

Health Standards Section: Healthcare Facility Licensing and Certification

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Agenda

- Licensing
- Certification
- Complaints
- Sanctions
- State Civil Fines

Favorite Things – Football & Licensing



Legal Issues & Topics

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Licensing & Certification Regulatory Matters

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Health Standards Section

- The Health Standards Section (HSS) sits within LDH's Office of the Secretary.
- HSS is the licensing and certification bureau of LDH.
- The mission of HSS is to enforce regulatory compliance for licensed and certified healthcare providers in the state of Louisiana, including:
 - Periodic surveys/inspections of providers which are licensed and/or certified to operate in Louisiana; and
 - Investigating complaints received regarding allegations of abuse, neglect, exploitation, and extortion, and noncompliance with federal and/or state healthcare provider regulations.

Health Standards Section

Licensing/Certification of Healthcare Facilities

- **Adult brain injury:** 6
- **Adult day healthcare:** 26
- **Adult residential care:** 168
- **Ambulatory surgical centers:** 94
- **Behavioral health service providers:** 521
 - PSR, CPST, OTP, substance abuse facilities, addiction treatment facilities, mental health clinics, mental health rehab
- **Case management:** 64
- **Community mental health centers:** 4
- **Comprehensive outpatient rehabilitation facilities:** 0
- **Crisis receiving centers:** 1
- **End-stage renal disease centers:** 175
- **Federally qualified health centers (FQHCs):** 325 (complaints only)
- **Forensic supervised transitional residential and aftercare:** 6
- **Free-standing birthing centers:** 6
- **Home and community-based services (HCBS):** 583
 - Adult daycare, family support services, personal care attendant, respite care, substitute family care, supervised independent living (SIL), supported employment, monitored in-home care
- **Home health agencies:** 181
- **Hospice providers inpatient and outpatient:** 124
- **Hospitals:** 205
- **Intermediate care facilities for Individuals with intellectual disabilities (ICF/IID):** 484
- **Labs (CLIA):** 5,425
- **Nurse aide training programs:** 163
- **Nurse staffing agencies:** 202
- **Nursing homes:** 271
- **Outpatient physical therapy:** 21
- **Pain management clinics:** 6
- **Pediatric day healthcare:** 20
- **Portable x-ray:** 15
- **Psychiatric residential treatment facilities:** 7
- **Rural health clinics:** 242
- **Therapeutic group homes:** 13

Are You Ready for Some Football?



Licensing & Certification

Licensing

- A license is required to operate specific healthcare providers in Louisiana.
- Licensure is authorized by state statute.
 - HSS is only authorized to conduct regulatory investigation on those provider types for which they have statutory authority.
- Licenses are issued by LDH HSS.
- Licensing rules are promulgated by LDH HSS.
- A license does not guarantee any payment mechanism.

Licensing

- Licensing of healthcare facilities is the responsibility of LDH HSS.
- HSS staffing:
 - Total staff: 221 full time and 17 part-time
 - 131 surveyors
 - Currently, HSS has 16 surveyor positions either in the process of interviewing or filled by a surveyor in orientation/training.
 - 90 program office staff
 - 6 field offices throughout the state

Licensing: Surveyor Qualifications

- **Surveyor qualifications:** 12-month training process
 - Licensed healthcare professional
 - Registered nurse (RN), nurse practitioner (NP)
 - Physician
 - Licensed certified social worker
 - State training
 - CMS training
- **Surveyor process:**
 - CMS state operations manual, surveyor guidelines
 - Observations, record reviews, interviews
 - Principals of documentation

Licensing: Survey Types

The Health Standards Section conducted the following surveys for FFY 2025 (Federal Fiscal Year October 1, 2024, to September 30, 2025)

- **Total surveys:** 4,101
- **Certification surveys:** 1,260
- **Complaint surveys:** 1,954
 - **Administrative review complaints:** 4,357
 - **Total complaints:** 6,311
- **Follow-up surveys:** 664
- **Monitoring surveys:** 104
- **Verification of operation (VOO):**
 - Emergency situations or disasters
 - Settlement agreements in lieu of revocation of licensure

Licensing

Statutory Authority

- The Legislature must give authority for LDH to license a healthcare provider type. If there are no statute and no licensing rules, then LDH HSS has no authority/jurisdiction.
 - HSS does not license **all** healthcare provider types, but only those for which it has statutory authority to regulate.
- Revised statutes: Title 40 and Title 28

Facility Need Review

- Facility Need Review (FNR) [aka Certificate of Need (CON)]
- RS 40:2116 mandates that LDH establish a FNR program for:
 - HCBS program (PCA, Respite, SIL, MIHC)
 - Hospice providers
 - Pediatric day healthcare (PDHC) facilities
 - Behavioral health service providers
 - Community psychiatric support and treatment (CPST)
 - Psychosocial rehab (PSR)
 - Opioid treatment (methadone clinic)
 - Residential substance abuse treatment (RSAT)
 - ICF/DD
- RS 40:2116.1: FNR on nursing homes, but for moratorium

Facility Need Review

- If the provider type that you want to open, is one subject to FNR, then you must obtain FNR approval before proceeding to the licensing application.
- **FNR Application Process:** The provider may submit any and all documentation to meet the criteria:
 - **Criteria:** Establish the probability of serious, adverse consequences to recipients' ability to access healthcare if the provider is not allowed to be licensed.
 - The FNR Rule has a list of items/data that can be submitted to establish the criteria.
- **FNR Review Committee:** Established by statute.
- **FNR website:** <https://ldh.la.gov/health-standards-section/facility-need-review>

Facility Need Review

- If the FNR application is denied initially, there is a supplemental review process.
 - Applicant submits additional documentation, data, evidence to supplement.
 - Applicant has opportunity to meet with members of the FNR Committee to ask questions, can submit additional info after that.
- If the Supplemental FNR Review still results in denial, the applicant may file an appeal with the Division of Administrative Law.

Licensing Pre-Game Warm Up



Licensing

Health Standards

- Statute passed for facility/provider licensed type.
 - General authority, some specifics, rulemaking takes approximately 9-12 months.
- Rules published via APA in the Louisiana Register.
- Rules then codified in Louisiana Administrative Code (LAC)
- LDH Licensing Rules: Title 48 of the LAC
 - doa.la.gov/media/15odwaqn/48v01.pdf
 - doa.la.gov/media/52pfpizc/48v2.pdf
- LDH Medicaid Rules: Title 50 of the LAC
 - doa.la.gov/media/vs3btetk/50.pdf

Licensing & Certification

Certification

- Certification is required for participation in Medicaid and Medicare programs. It is necessary for reimbursement for services provided by the program.
- Certification is separate from licensing rules/standards.
- Regulations:
 - Code of Federal Regulations
 - Medicaid Manual
- The Centers for Medicare and Medicaid Services (CMS) has ultimate jurisdiction over certification.
 - HSS is the state licensing survey agency that is contracted with CMS to conduct the certification activities for healthcare providers in Louisiana.

Licensing & Certification

- HSS is the state licensing agency in partnership with CMS, who provides Federal Certification Surveys.
- CMS is within the U.S. Department of Health and Human Services (DHHS).
 - While CMS has the authority over the Medicaid programs, it also is over the certification programs.
 - New leadership at DHHS and CMS:
 - **Robert F. Kennedy Jr.:** 26th Secretary of DHHS
 - **Dr. Mehmet Oz:** – Administrator of CMS
 - **Shannon Hills:** Administrator of CMS Region 6, encompassing Louisiana, Arkansas, Oklahoma, Texas and New Mexico

HSS Process is Like a Football Game



Licensing Application

- **Licensing packet:** In general
 - Application and licensing fee
 - Provider/facility name, address, ownership, key personnel, hours of operation, line of credit, professional liability and workman's comp insurance policies
 - Application must also contain (as applicable):
 - Architectural plan review
 - On-site inspection report/approval from Office of State Fire Marshal (OSFM)
 - On-site inspection report/approval from Office of Public Health (OPH)
 - Ownership disclosure (5% or more)
 - Tax ID numbers
 - Criminal background checks as per statute for all unlicensed personnel, owners, administrators

Licensing Process – Criminal Background Checks

In Louisiana, an individual is prohibited from being the owner or administrator of certain healthcare facilities if they have been convicted of a felony, particularly crimes related to client care, financial fraud, or violence. The specific convictions that bar a person from owning a healthcare provider depend on various situations, including but not limited to, provider type, the age of the clients served, and whether the convictions involve financial misconduct or patient harm.

**Also see R.S. 46: 437.14 if the provider plans to enroll in the medical assistance program*

Licensing Process – Criminal Background Checks

What about non-licensed staff (i.e., CNAs or direct care staff)?

Anyone who meets one of the following:

1. Who is not a licensed healthcare professional and who provides nursing care or other health-care related services directly related to patient care:
 - a. to patients or residents in one of the enumerated facilities in said statute; or
 - b. to patients or residents in their own homes via HHA , hospice, or HCBSP
2. Who is a direct service worker pursuant to R.S. 40:2179 and R.S. 40: 2179.1.
3. Who is a student/trainee applying for enrollment in (a) a clinical preceptor training program (R.S. 40:1201.1 et. seq.), or (b) a nurse aide training program approved by the Department pursuant to federal and state law or regulation

These unlicensed persons will need a background check pursuant to RS 40:1203.1 et seq.

Licensing Process – Criminal Background Checks

An employer should require a criminal history check and security check when an offer of employment or contract is extended to a non-licensed person who will work primarily in the immediate boundaries of the facility, home, or institution.

The provider must review the following, when deciding whether a non-licensed person can be employed or contracted:

- Statute
- Rule
- Facility policy

Licensing Process – Criminal Background Checks

Providers are prohibited from employing or contracting non-licensed persons or ambulance persons with non-hireable criminal convictions as provided in R.S. 40:1203.3, unless the convictions are appropriately pardoned or expunged in accordance with law.

Time Out – Talk to HSS



Time Out for Big Projects

LDH:

- Coordination for large projects
- Regarding application packet

Application packet review process:

- 90 days to submit missing documentation/information.
- Waiver application if there is a problem.
- Once the completed application is approved, the provider is notified that HSS is ready to conduct an initial licensing survey.
- This is a scheduled, announced survey.
- Other surveys are unannounced.

Licensing Process



Initial Licensure Survey Process

- Scheduling on-site survey
 - Process in scheduling an onsite survey
 - HSS will send applicant detailed checklist letter
- Timeframe allowed to obtain licensure
- Onsite licensing survey conducted
 - Surveyors determine whether provider is in compliance with the licensing regulations
 - Review employees' files, providers' policies/procedures, patient care, lab, dietary, nursing, etc.
 - Conduct staff interviews
 - Be prepared before the surveyors come on site

Key Points to Consider

- Surveys are stressful for providers.
- Usually very thorough investigation by the surveyors.
- Best advice is be prepared and be cooperative.
- Request waiver as necessary.
 - Must show how health, safety, and welfare not compromised.
- The Department will work with you provided that the waiver request is not against state and federal laws.

Expediting Licensure

- Per R.S. 40:2006.2, LDH does offer expedited licensure survey.
- The final rule was published in the Louisiana Register on December 20, 2018.
- Any person, partnership, corporation, unincorporated association or other legal entity currently operating, or planning to operate, any of the healthcare facilities or providers licensed by the Department may seek an expedited licensing process.
- A request for an expedited licensure survey must be made to HSS.
- Fees for expedited surveys are in addition to licensing fees and are stipulated in the rule based upon a tiered system
- Fees depend on the provider/facility type and tier and range from \$5,000 to \$7,000.*
- The expedited survey shall be conducted within 10 working days after:
 - The licensing packet has been completed.
 - The expedited fee and licensing fee has been received by the State Office and cleared with the financial institution.

*Expedited licensing rule: ldh.la.gov/assets/medicaid/hss/docs/Expedited_Licensing_Process/LAC_48_1_Chapter_41.pdf

Licensing Process

Results for the On-Site Licensing Survey

Option 1: If the provider is in compliance with all licensing regulations, then the provider is notified onsite.

- License will be issued from state office
- License effective as of the day the surveyors exit
- License is a full initial license, good for one year

It's a touchdown!

Initial Licensure Survey



Licensing Process

- **Option 2-A:** Deficiencies are cited — the provider is not found to be in compliance with licensing regulations, but only “paper non-compliance” (policies not complete, perhaps).
- **A. Provisional License:**
 - If the deficiencies do not present a potential threat or danger to the health, safety, or welfare of residents or patients, then HSS has the discretion to issue an initial provisional license.
 - Generally, provisional licenses are good for six months.
 - During those six months, the provider must correct the deficiencies and get an approved plan of correction.
 - HSS will usually conduct a desk review to clear deficiencies.
 - Then, a full initial license is issued for the remainder of the year. If not cleared, the provisional license expires, and the license process starts over.

Licensing Process

Option 2-B: Deficiencies are cited — the provider is not found to be in compliance with licensing regulations.

B. Provisional License:

- Again, if the deficiencies do not present a potential threat or danger to the health, safety, or welfare of residents or patients, then HSS has the discretion to issue an initial provisional license.
 - Generally, the provisional license is good for six months.
 - During those six months, the provider must correct the deficiencies and get an approved plan of correction.
 - HSS will conduct an unannounced, onsite follow-up survey.
 - The provider must be ready to show how compliance.
 - If deficiencies are cleared at the onsite follow-up survey, a full initial license is issued for the remainder of the year. If not cleared, the provisional license expires, and the license process starts again.

QB Scramble ... Touchdown



Waiver Request



Licensing Process

- **Waivers:** Providers can request waivers for building and construction guidelines or requirements and to provisions of the licensing rules involving the clinical operation as their state licensing regulations allow.
 - No fees are required for a waiver request.
 - Providers submit a waiver request form detailing the request and how granting the waiver will not impact patient care/safety negatively. The waiver request form can be found on the Health Standards webpage.
 - Once received, the waiver is reviewed by the waiver review committee and the director of the licensing section. A recommendation is then made to the Secretary or the Secretary's designee.
 - LDH will work with you provided it is not against state and federal laws.
 - The Department shall issue a written decision of the waiver request to the provider/facility.

Licensing Process



Licensing Process

- **Option 3: License denial**
 - Deficiencies are cited — the provider is not found to be in compliance with licensing regulations. Deficiencies are significant and present a potential threat/danger to the health, safety, or welfare for residents or patients. HSS will deny the initial license.
 - Right to an informal reconsideration
 - Right to appeal
 - Cannot operate during the pendency of the IR or appeal.
 - Administrative appeal with Division of Administrative Law
 - Burden on provider to show denial was improper
 - Subsequent correction of deficiencies not a defense

Statement of Deficiencies (SOD)

- Standard form for deficiencies
 - CMS 2567 – Statement of Deficiencies (SOD)
 - LIC 1 – Licensing Statement of Deficiencies
- SOD is used for initial, certification, complaint, and follow-up surveys.
- **Left side:** Deficiencies are cited.
 - Survey staff must cite the regulation/provision being violated.
 - Survey staff must then give the evidence/documentation as to the deficient practice.
- **Right side:** The provider must review all deficiencies and submit a plan of correction (POC) for HSS to approve.
- Once the POC has been approved, HSS will conduct onsite follow-up to determine whether the deficiencies can be cleared.

Posting of Statement of Deficiencies

- SODs shall be posted with the annual licensing survey in a conspicuous place located within the facility.
- SODs are public record after a period of time.

Licensing: Renewal Process

- **Renewal process**
 - Renewal application and renewal licensing fee
 - Due 30 days prior to expiration of current license
 - Must include current Fire Marshal and OPH inspection report/approvals
 - Update disclosure of ownership information
 - HSS may conduct onsite survey
 - Failure to submit timely completed license renewal shall result in voluntary non-renewal of license
 - No appeal rights for non-renewal by provider

Licensing Process

- Generally, licenses are issued for one year unless revoked, suspended, or modified.
- Licenses are not transferrable and are only valid for the provider/facility to which they are issued and for that geographical location.
- Licenses expire unless renewed timely.
- License cannot be sold, assigned, donated, or transferred.
 - Change of ownership is allowed and requires a new license.

Licensing Process: CHOW

- **Change of Ownership (CHOW)**
 - HSS will process a change of ownership for a licensed entity.
 - CHOW must be reported to HSS, generally within five days of the change of ownership.
 - CHOW is a legal document submitted by the new owner.
 - A licensing application and fee must be submitted.
 - Once CHOW is approved, a license is issued to the new owner.
 - CHOWs are not allowed in certain cases:
 - A provider that is under a license revocation or denial may not undergo a CHOW.
 - A provider with an inactivated license may not undergo a CHOW.
 - If a provider requires FNR, then the provider shall provide evidence that FNR approval was transferred in the sale to the new owner.

Certification Activity



Certification Activity

- After the initial licensing survey, HSS may also conduct an initial certification survey.
 - **Note:** CMS now requires most facilities to go through an accreditation organization (AO) survey and will accept accreditation in lieu of a certification survey.
 - A few facilities must still go through certification survey.
 - Nursing homes, end-stage renal disease (ESRDs), community mental health centers (CMHCs)
 - **Certification survey:** Provider shall be in compliance with the federal regulations (separate from licensing).

Certification

- A healthcare provider/facility must be certified to participate in Medicare and Medicaid.
 - HSS conducts initial certification surveys and/or verifies accreditation for healthcare facilities, per its contract with CMS.
 - HSS conducts re-certification surveys for CMS.
 - Surveys are conducted according to the mission priority document.
 - **Nursing homes, ICF/DDs:** Annual recertification
 - **Hospitals, etc.:** Recertification every three years

Certification Surveys

- If a healthcare provider/facility is not certified, then it cannot participate in Medicare and Medicaid.
 - No Medicare/Medicaid payments
- A healthcare provider/facility may lose its certification due to survey deficiencies.
 - On recertification survey or on a complaint survey, if HSS cites federal deficiencies, then the provider/facility can be placed on a 23-day term track or a 90-day term track.
 - **23-day term track:** Must correct in 23 days
 - Immediate jeopardy (IJ) situation
 - Actual harm
 - **90-day term track:** Must correct in 90 days

Termination of Certification

- If a provider/facility is placed on a termination track, then the provider must submit a plan of correction for approval.
- HSS will review the plan of correction to determine if it is acceptable. If it is not acceptable, HSS may issue a directed plan of correction.
- If all deficiencies are not cleared and new deficiencies are cited at follow-up, HSS issues notice to the provider and CMS.
- If the provider has made progress, HSS will do a second follow-up survey. CMS approval is required for a third follow-up survey.

Complaint Surveys

- HSS also conducts complaint surveys at healthcare facilities.
 - Federal regulations
 - State licensing regulations
- State Complaint Law: RS 40:2009.13 et seq
 - Anyone can file a complaint
 - Allege violations of federal law or regulation and/or state law/standard/rule/regulation
 - HSS reviews/triages complaints

Complaint Surveys

- **Review/triage:**
 - HSS can reject any complaint that is outdated or trivial; can reject any complaint that is not made in good faith.
 - Outdated defined as incidents occurring more than 120 days before it is reported.
 - HSS not required to investigate issues not within their jurisdiction (e.g., doctor was rude to me).
 - HSS can refer complaints to professional boards, AG's Office, local law enforcement, district attorney.
 - HSS works closely with LDH Program Integrity and the AG's Medicaid Fraud Control Unit (MFCU).

Sanctions

- LDH HSS can impose various sanctions for deficiencies:
 - Individual license statutes: Provide for license revocation, denial of license renewal, license suspension.
 - Additional sanction laws
 - **Nursing homes:** RS 40:2009.11, 40:2009.23
 - **Other healthcare facilities:** RS 40:2199, RS 40:2199.1
- **Sanctions and penalties:**
 - Operating without license: Misdemeanor, fine of \$1,000 to \$5,000
 - Denial of new admits, denial of Medicaid payment
 - Temporary management
 - State civil fines for violations; limited by statute
 - Removal from Freedom of Choice List
 - Transfer of residents, clients, patients
 - License revocation

State Civil Fines for Nursing Homes

- Right to an administrative appeal of imposition of a sanction or civil fine.
- Appeal heard by Administrative Law Judge (ALJ) in the Division Administrative Law (DAL)
- Fines collected go into Nursing Home Residents' Trust Fund
 - Subject to appropriation
 - Federal protection of fund
 - Restricted uses

State Civil Fines for Others

- RS 40:2199 Non-nursing home: Funds collected go into Healthcare Facility Fund
- Subject to appropriation
- Protection of health, welfare, rights, property
- Education, employment, training of staff
- Programs designed to improve quality of care
- Funds that are collected from home health agencies go into a separate fund known as the Home Health Agency Trust Fund.
 - Funds subject to appropriation
 - Funds protected by federal law
 - Funds can be used per 42 CFR Part 488, subject to approval by CMS

Licensed and Certified – You Did It



Questions?

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THANK YOU

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HSS website: ldh.la.gov/microsite/32