

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 area  
7           in which the clinical perfusionist performs; prescribing  
8           duties of a clinical perfusionist; requiring a clinical  
9           perfusionist to convey that he or she is a clinical  
10          perfusionist to a patient; authorizing a clinical  
11          perfusionist to perform medical tasks and services within  
12          a certain protocol; prohibiting a clinical perfusionist  
13          from prescribing, ordering, compounding, or dispensing  
14          certain drugs or medical devices; providing that a  
15          clinical perfusionist may administer certain drugs,  
16          fluids, and blood products under the supervision of a  
17          physician; exempting a perfusionist in training from  
18          requirements of a clinical perfusionist; requiring board  
19          approval of training programs for clinical perfusionists;  
20          providing certification requirements; providing  
21          provisional certification requirements; providing for a  
22          temporary certificate as a clinical perfusionist;  
23          authorizing the Board of Medicine and the Board of  
24          Osteopathic Medicine to impose a penalty against a  
25          clinical perfusionist found guilty of or investigated for  
26          violating ch. 456, ch. 457, or ch. 458, F.S.; authorizing  
27          the chairs of the Board of Medicine and the Board of  
28          Osteopathic Medicine to appoint certain persons to advise

29 | the boards regarding rules for the certification of  
 30 | clinical perfusionists; providing duties of the boards;  
 31 | providing for the denial, suspension, or revocation of a  
 32 | certification; requiring the boards to adopt rules;  
 33 | requiring the Department of Health to allocate fees  
 34 | collected to the boards; providing exemptions from  
 35 | certification requirements for clinical perfusionists;  
 36 | excluding hospitals from payment of certain costs;  
 37 | providing that the act does not prevent reimbursement of  
 38 | the employers of clinical perfusionists; 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,  
 48 | the Board of Acupuncture, the Board of Chiropractic Medicine,  
 49 | the Board of Podiatric Medicine, and the Board of Dentistry  
 50 | shall, by rule, require that all health care practitioners  
 51 | licensed under the respective board, and the Board of Medicine  
 52 | and the Board of Osteopathic Medicine shall, by rule, require  
 53 | that all anesthesiologist assistants licensed pursuant to s.  
 54 | 458.3475 or s. 459.023, and clinical perfusionists certified  
 55 | pursuant to s. 468.901, and the Board of Nursing shall, by rule,  
 56 | require that advanced registered nurse practitioners certified

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57 | under s. 464.012, and the department shall, by rule, require  
58 | that midwives maintain medical malpractice insurance or provide  
59 | proof 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

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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  
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  
115 to read:

116 468.901 Clinical perfusionists.--

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 is approved by the  
120 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 pursuant to  
125 this section to perform medical services, and who is prescribed,  
126 delegated, or 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  
133 supervision of a physician licensed under chapter 458 or chapter  
134 459, through extracorporeal circulation, long-term clinical  
135 support techniques, including extracorporeal carbon-dioxide  
136 removal and extracorporeal membrane oxygenation, and associated  
137 therapeutic and diagnostic technologies, such as counter  
138 pulsation, ventricular assistance, auto transfusion, blood  
139 conservation techniques, myocardial and organ preservation,  
140 extracorporeal life support, isolated limb perfusion,

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

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

152 (h) "Direct supervision" means the onsite, personal  
153 supervision by a clinical perfusionist who is present when a  
154 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 kidneys, 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 clinical  
165 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, clinical perfusionists, and other health care  
 170 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  
 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) "Temporary clinical perfusionist" means a person  
 179 granted a temporary certificate under this section.

180 (2) PERFORMANCE OF A SUPERVISING PHYSICIAN.--A physician  
 181 who 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.
- 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  
 212 fluids via the therapeutic apheresis circuit.
- 213        20. Perform pacemaker lead and battery analysis.
- 214        (b) A clinical perfusionist shall clearly convey to a  
 215 patient that he or she is a clinical perfusionist.
- 216        (c) A clinical perfusionist may perform medical tasks and  
 217 services within the framework of a written practice protocol  
 218 developed between the supervising physician and the clinical  
 219 perfusionist.
- 220        (d) A clinical perfusionist may not prescribe, order,  
 221 compound, or dispense any controlled substance, legend drug, or  
 222 medical device to any patient. This paragraph does not prohibit  
 223 a clinical perfusionist from administering legend drugs,  
 224 controlled substances, intravenous drugs, fluids, or blood



225 products that are ordered by the physician and administered to a  
 226 patient while under the orders of such physician.

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

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

240 (6) CLINICAL PERFUSIONIST CERTIFICATION.--

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

- 244 1. Be at least 21 years of age.
- 245 2. Have satisfactorily passed a proficiency examination  
 246 approved by the boards. The boards, on receipt of an application  
 247 and application fee, shall waive the examination requirement for  
 248 an applicant who at the time of application holds a current  
 249 certificate issued by a certifying agency approved by the  
 250 boards.

251 3. Be certified in basic cardiac life support.

252 4. Have completed the application form and remitted an

253 application fee, not to exceed \$1,000, as set by the department.

254 An application must include:

255 a. A certificate of completion of an approved program or  
256 its equivalent.

257 b. A sworn statement of any prior felony convictions.

258 c. A sworn statement of any prior discipline or denial of  
259 certification or license in any state.

260 d. Two letters of recommendation, one from a physician and  
261 one from a clinical perfusionist.

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

266  
267 Before January 1, 2010, a person is eligible to apply to the  
268 boards and receive a certification notwithstanding the  
269 requirements of this subsection if the person was actively  
270 engaged in the practice of perfusion consistent with applicable  
271 law, the person was operating cardiopulmonary bypass systems  
272 during cardiac surgical cases in a licensed health care facility  
273 in this state as the person's primary function, and had been  
274 operating the system for at least 9 of the 10 years preceding  
275 the application for certification.

276 (b) Between October 1, 2009, and June 30, 2010, an  
277 applicant who was not a graduate of an accredited program before  
278 1981, but met the then-current eligibility requirements for  
279 certification as a clinical perfusionist and subsequently was  
280 certified, shall be certified as a clinical perfusionist if the

281 application otherwise complies with this section.

282 (c) A certificate must be renewed biennially. Each renewal  
283 must include:

284 1. A renewal fee, not to exceed \$1,000, as set by the  
285 department.

286 2. A sworn statement of no felony convictions in the  
287 immediately preceding 2 years.

288 (d) Each clinical perfusionist shall biennially complete  
289 continuing medical education as required by the boards.

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

296 2. A provisional certificate is valid for 2 years from the  
297 date it is issued and may be extended subject to rule by the  
298 boards. The application for extension must be signed by a  
299 supervising clinical perfusionist. However, if a provisional  
300 clinical perfusionist fails any portion of the certifying  
301 examination during an extension of the 2-year validity period,  
302 he or she must surrender the provisional certificate to the  
303 boards.

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

308 (g) At all times, a provisional clinical perfusionist,

309 temporary clinical perfusionist, or perfusionist in training may  
 310 only practice clinical perfusion under the supervision and  
 311 direction of a clinical perfusionist. The boards shall adopt  
 312 rules governing a clinical perfusionist's supervision of  
 313 provisional clinical perfusionists, temporary clinical  
 314 perfusionists, and perfusionists in training.

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

320 (7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST TO  
 321 ADVISE THE BOARDS.--

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

331 (b) In addition to its other duties and responsibilities  
 332 as 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  
349 to improve safety in the practice of clinical perfusion.

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

354 1. Refuse to certify the applicant;

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

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

364 (8) DENIAL, SUSPENSION, OR REVOCATION OF

365 CERTIFICATION.--The boards may deny, suspend, or revoke the  
 366 certification of a clinical perfusionist whom the boards  
 367 determine has violated any provision of this section, chapter  
 368 456, chapter 458, or chapter 459 or any rule adopted pursuant  
 369 thereto.

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

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

375 (11) EXEMPTIONS.--

376 (a) This section does not limit the practice of a  
 377 physician licensed under chapter 458 or chapter 459 or a  
 378 respiratory therapist licensed under chapter 468, so long as  
 379 that person does not hold himself or herself out to the public  
 380 as possessing a certificate, provisional certificate, or  
 381 temporary certificate issued under this section or use a  
 382 professional title protected by this section.

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

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

392 1. Is a qualified person in this state or another state or

393 territory who is employed by the United States Government or an  
 394 agency thereof while discharging his or her official duties.

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

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

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

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

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

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

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

420 (12) PAYMENTS AND REIMBURSEMENTS.--

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

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

427        Section 3. This act shall take effect October 1, 2010.