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Aspen State Regulation Set: U 1.01 HEALTH CARE CLINIC

ST - U0000 - Initial Comments

**Title** Initial Comments

**Rule**

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

ST - U0100 - License Required

**Title** License Required

**Rule** 408.804(1), F.S., 400.991(1)(a), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.804(1), F.S.

It is unlawful to provide services that require licensure, or operate or maintain a provider that offers or provides services that require licensure, without first obtaining from the agency a license authorizing the provision of such services or the operation or maintenance of such provider.

400.991(1)(a), F.S.

The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and to entities licensed by or applying for such licensure from the agency pursuant to this part. A license issued by the agency is required in order to operate a clinic in this state. Each clinic location shall be licensed separately regardless of whether the clinic is operated under the same business name or management as another clinic.

Licensure is by separate location. Each facility location or each mobile clinic requires a separate license, regardless of ownership.

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59A-33.003(1), F.A.C.

Licensure is required for all entities meeting the definition of " clinic " per Section 400.9905(4), F.S., that are not otherwise exempt under Section 400.9905(4)(a)-(j), F.S.

**ST - U0105 - License Required; Mobile Clinics**

**Title** License Required; Mobile Clinics

**Rule** 400.991(1)(b), F.S.

**Type** Rule

**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 may be licensed by administrative office as they do not provide direct health care services to individuals at their own facilities.

**ST - U0110 - License Required; Application Required**

**Title** License Required; Application Required

**Rule** 59A-33.003(2), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.003(2), F.A.C.

Any business that meets the definition of a health care clinic must submit an application in accordance with Rule 59A-33.002, F.A.C., within 5 days of becoming a health care clinic pursuant to Section 400.9935(2), F.S. An application for

**Interpretive Guideline**

This tag is not intended to be used for clinics operating under exempt status until application/survey is complete and license is issued. See U-111 for a clinic operating under exempt status until licensed.

Facilities that have a certificate of exemption or self-determined that their facility is exempt, or a facility that provides services in which payment is by cash, check, or credit card, not third-party payments, (insurance, HMO, Medicaid or

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licensure is required for health care clinics that have a current certificate of exemption or have self-determined they have exempt status, but do not qualify for an exemption under Section 400.9905(4), F.S.

Medicare), and which becomes a business that meets the definition of a health care clinic under s. 400.9905 (4), F.S., must immediately submit and obtain an application for a health care clinic license. Tendering of patient charges after an exemption no longer applies is considered to be unlicensed operation, which must be documented by the surveyor. The surveyor should also determine a deficiency under TAG U0135, s. 400.9935 (3), F.S., for Unlicensed Operation, Claims unenforceable.

**ST - U0111 - License Required; Change of Exempt Status**

**Title** License Required; Change of Exempt Status

**Rule** 59A-33.006(3), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.006(3), F.A.C.

When a change to the exempt status occurs to an exempt facility or entity that causes it to no longer qualify for an exemption, any exempt status claimed or reflected in a certificate of exemption ceases on the date the facility or entity no longer qualifies for a certificate of exemption. In such case, the health care clinic must file with the Agency a license application under the Act within 5 days of becoming a health care clinic and shall be subject to all provisions of the Act applicable to unlicensed health care clinics. Failure to timely file an application for licensure within 5 days 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 the Act.

**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 U-110 and U-130 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. If the five day standard is met the facility may continue to operate under their previous status until completion of the initial survey and issuance and receipt of the Health Care Clinic License. The surveyor can confirm the 5 day period is met by record review of documentation demonstrating the application was mailed or faxed to the Health Care Clinic Unit within the five (calendar) day period.

**ST - U0115 - License Required; Display**

**Title** License Required; Display

**Rule** 408.804(2), F.S.

**Type** Rule

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**Regulation Definition**

408.804(2), F.S.

A license must be displayed in a conspicuous place readily visible to clients who enter at the address that appears on the license and is valid only in the hands of the licensee to whom it is issued and may not be sold, assigned, or otherwise transferred, voluntarily or involuntarily. The license is valid only for the licensee, provider, and location for which the license is issued.

**Interpretive Guideline**

The Health Care Clinic license 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.

**ST - U0120 - License Required; Non Transferable**

**Title** License Required; Non Transferable

**Rule** 408.804(2), F.S., 59A-33.005(1)

**Type** Rule

**Regulation Definition**

408.804(2), F.S.

A license must be displayed in a conspicuous place readily visible to clients who enter at the address that appears on the license and is valid only in the hands of the licensee to whom it is issued and may not be sold, assigned, or otherwise transferred, voluntarily or involuntarily. The license is valid only for the licensee, provider, and location for which the license is issued.

**Interpretive Guideline**

59A-33.005(1), F.A.C.

A health care clinic license cannot be sold, assigned, encumbered, pledged as security, leased or otherwise transferred, directly or indirectly. A health care clinic license is good only for the location and owners originally approved by the Agency.

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**ST - U0125 - License Required; No Advertisement of Svcs**

**Title** License Required; No Advertisement of Svcs

**Rule** 408.812(1), F.S.

**Type** Rule

**Regulation Definition**

408.812(1), F.S.

A person or entity may not offer or advertise services that require licensure as defined by this part, authorizing statutes, or applicable rules to the public without obtaining a valid license from the agency. A licenseholder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

**Interpretive Guideline**

Facilities that are required to be licensed as a Health Care Clinic, but are not so licensed, are prohibited from advertising for health care services. Health Care Clinics that are licensed may only advertise those services in which the scope of services of the licensed or certified provider, as permitted in the respective practice acts, and who are employed or under contract, and in which appropriate equipment, as necessary, is on site to provide the services in the licensed facility. (Portable Equipment Providers under Part X, Ch. 400, F.S., must have the appropriate equipment with them.)

**ST - U0130 - Unlicensed Operation; Fail to File Applicatio**

**Title** Unlicensed Operation; Fail to File Applicatio

**Rule** 59A-33.006(3), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.006(3), F.A.C.

Failure to timely file an application for licensure within 5 days 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 the Act.

**Interpretive Guideline**

This tag is not intended to be used for clinics operating under exempt status until application/survey is complete and license is issued. See U-111 for a clinic operating under exempt status until licensed.

Facilities that have a certificate of exemption or self-determined that their facility is exempt, or a facility that provides services in which payment is by cash, check, or credit card, not third-party payments, (seek third party insurance, HMO, Medicaid or Medicare reimbursement), and who become a business that meets the definition of a health care clinic must immediately submit an application for licensure. Tendering of patient charges after an exemption no longer applies is considered to be unlicensed operation, which must be documented by the surveyor. The surveyor should also determine a deficiency under TAG U0135, s. 400.9935 (3), F.S., for Unlicensed Operation, Claims unenforceable. An unlicensed provider letter from FRAES should be delivered to the facility with the signature or approval of the Field Office Manager. The surveyor should confirm in 5 days that an application was mailed or

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courier-delivered to the Health Care Clinic Unit within a five (calendar) day period.

**ST - U0135 - Unlicensed Operation; Claims Unenforceable**

**Title** Unlicensed Operation; Claims Unenforceable

**Rule** 400.9935(3), F.S.

**Type** Rule

**Regulation Definition**

400.9935(3), F.S.

All charges or reimbursement claims made by or on behalf of a clinic that is required to be licensed under this part, but that is not so licensed, or that is otherwise operating in violation of this part, are unlawful charges, and therefore are noncompensable and unenforceable.

**Interpretive Guideline**

**ST - U0140 - Unlicensed Operation; Violation of this Part**

**Title** Unlicensed Operation; Violation of this Part

**Rule** 408.812(2), F.S.

**Type** Rule

**Regulation Definition**

408.812(2), F.S.

The operation or maintenance of an unlicensed provider or the performance of any services that require licensure without proper licensure is a violation of this part and authorizing statutes. Unlicensed activity constitutes harm that materially affects the health, safety, and welfare of clients. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the unlicensed provider or the performance of any services in violation of this part and authorizing statutes, until compliance

**Interpretive Guideline**

By definition " unlicensed activity " is " harm " that materially affects the health, safety, and welfare of clients. Surveyors should determine the number of days an unlicensed facility operates in which the facility sought to be reimbursed for services by a third-party insurance carrier. One patient, provided services in a day, in which third-party reimbursement is sought and sent to the payer, documents the unlicensed activity when no license has been issued to the clinic. The surveyor should then document each day of service to at least one patient in order to provide documentation of the total days of service for " request for sanction " purposes.

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with this part, authorizing statutes, and agency rules has been demonstrated to the satisfaction of the agency.

**ST - U0145 - Unlicensed Operation; Threat to Health/Safety**

**Title** Unlicensed Operation; Threat to Health/Safety

**Rule** 408.812(6), F.S.

**Type** Rule

**Regulation Definition**

408.812(6), F.S.

In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part, authorizing statutes, and agency rules.

**Interpretive Guideline**

Request guidance/permission from Central Office and Office of General Counsel prior to citing this tag.

**ST - U0150 - Unlicensed Operation; Report to AHCA**

**Title** Unlicensed Operation; Report to AHCA

**Rule** 408.812(7), F.S., 400.993(3), F.S.

**Type** Rule

**Regulation Definition**

408.812(7), F.S.

Any person aware of the operation of an unlicensed provider must report that provider to the agency.

400.993(3), F.S.

In addition to the requirements of part II of chapter 408, any health care provider who is aware of the operation of an

**Interpretive Guideline**

Evidence of violation should be documented and reported to AO Supervisor for subsequent referral to licensure board.

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unlicensed clinic shall report that facility to the agency.  
Failure to report a clinic that the provider knows or has reasonable cause to suspect is unlicensed shall be reported to the provider's licensing board.

**ST - U0155 - Notice of Insurance Fraud Display**

**Title** Notice of Insurance Fraud Display

**Rule** 400.9935(9), F.S.

**Type** Rule

**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 Insurance Fraud 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.

**ST - U0160 - Patient's Right to Report Complaints, Abuse**

**Title** Patient's Right to Report Complaints, Abuse

**Rule** 408.810(5), F.S.

**Type** Rule

**Regulation Definition**

408.810(5)(a)(b), F.S.  
(a) On or before the first day services are provided to a client, a licensee must inform the client and his or her immediate family or representative, if appropriate, of the right to report:

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1. Complaints. The statewide toll-free telephone number for reporting complaints to the agency must be provided to clients in a manner that is clearly legible and must include the words: "To report a complaint regarding the services you receive, please call toll-free (phone number)."

2. Abusive, neglectful, or exploitative practices. The statewide toll-free telephone number for the central abuse hotline must be provided to clients in a manner that is clearly legible and must include the words: "To report abuse, neglect, or exploitation, please call toll-free (phone number)." The agency shall publish a minimum of a 90-day advance notice of a change in the toll-free telephone numbers.

(b) Each licensee shall establish appropriate policies and procedures for providing such notice to clients.

**ST - U0175 - Level 2 Background Screening Required**

**Title** Level 2 Background Screening Required

**Rule** 408.810(1), F.S., 400.991(5)(b), F.S.

**Type** Rule

**Regulation Definition**

408.810(1), F.S.

An applicant for licensure must comply with the background screening requirements of s. 408.809.

400.991(5)(b), F.S.

Upon receipt of a completed, signed, and dated application, the agency shall require background screening of the applicant, in accordance with the level 2 standards for screening set forth in chapter 435. Proof of compliance with the level 2 background screening requirements of chapter 435 which has been submitted within the previous 5 years in

**Interpretive Guideline**

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

1. Individuals owning or controlling 10 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;
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.

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compliance with any other health care licensure requirements of this state is acceptable in fulfillment of this paragraph. Applicants who own less than 10 percent of a health care clinic are not required to submit fingerprints under this section.

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 should 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

**Rule** 408.810(8), F.S., 59A-33.009(1), F.A.C.

**Type** Rule

**Regulation Definition**

408.810(8), F.S.

The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited to, unpaid expenses necessary for the basic operations of the provider.

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

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.

**Interpretive Guideline**

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.

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**ST - U0185 - Evidence of Financial Instability-Notificatio**

**Title** Evidence of Financial Instability-Notificatio

**Rule** 59A-33.009, F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

59A-33.009, F.S.

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 Part X, Chapter 400, F.S., must be provided.

**ST - U0190 - Financial Instability-Plan of Correction**

**Title** Financial Instability-Plan of Correction

**Rule** 59A-33.009(2), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

59A-33.009(2), F.A.C.

The licensee shall submit to the Agency a written plan of correction to resolve specific financial problems that the Agency has identified as evidence of financial instability. Should the financial instability not be resolved within 90 days of the original notice, the licensee shall be subject to disciplinary action, fine, suspension or revocation of the license.

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**ST - U0195 - M.R.I. Accreditation**

**Title** M.R.I. Accreditation

**Rule** 400.9935(7)(a), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

400.9935(7)(a), F.S.

Each clinic engaged in magnetic resonance imaging services must be accredited by the Joint Commission on Accreditation of Healthcare Organizations, the American College of Radiology, or the Accreditation Association for Ambulatory Health Care, within 1 year after licensure. 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 can not 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.

**ST - U0200 - Right of Inspection**

**Title** Right of Inspection

**Rule** 408.811, F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.811(1), F.S.

An authorized officer or employee of the agency may make or cause to be made any inspection or investigation deemed necessary by the agency to determine the state of compliance

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with this part, authorizing statutes, and applicable rules. The right of inspection extends to any business that the agency has reason to believe is being operated as a provider without a license, but inspection of any business suspected of being operated without the appropriate license may not be made without the permission of the owner or person in charge unless a warrant is first obtained from a circuit court. Any application for a license issued under this part, authorizing statutes, or applicable rules constitutes permission for an appropriate inspection to verify the information submitted on or in connection with the application.

**ST - U0205 - Right of Inspection; Compliance**

**Title** Right of Inspection; Compliance

**Rule** 408.806(7)(a), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.806(7)(a), F.S.

An applicant must demonstrate compliance with the requirements in this part, authorizing statutes, and applicable rules during an inspection pursuant to s. 408.811, as required by authorizing statutes.

**ST - U0210 - Right of Inspection; Div of Insurance Fraud**

**Title** Right of Inspection; Div of Insurance Fraud

**Rule** 400.9935(9), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

400.9935(9), F.S.

An authorized employee of the Division of Insurance Fraud

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may make unannounced inspections of a clinic licensed under this part as necessary to determine whether the clinic is in compliance with this subsection. A licensed clinic shall allow full and complete access to the premises to such authorized employee of the division who makes an inspection to determine compliance with this subsection.

**ST - U0215 - Right of Inspection; Unannounced**

**Title** Right of Inspection; Unannounced

**Rule** 408.811(1)(a), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.811(1)(a), F.S.

All inspections shall be unannounced, except as specified in s. 408.806.

**ST - U0220 - Right of Inspection; Biennial**

**Title** Right of Inspection; Biennial

**Rule** 408.811(1)(b), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.811(1)(b), F.S.

Inspections for relicensure shall be conducted biennially unless otherwise specified by authorizing statutes or applicable rules.

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

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

**Rule** 408.806(7)(d), F.S.

**Type** Rule

**Regulation Definition**

408.806(7)(d), F.S.

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 - U0230 - Right of Inspection; Copies of Records**

**Title** Right of Inspection; Copies of Records

**Rule** 408.811(3), F.S.

**Type** Rule

**Regulation Definition**

408.811(3), F.S.

The agency shall have access to and the licensee shall provide copies of all provider records required during an inspection at no cost to the agency.

**Interpretive Guideline**

**ST - U0235 - Right of Inspection; Inspection Reports**

**Title** Right of Inspection; Inspection Reports

**Rule** 408.811(4)(a), F.S.

**Type** Rule

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**Regulation Definition**

408.811(4)(a), F.S.

Each licensee shall maintain as public information, available upon request, records of all inspection reports pertaining to that provider that have been filed by the agency unless those reports are exempt from or contain information that is exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution or is otherwise made confidential by law. Effective October 1, 2006, copies of such reports shall be retained in the records of the provider for at least 3 years following the date the reports are filed and issued, regardless of a change of ownership.

**Interpretive Guideline**

**ST - U0240 - Right of Inspection; Inspection Reports**

**Title** Right of Inspection; Inspection Reports

**Rule** 408.811(4)(b), F.S.

**Type** Rule

**Regulation Definition**

408.811(4)(b), F.S.

A licensee shall, upon the request of any person who has completed a written application with intent to be admitted by such provider, any person who is a client of such provider, or any relative, spouse, or guardian of any such person, furnish to the requester a copy of the last inspection report pertaining to the licensed provider that was issued by the agency or by an accrediting organization if such report is used in lieu of a licensure inspection.

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**ST - U0300 - Medical Director Required**

**Title** Medical Director Required

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

**Type** Rule

**Regulation Definition**

400.9935(1), F.S.

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.

59A-33.008(1), F.A.C.

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

**Interpretive Guideline**

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

**ST - U0301 - Medical Director Required; Written Agreement**

**Title** Medical Director Required; Written Agreement

**Rule** 59A-33.012(5)(b), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(b), F.A.C.

The health care clinic shall have a 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)-(g), F.S. If the medical or clinic director signs the application or change of medical or clinic director form, acknowledging these responsibilities as specified in Section 400.9935, F.S., this requirement is met.

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**ST - U0302 - Medical Director Required; Agreement Void**

**Title** Medical Director Required; Agreement Void

**Rule** 400.9935(2), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

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.

**ST - U0303 - Medical Director; Qualifications**

**Title** Medical Director; Qualifications

**Rule** 400.9905(5), F.S., 59A-33.008(2), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

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

Medical or Clinic Director should present DOH license to practice.

License must be current (not expired).

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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(2), F.A.C.

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

**Rule** 59A-33.012(3), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(3), 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. 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

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4. Records/Billing Personnel

**ST - U0305 - Medical Director; Max Number of Clinics**

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

**Rule** 59A-33.013, F.A.C.

**Type** Rule

**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**

**ST - U0306 - Clinic Responsibilities-Sign Identify Med Dir**

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

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

**Type** Rule

**Regulation Definition**

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

The medical director or the clinic director shall 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

**Rule** 59A-33.012(5)(p), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(p), F.A.C.  
The health care clinic shall have 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

**Rule** 59A-33.012(5)(r), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(r), F.A.C.  
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**

**Title** Clinic Responsibilities-Licensed Staff

**Rule** 400.9935(1)(b), F.S., 59A-33.012(j)

**Type** Rule

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**Regulation Definition**

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

The medical director or the clinic director shall ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license.

59A-33.012(5)(j), F.A.C.

The health care clinic shall have copies of professional licenses issued by the respective boards and the Department of Health under the several practice acts.

**Interpretive Guideline**

Clinic shall have a copy of DOH licenses on file for all health care practitioners.

Licenses must be current (not expired).

**ST - U0311 - Clinic Responsibilities-Staff Operations**

**Title** Clinic Responsibilities-Staff Operations

**Rule** 59A-33.012(5)(c), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(c), F.A.C.

The health care clinic shall have written policies, protocols, guidelines and procedures used or to be used by the facility staff in day-to-day operations. This includes, but is not limited to 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.

**Interpretive Guideline**

Clinic should have policies, procedures, protocols and guidelines for daily operations at the clinic.

Policies/procedures should be available for staff use.

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

**ST - U0315 - Clinic Responsibilities-Patient Contracts Rvw**

**Title** Clinic Responsibilities-Patient Contracts Rvw

**Rule** 400.9935(1)(c), F.S.

**Type** Rule

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**Regulation Definition**

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

The medical director or the clinic director shall review any patient referral contracts or agreements executed by the clinic.

**Interpretive Guideline**

**ST - U0316 - Clinic Responsibilities-Patient Contracts Rvw**

**Title** Clinic Responsibilities-Patient Contracts Rvw

**Rule** 59A-33.012(5)(k), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(k), F.A.C.

The health care clinic shall have 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.

**Interpretive Guideline**

**ST - U0317 - Clinic Responsibilities-Patient Referrals**

**Title** Clinic Responsibilities-Patient Referrals

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

**Type** Rule

**Regulation Definition**

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

The medical director or clinic director shall 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

**Interpretive Guideline**

The medical director of a licensed clinic may not refer his/her patient or the patient of any other physician from a separate (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)

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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.

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. This TAG does not apply to clinic directors.

Surveyor Questions for the Medical Director:

1. Are you also a member of a separate (group) practice?
  - If NO, there is no violation.
  - 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 - U0320 - Clinic Responsibilities-Level of Care**

**Title** Clinic Responsibilities-Level of Care

**Rule** 400.9935(1)(d), 59A-33.012(5)(j)

**Type** Rule

**Regulation Definition**

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

The medical director or the clinic director shall ensure that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided.

**Interpretive Guideline**

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59A-33.012(5)(j), F.A.C.

The health care clinic shall have copies of professional licenses issued by the respective boards and the Department of Health under the several practice acts.

**ST - U0321 - Clinic Responsibilities-Services Provided**

**Title** Clinic Responsibilities-Services Provided

**Rule** 59A-33.012(5)(n), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(n), F.A.C.

The health care clinic shall have a 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

**Rule** 400.9935(1)(e), F.S., 59A-33.010(1), FAC

**Type** Rule

**Regulation Definition**

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

The medical director or clinic director shall 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.

59A-33.010(1), F.A.C.

The medical or clinic director serves as the medical records owner while the health care clinic is in operation. After the cessation or change of ownership of the business, the treating health care practitioner creating the record is the medical records owner in accordance with Sections 456.057,

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456.0575, and 456.58, F.S., and the rules promulgated thereunder unless there is a written agreement between the practitioner and health care clinic to the contrary.

**ST - U0326 - Clinic Responsibilities-Clinic Records System**

**Title** Clinic Responsibilities-Clinic Records System

**Rule** 59A-33.012(5)(d), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(d), F.A.C.  
The health care clinic shall have 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.

**Interpretive Guideline**

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.

**ST - U0330 - Clinic Responsibilities-Recordkeeping**

**Title** Clinic Responsibilities-Recordkeeping

**Rule** 400.9935(1)(f), F.S., 59A-33.012(5)(e)

**Type** Rule

**Regulation Definition**

400.9935(1)(f), F.S.  
The medical director or the clinic director shall ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, the respective practice acts, and rules adopted under this part and part II of chapter 408.

**Interpretive Guideline**

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.

59A-33.012(5)(e), F.A.C.

The health care clinic shall have any policies, procedures, guidelines, checklists that demonstrate compliance with the

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medical records retention, disposition, reproduction, and disclosure requirements of the medical or clinic director ' s practice act.

**ST - U0331 - Clinic Responsibilities-Office Surgery**

**Title** Clinic Responsibilities-Office Surgery

**Rule** 400.9935(1)(f), F.S., 59A-33.012(5)(f)

**Type** Rule

**Regulation Definition**

400.9935(1)(f), F.S.  
The medical director or the clinic director shall ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, the respective practice acts, and rules adopted under this part and part II of chapter 408.

59A-33.012(5)(f), F.A.C.  
The health care clinic shall have any policies, procedures, guidelines, checklists that demonstrate compliance with the office surgery requirements of the practice acts for services performed at the facility.

**Interpretive Guideline**

Clinic shall demonstrate compliance with the office surgery requirements of the practice acts for services performed at the facility. This may include but not be limited to methods and techniques used, policies, procedures, guidelines, and checklists.

**ST - U0332 - Clinic Responsibilities-Adverse Incidents**

**Title** Clinic Responsibilities-Adverse Incidents

**Rule** 400.9935(1)(f), F.S., 59A-33.012(5)(g)

**Type** Rule

**Regulation Definition**

400.9935(1)(f), F.S.  
The medical director or the clinic director shall ensure compliance with the recordkeeping, office surgery, and

**Interpretive Guideline**

Clinic must demonstrate compliance with adverse incident reporting requirements and injury disclosure which may include but not be limited to methods and techniques used, policies, procedures, guidelines, and checklists.

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adverse incident reporting requirements of chapter 456, the respective practice acts, and rules adopted under this part and part II of chapter 408.

59A-33.012(5)(g), F.A.C.

The health care clinic shall have any policies, procedures, guidelines, checklists that demonstrate compliance with adverse incident reporting requirements and injury disclosure.

**ST - U0335 - Clinic Reponsibilities-Systematic Bill Rvw**

**Title** Clinic Reponsibilities-Systematic Bill Rvw

**Rule** 400.9935(1)(g), F.S., 59A-33.012(5)(m)

**Type** Rule

**Regulation Definition**

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

The medical director or the clinic director shall 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 the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care, and the American College of Radiology; 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.

**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.

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59A-33.012(5)(m), F.A.C.

The health care clinic shall have a 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 when 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

**Rule** 59A-33.012(5)(q), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(q), F.A.C.

The health care clinic shall have an all-inclusive and up to date listing of original signatures and initials of all persons entering information on billing and patient records, 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.

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**ST - U0342 - Clinic Responsibilities-Equipment Certified**

**Title** Clinic Responsibilities-Equipment Certified

**Rule** 59A-33.012(5)(o), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(o), F.A.C.

The health care clinic shall have 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

**Rule** 59A-33.012(5)(i), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.012(5)(i), F.A.C.

The health care clinic shall have 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.

**ST - U0350 - Clinic Responsibilities-Compliance by Med Dir**

**Title** Clinic Responsibilities-Compliance by Med Dir

**Rule** 59A-33.012(5)(s), F.A.C.

**Type** Rule

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**Regulation Definition**

59A-33.012(5)(s), F.A.C.

The health care clinic shall have 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 Section 400.9935(1)(a)-(g), F.S. Such documentation shall be made available to the authorized agency personnel upon request.

**Interpretive Guideline**

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.

Documentation must be in writing and include dates and specific action taken by medical director to maintain compliance with clinic responsibilities.

Documentation shall be made available to the authorized agency personnel upon request.

**ST - U0355 - Clinic Responsibilities-Provider Violation**

**Title** Clinic Responsibilities-Provider Violation

**Rule** 400.9935(5), F.S.

**Type** Rule

**Regulation Definition**

400.9935(5), F.S.

Any licensed health care provider who violates this part is subject to discipline in accordance with this chapter and his or her respective practice act.

**Interpretive Guideline**

Evidence of violation should be documented and reported to the AO Supervisor for subsequent referral to the appropriate licensure board.

**ST - U0400 - Violation of This Part; Lic Deny, Revoc, Fine**

**Title** Violation of This Part; Lic Deny, Revoc, Fine

**Rule** 400.995(1)(2), F.S.

**Type** Rule

**Regulation Definition**

400.995(1)(2), F.S.

(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

**Interpretive Guideline**

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finances of up to \$5,000 per violation for violations of the requirements of this part or rules of the agency. In determining 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 - U0405 - Violations Of This Part; Lic Deny or Revoke**

**Title** Violations Of This Part; Lic Deny or Revoke

**Rule** 408.815(1)(c), F.S.

**Type** Rule

**Regulation Definition**

408.815(1)(c), F.S.

In addition to the grounds provided in authorizing statutes, grounds that may be used by the agency for denying and revoking a license or change of ownership application include any of the following actions by a controlling interest:

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(c) A violation of this part, authorizing statutes, or applicable rules.

**ST - U0410 - Negligent Acts; License Deny or Revoke**

**Title** Negligent Acts; License Deny or Revoke

**Rule** 408.815(1)(b), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.815(1)(b), F.S.

In addition to the grounds provided in authorizing statutes, grounds that may be used by the agency for denying and revoking a license or change of ownership application include any of the following actions by a controlling interest:

(b) An intentional or negligent act materially affecting the health or safety of a client of the provider.

**ST - U0415 - Repeat Deficient Practice; Lic Deny or Revoke**

**Title** Repeat Deficient Practice; Lic Deny or Revoke

**Rule** 408.815(1)(d), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.815(1)(d), F.S.

In addition to the grounds provided in authorizing statutes, grounds that may be used by the agency for denying and revoking a license or change of ownership application include any of the following actions by a controlling interest:

(d) A demonstrated pattern of deficient performance.

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**ST - U0420 - Financial Instability; 2nd Degree Misdemeanor**

**Title** Financial Instability; 2nd Degree Misdemeanor

**Rule** 408.810(9), F.S., 59A-33.009(1), F.A.C.

**Type** Rule

**Regulation Definition**

408.810(9), F.S.  
A controlling interest may not withhold from the agency any evidence of financial instability, including, but not limited to, checks returned due to insufficient funds, delinquent accounts, nonpayment of withholding taxes, unpaid utility expenses, nonpayment for essential services, or adverse court action concerning the financial viability of the provider or any other provider licensed under this part that is under the control of the controlling interest. Any person who violates this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation is a separate offense.

**Interpretive Guideline**

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.

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

**ST - U0425 - Financial Instability; License Revoc, Fine**

**Title** Financial Instability; License Revoc, Fine

**Rule** 59A-33.009(2), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.009(2), F.A.C.  
The licensee shall submit to the Agency a written plan of correction to resolve specific financial problems that the Agency has identified as evidence of financial instability. Should the financial instability not be resolved within 90 days of the original notice, the licensee shall be subject to

**Interpretive Guideline**

Financial documentation must be produced by the provider; otherwise 2nd degree misdemeanor

See 0485 for requirements on plan of correction

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disciplinary action, fine, suspension or revocation of the license.

**ST - U0430 - No Medical Director; Emergency Suspension**

**Title** No Medical Director; Emergency Suspension

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

**Type** Rule

**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 the Act and this rule for such period of time as the health care clinic is without a medical or clinic director.

**Interpretive Guideline**

**ST - U0435 - Medicare,Medicaid Exclusion; Lic Deny, Revoke**

**Title** Medicare,Medicaid Exclusion; Lic Deny, Revoke

**Rule** 408.815(1)(e), F.S.

**Type** Rule

**Regulation Definition**

408.815(1)(e), F.S.

In addition to the grounds provided in authorizing statutes, grounds that may be used by the agency for denying and revoking a license or change of ownership application include any of the following actions by a controlling interest:

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(e) The applicant, licensee, or controlling interest has been or is currently excluded, suspended, or terminated from participation in the state Medicaid program, the Medicaid program of any other state, or the Medicare program.

**ST - U0440 - False Application; 3rd Degree Felony**

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

**Rule** 400.9935(4), F.S.

**Type** Rule

**Regulation Definition**

400.9935(4), F.S.

In addition to the requirements of s. 408.812, any person establishing, operating, or managing an unlicensed clinic otherwise required to be licensed under this part or part II of chapter 408, or any person who knowingly files a false or misleading license application or license renewal application, or false or misleading information related to such application or department rule, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

**Interpretive Guideline**

**ST - U0445 - False Application; License Deny or Revoke**

**Title** False Application; License Deny or Revoke

**Rule** 408.815(1)(a), F.S.

**Type** Rule

**Regulation Definition**

408.815(1)(a), F.S.

In addition to the grounds provided in authorizing statutes, grounds that may be used by the agency for denying and

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revoking a license or change of ownership application include any of the following actions by a controlling interest:

(a) False representation of a material fact in the license application or omission of any material fact from the application.

**ST - U0450 - Unlicensed Operation; 3rd Degree Felony**

**Title** Unlicensed Operation; 3rd Degree Felony

**Rule** 400.993(1), F.S., 400.9935(4), F.S.

**Type** Rule

**Regulation Definition**

400.993(1), F.S.

Any person who violates s. 408.812 regarding unlicensed activity commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

400.9935(4), F.S.

In addition to the requirements of s. 408.812, any person establishing, operating, or managing an unlicensed clinic otherwise required to be licensed under this part or part II of chapter 408, or any person who knowingly files a false or misleading license application or license renewal application, or false or misleading information related to such application or department rule, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

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**ST - U0455 - Unlicensed Operation; 2nd Degree Felony**

**Title** Unlicensed Operation; 2nd Degree Felony

**Rule** 400.993(2), F.S.

**Type** Rule

**Regulation Definition**

400.993(2), F.S.

Any person found guilty of violating s. 408.812 a second or subsequent time commits a felony of the second degree, punishable as provided under s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

**Interpretive Guideline**

**ST - U0460 - Unlicensed Operation; Unreported CHOW**

**Title** Unlicensed Operation; Unreported CHOW

**Rule** 400.995(5), F.S., 59A-33.005(5), F.A.C.

**Type** Rule

**Regulation Definition**

400.995(5), F.S.

Any clinic whose owner fails to apply for a change-of-ownership license and operates the clinic under the new ownership is subject to a fine of \$5,000.

59A-33.005(5), F.A.C.

When a health care clinic changes ownership according to the criteria set forth in this rule and the Act and operates before a change of ownership application is filed, it is in violation of Section 400.993(1), F.S., and the Agency shall issue a notice of intent to assess the statutory fine of \$5,000.

**Interpretive Guideline**

This deficiency requires an unreported CHOW and operation of the clinic without the proper licensure in order to cite.

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**ST - U0465 - Unlicensed Ops Before CHOW License Issued**

**Title** Unlicensed Ops Before CHOW License Issued

**Rule** 59A-33.005(6), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.005(6), F.A.C.  
When a health care clinic changes ownership and operates after an application is filed, but before the new change-of-ownership license is effective, the Agency shall issue a notice of intent to fine the applicant up to \$5,000 pursuant to Section 400.995(1), F.S.

**Interpretive Guideline**

This deficiency requires operation after a CHOW application has been filed but before the license is issued in order to cite.

**ST - U0467 - Unlicensed Operation While Lic Susp, Revoked**

**Title** Unlicensed Operation While Lic Susp, Revoked

**Rule** 59A-33.010(2), F.A.C.

**Type** Rule

**Regulation Definition**

59A-33.010(2), F.A.C.  
Operating a health care clinic while a license is suspended or revoked constitutes unlicensed operation of a clinic and subjects the clinic, owners and medical or clinic director, individually, to the criminal sanctions, and the clinic to per-day fines for operating without a license.

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ST - U0470 - Licensed Provider/ Unlicensed Clinic;\$1000/day

**Title** Licensed Provider/ Unlicensed Clinic;\$1000/day

**Rule** 408.812(5), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.812(5), F.S.

When a controlling interest or licensee has an interest in more than one provider and fails to license a provider rendering services that require licensure, the agency may revoke all licenses and impose actions under s. 408.814 and a fine of \$1,000 per day, unless otherwise specified by authorizing statutes, against each licensee until such time as the appropriate license is obtained for the unlicensed operation.

ST - U0475 - Licensed Provider/ Unlicensed Clinic;\$5000/day

**Title** Licensed Provider/ Unlicensed Clinic;\$5000/day

**Rule** 400.995(4), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

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.

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**ST - U0480 - Fail To Cease Unlicensed Ops After Notified**

**Title** Fail To Cease Unlicensed Ops After Notified

**Rule** 408.812(3), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.812(3), F.S.

It is unlawful for any person or entity to own, operate, or maintain an unlicensed provider. If after receiving notification from the agency, such person or entity fails to cease operation and apply for a license under this part and authorizing statutes, the person or entity shall be subject to penalties as prescribed by authorizing statutes and applicable rules. Each day of continued operation is a separate offense.

**ST - U0485 - Fail to Cease Unlicensed Operation; \$1000/day**

**Title** Fail to Cease Unlicensed Operation; \$1000/day

**Rule** 408.812(4), F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.812(4), F.S.

Any person or entity that fails to cease operation after agency notification may be fined \$1,000 for each day of noncompliance.

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**ST - U0490 - Plan of Correction; Alternative to Adm Action**

**Title** Plan of Correction; Alternative to Adm Action

**Rule** 400.995(6), F.S.

**Type** Rule

**Regulation Definition**

400.995(6), F.S.

The agency, as an alternative to or in conjunction with an administrative action against a clinic for violations of this part and adopted rules, shall make a reasonable attempt to discuss each violation and recommended corrective action with the owner, medical director, or clinic director of the clinic, prior to written notification. The agency, instead of fixing a period within which the clinic shall enter into compliance with standards, may request a plan of corrective action from the clinic which demonstrates a good faith effort to remedy each violation by a specific date, subject to the approval of the agency.

**Interpretive Guideline**

**ST - U0491 - Plan of Correction; Lic Deny, Revoke, Fine**

**Title** Plan of Correction; Lic Deny, Revoke, Fine

**Rule** 400.995(3), F.S.

**Type** Rule

**Regulation Definition**

Any action taken to correct a violation shall be documented in writing by the owner, medical director, or clinic director of the clinic and verified through followup visits by agency personnel. The agency may impose a fine and, in the case of an owner-operated clinic, revoke or deny a clinic's license when a clinic medical director or clinic director knowingly

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misrepresents actions taken to correct a violation.

**ST - U0495 - Moratorium; Emergency Suspension**

**Title** Moratorium; Emergency Suspension

**Rule** 408.814, F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

408.814, F.S.

(1) The agency may impose an immediate moratorium or emergency suspension as defined in s. 120.60 on any provider if the agency determines that any condition related to the provider or licensee presents a threat to the health, safety, or welfare of a client.

(2) A provider or licensee, the license of which is denied or revoked, may be subject to immediate imposition of a moratorium or emergency suspension to run concurrently with licensure denial, revocation, or injunction.

(3) A moratorium or emergency suspension remains in effect after a change of ownership, unless the agency has determined that the conditions that created the moratorium, emergency suspension, or denial of licensure have been corrected.

(4) When a moratorium or emergency suspension is placed on a provider or licensee, notice of the action shall be posted and visible to the public at the location of the provider until the action is lifted.

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**ST - U0497 - Injunctions**

**Title** Injunctions

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

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

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.

Such injunctive relief may be temporary or permanent.

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(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.

**ST - U9999 - Final Observations**

**Title** Final Observations

**Rule**

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**