

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 that he or
10 she is a clinical perfusionist to a patient;
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 a medical device; 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; excluding
38 hospitals from payment of certain costs; providing an
39 effective date.

40
41 Be It Enacted by the Legislature of the State of Florida:

42
43 Section 1. Section 456.048, Florida Statutes, is amended
44 to read:

45 456.048 Financial responsibility requirements for certain
46 health care practitioners.—

47 (1) As a prerequisite for licensure or license renewal, the
48 Board of Acupuncture, the Board of Chiropractic Medicine, the
49 Board of Podiatric Medicine, and the Board of Dentistry shall,
50 by rule, require that all health care practitioners licensed
51 under the respective board, and the Board of Medicine and the
52 Board of Osteopathic Medicine shall, by rule, require that all
53 anesthesiologist assistants licensed pursuant to s. 458.3475 or
54 s. 459.023, and clinical perfusionists certified pursuant to s.
55 s. 468.901, and the Board of Nursing shall, by rule, require
56 that advanced registered nurse practitioners certified under s.
57 464.012, and the department shall, by rule, require that
58 midwives maintain medical malpractice insurance or provide proof

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59 of financial responsibility in an amount and in a manner
60 determined by the board or department to be sufficient to cover
61 claims arising out of the rendering of or failure to render
62 professional care and services in this state.

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

66 (a) Any person licensed under chapter 457, s. 458.3475, s.
67 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, ~~or~~
68 chapter 467, or certified under s. 468.901 who practices
69 exclusively as an officer, employee, or agent of the Federal
70 Government or of the state or its agencies or its subdivisions.
71 For the purposes of this subsection, an agent of the state, its
72 agencies, or its subdivisions is a person who is eligible for
73 coverage under any self-insurance or insurance program
74 authorized by the provisions of s. 768.28(16) or who is a
75 volunteer under s. 110.501(1).

76 (b) Any person whose license or certification has become
77 inactive under chapter 457, s. 458.3475, s. 459.023, chapter
78 460, chapter 461, part I of chapter 464, chapter 466, ~~or~~ chapter
79 467, or s. 468.901 and who is not practicing in this state. Any
80 person applying for reactivation of a license must show either
81 that such licensee maintained tail insurance coverage which
82 provided liability coverage for incidents that occurred on or
83 after October 1, 1993, or the initial date of licensure in this
84 state, whichever is later, and incidents that occurred before
85 the date on which the license became inactive; or such licensee
86 must submit an affidavit stating that such licensee has no
87 unsatisfied medical malpractice judgments or settlements at the

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88 time of application for reactivation.

89 (c) Any person holding a limited license pursuant to s.
90 456.015, and practicing under the scope of such limited license.

91 (d) Any person licensed or certified under chapter 457, s.
92 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012,
93 chapter 466, ~~or~~ chapter 467, or s. 468.901 who practices only in
94 conjunction with his or her teaching duties at an accredited
95 school or in its main teaching hospitals. Such person may engage
96 in the practice of medicine to the extent that such practice is
97 incidental to and a necessary part of duties in connection with
98 the teaching position in the school.

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

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

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

114 Section 2. Section 468.901, Florida Statutes, is created to
115 read:

116 468.901 Clinical perfusionist.-

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117 (1) DEFINITIONS.—As used in this section, the term:

118 (a) "Approved program" means a program for the education
119 and training of clinical perfusion which has been approved by
120 the boards as provided in subsection (5).

121 (b) "Boards" means the Board of Medicine and the Board of
122 Osteopathic Medicine.

123 (c) "Clinical perfusionist" means a person who has
124 graduated from an approved program, who is certified to perform
125 medical services, and who is prescribed, delegated, or
126 supervised by a licensed physician.

127 (d) "Clinical perfusion" means the functions necessary for
128 the support, treatment, measurement, or supplementation of the
129 cardiovascular, circulatory, or respiratory systems or other
130 organs, or a combination of those activities, and the safe
131 management of physiologic functions by monitoring and analyzing
132 the parameters of the systems under an order and the supervision
133 of a physician licensed under chapter 458 or chapter 459,
134 through extracorporeal circulation, long-term clinical support
135 techniques, including extracorporeal carbon-dioxide removal and
136 extracorporeal membrane oxygenation, and associated therapeutic
137 and diagnostic technologies, such as counter pulsation,
138 ventricular assistance, auto transfusion, blood conservation
139 techniques, myocardial and organ preservation, extracorporeal
140 life support, isolated limb perfusion, therapeutic aphaeresis,
141 and platelet rich plasma sequestration.

142 (e) "Clinical perfusionists' certifying committee" means
143 the clinical perfusion certifying committee appointed by the
144 boards.

145 (f) "Continuing medical education" means courses recognized

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146 and approved by the boards, the American Academy of Physician
147 Assistants, the American Medical Association, the American
148 Osteopathic Association, the American Board of Cardiovascular
149 Perfusion, or the Accreditation Council on Continuing Medical
150 Education.

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

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

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

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

166 (k) "Perfusion protocols" means perfusion-related policies
167 and protocols developed or approved by a licensed health
168 facility or a physician through collaboration with
169 administrators, certified clinical perfusionists, and other
170 health care professionals.

171 (l) "Proficiency examination" means an entry-level
172 examination administered by the American Board of Cardiovascular
173 Perfusion.

174 (m) "Provisional clinical perfusionist" means a person

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175 provisionally certified under this section.

176 (n) "Supervising physician" means a physician licensed
177 under chapter 458 or chapter 459 who holds an active license.

178 (o) "Temporarily clinical perfusionist" means a person
179 granted a temporary certificate under this section.

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

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

188 1. Perform extracorporeal circulation and its clinical
189 support;

190 2. Perform or administer counter pulsation;

191 3. Perform circulatory support and ventricular assistance;

192 4. Perform extracorporeal membrane oxygenation and
193 extracorporeal life support;

194 5. Perform blood conservation techniques, autotransfusion,
195 and blood component sequestration;

196 6. Perform myocardial preservation;

197 7. Perform coagulation and hematologic monitoring;

198 8. Perform physiological monitoring;

199 9. Perform blood gas and blood chemistry monitoring;

200 10. Perform induction of hypothermia or hyperthermia with
201 reversal;

202 11. Perform hemodilution;

203 12. Perform hemofiltration;

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

206 14. Perform isolated limb and organ perfusion;

207 15. Provide surgical assistance;

208 16. Perform organ preservation;

209 17. Perform dialysis while on clinical bypass;

210 18. Perform therapeutic apheresis;

211 19. Administer blood, blood products, and supportive fluids
212 via the therapeutic apheresis circuit; and

213 20. Perform pacemaker lead and battery analysis.

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

217 (c) A clinical perfusionist shall clearly convey to a
218 patient that he or she is a clinical perfusionist.

219 (d) A clinical perfusionist may perform medical tasks and
220 services within the framework of a written practice protocol
221 developed between the supervising physician and the clinical
222 perfusionist.

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

230 (4) PERFORMANCE BY PERFUSIONISTS IN TRAINING.—The practice
231 of a perfusionist in training is exempt from the requirements of
232 this section while the perfusionist in training is performing

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233 assigned tasks as a perfusionist in training in conjunction with
234 an approved program. Before providing clinical perfusion in
235 conjunction with the requirements of an approved program, the
236 perfusionist in training shall clearly convey to the patient
237 that he or she is a perfusionist in training and is under direct
238 supervision.

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

244 (6) CLINICAL PERFUSIONIST CERTIFICATION.—

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

248 1. Be at least 21 years of age.

249 2. Have satisfactorily passed a proficiency examination
250 approved by the boards. The boards, on receipt of an application
251 and application fee, shall waive the examination requirement for
252 an applicant who at the time of application holds a current
253 certificate issued by a certifying agency approved by the
254 boards.

255 3. Be certified in basic cardiac life support.

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

258 An application must include:

259 a. A certificate of completion of an approved program or
260 its equivalent;

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

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

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

266 e. A set of fingerprints on a form and under procedures
267 specified by the department, along with payment in an amount
268 equal to the costs incurred by the department for a national
269 criminal history check of the applicant.

270
271 Before January 1, 2010, a person is eligible to apply to the
272 boards and receive a certification notwithstanding the
273 requirements of this subsection if the person was actively
274 engaged in the practice of perfusion consistent with applicable
275 law, and if the person was operating cardiopulmonary bypass
276 systems during cardiac surgical cases in a licensed health care
277 facility in this state as the person's primary function and had
278 been operating the system for at least 9 of the 10 years
279 preceding application for certification.

280 (b) Between July 1, 2009, and June 30, 2010, an applicant
281 who was not a graduate of an accredited program before 1981, but
282 met the then-current eligibility requirements for certification
283 as a certified clinical perfusionist and subsequently was
284 certified, shall be certified as a perfusionist if the
285 application otherwise complies with this section.

286 (c) A certificate must be renewed biennially. Each renewal
287 must include:

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

290 2. A sworn statement of no felony convictions in the

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291 immediately preceding 2 years.

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

294 (e)1. A certificate as a provisional certified clinical
295 perfusionist may be issued by the boards to a person who has
296 successfully completed an approved perfusion education program,
297 completed an application and remitted an application fee, and
298 submitted evidence satisfactory to the boards of the successful
299 completion of the requisite education requirements.

300 2. A provisional certified clinical perfusionist is under
301 the supervision and direction of a certified clinical
302 perfusionist at all times during which the provisional certified
303 perfusionist performs the prescribed duties. The boards shall
304 adopt rules governing supervisory requirements between clinical
305 perfusionists and provisional clinical perfusionists,
306 temporarily clinical perfusionists, and clinical perfusionists
307 in training.

308 3. A provisional certificate is valid for 2 years from the
309 date it is issued and may be extended subject to rule by the
310 boards. The application for extension must be signed by a
311 supervising certified clinical perfusionist. Upon notification
312 by the approved testing service, or the boards, that any portion
313 of the certifying examination has been failed after the 2-year
314 provisional certificate term, the provisional certificate must
315 be surrendered to the boards.

316 (f) A certificate as a temporarily clinical perfusionist
317 may be issued by the department to a person who has successfully
318 completed the perfusion certification application and met other
319 requirements as established by the boards.

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320 (g) The Board of Medicine may impose upon a clinical
321 perfusionist any penalty specified in s. 456.072 or s.
322 458.331(2) if the clinical perfusionist is found guilty of or is
323 investigated for an act that constitutes a violation of chapter
324 456, chapter 457, or chapter 458.

325 (7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST TO
326 ADVISE THE BOARDS.—

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

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

339 1. Recommend to the department the certification of
340 clinical perfusionists.

341 2. Develop rules regulating the use of clinical
342 perfusionists under chapter 458 or chapter 459, except for rules
343 relating to the formulary developed under s. 458.347(4). The
344 boards shall also develop rules to ensure that the continuity of
345 supervision is maintained in each practice setting. The boards
346 shall consider adopting a proposed rule at the regularly
347 scheduled meeting immediately following the submission of the
348 proposed rule. A proposed rule may not be adopted by either

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349 board unless both boards have accepted and approved the
350 identical language contained in the proposed rule. The
351 provisions of all the proposed rules must be approved by both
352 boards pursuant to each respective board's guidelines and
353 standards regarding the adoption of proposed rules.

354 3. Address concerns and problems of clinical perfusionists
355 to improve safety in the clinical practices of certified
356 clinical perfusionists.

357 (c) When the boards find that an applicant for
358 certification has failed to meet, to the boards' satisfaction,
359 any of the requirements for certification set forth in this
360 section, the boards may enter an order to:

361 1. Refuse to certify the applicant;

362 2. Approve the applicant for certification with
363 restrictions on the scope of practice; or

364 3. Approve the applicant for provisional or temporary
365 certification. Such conditions may include placement of the
366 applicant on probation for a period of time and subject to such
367 conditions as the boards specify, including, but not limited to,
368 requiring the applicant to undergo treatment, to attend
369 continuing medical education courses, or to take corrective
370 action.

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

376 (9) RULES.—The boards shall adopt rules to administer this
377 section.

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

381 (11) EXEMPTIONS.—

382 (a) This section does not limit the practice of a physician
383 licensed under chapter 458 or chapter 459 or a respiratory
384 therapist licensed under chapter 468, so long as that person
385 does not hold himself or herself out to the public as possessing
386 a certificate or provisional certificate issued under this
387 section or use a professional title protected by this section.

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

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

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

400 2. Is a student providing services regulated under this
401 chapter who is:

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

404 b. Providing services in a training setting, as long as
405 such services and associated activities constitute part of a
406 supervised course of study; and

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

408 (d) The boards shall establish by rule the qualifications
409 necessary for a clinical perfusionist who is not a resident of
410 this state and is licensed or certified by any other state or
411 territory of the United States. Such clinical perfusionist may
412 not offer services in this state for more than 30 days in any
413 calendar year.

414 (e) Except as stipulated by the boards, the exemptions in
415 this subsection do not apply to any person certified under this
416 section whose certificate has been revoked or suspended by
417 either of the boards or whose license or certification in
418 another jurisdiction has been revoked or suspended by the
419 licensing or certifying authority in that jurisdiction.

420 (f) This subsection does not exempt a person from meeting
421 the minimum standards of performance in professional activities
422 when measured against generally prevailing peer performance,
423 including the undertaking of activities for which the person is
424 not qualified by training or experience.

425 (12) PAYMENT OR REIMBURSEMENT BY HOSPITALS OF COSTS OF
426 COMPLIANCE WITH PART.—A hospital is not required to pay for, or
427 reimburse any person for, the costs of compliance with any
428 requirement of this section, including costs of continuing
429 medical education.

430 Section 3. This act shall take effect October 1, 2009.