These guidelines are meant solely to provide guidance to surveyors in the survey process.

400.9905 Definitions.-
(1) "Agency" means the Agency for Health Care Administration.
(2) "Applicant" means an individual owner, corporation, partnership, firm, business, association, or other entity that owns or controls, directly or indirectly, 5 percent or more of an interest in the clinic and that applies for a clinic license.
(3) "Chief financial officer" means an individual who has at least a minimum of a bachelor's degree from an accredited university in accounting or finance, or a related field, and who is the person responsible for the preparation of a clinic's billing.
(4) "Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. As used in this part, the term
Aspen State Regulation Set: U 2.02 Health Care Clinic

does not include and the licensure requirements of this part do not apply to:
(a) Entities licensed or registered by the state under chapter 395; entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.
chapter 395.

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any
Aspen State Regulation Set: U 2.02 Health Care Clinic

entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees at least two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

(g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, and that is wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner if one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care
practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) which provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

(h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.

(l) Orthotic, prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a
corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners where one or more of the persons responsible for the operations of the entity is a health care practitioner who is licensed in this state and who is responsible for supervising the business activities of the entity and is responsible for the entity's compliance with state law for purposes of this part.

(n) Entities that employ 50 or more licensed health care practitioners licensed under chapter 458 or chapter 459 where the billing for medical services is under a single tax identification number. The application for exemption under this subsection shall contain information that includes: the name, residence, and business address and phone number of the entity that owns the practice; a complete list of the names and contact information of all the officers and directors of the corporation; the name, residence address, business address, and medical license number of each licensed Florida health care practitioner employed by the entity; the corporate tax identification number of the entity seeking an exemption; a listing of health care services to be provided by the entity at the health care clinics owned or operated by the entity and a certified statement prepared by an independent certified public accountant which states that the entity and the health care clinics owned or operated by the entity have not received payment for health care services under personal injury protection insurance coverage for the preceding year. If the agency determines that an entity which is exempt under this subsection has received payments for medical services under personal injury protection insurance coverage, the agency may
deny or revoke the exemption from licensure under this subsection.

Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

(5) "Medical director" means a physician who is employed or under contract with a clinic and who maintains a full and unencumbered physician license in accordance with chapter 458, chapter 459, chapter 460, or chapter 461. However, if the clinic does not provide services pursuant to the respective physician practices acts listed in this subsection, it may appoint a Florida-licensed health care practitioner who does not provide services pursuant to the respective physician practices acts listed in this subsection to serve as a clinic director who is responsible for the clinic's activities. A health care practitioner may not serve as the clinic director if the services provided at the clinic are beyond the scope of that practitioner's license, except that a licensee specified in s. 456.053(3)(b) who provides only services authorized pursuant to s. 456.053(3)(b) may serve as clinic director of an entity providing services as specified in s. 456.053(3)(b).

(6) "Mobile clinic" means a movable or detached self-contained health care unit within or from which direct health care services are provided to individuals and which otherwise meets the definition of a clinic in subsection (4).

(7) "Portable equipment provider" means an entity that contracts with or employs persons to provide portable equipment to multiple locations performing treatment or diagnostic testing of individuals, that bills third-party payors
Aspen State Regulation Set: U 2.02 Health Care Clinic

for those services, and that otherwise meets the definition of a clinic in subsection (4).

59A-33.001 Definitions.
In addition to definitions contained in chapter 400, part X, F.S., the following definitions shall apply specifically to health care clinics.
(1) "Licensee" means an individual, general partner of a limited partnership, general partnership, joint venture, limited liability company, limited liability partnership, unincorporated association, corporation or any other business relationship or entity that owns or controls a health care clinic or is the lessee of the health care clinic having the right of possession of the health care clinic location or mobile unit.
(2) "Physician" means a person currently licensed to practice medicine, osteopathy, chiropractic, or podiatry pursuant to chapters 458, 459, 460 or 461, F.S., respectively.
(3) "Unencumbered license" means a license issued by the respective health practitioner board of the Department of Health that permits a physician to perform all duties authorized under a license without restriction.
(4) "The Health Care Clinic Act" or "Act" means chapter 400, part X, F.S.
(5) "F.S." means Florida Statutes.
(6) "F.A.C." means Florida Administrative Code.
(7) "Licensed medical provider" means a licensed health care practitioner.

ST - U0105 - License Required; Mobile Clinics

Title  License Required; Mobile Clinics

Type  Rule

        400.991(1)(b), F.S.
Aspen State Regulation Set: U 2.02 Health Care Clinic

Regulation Definition

400.991(1)(b), F.S.
Each mobile clinic must obtain a separate health care clinic license and must provide to the agency, at least quarterly, its projected street location to enable the agency to locate and inspect such clinic. A portable equipment provider must obtain a health care clinic license for a single administrative office and is not required to submit quarterly projected street locations.

Interpretive Guideline

Mobile clinics should be licensed at an administrative office with postal street address, and cannot provide direct health care services to individuals at their own facilities without first obtaining a health care clinic license for the address. A mobile clinic is self-contained and the client enters the unit. The unit may be either mobile (can be moved from place to place) or is detached from the clinic where the services are being provided. A trailer detached from a fixed location clinic is considered "mobile" under the definition.

Per 400.9905 definition:
(7) "Portable equipment provider" means an entity that contracts with or employs persons to provide portable equipment to multiple locations performing treatment or diagnostic testing of individuals, that bills third-party payors for those services, and that otherwise meets the definition of a clinic in subsection (4).

ST - U0111 - License Required; Change of Exempt Status

Title License Required; Change of Exempt Status
Type Rule
59A-33.006(14), F.A.C.

Regulation Definition

59A-33.006(14), F.A.C.
An entity becomes a "clinic" as defined in section 400.9905(4), F.S., when it does not qualify for an exemption, provides health care services to individuals, and bills third-party payors for those services. A facility or entity's exempt status expires when a change occurs that negates a facility or entity's qualification for the exemption. In such a case, the health care clinic must file with the Agency a license application under sections 400.900-400.995, F.S. and shall be subject to all provisions applicable to unlicensed health care clinics. Failure to timely file an application for licensure of becoming a health care clinic will render the health care clinic unlicensed and subject the owners, medical or clinic directors and the health care clinic to sanctions under sections 400.900-400.995, F.S.

Interpretive Guideline

If the final closing/sale of the clinic has been completed and exempt status no longer applies, application must be submitted within 5 days after the closing/sale. If no application has been submitted and the clinic is in operation, see Z827 for citation.

Facilities that have a certificate of exemption or self-determined that their facility is exempt, or a facility that provides services in which remuneration is by cash, check, or credit card, not third party payments, (seek third party insurance reimbursement), and who become a business that meets the definition of a health care clinic must submit an application within 5 days of meeting the definition. If the facility fails to meet the 5 day standard they are to be considered an unlicensed facility. The surveyor can confirm the 5 day period is met by record review of documentation demonstrating the application was mailed or faxed to the Heath Care Clinic Unit within the five (calendar) day period.

59A-33.012(l), FAC
For health care clinics that are in operation at the time of the survey, the surveyor will select a sample of at least five (5) patient medical records from the previous 6 months of operation with at least one Medicaid file, if certified as a
### Aspen State Regulation Set: U 2.02 Health Care Clinic

Medicaid provider, plus the five (5) billing records that correspond with the five patient records;

<table>
<thead>
<tr>
<th>Title</th>
<th>Notice of Insurance Fraud Display</th>
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<tbody>
<tr>
<td>Type</td>
<td>Rule</td>
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<td>400.9935(9), F.S.</td>
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</table>

**Regulation Definition**

400.9935(9), F.S.

In addition to the requirements of part II of chapter 408, the clinic shall display a sign in a conspicuous location within the clinic readily visible to all patients indicating that, pursuant to s. 626.9892, the Department of Financial Services may pay rewards of up to $25,000 to persons providing information leading to the arrest and conviction of persons committing crimes investigated by the Division of Investigative and Forensic Services arising from violations of s. 440.105, s. 624.15, s. 626.9541, s. 626.989, or s. 817.234.

**Interpretive Guideline**

The Notice of Insurance Fraud should be displayed in a public area within the clinic, such as the reception area or the front desk, at eye level where it is visible to all patients prior to entering an examination room.

<table>
<thead>
<tr>
<th>Title</th>
<th>Level 2 Background Screening Required</th>
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<tr>
<td>Type</td>
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<td>400.991(5)(a-b), F.S.</td>
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</table>

**Regulation Definition**

400.991(5), F.S.

(a) As used in this subsection, the term "applicant" means individuals owning or controlling, directly or indirectly, 5 percent or more of an interest in a clinic; the medical or clinic director, or a similarly titled person who is responsible for the day-to-day operation of the licensed clinic; the financial

**Interpretive Guideline**

Individuals who are required to be screened for Level II Standards:

1. Individuals owning or controlling 5 percent or more of an interest in a clinic;

2. The medical or clinic director, or a similarly titled person who is responsible for the day-to-day operation of the licensed clinic;
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officer or similarly titled individual who is responsible for the financial operation of the clinic; and licensed health care practitioners at the clinic.

(b) The agency shall require level 2 background screening for applicants and personnel as required in s. 408.809(1)(e) pursuant to chapter 435 and s. 408.809.

3. The financial officer or similarly titled individual who is responsible for the financial operation of the clinic; and

4. Licensed health care practitioners at the clinic.

Note: Surveyors may encounter, during the survey record review, telemedicine providers who interpret diagnostic tests, i.e. MRI, CT, X-Ray, EKG, EEG, Pulmonary Function, who are not classified as "practitioners at the clinic" and would not be required to undergo level II background screening even though the providers may be under global billing agreements with the health care clinic. If the telemedicine providers work, even only occasionally, in the physical facility of the clinic they are then required to be level II screened.

Clinic shall maintain a log of all natural persons required and who have been screened under Level II criteria.

See U-308, Clinic Responsibilities

ST - U0180 - Proof of Financial Ability to Operate

Title Proof of Financial Ability to Operate
Type Rule

59A-33.009(1), F.A.C.

Regulation Definition

Upon Agency request, clinic must provide the following documentation:
- Checks and drafts returned due to insufficient funds
- Delinquent bills for such items as personnel salaries, drugs, lease, mortgage, utilities or other operational costs
- Appointment of a receiver
- A voluntary or involuntary petition for bankruptcy
- A voluntary arrangement with creditors
- Health care clinic closure
- Discontinuance of health care clinic business for more than 60 consecutive days or insolvency.

Interpretive Guideline

59A-33.009(1), F.A.C.
When evidence of financial instability of a health care clinic is substantiated, the Agency will notify the health care clinic in writing that satisfactory proof of financial ability to comply with Chapter 400, Part X, F.S., must be provided.

(1) Evidence of financial instability of a health care clinic shall, without limitation, include issuance of checks and drafts for which there are insufficient funds, delinquent bills for such items as personnel salaries, drugs, lease, mortgage, utilities or other operational costs, appointment of a receiver, a voluntary or involuntary petition for bankruptcy, a voluntary arrangement with creditors, health care clinic closure,
discontinuance of health care clinic business for more than 60 consecutive days or insolvency.

ST - U0195 - M.R.I. Accreditation

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<td>400.9935(7)(a), F.S.</td>
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</table>

**Regulation Definition**

400.9935(7)(a), F.S.  
Each clinic engaged in magnetic resonance imaging services must be accredited by a national accrediting organization that is approved by the Centers for Medicare and Medicaid Services for magnetic resonance imaging and advanced diagnostic imaging services within 1 year after licensure. A clinic that is accredited or that is within the original 1-year period after licensure and replaces its core magnetic resonance imaging equipment shall be given 1 year after the date on which the equipment is replaced to attain accreditation. However, a clinic may request a single, 6-month extension if it provides evidence to the agency establishing that, for good cause shown, such clinic cannot be accredited within 1 year after licensure, and that such accreditation will be completed within the 6-month extension. After obtaining accreditation as required by this subsection, each such clinic must maintain accreditation as a condition of renewal of its license. A clinic that files a change of ownership application must comply with the original accreditation timeframe requirements of the transferor. The agency shall deny a change of ownership application if the clinic is not in compliance with the accreditation requirements. When a clinic adds, replaces, or modifies magnetic resonance imaging equipment and the accrediting agency requires new accreditation, the clinic must be accredited within 1 year after the date of the addition.
replacement, or modification but may request a single, 6-month extension if the clinic provides evidence of good cause to the agency.

**ST - U0225 - Right Of Inspection; Provider On Site**

**Title** Right Of Inspection; Provider On Site  
**Type** Rule

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408.806(7)(d), F.S.
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**Regulation Definition**

If a provider is not available when an inspection is attempted, the application shall be denied.

**Interpretive Guideline**

In the event a surveyor finds a facility closed on the day of inspection, the surveyor should attempt to contact the owner, manager, financial officer, or medical/clinic director by telephone and allow an opportunity to open the facility for surveyor inspection prior to a recommendation for denial of licensure.

If telephone contact is unsuccessful, call the Health Care Clinic Unit to determine hours of operation. Any recommendation for denial should be submitted to the Field Office supervisor for consultation with the Health Care Clinic Unit for approval.

**ST - U0300 - Medical Director Required**

**Title** Medical Director Required  
**Type** Rule

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400.9935(1), F.S., 59A-33.008(1)
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**Regulation Definition**

Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic.

**Interpretive Guideline**

See U0430 re: Administrative Action for no medical or clinic director

A licensed health care clinic may not operate or be maintained
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without the day-to-day supervision of a single medical or clinic director as defined in Section 400.9905(5), F.S.

ST - U0301 - Medical Director Required; Written Agreement

Title  Medical Director Required; Written Agreement

Type  Rule

59A-33.012(3)(b), FAC; 400.9935(2), FS

**Regulation Definition**

59A-33.012, F.A.C.

(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(b) Copy of medical or clinic director's written agreement with the health care clinic assuming the responsibilities for the statutory activities in Sections 400.9935(1)(a)-(i), F.S. If the medical or clinic director signs the Medical/Clinic Director Attestation, AHCA Form 3110-1028, incorporated by reference in Rule 59A-33.002, F.A.C., acknowledging these responsibilities as specified in Section 400.9935, F.S., this requirement is met;

400.9935(2), F.S.

Any contract to serve as a medical director or a clinic director entered into or renewed by a physician or a licensed health care practitioner in violation of this part is void as contrary to public policy. This subsection shall apply to contracts entered into or renewed on or after March 1, 2004.
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Title  Medical Director; Qualifications

Type  Rule

ST - U0303 - Medical Director; Qualifications

400.9905(5) FS; 59A-33.008(2) & .012(3)a

**Regulation Definition**

59A-33.012(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(a) The professional license or facsimile of the license for the medical or clinic director;

400.9905(5), F.S.

"Medical director" means a physician who is employed or under contract with a clinic and who maintains a full and unencumbered physician license in accordance with chapter 458, chapter 459, chapter 460, or chapter 461. However, if the clinic does not provide services pursuant to the respective physician practices acts listed in this subsection, it may appoint a Florida-licensed health care practitioner who does not provide services pursuant to the respective physician practices acts listed in this subsection to serve as a clinic director who is responsible for the clinic’s activities. A health care practitioner may not serve as the clinic director if the services provided at the clinic are beyond the scope of that practitioner's license, except that a licensee specified in s. 456.053(3)(b) who provides only services authorized pursuant to s. 456.053(3)(b) may serve as clinic director of an entity providing services as specified in s. 456.053(3)(b).

59A-33.008, F.A.C.

**Interpretive Guideline**

Medical or Clinic Director should present DOH license to practice.

License must be current (not expired).
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(2) By statutory definition in Section 400.9905(5), F.S., a medical director is a health care practitioner that holds an active and unencumbered Florida physician’s license in accordance with Chapters 458 (medical physician), 459 (osteopathic physician), 460 (chiropractic physician) or 461 (podiatric physician), F.S. A suspended or non-renewed license is considered an encumbered license, as is a license that restricts the license holder from performing health care services in a manner or under supervision different from a license holder without board or Department of Health restrictions.

ST - U0304 - Medical Director; On Site for Survey

**Title** Medical Director; On Site for Survey

**Type** Rule

59A-33.012(2), F.A.C.

**Regulation Definition**

59A-33.012(2), F.A.C.
The medical or clinic director must attend the survey entrance conference and be available when the survey is conducted for the surveyor to determine compliance with minimum standards and requirements for licensure. Other key personnel required include the financial director, a representative of management or ownership and persons responsible for patient records and billing.

**Interpretive Guideline**

Flexibility is left to the surveyor in determining "persons required to be present" for licensure survey, as a result of required person travel time and availability, (i.e.: physicians conducting surgical procedures off site). On "Initial", (announced) surveys the surveyor should require all required persons to be present. For unannounced re-licensure and complaint surveys the surveyor may use personal judgment in permitting contact with required facility personnel by telephone.

Persons who may be required to be present for licensure survey:

1. Medical or Clinic Director
2. Owner or Manager
3. Financial Director
4. Records/Billing Personnel
ST - U0305 - Medical Director; Max Number of Clinics

**Title**  Medical Director; Max Number of Clinics  
**Type**  Rule

59A-33.013, F.A.C.

**Regulation Definition**

59A-33.013, F.A.C.  
A medical or clinic director may not serve in that capacity for more than a maximum of five health care clinics with a cumulative total of more than 200 employees and persons under contract with the health care clinic at any given time. A medical or clinic director may not supervise a health care clinic more than 200 miles from any other health care clinic supervised by the same medical or clinic director.

**Interpretive Guideline**

Review copy of application to verify number of clinics for medical director and their locations.

ST - U0306 - Clinic Responsibilities-Sign Identify Med Dir

**Title**  Clinic Responsibilities-Sign Identify Med Dir  
**Type**  Rule

400.9935(1)(a), F.S.

**Regulation Definition**

400.9935(1), F.S.  
The medical director or the clinic director shall:  
(a) Have signs identifying the medical director or clinic director posted in a conspicuous location within the clinic readily visible to all patients.

**Interpretive Guideline**

A sign identifying the Medical or Clinic Director should be displayed in a public area within the clinic, such as the reception area or the front desk, at eye level where it is visible to all patients prior to entering an examination room.
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ST - U0307 - Clinic Responsibilities-Organizational Chart

Title Clinic Responsibilities-Organizational Chart
Type Rule
59A-33.012(3)(p), F.A.C.

**Regulation Definition**
59A-33.012, F.A.C.
(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(p) An organizational flow chart with lines of authority and names of key individuals and positions;

**Interpretive Guideline**
Clinic should have an organizational chart identifying Medical Director, Officers/Managers, and other key individuals in order of authority.

ST - U0308 - Clinic Responsibilities-Log of Level 2 Bkgd Ck

Title Clinic Responsibilities-Log of Level 2 Bkgd Ck
Type Rule
59A-33.012(3)(r), F.A.C.

**Regulation Definition**
59A-33.012, F.A.C.
(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(r) Log of all natural persons required and who have been screened under Level 2 criteria of Chapter 435 and Section 400.991, F.S.;

**Interpretive Guideline**
Clinic must present a log of persons screened for Level II standards. Log must include persons required to be screened by statute.

See U-0175, Background Screening Required
### ST - U0310 - Clinic Responsibilities-Licensed Staff

<table>
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<tr>
<th>Title</th>
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<tr>
<td>Type</td>
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**Regulation Definition**

400.9935, F.S.

(1) The medical director or the clinic director shall:

(b) Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license.

59A-33.012, F.A.C.

(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(j) Copies of professional licenses issued by the respective boards and the Department of Health under the several practice acts;

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<th>Interpretive Guideline</th>
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<tbody>
<tr>
<td>Clinic shall have a copy of DOH licenses on file for all health care practitioners.</td>
</tr>
<tr>
<td>Licenses must be current (not expired).</td>
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### ST - U0311 - Clinic Responsibilities-Staff Operations

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<tr>
<th>Title</th>
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**Regulation Definition**

59A-33.012, F.A.C.

(3) To facilitate a licensure survey, the health care clinic shall have policies, procedures, protocols and guidelines for daily operations at the clinic.

<table>
<thead>
<tr>
<th>Interpretive Guideline</th>
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<tbody>
<tr>
<td>Clinic should have policies, procedures, protocols and guidelines for daily operations at the clinic.</td>
</tr>
<tr>
<td>Policies/procedures should be available for staff use.</td>
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</tbody>
</table>
have the following materials readily available for review at the
time of the survey:
(c) Written policies, protocols, guidelines and procedures used
or to be used by the facility staff in day-to-day operations.
This includes protocols for physician assistants and advanced
registered nurse practitioners plus a copy of the supervision
form submitted to the Department of Health by the physician
supervisor

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<tr>
<th>Title</th>
<th>Clinic Responsibilities-Patient Contracts Rvw</th>
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<tr>
<td>Type</td>
<td>Rule</td>
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<td></td>
<td>400.9935(1)(c), F.S.</td>
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</table>

**Regulation Definition**

400.9935, F.S.

(1) The medical director or the clinic director shall:
(c) Review any patient referral contracts or agreements
executed by the clinic.

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<tr>
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<td></td>
<td>59A-33.012(3)(k), F.A.C.</td>
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</table>

**Regulation Definition**

59A-33.012, F.A.C.

(3) To facilitate a licensure survey, the health care clinic shall
have the following materials readily available for review at the

Clinic should have copy of the supervision form submitted to DOH by the physician supervisor on file for all PAs and
ARNPs on staff.
time of the survey:

(k) Any patient referral contracts or agreements of the health care clinic that are in writing and a disclosure to the surveyor of any such agreements that are not in writing including the names of the parties to the agreement, the date and the essential terms of agreement;

ST - U0317 - Clinic Responsibilities-Patient Referrals

Title Clinic Responsibilities-Patient Referrals
Type Rule

400.9935(1)(h), F.S.

Regulation Definition

400.9935, F.S.
(1) The medical director or the clinic director shall:

(h) Not refer a patient to the clinic if the clinic performs magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography. The term “refer a patient” means the referral of one or more patients of the medical or clinical director or a member of the medical or clinical director’s group practice to the clinic for magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography. A medical director who is found to violate this paragraph commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Interpretive Guideline

The medical director of a licensed clinic may not refer his/her patient or the patient of any other physician from his/her (group) practice to the licensed clinic for the following diagnostic tests/scans:

- Magnetic Resonance Imaging (MRI)
- Static Radiographs
- Computed Tomography (CT)
- Positron Emission Tomography (PET)

There must be two clinics involved to substantiate a violation: a licensed clinic and a separate (group) practice that the medical director is a member of and from which a patient referral is made. A medical director may not refer any patient to the licensed clinic for designated tests/scans at which he or she serves as the medical director when that patient is from his/her private (group) practice. Violation of this provision is a mandatory report to the Department of Health, MQA Consumer Services.

An internal referral of the medical director for a patient of the licensed clinic is not a violation.

Surveyor Questions for the Medical Director:

1. Are you also a member of a separate (group) practice?
   - If NO, there is no violation.
Aspen State Regulation Set: U 2.02 Health Care Clinic

- If YES, go to question 2.

2. Have you referred any patient of yours or a patient of the group practice to this clinic for MRI, X-RAY, CT or PET scan.
   - If NO, there is no violation.
   - If YES, document referrals using principles of documentation and follow recommended guidelines for discipline and outside referral.

This section of statute is not to be confused with §456.053, F.S. known as the Patient Self-Referral Act.

ST - U0318 - Clinic Responsibilities-Publish Fee Schedules

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<tr>
<th>Title</th>
<th>Clinic Responsibilities-Publish Fee Schedules</th>
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<tbody>
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<td>Type</td>
<td>Rule</td>
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</table>

400.9935(1)(i); 395.107; 395.002(30), FS

**Regulation Definition**

400.9935, F.S.
(1) The medical director or the clinic director shall:
(i) Ensure that the clinic publishes a schedule of charges for the medical services offered to patients. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be posted in a conspicuous place in the reception area of the urgent care center and must include, but is not limited to, the 50 services most frequently provided by the clinic. The schedule may group services by three price levels, listing services in each price level. The posting may be a sign that must be at least 15 square feet in size or through an electronic messaging board that is at least 3 square feet in size. The failure of a clinic to publish and post a schedule of charges as required by this section shall result in a fine of not more than $1,000, per day, until the schedule is published and posted.

**Interpretive Guideline**

Verify whether clinic meets definition as "Urgent Care Center" (395.002 (30), F.S.) upon statutory definitions.

Initial Survey:  Clinic must be in compliance with TAG in order to pass survey.  Clinic shall identify the 50 most frequently provided services and post on Schedule of Services and Prices in patients' waiting room.

Complaint, CHOW (when requested by central office) and Renewal surveys:  If fee schedule is appropriately published and posted, survey should sample billings to verify published fee schedule is still accurate.  Use POC for corrections.   If uncorrected, statement of deficiency may recommend a discretionary fine of up to $1,000.

For period of time clinic complies with clinic responsibility, there is no fine.

When survey substantiates clinic fails or failed to publish and post the fee schedule, survey should recommend fine of $1,000 per day for each day of substantiated non-compliance until compliance is met.

*A Plan of Correction will not prevent fine if there is no posted and published sign in patient or client reception area.

Contact central office for technical assistance.
"Urgent care center" means a facility or clinic that provides immediate but not emergent ambulatory medical care to patients. The term includes an offsite emergency department of a hospital that is presented to the general public in any manner as a department where immediate and not only emergent medical care is provided. The term also includes:

(a) An offsite facility of a facility licensed under this chapter, or a joint venture between a facility licensed under this chapter and a provider licensed under chapter 458 or chapter 459, that does not require a patient to make an appointment and is presented to the general public in any manner as a facility where immediate but not emergent medical care is provided.

(b) A clinic organization that is licensed under part X of chapter 400, maintains three or more locations using the same or a similar name, does not require a patient to make an appointment, and holds itself out to the general public in any manner as a facility or clinic where immediate but not emergent medical care is provided.

*A timely completed Plan of Correction will eliminate fine until January 1, 2012. After that date, the statutory fine will be imposed regardless of corrective action.
least 15 square feet in size, or may be through an electronic messaging board. If an urgent care center is affiliated with a facility licensed under this chapter, the schedule must include text that notifies the insured patients whether the charges for medical services received at the center will be the same as, or more than, charges for medical services received at the affiliated hospital. The text notifying the patient of the schedule of charges shall be in a font size equal to or greater than the font size used for prices and must be in a contrasting color. The text that notifies the insured patients whether the charges for medical services received at the center will be the same as, or more than, charges for medical services received at the affiliated hospital shall be included in all media and Internet advertisements for the center and in language comprehensible to a layperson.

(3) The posted text describing the medical services must fill at least 12 square feet of the posting. A center may use an electronic device or messaging board to post the schedule of charges. Such a device must be at least 3 square feet, and patients must be able to access the schedule during all hours of operation of the urgent care center.

(4) An urgent care center that is operated and used exclusively for employees and the dependents of employees of the business that owns or contracts for the urgent care center is exempt from this section.

(5) The failure of an urgent care center to publish and post a schedule of charges as required by this section shall result in a fine of not more than $1,000, per day, until the schedule is published and posted.
Aspen State Regulation Set: U 2.02 Health Care Clinic

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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<tbody>
<tr>
<td>59A-33.012(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey: (h) Personnel files;</td>
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ST - U0320 - Clinic Responsibilities-Level of Care

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<tr>
<th>Title</th>
<th>Clinic Responsibilities-Level of Care</th>
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<td>Type</td>
<td>Rule</td>
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<td></td>
<td>400.9935(1)(d), 59A-33.012(3)(j)</td>
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<tr>
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<tr>
<td>400.9935, F.S.</td>
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<tr>
<td>(1) The medical director or the clinic director shall:</td>
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<tr>
<td>(d) Ensure that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided.</td>
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<tr>
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<tr>
<td>59A-33.012, F.A.C.</td>
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<tr>
<td>(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey: (j) Copies of professional licenses issued by the respective boards and the Department of Health under the several practice acts;</td>
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</table>
Aspen State Regulation Set: U 2.02 Health Care Clinic

ST - U0321 - Clinic Responsibilities-Services Provided

Title Clinic Responsibilities-Services Provided
Type Rule

59A-33.012(3)(n), F.A.C.

**Regulation Definition**

59A-33.012, F.A.C.
(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:
(n) List of services provided or a general descriptor of scope, level and complexity of care for services provided;

**Interpretive Guideline**

Services being provided at the clinic should match those services listed on the licensure application.

ST - U0325 - Clinic Responsibilities-Clinic Records Owner

Title Clinic Responsibilities-Clinic Records Owner
Type Rule

400.9935(1)(e), F.S.

**Regulation Definition**

400.9935, F.S.
(1) The medical director or the clinic director shall:
(e) Serve as the clinic records owner as defined in s. 456.057.

**Interpretive Guideline**

For undisclosed change of ownership (CHOW) and closure only, request a copy of the written agreement regarding medical record ownership.

ST - U0326 - Clinic Responsibilities-Clinic Records System

Title Clinic Responsibilities-Clinic Records System
Type Rule

59A-33.012(3)(d), F.A.C.
(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(d) Any policies, procedures, guidelines, checklists and/or means that are used in the systematic creation and maintenance of the health care clinic's medical record system;

(e) Any policies, procedures, guidelines, checklists that demonstrate compliance with the medical records retention, disposition, reproduction, and disclosure requirements of the medical or clinic director's practice act;

(f) Any policies, procedures, guidelines, checklists that demonstrate compliance with the office surgery requirements of the practice acts for services performed at the facility.

Clinic shall demonstrate the means by which medical records are created and maintained, which may include but not be limited to, policies, procedures, guidelines, and/or checklists.

Clinic shall demonstrate compliance with the medical records retention, disposition, reproduction, and disclosure requirements of the medical or clinic director's practice act. This may include but not be limited to methods and techniques used, policies, procedures, guidelines, and checklists.

Clinic must demonstrate compliance with adverse incident reporting requirements and injury disclosure.
Aspen State Regulation Set: U 2.02 Health Care Clinic

Title  Clinic Responsibilities-Systematic Bill Rvw
Type  Rule

ST - U0335 - Clinic Responsibilities-Systematic Bill Rvw

400.9935(1)(g), F.S., 59A-33.012(3)(m)

Regulation Definition

400.9935, F.S.
(1) The medical director or the clinic director shall:
(g) Conduct systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful. Upon discovery of an unlawful charge, the medical director or clinic director shall take immediate corrective action. If the clinic performs only the technical component of magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography, and provides the professional interpretation of such services, in a fixed facility that is accredited by a national accrediting organization that is approved by the Centers for Medicare and Medicaid Services for magnetic resonance imaging and advanced diagnostic imaging services and if, in the preceding quarter, the percentage of scans performed by that clinic which was billed to all personal injury protection insurance carriers was less than 15 percent, the chief financial officer of the clinic may, in a written acknowledgment provided to the agency, assume the responsibility for the conduct of the systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful.

59A-33.012(1), F.A.C.

Interpretive Guideline

Clinic must present a description of systematic review including:

1. Sample(s) reviewed by the medical director or clinic director at least once every 30 days. Sample size is not specified in statute/rule.

2. Record maintained (for at least 3 years) identifying the medical records reviewed and when/what corrective action taken for fraudulent or unlawful billings.

3. A log of systematic reviews shall be kept and maintained in a discrete file at the health care clinic for review on request of the Agency during the retention period.

59A-33.012(1), FAC
For health care clinics that are in operation at the time of the survey, the surveyor will select a sample of at least five (5) patient medical records from the previous 6 months of operation with at least one Medicaid file, if certified as a Medicaid provider, plus the five (5) billing records that correspond with the five patient records;
Aspen State Regulation Set: U 2.02 Health Care Clinic

(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(m) Description of means by which the health care clinic conducts a systematic review of billings that ensures billings are not fraudulent or unlawful. A sample must be reviewed by the medical director or clinic director at least once every 30 days and a record maintained by the health care clinic for at least three years identifying the records reviewed and what action was taken to correct fraudulent or unlawful billings. A log of systematic reviews shall be kept and maintained in a discrete file at the health care clinic for review on request of the Agency during the retention period;

ST - U0340 - Clinic Responsibilities-Record Sign Off

Title Clinic Responsibilities-Record Sign Off
Type Rule

59A-33.012(3)(q), F.A.C.

**Regulation Definition**

59A-33.012, F.A.C.
(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(q) An all-inclusive and up to date listing of original signatures and initials of all persons entering information on billing and patient records, including the printed name and medical designation, if any, such as PA, RN, MD, etc. The log shall be kept and concurrently maintained at the health care clinic. Information required by this rule shall be stored and maintained by the health care clinic for a period of 5 years.

**Interpretive Guideline**

All-inclusive and up to date listing of original signatures and initials of all persons entering information on billing and patient records, including the printed name and medical designation, if any, such as PA, RN, MD, etc.

The log shall be kept and concurrently maintained at the health care clinic.

Information shall be stored and maintained by the health care clinic for a period of 5 years.
ST - U0342 - Clinic Responsibilities-Equipment Certified

Title Clinic Responsibilities-Equipment Certified
Type Rule

59A-33.012(3)(o), F.A.C.

**Regulation Definition**

59A-33.012, F.A.C.

(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(o) Current diagnostic and treatment equipment records showing equipment certification when such equipment must have regulatory certification. This requirement is met with presentation of a current maintenance agreement;

**Interpretive Guideline**

Current diagnostic and treatment equipment records showing equipment certification when such equipment must have regulatory certification.

This requirement is met with presentation of a current maintenance agreement.

ST - U0345 - Clinic Responsibilities-Med Dir Oversight

Title Clinic Responsibilities-Med Dir Oversight
Type Rule

59A-33.012(3)(i), F.A.C.

**Regulation Definition**

59A-33.012, F.A.C.

(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:

(i) Logs, charts or notes demonstrating day-to-day oversight of health care clinic activities by the medical or clinic director;

**Interpretive Guideline**

Clinic shall provide a description or manner of review demonstrating the oversight of daily clinic activities by the medical or clinic director which may include but not be limited to logs, charts or notes. Review may be weekly, bi-weekly, etc. but should document that daily activities have been reviewed.
Aspen State Regulation Set: U 2.02 Health Care Clinic

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<tr>
<th>ST - U0350 - Clinic Responsibilities-Compliance by Med Dir</th>
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<tbody>
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<td><strong>Title</strong> Clinic Responsibilities-Compliance by Med Dir</td>
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<td><strong>Type</strong> Rule</td>
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<td><strong>Regulation Definition</strong></td>
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<tr>
<td>59A-33.012(3)(s), F.A.C.</td>
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<tr>
<td>(3) To facilitate a licensure survey, the health care clinic shall have the following materials readily available for review at the time of the survey:</td>
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<tr>
<td>(s) Documentation for the past two years or from the date of licensure, whichever is earlier, demonstrating in writing compliance, when, and what action was taken by the medical or clinic director to perform the functions, duties and clinic responsibilities under Sections 400.9935(1)(a)-(i), F.S. Such documentation shall be made available to authorized agency personnel upon request.</td>
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<tr>
<td><strong>Interpretive Guideline</strong></td>
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<tr>
<td>The clinic shall have documentation for the past two years (or from the date of licensure, whichever is earlier) that demonstrates actions taken by the medical or clinic director to perform the functions, duties, and clinic responsibilities.</td>
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<tr>
<td>Documentation must be in writing and include dates and specific action taken by medical director to maintain compliance with clinic responsibilities.</td>
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<tr>
<td>Documentation shall be made available to the authorized agency personnel upon request.</td>
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<tr>
<th>ST - U0400 - Violation of This Part; Lic Deny, Revoc, Fine</th>
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<tr>
<td><strong>Title</strong> Violation of This Part; Lic Deny, Revoc, Fine</td>
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<tr>
<td><strong>Type</strong> Rule</td>
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<tr>
<td><strong>Regulation Definition</strong></td>
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<tr>
<td>400.995(1)-(2), F.S.</td>
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<tr>
<td>(1) In addition to the requirements of part II of chapter 408, the agency may deny the application for a license renewal, revoke and suspend the license, and impose administrative fines of up to $5,000 per violation for violations of the requirements of this part or rules of the agency. In determining</td>
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<td><strong>Interpretive Guideline</strong></td>
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if a penalty is to be imposed and in fixing the amount of the fine, the agency shall consider the following factors:
(a) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient will result or has resulted, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.
(b) Actions taken by the owner, medical director, or clinic director to correct violations.
(c) Any previous violations.
(d) The financial benefit to the clinic of committing or continuing the violation.

(2) Each day of continuing violation after the date fixed for termination of the violation, as ordered by the agency, constitutes an additional, separate, and distinct violation.

ST - U0430 - No Medical Director; Emergency Suspension

Title  No Medical Director; Emergency Suspension
Type  Rule

400.9915(1), F.S., 59A-33.008(3)

Regulation Definition

400.9915(1), F.S.
Failure by a clinic to employ a qualified medical director or clinic director constitutes a ground for emergency suspension of the license by the agency pursuant to s. 408.814.

59A-33.008(3), F.A.C.
The Agency shall issue an emergency order suspending the license of any health care clinic operated or maintained without a medical or clinic director as required by Sections 400.990-400.995, F.S., and this rule for such period of time as...
the health care clinic is without a medical or clinic director.

ST - U0440 - False Application; 3rd Degree Felony

**Title** False Application; 3rd Degree Felony

**Type** Rule

400.9935(4), F.S.

**Regulation Definition**

400.9935, F.S.

(4)(a) Regardless of whether notification is provided by the agency under s. 408.812, a person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the person knowingly:

1. Establishes, owns, operates, manages, or maintains an unlicensed clinic required to be licensed under this part or part II of chapter 408; or

2. Offers or advertises services that require licensure as a clinic under this part or part II of chapter 408 without a license.

(b) If the agency provides notification under s. 408.812 of, or if a person is arrested for, a violation of subparagraph (a)1. or subparagraph (a)2., each day during which a violation of subparagraph (a)1. or subparagraph (a)2. occurs constitutes a separate offense.

(c) A person convicted of a second or subsequent violation of subparagraph (a)1. or subparagraph (a)2. commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the agency provides notification of, or if a person is arrested for, a violation of this paragraph, each day that this paragraph is violated thereafter constitutes a...
Aspen State Regulation Set: U 2.02 Health Care Clinic

separate offense. For purposes of this paragraph, the term "convicted" means a determination of guilt which is the result of a trial or the entry of a plea of guilty or nolo contendere, regardless of whether adjudication is withheld.

(d) In addition to the requirements of part II of chapter 408, a health care provider who is aware of the operation of an unlicensed clinic shall report the clinic to the agency. The agency shall report to the provider's licensing board a failure to report a clinic that the provider knows or has reasonable cause to suspect is unlicensed.

(e) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the person knowingly:
   1. Files a false or misleading license application or license renewal application or files false or misleading information related to such application or agency rule; or
   2. Fails to report information to the agency as required by s. 408.810(3).

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<thead>
<tr>
<th>Title</th>
<th>Licensed Provider/ Unlicensed Clinic;$5000/day</th>
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<tbody>
<tr>
<td>Type</td>
<td>Rule</td>
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<tr>
<td>400.995(4), F.S.</td>
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**Regulation Definition**

400.995(4), F.S.

Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic shall be subject to an administrative fine of $5,000 per day.
Title  Injunctions
Type  Rule

408.816(1)(2), F.S.

Regulation Definition
408.816(1)(2), F.S.

(1) In addition to the other powers provided by this part, authorizing statutes, and applicable rules, the agency may institute injunction proceedings in a court of competent jurisdiction to:

(a) Restrain or prevent the establishment or operation of a provider that does not have a license or is in violation of any provision of this part, authorizing statutes, or applicable rules. The agency may also institute injunction proceedings in a court of competent jurisdiction when a violation of this part, authorizing statutes, or applicable rules constitutes an emergency affecting the immediate health and safety of a client.

(b) Enforce the provisions of this part, authorizing statutes, or any minimum standard, rule, or order issued or entered into pursuant thereto when the attempt by the agency to correct a violation through administrative sanctions has failed or when the violation materially affects the health, safety, or welfare of clients or involves any operation of an unlicensed provider.

(c) Terminate the operation of a provider when a violation of any provision of this part, authorizing statutes, or any standard or rule adopted pursuant thereto exists that materially affects the health, safety, or welfare of a client.

Interpretive Guideline
Such injunctive relief may be temporary or permanent.

(2) If action is necessary to protect clients of providers from immediate, life-threatening situations, the court may allow a temporary injunction without bond upon proper proofs being made. If it appears by competent evidence or a sworn, substantiated affidavit that a temporary injunction should be issued, the court, pending the determination on final hearing, shall enjoin the operation of the provider.