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CS/CS/HB 1471, Engrossed 2

2023 Legislature

1
2 An act relating to health care provider
3 accountability; amending s. 400.022, F.S.; revising
4 the rights of licensed nursing home facility
5 residents; providing definitions; amending s. 408.812,
6 F.S.; creating a cause of action for an ex parte
7 temporary injunction against continued unlicensed
8 activity; providing requirements for such injunction;
9 providing construction; authorizing the Agency for
10 Health Care Administration to provide certain records
11 to local law enforcement and state attorneys' offices
12 under certain circumstances; amending ss. 458.328 and
13 459.0138, F.S.; requiring the Department of Health to
14 complete an inspection of any physician's office
15 seeking registration to perform office surgeries
16 before the office may be registered; requiring
17 immediate suspension of a registration under specified
18 circumstances; requiring such offices to remain closed
19 for the duration of any suspensions; requiring a
20 suspension to remain in effect for a specified
21 timeframe; requiring physicians performing gluteal fat
22 grafting procedures in an office surgery setting to
23 adhere to specified standards of practice; specifying
24 surgeries that may not be performed in an office
25 surgery setting; requiring physicians performing

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26 | gluteal fat grafting procedures to conduct in-person
 27 | examinations of the patients; requiring the reporting
 28 | of specified adverse incidents; providing requirements
 29 | for the performance of gluteal fat grafting
 30 | procedures; providing an effective date.

31 |

32 | Be It Enacted by the Legislature of the State of Florida:

33 |

34 | Section 1. Paragraph (o) of subsection (1) of section
 35 | 400.022, Florida Statutes, is amended to read:

36 | 400.022 Residents' rights.—

37 | (1) All licensees of nursing home facilities shall adopt
 38 | and make public a statement of the rights and responsibilities
 39 | of the residents of such facilities and shall treat such
 40 | residents in accordance with the provisions of that statement.
 41 | The statement shall assure each resident the following:

42 | (o) The right to be free from mental and physical abuse,
 43 | sexual abuse, neglect, exploitation, corporal punishment,
 44 | extended involuntary seclusion, and ~~from~~ physical and chemical
 45 | restraints, except those restraints authorized in writing by a
 46 | physician for a specified and limited period of time or as are
 47 | necessitated by an emergency. In case of an emergency, restraint
 48 | may be applied only by a qualified licensed nurse who shall set
 49 | forth in writing the circumstances requiring the use of
 50 | restraint, and, in the case of use of a chemical restraint, a

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51 physician shall be consulted immediately thereafter. Restraints
52 may not be used in lieu of staff supervision or merely for staff
53 convenience, for punishment, or for reasons other than resident
54 protection or safety. For purposes of this paragraph, the terms
55 "sexual abuse," "neglect," and "exploitation" have the same
56 meanings as provided in 42 C.F.R. s. 483.5.

57 Section 2. Subsection (6) of section 408.812, Florida
58 Statutes, is amended to read:

59 408.812 Unlicensed activity.—

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

68 (a) There is created a cause of action for an ex parte
69 temporary injunction against continued unlicensed activity by a
70 person or entity violating subsection (1), not to exceed 30
71 days.

72 (b) A sworn petition seeking the issuance of an ex parte
73 temporary injunction against continued unlicensed activity shall
74 allege all of the following:

75 1. The location of the unlicensed activity.

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76 2. The names of the owners and operators of the unlicensed
 77 provider.

78 3. The type of services that require licensure.

79 4. The specific facts supporting the conclusion that the
 80 unlicensed provider is engaged in unlicensed activity, including
 81 the date, time, and location at which the unlicensed provider
 82 was notified by the agency to discontinue such activity.

83 5. That agency personnel have verified, through an onsite
 84 inspection, that the unlicensed provider is advertising,
 85 offering, or providing services that require licensure.

86 6. Whether the unlicensed provider prohibited the agency
 87 from conducting a subsequent investigation to determine current
 88 compliance with applicable laws and rules.

89 7. Any previous injunctive relief granted against the
 90 unlicensed provider.

91 8. Any previous agency determination that the unlicensed
 92 provider has been identified as engaging in unlicensed activity.

93 (c) A bond may not be required by the court for entry of
 94 an ex parte temporary injunction.

95 (d) Except as provided in s. 90.204, in a hearing to
 96 obtain an ex parte temporary injunction, evidence other than
 97 verified pleadings or affidavits by agency personnel or others
 98 with firsthand knowledge of the alleged unlicensed activity may
 99 not be used as evidence, unless the unlicensed provider appears
 100 at the hearing. A denial of a petition for an ex parte temporary

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101 injunction shall specify the grounds for denial in writing.

102 (e) If the court determines that the unlicensed provider
103 is engaged in continued unlicensed activity after agency
104 notification to cease such unlicensed activity, the court may
105 grant the ex parte temporary injunction restraining the
106 unlicensed provider from advertising, offering, or providing
107 services for which licensure is required. The court may also
108 order the unlicensed provider to provide to agency personnel
109 access to facility personnel, records, and clients for future
110 inspection of the unlicensed provider's premises.

111 (f) The agency must inspect the unlicensed provider's
112 premises within 20 days after entry of the ex parte temporary
113 injunction to verify compliance with such injunction. If the
114 unlicensed provider is in compliance, the agency shall dismiss
115 the injunction. If unlicensed activity has continued, the agency
116 may file a petition for permanent injunction within 10 days
117 after identifying noncompliance. The agency may also petition to
118 extend the ex parte temporary injunction until the permanent
119 injunction is decided.

120 (g) The agency may provide any inspection records to local
121 law enforcement or a state attorney's office upon request and
122 without redaction.

123 Section 3. Present subsection (2) of section 458.328,
124 Florida Statutes, is redesignated as subsection (3), a new
125 subsection (2) is added to that section, and paragraphs (a) and

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126 (e) of subsection (1) of that section are amended, to read:

127 458.328 Office surgeries.—

128 (1) REGISTRATION.—

129 (a)1. An office in which a physician performs a
 130 liposuction procedure in which more than 1,000 cubic centimeters
 131 of supernatant fat is removed, a Level II office surgery, or a
 132 Level III office surgery must register with the department
 133 unless the office is licensed as a facility under chapter 390 or
 134 chapter 395.

135 2. The department must complete an inspection of any
 136 office seeking registration under this section before the office
 137 may be registered.

138 (e)1. The department shall inspect a registered office at
 139 least annually, including a review of patient records, to ensure
 140 that the office is in compliance with this section and rules
 141 adopted hereunder unless the office is accredited by a
 142 nationally recognized accrediting agency approved by the board.
 143 The inspection may be unannounced, except for the inspection of
 144 an office that meets the description of a clinic specified in s.
 145 458.3265(1)(a)3.h., and those wholly owned and operated
 146 physician offices described in s. 458.3265(1)(a)3.g. which
 147 perform procedures referenced in s. 458.3265(1)(a)3.h., which
 148 must be announced.

149 2. The department must immediately suspend the
 150 registration of a registered office that refuses an inspection

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151 under subparagraph 1. The office must close during such
 152 suspension. The suspension must remain in effect for at least 14
 153 consecutive days and may not terminate until the department
 154 issues a written declaration that the office may reopen
 155 following the department's completion of an inspection of the
 156 office.

157 (2) STANDARDS OF PRACTICE.—

158 (a) A physician performing a gluteal fat grafting
 159 procedure in an office surgery setting shall adhere to standards
 160 of practice pursuant to this subsection and rules adopted by the
 161 board.

162 (b) Office surgeries may not:

163 1. Be a type of surgery that generally results in blood
 164 loss of more than 10 percent of estimated blood volume in a
 165 patient with a normal hemoglobin level;

166 2. Require major or prolonged intracranial, intrathoracic,
 167 abdominal, or joint replacement procedures, except for
 168 laparoscopic procedures;

169 3. Involve major blood vessels and be performed with
 170 direct visualization by open exposure of the major blood vessel,
 171 except for percutaneous endovascular intervention; or

172 4. Be emergent or life threatening.

173 (c)1. A physician performing a gluteal fat grafting
 174 procedure must conduct an in-person examination of the patient
 175 while physically present in the same room as the patient no

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176 later than the day before the procedure.

177 2. Before a physician may delegate any duties during a
178 gluteal fat grafting procedure, the patient must provide
179 written, informed consent for such delegation. Any duty
180 delegated by a physician during a gluteal fat grafting procedure
181 must be performed under the direct supervision of the physician
182 performing such procedure. Fat extraction and gluteal fat
183 injections must be performed by the physician and may not be
184 delegated.

185 3. Fat may only be injected into the subcutaneous space of
186 the patient and may not cross the fascia overlying the gluteal
187 muscle. Intramuscular or submuscular fat injections are
188 prohibited.

189 4. When the physician performing a gluteal fat grafting
190 procedure injects fat into the subcutaneous space of the
191 patient, the physician must use ultrasound guidance, or guidance
192 with other technology authorized under board rule which equals
193 or exceeds the quality of ultrasound, during the placement and
194 navigation of the cannula to ensure that the fat is injected
195 into the subcutaneous space of the patient above the fascia
196 overlying the gluteal muscle. Such guidance with the use of
197 ultrasound or other technology is not required for other
198 portions of such procedure.

199 (d) If a procedure in an office surgery setting results in
200 hospitalization, the incident must be reported as an adverse

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201 incident pursuant to s. 458.351.

202 (e) An office in which a physician performs gluteal fat
 203 grafting procedures must at all times maintain a ratio of one
 204 physician to one patient during all phases of the procedure,
 205 beginning with the administration of anesthesia to the patient
 206 and concluding with the extubation of the patient. After a
 207 physician has commenced, and while he or she is engaged in, a
 208 gluteal fat grafting procedure, the physician may not commence
 209 or engage in another gluteal fat grafting procedure or any other
 210 procedure with another patient at the same time.

211 Section 4. Present subsection (2) of section 459.0138,
 212 Florida Statutes, is redesignated as subsection (3), a new
 213 subsection (2) is added to that section, and paragraphs (a) and
 214 (e) of subsection (1) of that section are amended, to read:

215 459.0138 Office surgeries.—

216 (1) REGISTRATION.—

217 (a)1. An office in which a physician performs a
 218 liposuction procedure in which more than 1,000 cubic centimeters
 219 of supernatant fat is removed, a Level II office surgery, or a
 220 Level III office surgery must register with the department
 221 unless the office is licensed as a facility under chapter 390 or
 222 chapter 395.

223 2. The department must complete an inspection of any
 224 office seeking registration under this section before the office
 225 may be registered.

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226 (e)1. The department shall inspect a registered office at
 227 least annually, including a review of patient records, to ensure
 228 that the office is in compliance with this section and rules
 229 adopted hereunder unless the office is accredited by a
 230 nationally recognized accrediting agency approved by the board.
 231 The inspection may be unannounced, except for the inspection of
 232 an office that meets the description of clinic specified in s.
 233 459.0137(1)(a)3.h., and those wholly owned and operated
 234 physician offices described in s. 459.0137(1)(a)3.g. which
 235 perform procedures referenced in s. 459.0137(1)(a)3.h., which
 236 must be announced.

237 2. The department must immediately suspend the
 238 registration of a registered office that refuses an inspection
 239 under subparagraph 1. The office must close during such
 240 suspension. The suspension must remain in effect for at least 14
 241 consecutive days and may not terminate until the department
 242 issues a written declaration that the office may reopen
 243 following the department's completion of an inspection of the
 244 office.

245 (2) STANDARDS OF PRACTICE.-

246 (a) A physician performing a gluteal fat grafting
 247 procedure in an office surgery setting shall adhere to standards
 248 of practice pursuant to this subsection and rules adopted by the
 249 board.

250 (b) Office surgeries may not:

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251 1. Be a type of surgery that generally results in blood
252 loss of more than 10 percent of estimated blood volume in a
253 patient with a normal hemoglobin level;

254 2. Require major or prolonged intracranial, intrathoracic,
255 abdominal, or joint replacement procedures, except for
256 laparoscopic procedures;

257 3. Involve major blood vessels and be performed with
258 direct visualization by open exposure of the major blood vessel,
259 except for percutaneous endovascular intervention; or

260 4. Be emergent or life threatening.

261 (c)1. A physician performing a gluteal fat grafting
262 procedure must conduct an in-person examination of the patient
263 while physically present in the same room as the patient no
264 later than the day before the procedure.

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266 gluteal fat grafting procedure, the patient must provide
267 written, informed consent for such delegation. Any duty
268 delegated by a physician during a gluteal fat grafting procedure
269 must be performed under the direct supervision of the physician
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277 4. When the physician performing a gluteal fat grafting
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280 with other technology authorized under board rule which equals
281 or exceeds the quality of ultrasound, during the placement and
282 navigation of the cannula to ensure that the fat is injected
283 into the subcutaneous space of the patient above the fascia
284 overlying the gluteal muscle. Such guidance with the use of
285 ultrasound or other technology is not required for other
286 portions of such procedure.

287 (d) If a procedure in an office surgery setting results in
288 hospitalization, the incident must be reported as an adverse
289 incident pursuant to s. 458.351.

290 (e) An office in which a physician performs gluteal fat
291 grafting procedures must at all times maintain a ratio of one
292 physician to one patient during all phases of the procedure,
293 beginning with the administration of anesthesia to the patient
294 and concluding with the extubation of the patient. After a
295 physician has commenced, and while he or she is engaged in, a
296 gluteal fat grafting procedure, the physician may not commence
297 or engage in another gluteal fat grafting procedure or any other
298 procedure with another patient at the same time.

299 Section 5. This act shall take effect July 1, 2023.