

By Senator Peaden

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1 A bill to be entitled
2 An act relating to clinical perfusionists; amending s.
3 456.048, F.S.; specifying financial responsibility
4 requirements for clinical perfusionists; creating s.
5 468.901, F.S.; providing definitions; requiring a
6 supervising physician to be qualified in the medical
7 area in which the clinical perfusionist performs;
8 prescribing duties of a clinical perfusionist;
9 requiring a clinical perfusionist to convey to a
10 patient that he or she is a clinical perfusionist;
11 authorizing a clinical perfusionist to perform medical
12 tasks and services within a certain protocol;
13 prohibiting a clinical perfusionist from prescribing,
14 ordering, compounding, or dispensing certain drugs or
15 medical devices; providing that a clinical
16 perfusionist may administer certain drugs, fluids, and
17 blood products under the supervision of a physician;
18 exempting a perfusionist in training from requirements
19 of a clinical perfusionist; requiring board approval
20 of training programs for clinical perfusionists;
21 providing certification requirements; providing
22 provisional certifying requirements; providing for a
23 temporary certificate as a clinical perfusionist;
24 authorizing the Board of Medicine and the Board of
25 Osteopathic Medicine to impose a penalty against a
26 clinical perfusionist found guilty of or investigated
27 for violating ch. 456, ch. 457, or ch. 458, F.S.;
28 authorizing the chairpersons of the Board of Medicine
29 and the Board of Osteopathic Medicine to appoint

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30 certain persons to advise the boards regarding rules
31 for the certification of clinical perfusionists;
32 providing duties of the boards; providing for the
33 denial, suspension, or revocation of a certificate;
34 requiring the boards to adopt rules; requiring the
35 Department of Health to allocate fees collected to the
36 boards; providing exemptions from certification
37 requirements for clinical perfusionists; exempting
38 hospitals from payment of certain costs; providing
39 that the act does not prevent reimbursement of
40 employers of clinical perfusionists; providing an
41 effective date.

42
43 Be It Enacted by the Legislature of the State of Florida:

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45 Section 1. Section 456.048, Florida Statutes, is amended to
46 read:

47 456.048 Financial responsibility requirements for certain
48 health care practitioners.—

49 (1) As a prerequisite for licensure or license renewal, the
50 Board of Acupuncture, the Board of Chiropractic Medicine, the
51 Board of Podiatric Medicine, and the Board of Dentistry shall,
52 by rule, require that all health care practitioners licensed
53 under the respective board, and the Board of Medicine and the
54 Board of Osteopathic Medicine shall, by rule, require that all
55 anesthesiologist assistants licensed pursuant to s. 458.3475 or
56 s. 459.023, and clinical perfusionists certified pursuant to s.
57 468.901, and the Board of Nursing shall, by rule, require that
58 advanced registered nurse practitioners certified under s.

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59 464.012, and the department shall, by rule, require that
60 midwives maintain medical malpractice insurance or provide proof
61 of financial responsibility in an amount and in a manner
62 determined by the board or department to be sufficient to cover
63 claims arising out of the rendering of or failure to render
64 professional care and services in this state.

65 (2) The board or department may grant exemptions upon
66 application by practitioners meeting any of the following
67 criteria:

68 (a) Any person licensed under chapter 457, s. 458.3475, s.
69 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or
70 chapter 467, or certified under s. 468.901, who practices
71 exclusively as an officer, employee, or agent of the Federal
72 Government or of the state or its agencies or its subdivisions.
73 For the purposes of this subsection, an agent of the state, its
74 agencies, or its subdivisions is a person who is eligible for
75 coverage under any self-insurance or insurance program
76 authorized by the provisions of s. 768.28(16) or who is a
77 volunteer under s. 110.501(1).

78 (b) Any person whose license or certification has become
79 inactive under chapter 457, s. 458.3475, s. 459.023, chapter
80 460, chapter 461, part I of chapter 464, chapter 466, ~~or~~ chapter
81 467, or s. 468.901 and who is not practicing in this state. Any
82 person applying for reactivation of a license must show either
83 that such licensee maintained tail insurance coverage which
84 provided liability coverage for incidents that occurred on or
85 after October 1, 1993, or the initial date of licensure in this
86 state, whichever is later, and incidents that occurred before
87 the date on which the license became inactive; or such licensee

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88 must submit an affidavit stating that such licensee has no
89 unsatisfied medical malpractice judgments or settlements at the
90 time of application for reactivation.

91 (c) Any person holding a limited license pursuant to s.
92 456.015, and practicing under the scope of such limited license.

93 (d) Any person licensed or certified under chapter 457, s.
94 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012,
95 chapter 466, ~~or~~ chapter 467, or s. 468.901 who practices only in
96 conjunction with his or her teaching duties at an accredited
97 school or in its main teaching hospitals. Such person may engage
98 in the practice of medicine to the extent that such practice is
99 incidental to and a necessary part of duties in connection with
100 the teaching position in the school.

101 (e) Any person holding an active license or certification
102 under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter
103 461, s. 464.012, chapter 466, ~~or~~ chapter 467, or s. 468.901 who
104 is not practicing in this state. If such person initiates or
105 resumes practice in this state, he or she must notify the
106 department of such activity.

107 (f) Any person who can demonstrate to the board or
108 department that he or she has no malpractice exposure in the
109 state.

110 (3) Notwithstanding the provisions of this section, the
111 financial responsibility requirements of ss. 458.320 and
112 459.0085 shall continue to apply to practitioners licensed under
113 those chapters, except for anesthesiologist assistants licensed
114 pursuant to s. 458.3475 or s. 459.023 who must meet the
115 requirements of this section.

116 Section 2. Section 468.901, Florida Statutes, is created to

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117 read:

118 468.901 Clinical perfusionists.-119 (1) DEFINITIONS.-As used in this section, the term:120 (a) "Approved program" means a program for the education
121 and training of clinical perfusion which is approved by the
122 boards as provided in subsection (5).123 (b) "Boards" means the Board of Medicine and the Board of
124 Osteopathic Medicine.125 (c) "Clinical perfusionist" means a person who has
126 graduated from an approved program, who is certified pursuant to
127 this section to perform medical services, and who is prescribed,
128 delegated, or supervised by a licensed physician.129 (d) "Clinical perfusion" means the functions necessary for
130 the support, treatment, measurement, or supplementation of the
131 cardiovascular, circulatory, or respiratory systems or other
132 organs, or a combination of those activities, and the safe
133 management of physiologic functions by monitoring and analyzing
134 the parameters of the systems, under an order and the
135 supervision of a physician licensed under chapter 458 or chapter
136 459, through extracorporeal circulation, long-term clinical
137 support techniques, including extracorporeal carbon-dioxide
138 removal and extracorporeal membrane oxygenation, and associated
139 therapeutic and diagnostic technologies, such as counter
140 pulsation, ventricular assistance, auto transfusion, blood
141 conservation techniques, myocardial and organ preservation,
142 extracorporeal life support, isolated limb perfusion,
143 therapeutic aphaeresis, and platelet rich plasma sequestration.144 (e) "Clinical perfusionist's protocol" means perfusion-
145 related policies and protocols developed or approved by a

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146 licensed health facility or a physician through collaboration
147 with administrators, certified clinical perfusionists, and other
148 health care professionals.

149 (f) "Continuing medical education" means courses recognized
150 and approved by the boards, the American Academy of Physician
151 Assistants, the American Medical Association, the American
152 Osteopathic Association, the American Board of Cardiovascular
153 Perfusion, or the Accreditation Council on Continuing Medical
154 Education.

155 (g) "Department" means the Department of Health.

156 (h) "Direct supervision" means the onsite, personal
157 supervision by a clinical perfusionist who is present when a
158 procedure is being performed and who is in all instances
159 immediately available to provide assistance and direction while
160 clinical perfusion services are being performed.

161 (i) "Extracorporeal circulation" means the diversion of a
162 patient's blood through a heart-lung machine or a similar device
163 that assumes the functions of the patient's heart, lungs,
164 kidney, liver, or other organs.

165 (j) "Perfusionist in training" means a student enrolled in
166 an approved program who has not yet passed the proficiency
167 examination and works under the direct supervision of a clinical
168 perfusionist.

169 (k) "Proficiency examination" means an entry-level
170 examination administered by the American Board of Cardiovascular
171 Perfusion.

172 (l) "Provisional certified clinical perfusionist" means a
173 person provisionally certified under this section.

174 (m) "Supervising physician" means a physician licensed

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175 under chapter 458 or chapter 459 who holds an active license.

176 (n) "Temporary clinical perfusionist" means a person
177 granted a temporary certificate under this section.

178 (2) PERFORMANCE OF A SUPERVISING PHYSICIAN.—A physician who
179 supervises a clinical perfusionist must be qualified in the
180 medical areas in which the clinical perfusionist performs.

181 (3) (a) PERFORMANCE OF CLINICAL PERFUSIONISTS.—A clinical
182 perfusionist may perform duties established by rule by the
183 boards, including the following duties that are included in the
184 clinical perfusionist's protocol, if prescribed by a physician
185 or under the supervision of a physician:

186 1. Perform extracorporeal circulation and its clinical
187 support;

188 2. Perform or administer counter pulsation;

189 3. Perform circulatory support and ventricular assistance;

190 4. Perform extracorporeal membrane oxygenation and
191 extracorporeal life support;

192 5. Perform blood conservation techniques, autotransfusion,
193 and blood component sequestration;

194 6. Perform myocardial preservation;

195 7. Perform coagulation and hematologic monitoring;

196 8. Perform physiological monitoring;

197 9. Perform blood gas and blood chemistry monitoring;

198 10. Perform induction of hypothermia or hyperthermia with
199 reversal;

200 11. Perform hemodilution;

201 12. Perform hemofiltration;

202 13. Administer blood, blood products, supportive fluids,
203 and anesthetic agents via the extracorporeal circuit;

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204 14. Perform isolated limb and organ perfusion;

205 15. Provide surgical assistance;

206 16. Perform organ preservation;

207 17. Perform dialysis while on clinical bypass;

208 18. Perform therapeutic apheresis;

209 19. Administer blood, blood products, and supportive fluids
210 via the therapeutic apheresis circuit; and

211 20. Perform pacemaker lead and battery analysis.

212 (b) A clinical perfusionist shall clearly convey to a
213 patient that he or she is a clinical perfusionist.

214 (c) A clinical perfusionist may perform medical tasks and
215 services within the framework of a written practice protocol
216 developed between the supervising physician and the clinical
217 perfusionist.

218 (d) A clinical perfusionist may not prescribe, order,
219 compound, or dispense any controlled substance, legend drug, or
220 medical device to any patient. This paragraph does not prohibit
221 a clinical perfusionist from administering legend drugs,
222 controlled substances, intravenous drugs, fluids, or blood
223 products that are ordered by the physician and administered to a
224 patient while under the orders of such physician.

225 (4) PERFORMANCE BY PERFUSIONISTS IN TRAINING.—The practice
226 of a perfusionist in training is exempt from the requirements of
227 this section while the perfusionist in training is performing
228 assigned tasks in conjunction with an approved program. Before
229 providing clinical perfusion in conjunction with the
230 requirements of an approved program, the perfusionist in
231 training shall clearly convey to the patient that he or she is a
232 perfusionist in training and is under direct supervision.

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233 (5) PROGRAM APPROVAL.—The boards shall approve programs for
234 the education and training of clinical perfusionists which hold
235 full accreditation or provisional accreditation from the
236 Commission on Accreditation of Allied Health Education Programs
237 or a successor organization, as approved by the boards.

238 (6) CLINICAL PERFUSIONIST CERTIFICATION.—

239 (a) Any person seeking to be certified as a clinical
240 perfusionist must apply to the department. The department shall
241 issue a certificate to any person certified by the boards to:

242 1. Be at least 21 years of age.

243 2. Have satisfactorily passed a proficiency examination
244 approved by the boards. The boards, on receipt of an application
245 and application fee, shall waive the examination requirement for
246 an applicant who at the time of application holds a current
247 certificate issued by a certifying agency approved by the
248 boards.

249 3. Be certified in basic cardiac life support.

250 4. Have completed the application form and remitted an
251 application fee, not to exceed \$1,000, as set by the department.

252 An application must include:

253 a. A certificate of completion of an approved program or
254 its equivalent;

255 b. A sworn statement of any prior felony convictions;

256 c. A sworn statement of any prior discipline or denial of
257 certification or license in any state;

258 d. Two letters of recommendation, one from a physician and
259 one from a certified clinical perfusionist; and

260 e. A set of fingerprints on a form and under procedures
261 specified by the department, along with payment in an amount

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262 equal to the costs incurred by the department for a national
263 criminal history check of the applicant.

264

265 Before January 1, 2011, a person is eligible to apply to the
266 boards and receive a certification notwithstanding the
267 requirements of this subsection if the person was actively
268 engaged in the practice of perfusion consistent with applicable
269 law, and if the person was operating cardiopulmonary bypass
270 systems during cardiac surgical cases in a licensed health care
271 facility in this state as the person's primary function and had
272 been operating the system for at least 9 of the 10 years
273 preceding application for certification.

274 (b) Between July 1, 2010, and June 30, 2011, an applicant
275 who was not a graduate of an accredited program before 1981, but
276 met the then-current eligibility requirements for certification
277 as a certified clinical perfusionist and subsequently was
278 certified, shall be certified as a perfusionist if the
279 application otherwise complies with this section.

280 (c) A certificate must be renewed biennially. Each renewal
281 must include:

282 1. A renewal fee, not to exceed \$1,000, as set by the
283 department; and

284 2. A sworn statement of no felony convictions in the
285 immediately preceding 2 years.

286 (d) Each certified clinical perfusionist shall biennially
287 complete continuing medical education as required by the boards.

288 (e)1. A certificate as a provisional certified clinical
289 perfusionist may be issued by the boards to a person who has
290 successfully completed an approved perfusion education program,

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291 completed an application and remitted an application fee, and
292 submitted evidence satisfactory to the boards of the successful
293 completion of the requisite education requirements.

294 2. A provisional certified clinical perfusionist must be
295 under the supervision and direction of a certified clinical
296 perfusionist at all times during which the provisional certified
297 clinical perfusionist performs the prescribed duties.

298 3. A provisional certificate is valid for 2 years following
299 the date it is issued and may be extended subject to rule by the
300 boards. The application for extension must be signed by a
301 supervising certified clinical perfusionist. Upon notification
302 by the approved testing service, or the boards, that any portion
303 of the certifying examination has been failed after the 2-year
304 provisional certificate term, the provisional certificate must
305 be surrendered to the boards.

306 (f) A certificate as a temporary clinical perfusionist may
307 be issued by the department to a person who has successfully
308 completed the application for perfusion certification and met
309 other requirements as established by the boards.

310 (g) The boards shall adopt rules governing supervisory
311 requirements between clinical perfusionists and provisional
312 certified clinical perfusionists, temporary clinical
313 perfusionists, and clinical perfusionists in training.

314 (h) The Board of Medicine may impose upon a clinical
315 perfusionist any penalty specified in s. 456.072 or s.
316 458.331(2) if the clinical perfusionist is found guilty of or is
317 investigated for an act that constitutes a violation of chapter
318 456, chapter 457, or chapter 458.

319 (7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST TO

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320 ADVISE THE BOARDS.-

321 (a) The chairpersons of the Board of Medicine and the Board
322 of Osteopathic Medicine may appoint a cardiovascular surgeon and
323 a certified clinical perfusionist to advise the boards as to the
324 adoption of rules for the certification of clinical
325 perfusionists. The boards may use a committee structure that is
326 most practicable in order to receive any recommendations to the
327 boards regarding rules and all matters relating to clinical
328 perfusionists, including, but not limited to, recommendations to
329 improve safety in the clinical practices of certified clinical
330 perfusionists.

331 (b) In addition to its other duties and responsibilities as
332 prescribed by law, the boards shall:

333 1. Recommend to the department the certification of
334 clinical perfusionists.

335 2. Develop rules regulating the use of clinical
336 perfusionists under chapter 458 or chapter 459, except for rules
337 relating to the formulary developed under s. 458.347(4). The
338 boards shall also develop rules to ensure that the continuity of
339 supervision is maintained in each practice setting. The boards
340 shall consider adopting a proposed rule at the regularly
341 scheduled meeting immediately following the submission of the
342 proposed rule. A proposed rule may not be adopted by either
343 board unless both boards have accepted and approved the
344 identical language contained in the proposed rule. The
345 provisions of all the proposed rules must be approved by both
346 boards pursuant to each respective board's guidelines and
347 standards regarding the adoption of proposed rules.

348 3. Address concerns and problems of clinical perfusionists

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349 to improve safety in the clinical practices of certified
350 clinical perfusionists.

351 (c) When the boards find that an applicant for
352 certification has failed to meet, to the boards' satisfaction,
353 any of the requirements for certification set forth in this
354 section, the boards may enter an order to:

355 1. Refuse to certify the applicant;

356 2. Approve the applicant for certification with
357 restrictions on the scope of practice; or

358 3. Approve the applicant for provisional or temporary
359 certification. Such conditions may include placement of the
360 applicant on probation for a period of time and subject to such
361 conditions as the boards specify, including, but not limited to,
362 requiring the applicant to undergo treatment, to attend
363 continuing medical education courses, or to take corrective
364 action.

365 (8) DENIAL, SUSPENSION, OR REVOCATION OF CERTIFICATION.—The
366 boards may deny, suspend, or revoke the certification of a
367 clinical perfusionist whom the boards determine have violated
368 any provision of this section, chapter 456, chapter 458, or
369 chapter 459 or any rule adopted pursuant thereto.

370 (9) RULES.—The boards shall adopt rules to administer this
371 section.

372 (10) FEES.—The department shall allocate the fees collected
373 under this section to the boards for the sole purpose of
374 administering the provisions of this section.

375 (11) EXEMPTIONS.—

376 (a) This section does not limit the practice of a physician
377 licensed under chapter 458 or chapter 459 or a respiratory

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378 therapist licensed under chapter 468, so long as that person
379 does not hold himself or herself out to the public as possessing
380 a certificate or provisional certificate issued under this
381 section or use a professional title protected by this section.

382 (b) This section does not limit the practice of nursing or
383 prevent qualified members of other regulated health professions
384 from doing work of a nature consistent with the state laws and
385 rules that govern their respective health professions, so long
386 as those persons do not hold themselves out to the public as
387 possessing a certificate or provisional certificate issued under
388 this section or use a professional title protected by this
389 section.

390 (c) A person need not be certified under this section who:

391 1. Is a qualified person in this state or another state or
392 territory who is employed by the United States Government or an
393 agency thereof while discharging his or her official duties.

394 2. Is a student providing services regulated under this
395 chapter who is:

396 a. Pursuing a course of study that leads to a degree in a
397 profession regulated by this chapter;

398 b. Providing services in a training setting, as long as
399 such services and associated activities constitute part of a
400 supervised course of study; and

401 c. Designated by the title "perfusionist in training."

402 (d) The boards shall establish by rule the qualifications
403 necessary for a clinical perfusionist who is not a resident of
404 this state and is licensed or certified by any other state or
405 territory of the United States. Such clinical perfusionist may
406 not offer services in this state for more than 30 days in any

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407 calendar year.

408 (e) Except as stipulated by the boards, the exemptions in
409 this subsection do not apply to any person certified under this
410 section whose certificate has been revoked or suspended by
411 either of the boards or whose license or certification in
412 another jurisdiction has been revoked or suspended by the
413 licensing or certifying authority in that jurisdiction.

414 (f) This subsection does not exempt a person from meeting
415 the minimum standards of performance in professional activities
416 when measured against generally prevailing peer performance,
417 including the undertaking of activities for which the person is
418 not qualified by training or experience.

419 (12) PAYMENTS AND REIMBURSEMENTS.—

420 (a) A hospital is not required to pay for, or reimburse any
421 person for, the costs of compliance with any requirement of this
422 section, including costs of continuing medical education.

423 (b) This section does not prevent third-party payors from
424 reimbursing employers of clinical perfusionists for covered
425 services rendered by such clinical perfusionists.

426 Section 3. This act shall take effect July 1, 2010.