Regulatory Update

Presented to

Arizona Hospital and Healthcare Association

August 30, 2022
Topics

- ADHS Mission and Vision
- Public Health Services Licensing
- Administrative Update
- State Rulemaking
  - TB
  - Architecture Review
  - OTC Exemption
Vision for Arizona

Arizona will be the number one state to live, work, play, visit, recreate, retire and get an education.

–Governor Doug Ducey
Arizona Department of Health Services (ADHS)

- One of the largest Departments in Arizona State Government
- Budget of more than $1 Billion
- Workforce of 1600 employees
ADHS Mission and Vision

• Our Vision
  – Health and Wellness for all Arizonans

• Our Mission
  – To promote, protect and improve the health and wellness of individuals and communities in Arizona

Our Strategic Map
Strengthen Arizona’s Public Health System Through Alignment and Coordination
ADHS “Health and Wellness for all Arizonans”

• Improve Arizona’s Health Outcomes
• Promote and Support Public Health and Safety
• Improve the Public Health Infrastructure
• Maximize Agency Effectiveness
• Implement the Arizona Health Improvement Plan
Cross Cutting Strategies

- Practice Continuous Quality Improvement
- Improve the Customer Experience
- Foster Open Communication and Transparency
- Implement Best, Promising and Evidence-Based Practices
ADHS Leadership

• Interim Director- Don Herrington
• Deputy Director for Public Health-Carla Berg

Organization Structure

– Four Divisions:
  • Arizona State Hospital
  • Planning and Operations
  • Policy and Intergovernmental Affairs
  • Public Health Services
    – Preparedness
    – Prevention
    – Licensing
Public Health Services- Licensing

• Assistant Director- Tom Salow
  – 2 Branches
    • Centralized Services
      – Child Care Licensing
      – Special Licensing
      – Vital Records
      – Radiation Control
    • Health Care Institutions
      – Long Term Care
      – Residential
      – Medical Facilities
      – Physical Plant/Life Safety Code
Public Health Services- Licensing

• Our Mission
  – To protect the health and safety of Arizonans by providing information, establishing standards, and licensing and regulating health and child care facilities

• Our Primary Focus
  – Health and Safety of Patients/Residents

• Our Goal
  – Deficiency Free Arizona
Public Health Services- Licensing

• **Our Key Work Processes in Licensing**
  – State Licensing
    • Laws (Statutes) and Rules
    • Foundational rules to operate a Health Care Institution
  – Medicare Certification
    • Conditions of Participation
    • #1 Condition of Participation- Comply with all State statutes and rules
Public Health Services- Licensing

• Our Tools
  – Evidence Based Outcome Survey Process
  – Technical Assistance
  – Transparency
  – Collaboration/Engagement
Regulatory Authority

• State Law: Arizona Revised Statutes (A.R.S)
  Title 36 - Public Health and Safety
  Chapter 4 - Health Care Institutions
• Licensing Rules: Arizona Administrative Code (A.A.C)
  Title 9 - Health Services
  Chapter 10 – Department of Health Services-Health Care Institutions-Licensing
• Federal Regulations: Code of Federal Regulations (CFR)
Health Care Institutions
“Health Care Institution”

Means every place, institution, building or agency, whether organized for profit or not, which provides facilities with medical services, nursing services, behavioral health services, health screening services, other health related services, supervisory care services, personal care services, or directed care services and includes home health agencies as defined in ARS 36-151, outdoors behavioral health care programs and hospice service agencies. Health care institution does not include a community residential setting as defined in ARS 36-551
Health Care Institutions

Bureau of Medical Facilities Licensing
Odette Colburn, Chief

Bureau of Residential Facilities Licensing
Tiffany Slater, Interim Chief

Bureau of Long Term Care Licensing
Megan Whitby, Interim Chief
Licensing by Medical Facilities

- Hospital (General, Rural and Special Hospital)
- Behavioral Health Inpatient Facility
- Hospice
- Outpatient Surgery Center
- Outpatient Treatment Center
- Home Health Agency
- Behavioral Health Specialized Transitional Facility
- Substance Abuse Transitional Facility
- Abortion Clinic
- Unclassified health care institution
- Counseling facility
- Pain Management Clinics
- Recovery Care Center
Federal Certification by Licensing

- Hospitals-Appendix A
- HHAs-Appendix B
- Portable X-Ray-Appendix D
- OPTP-Appendix E
- CMHC-Appendix F
- RHC-Appendix G
- ESRD-Appendix H
- LSC-Appendix I
- CORF-Appendix K
- ASC-Appendix L
- Hospice-Appendix M
- IJ-Appendix Q
- CAH-Appendix W
- Transplant-Appendix X
- OPO-Appendix Y
- EP-Appendix Z
Medical Facilities Licensing
(602) 364-3030

• Odette Colburn, Bureau Chief
• Katrina Trinchera, Deputy Bureau Chief
• Rebecca Gardner, Healthcare Compliance Manager
• Daniel Hernandez, Healthcare Compliance Manager, OTCs
• Shirley Soden, Healthcare Compliance Manager, Hospitals and OSCs
• James Ward, Healthcare Compliance Manager, Hospitals, Home Health/Hospice
• Christine Pereira, Healthcare Compliance Manager, ESRD
• Matthew Harris, Healthcare Compliance Manager, Behavioral Health
• ADHS established minimum standards for health and safety
• Licensed facilities required to develop and implement additional set of evidence based policies and procedures
• Licensed facilities required to measure patient and resident outcomes and take action to improve
• ADHS conducts outcome based survey to assure compliance to the state licensing rules and the licensed facilities policies and procedures to meet the needs of the patients/residents they serve
• State Rules
  – Provides the “what” has to be in place to be licensed
    • “An Administrator shall ensure that:...An infection control program is established..”
  – The “how” is left to each individual facility
    • “...under the direction of an individual qualified according to policies and procedures, to prevent...” (R9-10-1028 Infection Control)

• Facilities will have more flexibility to manage according to best practices in the industry
  – Many rules refer to policies and procedures of facility
  – Rather have facility fix issue than cite
  – Does not mean citations will not be issued
ARIZONA OUTCOME-BASED REGULATION GOALS

• Improve compliance “Do it right the first time”
  – Facility conforming to their own policies and procedures
  – Education and technical assistance
• Reduce enforcement
  – Compliance vs. Enforcement
  – “Deficiency-Free Arizona”
• Improve public health outcomes
  – Use evidence-based regulations
  – Encourage continuous quality improvement (Quality Management)
  – Provide licensed facilities with the licensing information to improve outcomes and practices to improve outcomes and create positive change
ACCEPTABLE PLAN OF CORRECTION
Points to Consider

• The PoC must be specific, realistic and complete
• The PoC must be legible!
• The completed PoC must be returned to the Department within 10 calendar days of receipt of SOD
• If the PoC is not properly completed or if additional information is needed, you will be contacted for clarifications and modifications
Summary

• The PoC should include:
  – proactive processes or actions to identify system failure;
  – interventions and actions the facility will develop/revise and implement to address the issues;
  – an ongoing system to evaluate the effectiveness or progress of implemented systems;
  – a person who will be responsible for the system/actions; and
  – a person who will be responsible for evaluating the effectiveness of the implemented systems.
More than Correcting Deficiencies

• Maintaining compliance involves more than just reading a deficiency and developing a plan to correct it

• The importance of developing a good, acceptable plan of correction cannot be over-emphasized

• Submitting and following an acceptable plan of correction goes a long way toward ensuring continued quality care for the individuals receiving the facility’s services
Citation Check

AZ Care Check
Internet Quality Improvement and Evaluation System (iQIES)

• CMS’s new platform to manage provider and patient information and ensure quality healthcare for the most vulnerable patients

• Web-based system allows for streamlined workflows, powerful reporting capabilities and intuitive design
Internet Quality Improvement and Evaluation System (iQIES)

- Facility’s are transitioning to iQIES in scheduled phases
- HHAs transitioned in October 2021
- ASCs transitioned to this new platform May 9th, 2022
- Hospice will be next to transition in October 2022
- LTC planned for early 2023
State Rulemaking

• TB Updates
• Architecture Review SB1293
• OTCs and Hospitals HB2450
Tuberculosis Screening
R9-10-113, Article 1. General
Tuberculosis Screening

- The Department has requirements related to tuberculosis screening in health care institutions in A.A.C. R9-10-113, citing to guidelines of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). The CDC has recently updated the recommendations for tuberculosis screening in a manner that removed the requirement for annual screening if certain conditions are met. Health care institutions have requested that the Department change the rule to incorporate by reference the 2019 CDC recommendations. After receiving an exception from the rulemaking moratorium pursuant to Executive Order 2020-02, the Department is revising A.A.C. R9-10-113 to address these concerns and making clarifying changes in other rules that reference this rule.
Tuberculosis Screening

As of May 4, 2022, A.A.C. R9-10-113 has been revised and includes tuberculosis screening requirements relating to health care institutions (“HCI”). In general, A.A.C. R9-10-113:

- Requires that an HCI establishes, documents, and implements tuberculosis infection control activities such as risk assessments of individuals and the HCI, annual training and education related to recognizing the signs and symptoms of tuberculosis, and reporting requirements.
- Requires that an individual for whom baseline screening and documentation of freedom from infectious tuberculosis is required, obtains evidence of freedom from infectious tuberculosis such as a negative Mantoux skin test or other tuberculosis screening test recommended by the CDC.
- As part of an annual assessment of the HCI’s risk of exposure to infectious tuberculosis, ensure individuals obtain documentation that indicates the individual’s freedom from symptoms of infectious tuberculosis and is signed by a medical practitioner, occupation health provider as defined in A.A.C. R9-6-801, or local health agency, as defined in A.A.C. R9-6-101.
Tuberculosis Screening

TB Rulemaking 2022

TB Screening in Health Care Institutions
Architecture

SB 1203 health care institutions; architectural plans (Chapter 34)

• Requires a health care institution license application to include a notarized attestation from a licensed architect that verifies architectural plans meet or exceed ADHS standards.
• Eliminates the requirement that ADHS provide architectural plan reviews for health care institutions.
Architecture

A.R.S. 36-421. Construction or modification of a health care institution

Sec. 3. Section 36-421, Arizona Revised Statutes (A.R.S.), is amended to read:

A. A license application for a health care institution shall include, on a form provided by the Department, a notarized attestation from an architect registered pursuant to Title 32, Chapter 1 that verifies the architectural plans and specifications meet or exceed standards adopted by the Department. These plans and specifications shall meet the minimum standards for licensure within the class or subclass of health care institution for which it is intended.
Architecture

- Department’s attestation form currently being finalized
- Draft attestation form will be available on the Department’s website
- Form will be available for use September 24, 2022
- Attestation will be submitted with initial application or modification application.
Architecture

- Architect on record will attest to currently adopted codes and standards found in A.A.C. R9-10 Article 1
- Narrative description of project will also be provided
Architecture

A.A.C. R9-10-104.01 Codes and Standards

- 2018 Guidelines for Design and Construction of Health Care Facilities
- 2012 National Fire Codes
- 2018 International Building Code
- 2018 International Mechanical Code
- 2018 International Plumbing Code
- 2018 International Fire Code
- 2018 International Fuel Gas Code
- 2018 International Private Sewage Disposal Code
Architecture

- As the authority having jurisdiction (AHJ), the architect on record will attest to any nonconfirming conditions using the Department’s attestation.

When renovating or expanding existing facilities, it is not always feasible to renovate or upgrade an entire existing facility to totally conform with requirements in the Guidelines. Therefore, authorities having jurisdiction are permitted to grant approval to renovate portions of a structure, space, or system if facility operations and patient safety in renovated and existing areas are not jeopardized by existing features of areas retained without complete corrective measures.

This recommendation does not guarantee an AHJ will grant an exception, but attempts to minimize restrictions on those improvements where total compliance would create an unreasonable hardship and would not substantially improve safety.
The Department will be available for support but will no longer provide the final sign off for architecture plans and specifications.

The goal is to empower facilities to work with their architect to design and implement codes and standards for safe patient care.

Architecture review timeframe is eliminated from the licensing process.
OTC Exemption

HB 2450 outpatient treatment centers; licensure; exemption (Chapter 128)

- Exempts an OTC that has the same governing authority as a licensed hospital and that is staffed by licensed health care providers, with exceptions, from licensure, supervision, regulation or control of ADHS.
- Permits ADHS to inspect an exempt OTC if there is reasonable cause to believe that patient harm is occurring.
OTC Exemption

“Governing authority” means the individual, agency, partners, OWNER, group or corporation, whether appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the health care institution are vested.

(FOR THE PURPOSES OF THIS PARAGRAPH, “OWNER” MEANS A PERSON WHO HAS AN OWNERSHIP INTEREST OF AT LEAST FIFTY-ONE PERCENT OF A HEALTH CARE INSTITUTION.)
OTC Exemption

This statutory change does not exempt hospital satellite clinics from licensure. Single Group Licenses (SGLs) are specifically referred to in statute and will be added to the hospital license at the licensee’s request.

- R9-10-101(203) “Satellite facility” has the same meaning as in A.R.S. §36-422.(F) or (G)
- ARS 36-422(F) If a person operates a hospital...in a setting that includes satellite facilities of the hospital that are located separate from the main hospital building, the department at the request of the applicant or licensee shall issue a single group license to the hospital and its designated satellite facilities...”
- ARS 36-422(O)(2) “Satellite facility” means an outpatient facility at which the hospital provides outpatient medical services.
OTC Exemption

- Department is requesting that hospitals associated with exempt OTCs, submit a one time notification to the Department within 30 days of implementation to delicense its exempt OTCs or convert to an SGL.
- Written notification should include the following:
  - Current license number, exempt OTC name and address, name and address of governing authority, license number of associated hospital
OTC Exemption

- For each exempt OTC delicensed, a letter will be sent confirming that the license has been closed.
- A previously licensed OTC can be added to a hospital's state license as an SGL as long as both facilities have the same owner.
Regulations

- Arizona Administrative Code Title 9 Chapter 10
- Centers of Medicare and Medicaid Services State Operations Manual (SOM)
- 2018 FGI Guidelines
Questions?
THANK YOU

Odette Colburn | Bureau Chief | Medical Facilities Licensing
odette.colburn@azdhs.gov | 602-364-3446
azhealth.gov

@azdhs

facebook.com/azdhs