

# Hospital Licensure Enforcement in Ohio: Inspections, Plans of Correction, Penalties, and Appeals

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# Presented by



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# Our Agenda

- Overview
- Hospital Licensure Statutes and Regulations
- Important Forms
- Recent Experiences with ODH Surveys
- Penalties & Plans of Correction
- Chapter 119 Appeals – Theory and Practice
- Practical Considerations with Appeals of ODH Penalties/Orders
- Questions/Contact Info

# Overview of Hospital Licensure

## A Quick Look Back

- Two years into Ohio licensure
- ORC 3722.02 – Hospital license requirement

*(B) Beginning on September 30, 2024, no person and no political subdivision, agency, or instrumentality of this state shall operate a hospital without holding a license issued by the director of health . . . .*

# Ohio *had* been the only state that did not license hospitals.

## A Quick Look Back

- Previously, Ohio only required registration.
- Governor DeWine supported licensure.
- H.B. 110 – the 134th General Assembly’s Budget Bill for TY 2022-2023.
  - Hospital licensure codified in Chapter 3722 of the Ohio Revised Code.
  - ODH promulgated rules governing hospital licensure and enforcement under Chapter 3701-22 of the Ohio Administrative Code.
- September 30, 2024 deadline.

# Hospital Licensure Statutes

## ORC Chapter 3722

- Section 3722.01 | Definitions.
- Section 3722.02 | Hospital license requirement; exemptions.
- Section 3722.03 | Applications for licensure.
- Section 3722.04 | License transfer.
- Section 3722.05 | Inspections.
- Section 3722.06 | Rules.
- Section 3722.07 | Enforcement.
- Section 3722.08 | Imminent threat of harm.
- Section 3722.09 | Technical assistance.
- Section 3722.10 | Hospital governing board.
- Section 3722.11 | Reporting - opioid dependent newborns.
- Section 3722.12 | Reporting - diseases, illnesses, conditions, etc.
- Section 3722.13 | Fees.
- Section 3722.14 | Transition to 9/30/2024 hospital license requirement.
- Section 3722.99 | Penalty for operating without a license.

# Hospital Licensure Rules

Rule 3701-22-01 | Definitions.

Rule 3701-22-02 | Applicability of rules.

Rule 3701-22-03 | Application for initial, renewal, or transfer

Rule 3701-22-04 | Prohibitions.

Rule 3701-22-05 | Inspections; compliance actions.

Rule 3701-22-06 | Administration.

Rule 3701-22-07 | Basic hospital functions.

Rule 3701-22-08 | Optional hospital functions.

Rule 3701-22-09 | Critical access hospitals.

Rule 3701-22-10 | Rural emergency hospitals.

Rule 3701-22-11 | Quality assurance and patient health and

Rule 3701-22-12 | Annual report.

Rule 3701-22-13 | Data collection.

Rule 3701-22-14 | Hospital Zones.

Rule 3701-22-19 | Variances; waivers.

Rule 3701-22-20 | Maternity unit and newborn care nursery general facilities and equipment

Rule 3701-22-21 | Level I service standards.

Rule 3701-22-22 | Level II service standards.

Rule 3701-22-23 | Level III service standards.

Rule 3701-22-24 | Level IV service standards.

Rule 3701-22-25 | Freestanding children's hospitals with level III or level IV neonatal care s

Rule 3701-22-26 | Freestanding children's hospitals with level III or level IV neonatal care s

Rule 3701-22-27 | Freestanding children's hospitals with a level IV neonatal care services at

Rule 3701-22-28 | Newborn nutrition.

Rule 3701-22-29 | Record keeping.

Rule 3701-22-30 | Health care service notification requirements.

Rule 3701-22-31 | Solid organ transplant service standards.

Rule 3701-22-32 | Patient selection criteria.

Rule 3701-22-33 | Utilization levels - solid organ transplant services.

Rule 3701-22-34 | Bone marrow transplantation service standards.

Rule 3701-22-35 | Personnel/staffing - bone marrow transplantation service.

Rule 3701-22-36 | Facilities/safety standards - bone marrow transplantation service.

Rule 3701-22-37 | Patient selection/utilization - blood and bone marrow transplantation service.

Rule 3701-22-38 | General adult cardiac catheterization service standards.

Rule 3701-22-38.1 | Level I cardiac catheterization service standards.

Rule 3701-22-38.2 | Level II cardiac catheterization service standards.

Rule 3701-22-38.3 | Level III adult cardiac catheterization service standards.

Rule 3701-22-38.4 | Adult electrophysiology procedure rooms.

Rule 3701-22-39 | General personnel/staffing - adult cardiac catheterization service.

Rule 3701-22-40 | General facilities, equipment, and supplies - adult cardiac catheterization service.

Rule 3701-22-41 | Safety standards - adult cardiac catheterization service.

Rule 3701-22-42 | Adult cardiac catheterization service performance measures.

Rule 3701-22-42.1 | Inspection and review of adult cardiac catheterization services.

Rule 3701-22-43 | Open-heart surgery service standards.

Rule 3701-22-55 | Personnel/staffing - pediatric cardiac catheterization service.

Rule 3701-22-56 | Facilities, equipment, and supplies - pediatric cardiac catheterization service.

Rule 3701-22-57 | Safety standards - pediatric cardiac catheterization service.

Rule 3701-22-58 | Pediatric cardiac catheterization service - performance measures.

Rule 3701-22-59 | Quality assessment and performance improvement - pediatric cardiac catheterization services.

Rule 3701-22-60 | Pediatric cardiovascular surgery service standards.

Rule 3701-22-61 | Personnel/staffing - pediatric cardiovascular surgery service.

Rule 3701-22-62 | Facilities, equipment, and supplies - pediatric cardiovascular surgery service.

Rule 3701-22-63 | Pediatric cardiovascular surgery service - performance measures.

Rule 3701-22-64 | Quality assessment and performance improvement - pediatric cardiovascular surgery service.

Rule 3701-22-65 | Order to suspend operations of a health care service.

Rule 3701-22-44 | Personnel/staffing - open-heart surgery service.

Rule 3701-22-45 | Facilities, equipment, and supplies - open-heart surgery service.

Rule 3701-22-46 | Quality assessment and performance improvement - open-heart surgery service.

Rule 3701-22-47 | Adult open- heart surgery service performance measures.

Rule 3701-22-48 | Pediatric intensive care service standards.

Rule 3701-22-49 | Personnel and staffing standards - pediatric intensive care service.

Rule 3701-22-50 | Physical design and facilities - pediatric intensive care service.

Rule 3701-22-51 | Equipment and supplies - pediatric intensive care service.

Rule 3701-22-52 | Quality assessment and performance improvement program - pediatric intensive care service.

Rule 3701-22-53 | Radiation therapy, stereotactic radiosurgery, and stereotactic radiotherapy service standards.

Rule 3701-22-54 | Pediatric cardiac catheterization service standards.

# Hospital Licensure

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

## Applications and Forms

- [Hospital License Application](#)
  - For an initial license, temporary license or change of owner application
- [Capacity Change Form](#)
  - For bed number changes or bed relocation
- [Director Notifications Form](#)
  - For circumstances requiring written notifications to the Director of Health
- [Emergency Director Notifications Form](#)
  - For reporting emergencies resulting in an interruption of hospital services
    - Note- Emergencies may also be reported by phone using the phone number provided on this form
- Service Change Form (*coming soon*)

# Surveys

## ORC 3722.05 Inspections

- ODH may inspect the hospital before issuing or denying an initial licensure application.
- Applicant hospital may avoid inspection by submitting most-recent final on-site survey report from CMS or an accrediting organization (and the final on-site survey submitted with the application does not become a public record, under OPC 3722.05(C))
- But ODH may inspect a hospital at any time to:
  - Address an incident that may impact public health.
  - Respond to a complaint.
  - Otherwise ensure the safety of the hospital's patients.

# Surveys

## OAC 3701-22-05 Inspections; compliance actions

- (A) ODH “may at any time inspect a licensed hospital in order to address an incident that may impact public health, respond to a complaint..., or otherwise ensure the safety of patients...”
- Inspections may be scheduled and announced, or they may be random and unannounced.

# Recent Experiences with ODH Surveys

## Trends

- Batching of Surveys
- Complaint Surveys
  - Longer surveys; more surveyors
  - Surveyors' experience levels vary
  - Surveyors' behavior varies

# Recent Experiences with ODH Surveys

## Maternity Surveys

- ORC 3722.05(D) – ODH shall inspect each licensed hospital’s maternity unit, newborn care nursery, and any unit providing health care services at least once every three years.
  - Increase in intensity
  - More surveyors
  - More extensive requests from surveyors

# Recent Experiences with ODH Surveys

## Health Care Services (HCS) Surveys

- ORC 3722.01(B)
- Includes organ and bone marrow transplant, heart catheterization, open heart surgery, peds ICU, others.
- Trends:
  - Less intense compared to maternity surveys.
  - Some surveyors have sought to observe procedures.
  - Sometimes do not send personnel worksheets or documents ahead of time; provide on first day of survey and expect immediate responses.
  - Sometimes coincide with timing of maternity surveys.

# Recent Experiences with ODH Surveys

## Technology

- Surveyors requesting documents be submitted by electronic drop-box.
- Varying experience among surveyors' familiarity with secure uploads or comfort with PDF versions of medical records.
- Surveyors report inability to open encrypted emails containing PHI.
- Hard copies must be 8.5x11" to meet surveyors' scanning needs.

# Penalties & Plans of Correction

## ORC 3722.07 - Enforcement

- If ODH finds that a hospital has violated one of the licensure law's requirements or associated rules, ODH may do any of the following:
  - CMP of \$1,000 to \$250,000.
  - Plan of correction.
  - Suspend a HCS or the hospital's license if the violation reflects substantial non-compliance with the statute or administrative rules. In the case of suspension for substantial non-compliance, there is a notice and correction process that resembles CMS's similar process.

# Imminent Threat of Harm

## ORC 3722.08

- “Imminent threat of harm” means “imminent danger of serious physical or life-threatening harm to one or more occupants of a hospital.” ORC 3722.08(A).
- If ODH determines a violation represents an “imminent threat of harm” to one or more hospital patients, ODH may either:
  - Petition the court of common pleas of the county where the hospital is located to issue an injunction to close the hospital, suspend a service in the hospital, transfer patients to other hospitals or care settings, or otherwise eliminate the imminent threat of harm; or
  - Give the hospital notice of:
    - The conditions that constitute the imminent threat;
    - The measures ODH determines the hospital must take to respond to those conditions;
    - The date when ODH intends to seek a court injunction if the conditions that gave rise to the imminent threat of harm remain.

# Imminent Threat of Harm

## ORC 3722.08 *continued*

- If the hospital timely notifies ODH that it has corrected the conditions that gave rise to the imminent threat of harm, ODH shall conduct an inspection to determine whether the conditions remain. If they do, ODH may still seek an injunction in court.
- If a court does impose an injunction due to an imminent threat, it can lift that injunction once the hospital shows the threat has been eliminated and will not recur.
- ODH must give notice to the hospital's administrator and its statutory agent.

# Compliance Actions

## OAC 3701-22-05 Inspections; compliance actions

- If ODH determines that a hospital has violated the licensure statutes or rules, ODH may do any of the following:
  - Require the hospital to submit a plan of correction;
  - Under ORC Chapter 119, impose a civil monetary penalty based on the severity of the violation:
    - Imminent Threat/Serious Threat to Health of Patient = \$100,000 to \$200,000
    - Directly Threaten Health/Safety = \$10,000 to \$100,000
    - Indirectly Threaten Health/Safety = \$1,000 to \$10,000
    - Plus \$1,000/day penalties for ongoing violations.
  - Factors affecting need for monetary penalty include imminence of threat, how direct the threat is, number of patients affected, number of staff involved in the violation, and timelines and sufficiency of the hospital's response.

# Settlement of CMPs

## OAC 3701-22-05(D) – Settlement of civil monetary penalties

- ODH may settle civil monetary penalties with the affected hospital, including with any of the following:
  - A lesser penalty than ODH originally proposed;
  - Allowing the hospital to invest an amount equal to the penalty on remedial measures (usually provided by a third party) to prevent similar violations in the future; or
  - Alternative remedies warranted by the deficient practice or negotiations.

# Suspensions and Revocations

## OAC 3701-22-05(E)

- If ODH suspends a HCS or revokes a hospital's license, ODH will issue a written order to the hospital.
- The hospital may request a hearing of ODH's decision (and can also contest civil monetary penalties); the hearing would be heard by a Hearing Examiner hired by ODH.
- The Rule provides that the hearing would occur within seven days of the hospital's request; as a practical matter, the hospital and ODH would typically agree to a longer schedule.
- The Rule also addresses what happens if the hospital lets ODH know that it has corrected the condition giving rise to the violation, and also what happens if the hospital fails to correct the violation – in the latter case, the hospital can revoke the hospital's license, and can also ask the attorney general to take legal action to have a court order the hospital to stop operating.
- While the hearing is pending, ODH's suspension of the hospital's license remains in effect. After the adjudication hearing, the Hearing Examiner would issue a decision within 14 days.

# Chapter 119 Appeals – Theory and Practice

## Process for Appealing from Administrative Actions

- ODH provides notice of its decisions to impose plans of correction, propose penalties, or suspend services or revoke licenses. Notice is provided under ORC 119.05.
- Requests for hearing must be made within 30 days of receiving notice. ORC 119.07.
- The hearing would be conducted by an ODH-hired Hearing Examiner.
- Unless ODH and the hospital otherwise agree (which they often might), the hearing would be set to occur after 7 days, and within 15 days, of the hospital's request for a hearing.
- As a practical matter, if the hearing contests only a penalty but does not implicate a license revocation, the parties may agree to a more lengthy timeline. ORC 119.07.

# Chapter 119 Appeals – Theory and Practice

## OAC 119.09 – Adjudication Hearing – Procedures

- ODH or the hospital may subpoena books and records, and compel testimony;
- Depositions may be taken as in civil lawsuits.
- Fees and mileage for witnesses paid by the state.
- If witness refuses to comply with subpoena, court of the county where the refusal occurs can conduct contempt proceedings.
- The hearing will be recorded by stenographic means or by audio electronic recording.
- Hearing Examiner (who must be an attorney and meet other ODH requirements) would rule on evidentiary/admissibility matters, and even if ODH does not admit the evidence, the hospital could make a proffer of the evidence (which could then be addressed on an appeal to common pleas court).
- Hearings are public.

# Chapter 119 Appeals – Theory and Practice

## OAC 119.09 – Adjudication Hearing – Procedures *continued*

- After conducting the hearing, the Hearing Examiner “shall submit to the agency a written report setting forth the [Hearing Examiner’s] findings of fact and conclusions of law and recommendation of the action to be taken by [ODH].”
- Within five days of ODH receiving the Hearing Examiner’s report, ODH must serve the report on the hospital or its attorney.
- The hospital may file written objections within 10 days.
- ODH must consider the objections, and then approve, modify, or disapprove the Hearing Examiner’s recommendation; it can also accept more testimony or documents.
- ODH may approve, modify, or disapprove of the recommendation, and its decision becomes final when it is confirmed and approved by ODH on its record of proceedings, also called its journal.
- ODH must serve a certified copy of its order on the hospital and its lawyers, and must include a statement of the time and method by which the hospital could appeal.

# Chapter 119 Appeals – Theory and Practice

## OAC 119.12 – Appeals to Court after ODH Hearing and Certification of Decision

- To appeal from post-hearing ODH order, hospital would file notice of appeal with common pleas court of the hospital's county or Franklin County. OAC 119.12(B)(6).
- Notice of appeal only needs to state that ODH's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. Can be more detailed, but does not have to be.
- Notice of appeal must be filed with court and ODH within 15 days of service. OAC 119.12(D).
- Filing of appeal to court does not stay ODH's earlier decision.
- Within 30 days of receiving the hospital's notice of appeal to common pleas court, ODH shall prepare and certify to the court a complete record of the proceedings in the case. OAC 119.12(J).

# Chapter 119 Appeals – Theory and Practice

## OAC 119.12 – Appeals to Court after ODH Hearing & Certification of Decision *continued*

- The court hearing the appeal is typically confined to reviewing ODH’s certified record; the court may accept newly discovered evidence if that evidence could not with reasonable diligence have been ascertained before the ODH hearing. OAC 119.12(L).
- The court will conduct a hearing of the appeal, which shall proceed as a trial in a civil action. The court may hear oral argument, briefs may be submitted, and evidence may be introduced if the court has granted a request for the presentation of additional evidence. OAC 119.12(M).
- The court may affirm ODH’s order if it finds that the order was supported by reliable, probative, and substantial evidence and is in accordance with law. OAC 119.12(N). If the order is not supported with evidence or is not in accordance with law, the court may “reverse, vacate, or modify the order or make such other ruling as is supported by reliable, probative, and substantial evidence and is in accordance with law.
- If the hospital prevails, it may be entitled to an award of its reasonable attorney fees; in contrast, ODH would not be entitled to an award, even if it wins. OAC 119.12(N); ORC 2335.39.
- Either ODH or the hospital could appeal the common pleas court’s decision to the court of appeals.

# Practical Considerations with Appeals of ODH Penalties/Orders

## Negotiating Settlement with ODH

- Hearing Officer
- Bad Facts
- Common approach
- Public nature
- Other things to consider

# Practical Considerations with Appeals of ODH Penalties/Orders

## Negotiating Settlement with ODH

- Settlement agreement will be a public record.
- What seems to work:
  - Negotiation
  - Flexibility on penalty allocation
- Which remedial measures seem to receive approval to count toward penalty?

# Questions and Discussion

# Speakers

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