) Nursing facility beds certified under Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981) and Title XIX of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981) and which are not licensed under Chapter 3721. of the Revised Code; or

(iv) Special skilled nursing beds certified as skilled nursing facility beds under Title XVIII of the Social Security Act, 49 Stat. 620 (1935), 42 U.S.C. 301, as amended (1981) that were originally authorized by and are operated in accordance with section 3702.521 of the Revised Code or its predecessor;

(i) Neonatal, reported in the following categories:

(i) Level I;

(ii) Level II;

(iii) Level III;

(iv) Level IV;

(j) Obstetric, reported in the following categories:

(i) Level I;

(ii) Level II;

(iii) Level III, including special delivery beds;

(iv) Level IV, including special delivery beds;

(k) Outpatient;

- (l) Pediatric intensive care (beds in a separate and distinct pediatric intensive care unit where pediatric patients suffering from critical illness receive care);
- (m) Pediatric - general (services for patients less than twenty-two years of age are provided);
- (n) Physical rehabilitation; and
- (o) Psychiatric care.
- (B) If the applicant satisfies the requirements described in paragraph (A) of this rule, the director will, as applicable, issue to the applicant a license to operate a hospital, or renew an applicant's license unless the applicant to renew is barred from renewing in accordance with rule 3701-22-05 of this chapter.
- (C) The license is valid only for the hospital and any department(s) of a provider, remote location(s) of the hospital, and satellite facility(ies) that provide basic hospital services, outpatient surgical services, or emergency services identified in the application.
- (D) The license holder will post a copy of the license in a conspicuous place in the hospital and department(s) of the provider that provides outpatient surgical services or emergency services, remote location(s) of the hospital, and satellite facility, identified in paragraph (A)(4) of this rule.
- (E) Each license issued under this rule is valid for a three-year period unless revoked or suspended. A license expires on the date that is three years from the date of issuance and may be renewed for additional three-year periods.
- (F) The license renewal fee, including one-third payments, specified in paragraph (A) of this rule will be paid not later than sixty days after the director of health mails an invoice for the fee to the license holder. A penalty of ten per cent of the amount of the renewal fee will be assessed for each month the fee is overdue.
- (G) The licensee will notify the director, in writing, within seven days if either of the following occur: of any change in administrator, primary agent, or name of the hospital.

 - (1) A change in administrator, primary agent, or name of the hospital; or
 - (2) The voluntary suspension of operation or closing of the hospital. In the event of involuntary closure, the licensee will provide written notice as soon as possible after learning of the closure.
- (H) The licensee will notify the director, in writing, at least thirty days prior to any

construction, modernization, major acquisition, or significant alteration that:

(1) Adds a department(s) of a provider, remote location(s) of the hospital, or satellite facility(eies) that provide basic hospital services, outpatient surgical services, or emergency services to be operated under the hospital's license;

(2) Adds hospital building(s), replaces hospital building(s), or expands hospital building(s) patient care areas;

(3) Changes the layout of a patient care area of the hospital that involves removing or replacing walls, adding new or extending existing plumbing or electric service, adding new or extending existing heating, ventilation, or air conditioning service; or adding vacuum or gases;

(4) Converts non-patient care area(s) to patient care area(s) that involves removing or replacing walls, adding new or extending existing plumbing or electric service, adding new or extending existing heating, ventilation, or air conditioning service; or adding vacuum or gases.

(I) If a hospital licensed under this chapter is assigned, sold, or transferred to a new operator, at least sixty days prior to the assignment, sale, or transfer, the new operator is:

(1) Obligated to apply for a license transfer and provide the information required by paragraphs (A)(3) to (A)(7) of this rule. For purposes of this paragraph, a change in the majority ownership of a person licensed to operate a hospital is a change of operator;

(2) Responsible for compliance with any action taken or proposed by the director under sections 3722.07 or 3722.08 of the Revised Code, or rule 3701-22-05 of this chapter. If a notice has been issued under section 119.07 of the Revised Code, the new operator becomes party to the notice.

3701-22-04

Prohibitions.

(A) Upon licensure as a hospital by the director of health or September 30, 2024, whichever is sooner, no person and no political subdivision, agency, or instrumentality of this state may operate a hospital without holding a license issued by the director of health under section 3722.03 of the Revised Code.

(B) If the director of health determines that a hospital is operating without a license in violation of chapter 3722. of the Revised Code or this chapter, the director may do any of the following:

(1) Notify the hospital that it is operating without a license and provide it with an opportunity to apply for licensure, but only within the thirty-day period beginning on the date the hospital received the director's notice;

(2) Direct the hospital to cease operations;

(3) Impose a civil penalty of not more than two hundred fifty thousand dollars;

(4) In addition to the imposition of a civil money penalty, impose a penalty of not less than one thousand dollars and not more than ten thousand dollars for each day the hospital operates without a license.

(C) If the hospital described in section (B) of this rule continues to operate without a license, the director may petition the court of common pleas of the county in which the hospital is located for an order enjoining the hospital from operating.

(D) No person and no political subdivision, agency, or instrumentality of this state may:

(1) Interfere with an inspection or investigation of a hospital, maternity unit, or health care service. As used in this paragraph, "interfere" means to obstruct directly or indirectly any individual conducting an authorized inspection or investigation from carrying out his or her duties, including:

(a) Harassment;

(b) Intimidation;

(c) Refusal to permit the director upon presentation of official department identification, to inspect or investigate the operation of a hospital, maternity unit, or health care service; or

(d) Refusal to permit the director upon presentation of official department identification to enter and inspect records that are kept concerning the operations of the hospital, maternity unit, or health care service, for information necessary to determine compliance with the applicable rules of this chapter.

(2) Materially misrepresent any information provided to the director pursuant to chapter 3722. of the Revised Code and this chapter

(E) Nothing in this chapter is to be construed as authorizing individuals to provide services outside their licensed scope of practice.

3701-22-05

Inspections; compliance actions.

(A) The director of health monitors compliance with Chapter 3722. of the Revised Code and Chapter 3701-22 of the Administrative Code. The director may at any time inspect a licensed hospital in order to address an incident that may impact public health, respond to a complaint submitted to the director, or otherwise ensure the safety of patients cared for by the hospital. Inspections may be scheduled and announced or random and unannounced.

(B) If the director determines the existence of a violation of any provision of Chapter 3722. of the Revised Code or Chapter 3701-59 of the Administrative Code, the director may do any of the following:

(1) Request the licensee to submit an acceptable plan of correction to the director stating the actions being taken or to be taken to correct a violation, the time frame for completion and the means by which continuing compliance will be monitored; and

(2) In accordance with Chapter 119. of the Revised Code:

(a) Impose a civil penalty based on the severity of the violation as follows:

(i) For violations that present an imminent threat of serious physical or life threatening danger, or an immediate serious threat to the health, safety or security of one or more patients, a civil penalty of not less than one hundred thousand dollars and not more than two hundred thousand dollars, not including per day civil penalties for ongoing violations;

(ii) For violations that directly health, safety, or security of one or more patients, a civil penalty of not less than ten thousand dollars and not more than one hundred thousand dollars, not including per day civil penalties for ongoing violations; or

(iii) For violations that indirectly threaten or potentially threaten the health, safety, or security of one or more patients, a civil penalty of not less than one thousand dollars and not more than ten thousand dollars, not including per day civil penalties for ongoing violations;

The director will impose a civil penalty of one thousand dollars per day for each day the director determines a violation is ongoing.

(b) Suspend a health care service or revoke the hospital's license, in accordance with paragraph (D)(3) of this rule, if the director believes that there is clear and convincing evidence that the continued operation of the hospital, maternity unit, newborn care nursery, or

health care service unit present a danger of immediate and serious harm to patients or residents. The director will provide the hospital with written notice of the proposed action actions the hospital that specifies the:

(i) Nature of the conditions giving rise to the director's judgment;

(ii) Measures that the director determines the hospital must take to respond to the conditions;

(iii) Date, which will be not later than thirty days after the notice is delivered, on which the director intends to suspend the health care service or revoke the hospital's license if the conditions are not corrected and the director determines that the license holder has not come into substantial compliance;

(C) In determining whether a violation warrants a civil money penalty, the director may consider all of the following:

(1) The number of patients directly affected by the violation;

(2) The number of hospital staff involved in the violation;

(3) Any actions taken by the hospital to correct or mitigate the violation, including the timeliness and sufficiency of the hospital's response to the violation and the outcome of that response; and

(4) The hospital's history of compliance.

(D) If the director determines the need for a civil money penalty under this rule, the director may enter into settlement negotiations with the affected hospital. Settlements may include any or all of the following:

(1) A lesser civil money penalty than initially proposed;

(2) Allowing the hospital to invest an amount equal to the proposed civil penalty on remedial measures designed to reduce the likelihood of similar violations occurring in the future. Unless authorized by the director, such remedial measures must be conducted or undertaken by a third party; or

(3) Other penalties warranted by the deficient practice and negotiations.

(E) If the director suspends a health care service or revokes the license of a hospital under paragraph (B)(2)(b) of this rule, the director will issue a written order of suspension or a revocation, as applicable, and cause it to be delivered by certified mail or in person in accordance with section 119.07 of the Revised Code. The order is not subject to suspension by the court while an appeal filed under section 119.12 of the

Revised Code is pending. If the license holder subject to the suspension or revocation requests an adjudication, the date set for the adjudication will be within seven days after the license holder makes the request, unless another date is agreed to by both the license holder and the director. The suspension of the health care service or revocation of a hospital's license will remain in effect, unless reversed by the director, until a final adjudication order issued by the director pursuant to this chapter and Chapter 119. of the Revised Code becomes effective. The director will issue a final adjudication order not later than fourteen days after completion of the adjudication. If the director does not issue a final order within the fourteen-day period, the suspension or revocation is void, but any final adjudication order issued subsequent to the fourteen-day period is not affected.

(F) During the period specified in paragraph (B)(2)(b)(iii) of this rule, the hospital may, without staying the proceedings, notify the director that the conditions giving rise to the director's determination have been corrected and that the hospital is in substantial compliance with section 3722. of the Revised Code and this chapter, the director shall conduct an inspection. Based on this inspection, if the director determines that the conditions have not been corrected and the license holder has not come into substantial compliance, the director may suspend the health care service or revoke the license.

(G) If the licensed hospital fails to notify the director, within the period of time specified in paragraph (B)(2)(b)(iii) of this rule, that the conditions giving rise to the director's determination have been corrected and that the hospital is in substantial compliance with this chapter and shall not be affected, the director may suspend the health care service or revoke the license.

(H) If the director issues a final adjudication order suspending a health care service or suspending or revoking a license issued under this chapter and the license holder continues to operate a hospital, the director may ask the attorney general to apply to the court of common pleas of the county in which the hospital is located for an order enjoining the license holder from operating the hospital.

3701-22-06

Administration.

Each hospital, other than a critical access hospital or a rural emergency hospital, is to provide effective administration responsible for the following areas:

(A) Compliance with federal, state, and local laws, in accordance with 42 CFR 482.11 (as in effect the effective date of this rule), including cooperation with any public health investigation;

(B) Governing body, in accordance with 42 CFR 482.12 (as in effect the effective date of this rule);

(C) Patient's rights, in accordance with 42 CFR 482.13 (as in effect the effective date of this rule);

(D) Emergency preparedness, in accordance with 42 CFR 482.15 (as in effect the effective date of this rule).

3701-22-07

Basic hospital functions.

Each hospital, other than a critical access hospital or a rural emergency hospital, is to provide for the following:

(A) A quality assessment and performance improvement program, in accordance with 42 CFR 482.21 (in effect on the effective date of this rule). In addition, the hospital will participate in quality assessment and performance improvement projects identified by the director in consultation with the representatives of the regulated industry. Such projects may include those:

(1) Required by the United States centers for medicare and medicaid services or the hospital's accrediting organization; or

(2) For a hospital with a maternity unit and newborn care nursery, implementation of one or more maternal safety bundle(s) developed by the alliance for innovation in maternal health.

(B) The director may establish regional hospital zones to respond to public health events, outbreaks of disease, or similar incidents, as well as ongoing public health considerations resulting from those events. Such zones may include health care providers, including but not limited to, hospitals, nursing homes, residential care facilities, home health agencies, and hospice care programs.

(C) Medical staff, in accordance with 42 CFR 482.22 (in effect on the effective date of this rule);

(D) Nursing services, in accordance with 42 CFR 482.23 (in effect on the effective date of this rule);

(E) Medical records services, in accordance with 42 CFR 482.24 (in effect on the effective date of this rule);

(F) Pharmaceutical services, in accordance with 42 CFR 482.25 (in effect on the effective date of this rule);

(G) Radiologic services, in accordance with 42 CFR 482.26 (in effect on the effective date of this rule);

(H) Laboratory services, in accordance with 42 CFR 482.27 (in effect on the effective date of this rule);

(I) Food and dietetic services, in accordance with 42 CFR 482.28 (in effect on the effective date of this rule);

(J) Utilization review, in accordance with 42 CFR 482.30 (in effect on the effective date of this rule);

3701-22-07

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(K) Physical environment, in accordance with 42 CFR 482.41 (in effect on the effective date of this rule):

(L) Infection prevention and control and antibiotic stewardship programs, in accordance with 42 CFR 482.42 (in effect on the effective date of this rule). In addition, the hospital will:

(1) Maintain and implement a tuberculosis control plan that is based on the facility's assessment of the facility and consistent with the United States centers for disease control and prevention "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005." MMWR 2005, Volume 54, No. RR-17 and "Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and Centers for Disease Control and Prevention, 2019," MMWR May 17, 2019, 68(19):439-44;

(2) A written surveillance plan outlining the activities for monitoring/tracking infections based on nationally-recognized surveillance criteria such as the CDC's national healthcare safety network (NHSN) criteria to define infections or other nationally recognized system for hospitals and:

(a) Includes a surveillance system that includes a data collection tool; and

(b) Uses surveillance data to timely corrective actions when:

(i) A greater than expected number healthcare-associated infections are detected;

(ii) Transmission of targeted multi-drug resistant organisms (e.g., cre, candida auris) are detected;

(3) Establish and implement an effective water management program to identify hazardous conditions, and take steps to manage the risk of occurrence and transmission of waterborne pathogens, including but not limited to legionella, in building water systems in accordance with guidance from the United States centers for disease control and prevention (available at <https://www.cdc.gov/legionella/wmp/toolkit/index.html>) and recommendations of the United States centers for disease control and prevention healthcare infection control practices advisory committee, "Environmental Infection Control Guidelines" (2019). An effective water management program includes:

(a) Establishing a water management program team that includes representatives from the facility or engaged by the facility necessary to ensure comprehensive and complete actions are implemented to reduce and manage the risk of legionella and other waterborne pathogens in the

building water systems:

(b) A written water management plan, update annually or when changes are made to the potable water system, which includes all components as identified by the United States centers for disease control and prevention; and

(c) At least twice-yearly validation testing in the building water system for a set of water samples that is representative of all hot potable water loops and water sources based upon the risk assessment and conditions identified in the water management plan, including but not limited to cooling towers, therapy spas, decorative fountains or water features where exposure to aerosols may occur to evaluate the performance of the water management program in controlling legionella risk or other waterborne pathogens. A hospital with a continuous secondary disinfection system that has demonstrated detections of less than one cfu/ml of legionella through at least four prior validation test sets collected over a two year period may conduct annual validation testing in lieu of twice-yearly testing. Validation testing includes all of the following:

(i) At least one cold water sample obtained from the incoming water mains from the public water system or the water source;

(ii) At minimum, representative samples obtained from distal and proximal locations on each hot water loop on the hot water distribution system; and

(iii) Measurement of total or free chlorine residual, as appropriate, at the time of sample collection, and the observed sustained maximum temperatures for cold and hot water samples;

Collection of water samples under this paragraph will conform to the United States centers for disease control and prevention's guidance documents "Sampling Procedure and Potential Sampling Sites" (2019), except samples collected may be less than one liter in volume. Collected samples are to be analyzed at a laboratory that has been accredited by a national or international accrediting body according to national or international recognized standards, that has legionella culture testing included in the laboratory's scope of accreditation.

(4) As it relates to waterborne pathogens, coordinate with the Ohio department of health and the local health district having jurisdiction when there is a legionellosis presumptive healthcare-associated case, there are two or more legionellosis possible healthcare-associated cases in a twelve-month period.

or when an legionellosis outbreak occurs. When an investigation is required, investigation activities are coordinated with the disease surveillance and recommendations in the Ohio department of health's "Infectious Disease Control Manual" (2022), available online at <https://odh.ohio.gov/know-our-programs/infectious-disease-control-manual>, and includes any or all of the following:

(a) Implementing water use restrictions and/or installation of absolute 0.2 micron biological United States food and drug administration-approved point of use filters on potable hot water fixtures throughout the facility as appropriate or where separate water loops are present and can be isolated within the facility, in locations where the legionellosis case or cases resided, or received treatment or services while in the facility, or otherwise may have been exposed to aerosols from the hot water system or other water features. A hospital with a continuous secondary disinfection system that has demonstrated detections of less than one cfu/ml of legionella through validation testing and control measures specified in the water management plan, may, after consultation of the Ohio department of health and the local health district having jurisdiction, avoid installation of point of use water filters;

(b) Conducting or updating an environmental facility assessment using the United States centers for disease control and prevention's "Legionella Environmental Assessment Form", available online at <https://www.cdc.gov/legionella/downloads/legionella-environmental-assessment-p.pdf>, or equivalent assessment, for the facility to identify risk conditions that may promote the growth of Legionella or other waterborne pathogens;

(c) Providing a copy of the water management plan and at least one year of prior validation testing results to the Ohio department of health and the health district having jurisdiction;

(d) Identification and collection of a set of water samples that is representative of all potable water loops and water sources associated with the investigation, including but not limited to cooling towers, therapy spas, decorative fountains or water features where exposure to aerosols may occur. Water sample testing includes:

(i) At least one cold water sample will be obtained from the incoming water mains from the public water system or the water source;

(ii) Representative samples obtained from a minimum of distal and proximal locations on each floor of each hot water loop on the hot water distribution system, including hot water storage tanks or storage units when present, both a swab or first draw sample, and a bulk water sample from the fixture or location;

(iii) A sample or samples from locations in the hot water system or water features where the legionellosis case or cases resided, or received treatment or services while in the facility, or otherwise may have been exposed to aerosols from the hot water system or other water features;

(iv) Measurement of total and free chlorine residual, as appropriate, at the time of sample collection, and the observed sustained maximum temperatures for cold and hot water samples.

Collection of water samples under this paragraph will conform to the United States centers for disease control and prevention's guidance document "Sampling Procedure and Potential Sampling Sites" (2019), to include collection of one liter samples, and "CDC Laboratory Guidance for Processing Environmental Samples" (2005), respectively, with collected samples to be analyzed at a laboratory that has been accredited by a national or international accrediting body according to national or international recognized standards, that has legionella culture testing included in the laboratory's scope of accreditation, and that has demonstrated proficiency in the detection of legionella culture in accordance with the United States centers for disease control and prevention environmental legionella isolation techniques evaluation program.

(v) Preservation and provision of all cultured water and swab samples with observed Legionella cultures that were collected during an investigation of a case or outbreak to the Ohio department of health's public health laboratory for potential comparison against clinically cultured samples.

(e) Implementation of identified actions to correct the risk conditions identified as part of the environmental facility assessment, and environmental water testing results, which may include but not be limited to:

(i) Adjustments to hot water temperatures in storage tanks or circulation systems;

(ii) Correction of areas of poor water flow or stagnation;

(iii) Conducting short-term remediation; or

(iv) Installing permanent disinfection systems;

(f) Provision of appropriate communications to patients, employees, and

visitors regarding the investigative and corrective actions to help reduce risk of further exposures;

(g) After remediation actions are completed, or permanent disinfection is installed, collection of the same sample locations and types as set forth in paragraph (K)(6)(d) of this rule as follows:

(i) The first sample set, at least 48 hours after remediation actions have ceased; and

(ii) For the second and subsequent sample sets, after at least ten days have elapsed since the last sample collection date;

All sample results collected under this paragraph are to be reported to both the Ohio department of health and the local health district having jurisdiction.

(h) Obtaining the concurrence of the Ohio Department of Health and the local health district having jurisdiction, on lifting of water restrictions or removal of point of use water filters from fixtures when all water or swab samples have legionella detections of less than 1 colony forming unit per milliliter for potable water

(i) Flushing of all hot water distribution systems and fixtures after water restrictions are lifted and/or point of use water filters are removed; and

(j) Revising the hospital's water management program or plan based on the full investigations results and the recommendations of the Ohio Department of Health and the local health district.

(5) Coordinate with the Ohio department of health and the local health district having jurisdiction to implement as appropriate, sections (K)(6)(b) through (K)(6)(f) of this rule when a possible healthcare-associated waterborne pathogen case has occurred at the hospital.

(M) Discharge planning, in accordance with 42 CFR 482.43 (in effect on the effective date of this rule); and

(N) Organ, tissue, and eye procurement, in accordance with 42 CFR 482.45 (in effect on the effective date of this rule).

3701-22-08

Optional hospital functions.

Each hospital, other than a critical access hospital which may provide these services under rule 3701-22-09 of this chapter, may provide for any or all the following:

(A) Surgical services, in accordance with 42 CFR 482.51 (in effect on the effective date of this rule);

(B) Anesthesia services, in accordance with 42 CFR 482.52 (in effect on the effective date of this rule);

(C) Nuclear medicine services, in accordance with 42 CFR 482.53 (in effect on the effective date of this rule);

(D) Outpatient services, in accordance with 42 CFR 482.54 (in effect on the effective date of this rule);

(E) Emergency services, in accordance with 42 CFR 482.55 (in effect on the effective date of this rule);

(F) Rehabilitation services, in accordance with 42 CFR 482.56 (in effect on the effective date of this rule);

(G) Respiratory services, in accordance with 42 CFR 482.57 (in effect on the effective date of this rule); or

(H) Special requirements for hospital providers of long-term care services ("swing-beds"), in accordance with 42 CFR 482.58 (in effect on the effective date of this rule).

3701-22-09

Critical access hospitals.

Each critical access hospital is to comply with 42 CFR 485 subpart F (in effect on the effective date of this rule). In addition, each critical access hospital will:

- (A) Participate in quality assessment and performance improvement projects identified by the director in consultation with the representatives of the regulated industry. Such projects may include those required by the United States centers for medicare and medicaid services or the hospital's accrediting organization.
- (B) The director may establish regional hospital zones to respond to public health events, outbreaks of disease, or similar incidents, as well as ongoing public health considerations resulting from those events. Such zones may include health care providers, including but not limited to, hospitals, nursing homes, residential care facilities, home health agencies, and hospice care programs.
- (C) Meet the infection control and waterborne pathogen provisions sets forth in paragraphs (L)(1) to (L)(6) of rule 3701-22-07 of this chapter.
- (D) Cooperate with any public health investigation.

3701-22-10

Rural emergency hospitals.

Each rural emergency hospital is to comply with 42 CFR 485 subpart E (in effect on the effective date of this rule). In addition, each rural emergency hospital is to:

- (A) Participate in quality assessment and performance improvement projects identified by the director in consultation with the representatives of the regulated industry. Such projects may include those required by the United States centers for medicare and medicaid services or the hospital's accrediting organization.
- (B) The director may establish regional hospital zones to respond to public health events, outbreaks of disease, or similar incidents, as well as ongoing public health considerations resulting from those events. Such zones may include health care providers, including but not limited to, hospitals, nursing homes, residential care facilities, home health agencies, and hospice care programs.
- (C) Meet the infection control and waterborne pathogen provisions sets forth in paragraphs (L)(1) to (L)(6) of rule 3701-22-07 of this chapter.
- (D) Cooperate with any public health investigation.

*** DRAFT - NOT YET FILED ***

3701-22-11

Quality assurance and patient health and safety.

The director will work with representatives of the regulated industry to determine reporting requirements that help to assure quality and patient health and safety within the hospital. Reporting requirements for quality and patient health and safety are subject to any state or federal privacy laws or regulations.

*** DRAFT - NOT YET FILED ***

3701-22-12

Annual report.

(A) Until September 30, 2024, each hospital is obligated to continue reporting information annually to the director in accordance with chapter 3701-59 of the Administrative Code.

(B) The Ohio department of health will work with the regulated industry to develop new annual reporting requirements for hospitals to report to the department after September 30, 2024.

*** DRAFT - NOT YET FILED ***

3701-22-13

Data collection.

After consultation with representatives of the regulated industry, the director may require hospitals to submit data in areas including performance, quality, or other agreed upon areas.

3701-22-15

Variances; waivers.

- (A) The director may grant a variance or waiver from any requirement established by Chapter 3701-22 of the Administrative Code, unless the requirement is mandated by statute.
- (B) Written requests by a hospital seeking a variance or waiver should include the following information:
- (1) The specific nature of the request and the rationale for the request;
 - (2) The specific building or safety requirement in question, with a reference to the relevant administrative code provision;
 - (3) The time period for which the variance or waiver is requested;
 - (4) If the request is for a variance, a statement of how the hospital will meet the intent of the requirement in an alternative manner; and
 - (5) If the request is for a waiver, a statement regarding why application of the requirement will cause undue hardship to the hospital and why granting the waiver will not jeopardize the health and safety of any patient.
- (C) Upon written request of the hospital the director may grant:
- (1) Request additional information from the hospital seeking a variance or waiver;
 - (2) Grant a variance if the director determines that the requirement has been met in an alternative manner; or
 - (3) Grant a waiver if the director determines that the strict application of the license requirement would cause an undue hardship to the hospital and that granting the waiver would not jeopardize the health and safety of any patient.
- (D) The director may stipulate a time period for which a variance or a waiver is to be effective and may establish conditions that the hospital must meet for the variance or waiver to be operative. Such time period may be different than the time period sought by the hospital in the written variance or waiver request.
- (E) The director may establish conditions that the hospital must meet for the variance or waiver to be operative. The director may, in the director's discretion, rescind the waiver or variance at any time upon determining that the hospital is not meeting such conditions.
- (F) The refusal of the director to grant a variance or waiver, in whole or in part, shall be final and shall not be construed as creating any rights to a hearing under Chapter 119. of the Revised Code.

(G) The granting of a variance or waiver by the director does not constitute a precedent for the granting of any other variance or waiver. All variance and waiver requests will be considered on a case-by-case basis.



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

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

Rule Contact Name and Contact Information:

Jayson Rogers, (614) 752-9156

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

Chapter 3701-22, Hospital Licensing

Rule Number(s): 3701-22-01 to 3701-22-13, 3701-22-15

Date of Submission for CSI Review: July 25, 2023

Public Comment Period End Date: August 24, 2023

Rule Type/Number of Rules:

New/ rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ rules (FYR?)

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.**

Please include the key provisions of the regulation as well as any proposed amendments.

Hospitals provide acute medical care to many Ohioans, yet they have not been subject to overall state licensing¹. This will change beginning September 30, 2024, where, pursuant to Substitute House Bill number 110, hospitals in Ohio will be required to be licensed by the Ohio Department of Health. As such, the Ohio Department of Health worked with hospitals and their industry representatives for over a year to develop rules to appropriately regulate hospitals in Ohio.

ODH's recommended new rules are set forth as follows:

Rule 3701-22-01

This rule contains the definitions for terms used in chapter 3701-22 of the Administrative Code. These include definitions brought in from current Chapters 3701-07

¹ Some specific parts of a hospital have had licensing for that specific part, such as maternity/newborn units and where health care services are provided. These licenses will now become part of the overall hospital license.

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(maternity/newborn), 3701-59 (hospital registration), and 3701-84 (health care services) of the Administrative Code, as well as rule developed from industry standards. These definitions are applicable to the entirety of Chapter 3701-22 of the Administrative Code.

Rule 3701-22-02

This rule sets forth the applicability of Chapter 3701-22. This rule, given that hospitals have until September 30, 2024, allows for hospitals to continue operating by meeting existing rules related to hospital registration, maternity/newborn units, and health care services, as applicable. Once the hospital licensing rules are in place, the rule provides hospitals with maternity/newborn units, and health care services, as applicable, must meet upon licensing as a hospital.

Rule 3701-22-03

This rule sets forth the requirements for initial, renewal, and transfer applications. The rule proposes a main licensing fee based on the number of beds within the hospital, and an additional fee(s) that is based on the number of maternity/newborn units and/or health care services provided by the hospital. The fees are structured so that ODH's work related to hospital licensing, including any required on-site inspection, is covered without the need to charge an additional inspection fee.

The rule requires the hospital to identify any additional locations of the hospital, but only to department of a hospital, a remote location of a hospital, and satellite facilities where certain services are provided that will be captured under the hospital's license. Additionally, the hospital is required to report the type and number of beds, and to identify and maternity/newborn units and/or health care services at the main hospital and any remote locations, if applicable.

The rule also requires notice to the Director of Health prior to when being used for patient care, opening a new location, adding a building(s), replacing a building(s), or expanding a building's patient care areas; when changing the layout of a patient care area of the hospital; and when converting non-patient care areas to patient care areas.

3701-22-04

This rule sets forth prohibitions against operating a hospital without a license, as well as interfering with an inspection of a hospital or material misrepresenting information to ODH.

3701-22-05

This rule allows for inspections of hospitals by ODH to address an incident that may impact public health, respond to a complaint submitted to the director, or otherwise ensure the safety of patients cared for by the hospital.

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This rule also sets forth ODH's ability to - when a violation of Chapter 3722. of the Revised Code has occurred - take enforcement action(s) against a hospital that is not in compliance. These actions include requiring a plan of correction to address the deficiency; imposition of civil money penalties based on the nature and seriousness of the deficiency; or suspension of a hospital's license.

The rule contains requirements for the director to consider when choosing a civil money penalty, and allowance for a settlement when a civil money penalty is proposed.

Rule 3701-22-06

This rule contains requirements related to the effective administration of the hospital, including compliance with applicable federal, state, and local laws, that the hospital have a governing body, that the hospital be responsible for patients' rights, as well as emergency preparedness.

In accordance with input from the regulated industry, these rules incorporate existing federal hospital requirements from 42 CFR 482.

Rule 3701-22-07

This rule establishes the basic hospital functions for all hospitals other than critical access hospitals. The rule requires hospitals to provide for a quality assessment and performance improvement program; the establishment of regional hospital zones to respond to public health events and/or outbreaks or disease; and requirements related to various services within the hospital, such as the medical staff, the nursing staff, and pharmaceutical services, among others.

In accordance with input from the regulated industry, these rules incorporate existing federal hospital requirements from 42 CFR 482; however, ODH has expanded the infection control and protection to require a tuberculosis plan, a surveillance plan for healthcare associated infections and multi-drug resistant organism, and a water management plan to help manage the risk and transmission of waterborne pathogens, such as *legionella* in the building water system(s).

Rule 3701-22-08

This rule establishes those services that a hospital can elect to provide, such as surgical, outpatient, and emergency services. Hospitals that elect to provide these optional services must then follow the applicable regulations for those services, which, at the request of the regulated industry, incorporates by reference applicable provisions of 42 CFR 482.

3701-22-09

This rule establishes requirements for critical access hospitals. Critical access hospitals are generally small (under 25 beds) hospitals in rural areas that are intended to provide short-

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term acute and emergency care to rural residents. There are currently 32 critical access hospitals in Ohio.

At the request of the regulated community, provisions for 42 CFR 482 applicable to critical access hospitals have been incorporated by reference, with expansion of requirements:

- To participate in quality assessment and performance improvement projects;
- Allows the director to establish regional hospital zones;
- Related to infection control and waterborne pathogens; and
- Cooperation with any public health investigation.

Rule 3701-22-11

This rule establishes requirements for rural emergency hospitals. Rural emergency hospitals are generally small hospitals in rural areas that are intended to provide care with a length of stay not to exceed 24 hours and emergency care to rural residents. This will allow hospitals in rural areas to apply to CMS to become rural emergency hospitals.

At the request of the regulated community, provisions for 42 CFR 482 applicable to rural emergency hospitals have been incorporated by reference, with expansion of requirements:

- To participate in quality assessment and performance improvement projects;
- Allows the director to establish regional hospital zones;
- Related to infection control and waterborne pathogens; and
- Cooperation with any public health investigation.

Rule 3701-22-11

This rule establishes ODH's intent to work with the regulated industry to develop reporting requirements related to patient care and safety to go into effect after October 1, 2024.

Rule 3701-22-12

This rule establishes ODH's intent to work with the regulated industry to develop annual reporting requirements to go into effect after October 1, 2024. The rule requires hospitals to continue reporting information under current chapter 3701-59 of the Administrative Code until new reporting requirements are developed.

Rule 3701-22-13

This rule establishes ODH's intent to work with the regulated industry to develop data reporting requirements in agreed-upon areas to determine areas within hospitals that can be assisted with a technical assistance program developed by ODH.

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Rule 3701-22-13

This rule establishes the process through which a hospital may request a waiver or variance from a regulatory requirement.

- 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.**

ORC § 3722.06

- 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?**

If yes, please briefly explain the source and substance of the federal requirement.

No.

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

Not applicable.

- 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)?**

The Department of Health is required (RC § 3722.06) to set forth regulations governing hospitals, including establishing health, safety, welfare, and quality standards. These rules serve to protect the health and safety of Ohioans who need hospitals services.

- 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. This process is generally conducted once every twelve months. Successful outcomes would be indicated by a finding of compliance with the Chapter 3701-22 requirements. 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?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Not applicable.

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Development of the Regulation

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

If applicable, please include the date and medium by which the stakeholders were initially contacted.

Stakeholders were contacted by email in April, 2022 and virtual stakeholder meetings were held on May 16, 2022, and May 18, 2022. Each session had over 100 participants, including:

Ohio Hospital Association
Ohio Children's Hospital Association
The Ohio State University Wexner Medical Center
Cleveland Clinic
University Hospitals Health System
Licking Memorial Hospital
Mercy Health
Ohio Health
Mount Carmel Health System
Kettering Health
Nationwide Childrens Hospital
Southeastern Ohio Regional Medical Center
Joint Township District Memorial Hospital
Universal Health Services

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

Stakeholders provided significant input to nearly every rule and these draft rules reflect the groups comments and suggestions.

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?

Scientific data related to infection control and waterborne pathogens was utilized to develop regulations in those areas.

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?

ODH did not consider any alternatives to the proposed regulation. ODH is required to implement section 3722.06 of the Revised Code. These rules reflect the current statutory requirement for licensing of hospitals.

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

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Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Performance-based regulations were not deemed appropriate for this rule set. ODH is required to implement section 3722.06. of the Revised Code. Rules 3701-22-01 to 3701-22-13 contain both structural (process) and performance (outcome) based requirements through incorporation by reference of existing federal requirements in this area. When there is a poor outcome, ODH can then look to ensure that processes were implemented correctly and can identify breakdowns in the processes that lead to those poor outcomes.

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 acute care, crucial access, or rural emergency hospitals. Where there are currently statutes and rules in place – namely those regarding maternity units, newborn care nurseries, and health care services – those will end September 30, 2024 and the regulations will be folded in Chapter 3701-22.

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.

Hospitals will be subject to joint state/federal surveys when directed by the Centers for Medicare and Medicaid Services. Parts of the hospital, such as maternity/newborn units and health care services, will be surveyed every three years, to determine compliance with the regulations. The survey will be done by non-long term care program staff using a standard survey tool. This staff will have been trained in the survey process, including understanding of the regulation(s).

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; and

All hospitals in Ohio.

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

In general, these rules do not represent costs that are independent of those already obligated to the licensee by the virtue of their participation in the industry. Those costs include, but are not limited to, the costs associated with the purchase or lease of real estate, equipment,

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and personnel. There are also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assurance 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.

The adverse impact of these rules as a whole consists of license suspension, denial, or revocation, as well as civil money penalties. Individual rules have additional adverse impacts, including application fee, reporting, recordkeeping, as well as time completing and submitting required forms to ODH.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Compliance with these rules may require:

(1) Triennial application fees based on the number of beds and whether the hospital provides for maternity/newborn care and/or health care services.

- 1-50, \$4425.00
- 51-100, \$8850.00
- 101-150, \$13250.00
- 150-300, \$17675.00
- 301-500, \$26700.00
- 501-750, \$35350.00
- 751-1000, \$44175.00
- 1001-1500, \$53000.00
- >1500, \$61850.00

(2) A service fee as follows:

- For each newborn care nursery, or maternity unit or health care service, \$3000.00

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(3) Filing of initial/renewal license applications with ODH may require four (4) to eight (8) hours of work by Medical and Health Service Manager.¹

(6) Time to read the rules; up to one (4) hours for applicable portions of the Chapter.¹

¹ 11-9111, Medical And Health Services Manager: An average of \$62.22 per hour.*

*Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2021, using the code for Medical and Health Services Managers (11-9111) working in general medical and surgical hospitals.

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

Section 3722.06 requires ODH to establish rules regarding the licensure of hospitals. These rules establish those licensing requirements for hospitals to help ensure that quality care is provided. Additionally, in accordance with 3722.06(B)(4) and (C)(1), these fees are limited to what is necessary to support hospital inspections and licensure.

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. The requirements for a waiver or variance are set forth in rule 3701-22-15 and are determined on a case-by-case basis.

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 Office of General Counsel 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/about-us/offices-bureaus-and-departments/ogc/Statement-on-Paperwork-Violations>.

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

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The agency maintains program staff that can assist and provide guidance to licensees through the Bureaus of Regulatory Operations and Survey and Certification.

<https://odh.ohio.gov/know-our-programs/hospitals/hospitals>

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