1 A bill to be entitled 2 An act relating to the practice of pharmacy; amending 3 s. 381.0031, F.S.; requiring specified licensed 4 pharmacists to report certain information relating to 5 public health to the Department of Health; amending s. 6 465.003, F.S.; revising the definition of the term 7 "practice of the profession of pharmacy"; creating s. 8 465.1865, F.S.; providing definitions; providing 9 requirements for pharmacists to provide services under 10 a collaborative pharmacy practice agreement; requiring the terms and conditions of such agreement to be 11 12 appropriate to the training of the pharmacist and the scope of practice of the physician; requiring 13 14 notification to the board upon practicing under a collaborative pharmacy practice agreement; requiring 15 pharmacists to submit a copy of the signed 16 17 collaborative practice agreement to the Board of Pharmacy; providing for the maintenance of patient 18 19 records for a certain period of time; providing for renewal of such agreement; requiring a pharmacist and 20 21 the collaborating physician to maintain on file and 22 make available the collaborative pharmacy practice 23 agreement; prohibiting certain actions relating to the collaborative pharmacy practice agreement; requiring 24 25 specified continuing education for a pharmacist who

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26 practices pursuant to a collaborative pharmacy 27 practice agreement; requiring the Board of Pharmacy to 28 adopt rules; creating s. 465.1895, F.S.; establishing 29 a committee to identify minor, nonchronic health 30 conditions that a pharmacist may test or screen for and treat; defining "minor, nonchronic health 31 32 conditions"; providing requirements for a pharmacist to test or screen for and treat minor, nonchronic 33 health conditions; requiring the committee to develop 34 35 a formulary of medicinal drugs that a pharmacist may 36 prescribe; providing requirements for a pharmacist to 37 test or screen for and treat minor, nonchronic health conditions; providing requirements for the written 38 39 protocol between a pharmacist and a supervising physician; prohibiting a pharmacist from providing 40 certain services under certain circumstances; 41 42 requiring a pharmacist to complete a specified amount 43 of continuing education; providing an effective date. 44 45 Be It Enacted by the Legislature of the State of Florida: 46 Subsection (2) of section 381.0031, Florida 47 Section 1. 48 Statutes, is amended to read: 49 381.0031 Epidemiological research; report of diseases of 50 public health significance to department.-

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51 Any practitioner licensed in this state to practice (2)52 medicine, osteopathic medicine, chiropractic medicine, 53 naturopathy, or veterinary medicine; any licensed pharmacist 54 authorized pursuant to a protocol with a supervising licensed physician, under s. 465.1895, or a collaborative pharmacy 55 56 practice agreement, as defined in s. 465.1865, to perform or 57 order and evaluate laboratory and clinical tests; any hospital 58 licensed under part I of chapter 395; or any laboratory 59 appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement 60 Amendments and the federal rules adopted thereunder which 61 62 diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the 63 64 Department of Health.

65 Section 2. Subsection (13) of section 465.003, Florida66 Statutes, is amended to read:

67

465.003 Definitions.-As used in this chapter, the term:

68 (13) "Practice of the profession of pharmacy" includes 69 compounding, dispensing, and consulting concerning contents, 70 therapeutic values, and uses of any medicinal drug; consulting 71 concerning therapeutic values and interactions of patent or 72 proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or 73 74 orders; and conducting other pharmaceutical services. For 75 purposes of this subsection, "other pharmaceutical services"

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means the monitoring of the patient's drug therapy and assisting 76 77 the patient in the management of his or her drug therapy, and 78 includes review of the patient's drug therapy and communication 79 with the patient's prescribing health care provider as licensed 80 under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such 81 82 provider's agent or such other persons as specifically 83 authorized by the patient, regarding the drug therapy; and initiating, modifying, or discontinuing drug therapy for a 84 85 chronic health condition pursuant to a collaborative pharmacy practice agreement. However, Nothing in this subsection may be 86 87 interpreted to permit an alteration of a prescriber's 88 directions, the diagnosis or treatment of any disease, the 89 initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by 90 law or specifically authorized by s. 465.1865 or s. 465.1895. 91 92 "Practice of the profession of pharmacy" also includes any other 93 act, service, operation, research, or transaction incidental to, 94 or forming a part of, any of the foregoing acts, requiring, 95 involving, or employing the science or art of any branch of the 96 pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from 97 persons authorized to prescribe medicinal drugs to their 98 patients. The practice of the profession of pharmacy also 99 100 includes the administration of vaccines to adults pursuant to s.

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101	465.189, the testing or screening for and treatment of minor,
102	nonchronic health conditions pursuant to s. 465.1895, and the
103	preparation of prepackaged drug products in facilities holding
104	Class III institutional pharmacy permits.
105	Section 3. Section 465.1865, Florida Statutes, is created
106	to read:
107	465.1865 Collaborative pharmacy practice for chronic
108	health conditions
109	(1) For purposes of this section, the term:
110	(a) "Collaborative pharmacy practice agreement" means a
111	written agreement between a pharmacist who meets the
112	qualifications of this section and a physician licensed under
113	chapter 458 or chapter 459 in which a collaborating physician
114	authorizes a pharmacist to provide specified patient care
115	services to the collaborating physician's patients.
116	(b) "Chronic health condition" means a condition that
117	typically lasts more than 1 year and requires ongoing medical
118	attention, limits activities of daily living, or both. Such
119	condition may include, but is not limited to:
120	1. Arthritis;
121	2. Asthma;
122	3. Congestive heart failure;
123	4. Chronic obstructive pulmonary diseases;
124	5. Diabetes;
125	6. Emphysema;
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126	7. Human immunodeficiency virus or acquired
127	immunodeficiency syndrome;
128	8. Hypertension;
129	9. Obesity;
130	10. Renal disease; or
131	11. Any other chronic condition or co-morbidity identified
132	by the collaborating physician.
133	(2) To provide services under a collaborative pharmacy
134	practice agreement, a pharmacist must:
135	(a) Hold an active and unencumbered license to practice
136	pharmacy in this state.
137	(b) Have earned a degree of doctor of pharmacy or have
138	completed 5 years of experience as a licensed pharmacist.
139	(c) Complete an initial 20-hour course approved by the
140	board that includes, at a minimum, instruction on the following:
141	1. Performance of patient assessments.
142	2. Ordering, performing, and interpreting clinical and
143	laboratory tests related to collaborative pharmacy practice.
144	3. Evaluating and managing diseases and health conditions
145	in collaboration with other health care practitioners.
146	4. Any other area required by the board by rule.
147	(d) Maintain at least \$250,000 of professional liability
148	insurance coverage. However, a pharmacist who maintains
149	professional liability insurance coverage pursuant to s.
150	465.1895 satisfies this requirement.
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151	(e) Submit a copy of the signed collaborative pharmacy
152	practice agreement and proof of satisfying the conditions of
153	this section to the board before commencing practice.
154	(f) Maintain records of all patients receiving services
155	under a collaborative pharmacy practice agreement for a period
156	of 5 years.
157	(3) The terms and conditions of the collaborative pharmacy
158	practice agreement must be appropriate to the pharmacist's
159	training and the services delegated to the pharmacist must be
160	within the collaborating physician's scope of practice.
161	(a) A collaborative pharmacy practice agreement must
162	include the following:
163	1. Name of the patient or patients for whom a pharmacist
164	may provide services.
± 0 1	
165	2. Each chronic disease to be collaboratively managed.
165	2. Each chronic disease to be collaboratively managed.
165 166	<ol> <li>Each chronic disease to be collaboratively managed.</li> <li>Specific medicinal drug or drugs to be managed by the</li> </ol>
165 166 167	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist.
165 166 167 168	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist. 4. Circumstances under which the pharmacist may order or
165 166 167 168 169	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist. 4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests.
165 166 167 168 169 170	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist. 4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests. 5. Conditions and events upon which the pharmacist must
165 166 167 168 169 170 171	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist. 4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests. 5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe
165 166 167 168 169 170 171 172	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist. 4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests. 5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur.
165 166 167 168 169 170 171 172 173	2. Each chronic disease to be collaboratively managed. 3. Specific medicinal drug or drugs to be managed by the pharmacist. 4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests. 5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur. 6. Beginning and ending dates for the collaborative

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176	records transfers.
177	7. A statement that the collaborative pharmacy practice
178	agreement may be terminated, in writing, by either party at any
179	time.
180	(b) A collaborative pharmacy practice agreement must be
181	renewed at least every 2 years.
182	(c) The pharmacist, along with the collaborating
183	physician, must maintain on file the collaborative pharmacy
184	practice agreement at his or her practice location, and must
185	make such agreements available upon request or inspection.
186	(4) A pharmacist may not:
187	(a) Modify or discontinue medicinal drugs prescribed by a
188	health care practitioner with whom he or she does not have a
189	collaborative practice agreement.
190	(b) Enter into a collaborative pharmacy practice agreement
191	while acting as an employee without the written approval of the
192	owner of the pharmacy.
193	(5) A physician may not delegate the authority to initiate
194	or prescribe a controlled substance as defined in s. 893.03 or
195	21 U.S.C. s. 812 to a pharmacist.
196	(6) A pharmacist who practices pursuant to a collaborative
197	pharmacy practice agreement must complete an 8-hour continuing
198	education course approved by the board that addresses issues
199	related to collaborative pharmacy practice each biennial
200	licensure renewal in addition to the continuing education
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201 requirements under s. 465.009. A pharmacist must submit 202 confirmation of having completed such course when applying for 203 licensure renewal. A pharmacist who fails to comply with this subsection shall be prohibited from practicing under a 204 205 collaborative pharmacy practice agreement as authorized in this 206 section. 207 (7) The board shall adopt rules pursuant to ss. 120.536(1) 208 and 120.54 to implement this section. Section 4. Section 465.1895, Florida Statutes, is created 209 210 to read: 465.1895 Testing or screening for and treatment of minor, 211 212 nonchronic health conditions.-213 (1) The board, in consultation with the Board of Medicine 214 and the Board of Osteopathic Medicine, shall adopt rules 215 identifying the minor, nonchronic health conditions for which a pharmacist may test or screen for and treat. For purposes of 216 217 this section a minor, nonchronic health condition is typically a short-term condition that is generally managed with minimal 218 treatment or self-care, including, but not limited to, the 219 220 following: 221 (a) Influenza. 222 (b) Streptococcus. (c) Lice. 223 224 (d) Skin conditions, such as ringworm and athlete's foot. 225 (e) Minor, uncomplicated infections.

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226 A pharmacist who tests or screens for and treats (2) 227 minor, nonchronic health conditions pursuant to this section 228 must: 229 Hold an active and unencumbered license to practice (a) 230 pharmacy in this state. 231 (b) Complete an initial 20-hour education course approved 232 by the board. The course, at a minimum, must address patient 233 assessments, point-of-care testing procedures, safe and effective treatment of minor, nonchronic health conditions, and 234 235 identification of contraindications. 236 (c) Maintain at least \$250,000 of liability coverage. A 237 pharmacist who maintains liability coverage pursuant to s. 238 465.1865 satisfies this requirement. 239 (d) Report a diagnosis or suspected existence of a disease 240 of public health significance to the department pursuant to s. 241 381.0031. 242 (e) Upon request of a patient, furnish patient records to 243 a health care practitioner designated by the patient. 244 (f) Maintain records of all patients receiving services 245 pursuant to this section for a period of 5 years. (3) The board shall adopt, by rule, a formulary of 246 medicinal drugs that a pharmacist may prescribe for the minor, 247 248 nonchronic health conditions approved under subsection (1). The 249 formulary must include medicinal drugs approved by the United 250 States Food and Drug Administration that are indicated for

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251 treatment of the minor, nonchronic health condition, including 252 any over-the-counter medication. The formulary may not include 253 any controlled substance, as defined in s. 893.03 or 21 U.S.C. 254 s. 812. 255 (4) A pharmacist who tests or screens for and treats 256 minor, nonchronic health conditions pursuant to this section may 257 use any tests that may guide diagnosis or clinical 258 decisionmaking which the Centers for Medicare and Medicaid 259 Services has determined qualifies for a waiver under the federal 260 Clinical Laboratory Improvement Amendments of 1988, or the 261 federal rules adopted thereunder, or any established screening 262 procedures that can safely be performed by a pharmacist. 263 (5) A pharmacist who tests for and treats influenza or 264 streptococcus pursuant to this section may only provide such 265 services within the framework of an established written protocol 266 with a supervising physician licensed under chapter 458 or 267 chapter 459, and must submit the protocol to the board. 268 The protocol between a pharmacist and supervising (a) 269 physician under this subsection must include particular terms 270 and conditions imposed by the supervising physician relating to 271 the testing for and treatment of influenza and streptococcus 272 pursuant to this section. The terms and conditions must be 273 appropriate to the pharmacist's training. At a minimum, the 274 protocol shall include: 1. Specific categories of patients who the pharmacist is 275

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276	authorized to test for and treat influenza and streptococcus.
277	2. The supervising physician's instructions for the
278	treatment of influenza and streptococcus based on the patient's
279	age, symptoms, and test results, including negative results.
280	3. A process and schedule for the supervising physician to
281	review the pharmacist's actions under the protocol.
282	4. A process and schedule for the pharmacist to notify the
283	supervising physician of the patient's condition, tests
284	administered, test results, and course of treatment.
285	5. Other requirements, as established by the board in
286	<u>rule.</u>
287	(b) A pharmacist authorized to test for and treat
288	influenza and streptococcus under the protocol shall provide
289	evidence of current certification by the board to the
290	supervising physician. A supervising physician shall review the
291	pharmacist's actions in accordance with the protocol.
292	(6) A pharmacist providing services pursuant to this
293	section may not perform such services while acting as an
294	employee without the written approval of the owner of the
295	pharmacy.
296	(7) A pharmacist providing services pursuant to this
297	section must complete a 3-hour continuing education course
298	approved by the board addressing issues related to minor,
299	nonchronic health conditions each biennial licensure renewal in
300	addition to the continuing education requirements under s.
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301	465.009. Each pharmacist must submit confirmation of having
302	completed the course when applying for licensure renewal. A
303	pharmacist who fails to comply with this subsection may not
304	provide testing, screening, and treatment services.
305	Section 5. This act shall take effect July 1, 2019.

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