CS for SB 1316

By the Committee on Health Regulation; and Senator Gaetz

588-03223-12

20121316c1

1	A bill to be entitled
2	An act relating to health care; amending s. 395.002,
3	F.S.; redefining the term "accrediting organizations"
4	as it applies to the regulation of hospitals and other
5	licensed facilities; amending s. 400.474, F.S.;
6	revising the fine that may be imposed against a home
7	health agency for failing to timely submit certain
8	information to the Agency for Health Care
9	Administration; amending s. 400.9905, F.S.; revising
10	the definition of the term "clinic" as it relates to
11	the Health Care Clinic Act; amending s. 409.221, F.S.;
12	revising the background screening requirements for
13	persons rendering care in the consumer-directed care
14	program administered by the Agency for Health Care
15	Administration; amending s. 409.907, F.S.; extending
16	the records-retention period for certain Medicaid
17	provider records; revising the provider agreement to
18	require Medicaid providers to report changes in any
19	principal of the provider to the agency; defining the
20	term "administrative fines" for purposes of revoking a
21	Medicaid provider agreement due to changes of
22	ownership; authorizing, rather than requiring, an
23	onsite inspection of a Medicaid provider's service
24	location before entering into a provider agreement;
25	specifying the principals of a hospital or nursing
26	home provider for the purposes of submitting
27	fingerprints for background screening; removing
28	certain providers from being subject to agency
29	background checks; amending s. 409.913, F.S.; defining

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30	the term "Medicaid provider" or "provider" for
31	purposes of oversight of the integrity of the Medicaid
32	program; authorizing the agency to review and analyze
33	information from sources other than Medicaid-enrolled
34	providers for purposes of determining fraud, abuse,
35	overpayment, or neglect; extending the records-
36	retention period for certain Medicaid provider
37	records; revising the grounds for terminating a
38	provider from the Medicaid program; requiring the
39	agency to base its overpayment audit reports on
40	certain information; deleting a requirement that the
41	agency pay interest on certain withheld Medicaid
42	payments; requiring payment arrangements for
43	overpayments and fines to be made within a certain
44	time; specifying that the venue for all Medicaid
45	program integrity cases lies in Leon County;
46	authorizing the agency and the Medicaid Fraud Control
47	Unit to review certain records; amending s. 409.920,
48	F.S.; clarifying the applicability of immunity from
49	civil liability extended to persons who provide
50	information about fraud or suspected fraudulent acts
51	by a Medicaid provider; amending s. 409.967, F.S.;
52	specifying required components of a Medicaid managed
53	care plan relating to the provisions of medications;
54	amending s. 429.23, F.S.; requiring the agency to
55	submit a report to the Legislature on adverse incident
56	reports from assisted living facilities; amending s.
57	429.26, F.S.; authorizing the agency to require a
58	resident of an assisted living facility to undergo a

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588-03223-12 20121316c1 59 physical examination if the agency questions the 60 appropriateness of the resident's placement in that 61 facility; authorizing release of the results of the 62 examination to a medical review team to be used along with additional information to determine whether the 63 64 resident's placement in the assisted living facility 65 is appropriate; providing for resident notification and relocation if the resident's continued placement 66 67 in the facility is not appropriate; authorizing the 68 agency to require the evaluation of a mental health resident by a mental health professional; authorizing 69 70 an assisted living facility to discharge a resident 71 who requires more services or care than the facility 72 is able to provide; amending s. 456.0635, F.S.; 73 revising the grounds under which the Department of 74 Health or corresponding board is required to refuse to 75 admit a candidate to an examination and refuse to 76 issue or renew a license, certificate, or registration 77 of a health care practitioner; providing an exception; 78 amending s. 456.036, F.S.; providing that all persons 79 who were denied renewal of licensure, certification, or registration under s. 456.0635(3), F.S., may regain 80 licensure, certification, or registration only by 81 82 completing the application process for initial 83 licensure; providing an exception; amending s. 84 456.074, F.S.; revising the federal offenses for which 85 the Department of Health must issue an emergency order 86 suspending the license of certain health care 87 professionals; amending ss. 458.309 and 459.005, F.S.;

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88	requiring a physician or osteopathic physician who
89	performs certain medical procedures relating to
90	liposuction in an office setting to register the
91	office with the Department of Health unless that
92	office is licensed as a facility under ch. 395, F.S.,
93	relating to hospital licensing and regulation;
94	amending s. 463.002, F.S.; conforming provisions to
95	changes made by the act; amending s. 463.005, F.S.;
96	authorizing the Board of Optometry to adopt rules for
97	the administration and prescription of ocular
98	pharmaceutical agents; amending s. 463.0055, F.S.;
99	authorizing certified optometrists to administer and
100	prescribe pharmaceutical agents under certain
101	circumstances; requiring that a certified optometrist
102	complete a course and subsequent examination on
103	general and ocular pharmacology; providing
104	requirements for the course; requiring that the
105	Florida Medical Association and the Florida Optometric
106	Association jointly develop and administer the course
107	and examination; revising qualifications of certain
108	members of the formulary committee; providing for a
109	formulary of topical ocular pharmaceutical agents
110	which the committee may modify; specifying the agents
111	that make up the statutory formulary of oral
112	pharmaceutical agents; authorizing the deletion of an
113	oral pharmaceutical agent listed in the statutory
114	formulary under certain circumstances; prohibiting the
115	board, the Department of Health, or the State Surgeon
116	General from deleting an oral pharmaceutical agent

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117	listed in the statutory formulary; amending ss.
118	463.0057 and 463.006, F.S.; conforming provisions to
119	changes made by the act; amending s. 463.0135, F.S.;
120	requiring that a certified optometrist administer and
121	prescribe oral ocular pharmaceutical agents in a
122	certain manner; requiring that a licensed practitioner
123	who diagnoses a patient who has a neovascular form of
124	glaucoma or progressive glaucoma immediately refer the
125	patient to a physician who is skilled in the diseases
126	of the eye; requiring that comanagement of
127	postoperative care be conducted pursuant to an
128	established protocol; requiring that the patient be
129	informed that a physician will be available for
130	emergency care throughout the postoperative period;
131	requiring that the patient consent in writing to the
132	comanagement relationship; amending s. 463.014, F.S.;
133	revising certain prohibited acts regarding an
134	optometrist conducting surgery and dispensing,
135	administering, ordering, supplying, or selling certain
136	drugs; creating s. 463.0141, F.S.; requiring that
137	adverse incidents in the practice of optometry be
138	reported to the Department of Health; providing
139	requirements for notifying the department of an
140	adverse incident; providing a definition; requiring
141	that the department review each incident and determine
142	whether it involved conduct that is subject to
143	disciplinary action; requiring that the Board of
144	Optometry take disciplinary action if necessary;
145	amending s. 483.035, F.S., relating to licensure and

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146	regulation of clinical laboratories operated by
147	practitioners for exclusive use; providing
148	applicability to clinical laboratories operated by
149	practitioners licensed to practice optometry; amending
150	s. 483.041, F.S.; revising the definition of the term
151	"licensed practitioner" to include a practitioner
152	licensed under ch. 463, F.S.; amending s. 483.181,
153	F.S.; requiring clinical laboratories to accept human
154	specimens submitted by practitioners licensed to
155	practice under ch. 463, F.S.; amending s. 499.003,
156	F.S.; removing a requirement that a contract provider
157	or subcontractor maintain prescription drugs of the
158	agency or entity in its possession separate and apart
159	from other prescription drugs; amending s. 766.102,
160	F.S.; providing that the claimant has the burden of
161	proving by clear and convincing evidence that the
162	actions of a health care provider represented a breach
163	of the prevailing professional standard of care in an
164	action for damages based on death or personal injury
165	which alleges that the death or injury resulted from
166	the failure of a health care provider to order,
167	perform, or administer supplemental diagnostic tests;
168	amending s. 766.106, F.S.; authorizing a prospective
169	defendant to obtain informal discovery by conducting
170	ex parte interviews of treating health care providers;
171	requiring advance notice to the claimant of an ex
172	parte interview; creating s. 766.1091, F.S.;
173	authorizing a health care provider or health care
174	clinic and a patient to agree to submit a claim of

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175	medical negligence to arbitration; requiring that the
176	arbitration agreement be governed by ch. 682, F.S.;
177	authorizing the arbitration agreement to contain a
178	provision that limits an award of damages; amending s.
179	893.02, F.S.; revising the definition of the term
180	"practitioner" to include certified optometrists for
181	purposes of the Florida Comprehensive Drug Abuse
182	Prevention and Control Act; amending s. 893.05, F.S.;
183	prohibiting certified optometrists from administering
184	and prescribing certain controlled substances;
185	requiring the Agency for Health Care Administration to
186	prepare a report for public comment and submission to
187	the Legislature following the expansion of services to
188	new populations or of new services; providing
189	effective dates.
190	
191	Be It Enacted by the Legislature of the State of Florida:
192	
193	Section 1. Subsection (1) of section 395.002, Florida
194	Statutes, is amended to read:
195	395.002 Definitions.—As used in this chapter:
196	(1) "Accrediting organizations" means <u>national</u>
197	accreditation organizations that are approved by the Centers for
198	Medicare and Medicaid Services and whose standards incorporate
199	comparable licensure regulations required by the state the Joint
200	Commission on Accreditation of Healthcare Organizations, the
201	American Osteopathic Association, the Commission on
202	Accreditation of Rehabilitation Facilities, and the
203	Accreditation Association for Ambulatory Health Care, Inc.

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588-03223-12 20121316c1 Section 2. Subsection (6) of section 400.474, Florida 204 205 Statutes, is amended, present subsection (7) of that section is renumbered as subsection (8), and a new subsection (7) is added 206 207 to that section, to read: 208 400.474 Administrative penalties.-209 (6) The agency may deny, revoke, or suspend the license of 210 a home health agency and shall impose a fine of \$5,000 against a 211 home health agency that: (a) Gives remuneration for staffing services to: 212 213 1. Another home health agency with which it has formal or 214 informal patient-referral transactions or arrangements; or 215 2. A health services pool with which it has formal or 216 informal patient-referral transactions or arrangements, 217 218 unless the home health agency has activated its comprehensive 219 emergency management plan in accordance with s. 400.492. This 220 paragraph does not apply to a Medicare-certified home health 221 agency that provides fair market value remuneration for staffing services to a non-Medicare-certified home health agency that is 222 223 part of a continuing care facility licensed under chapter 651 for providing services to its own residents if each resident 224 225 receiving home health services pursuant to this arrangement 226 attests in writing that he or she made a decision without 227 influence from staff of the facility to select, from a list of 228 Medicare-certified home health agencies provided by the 229 facility, that Medicare-certified home health agency to provide 230 the services. 231 (b) Provides services to residents in an assisted living

facility for which the home health agency does not receive fair

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588-03223-12 20121316c1 233 market value remuneration. (c) Provides staffing to an assisted living facility for 235 which the home health agency does not receive fair market value 236 remuneration. 237 (d) Fails to provide the agency, upon request, with copies 238 of all contracts with assisted living facilities which were 239 executed within 5 years before the request. 240 (e) Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who 241 is involved in the discharge planning process of a facility 242 243 licensed under chapter 395, chapter 429, or this chapter from 244 whom the home health agency receives referrals. (f) Fails to submit to the agency, within 15 days after the 245 end of each calendar guarter, a written report that includes the 246 247 following data based on data as it existed on the last day of 248 the quarter: 249 1. The number of insulin-dependent diabetic patients 250 receiving insulin-injection services from the home health 251 agency; 252 2. The number of patients receiving both home health 253 services from the home health agency and hospice services; 254 3. The number of patients receiving home health services 255 from that home health agency; and 256 4. The names and license numbers of nurses whose primary job responsibility is to provide home health services to 257 258 patients and who received remuneration from the home health 259 agency in excess of \$25,000 during the calendar quarter. 260 (f) (g) Gives cash, or its equivalent, to a Medicare or 261 Medicaid beneficiary.

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CODING: Words stricken are deletions; words underlined are additions.

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262	(g) (h) Has more than one medical director contract in
263	effect at one time or more than one medical director contract
264	and one contract with a physician-specialist whose services are
265	mandated for the home health agency in order to qualify to
266	participate in a federal or state health care program at one
267	time.
268	(h) (i) Gives remuneration to a physician without a medical
269	director contract being in effect. The contract must:
270	1. Be in writing and signed by both parties;
271	2. Provide for remuneration that is at fair market value
272	for an hourly rate, which must be supported by invoices
273	submitted by the medical director describing the work performed,
274	the dates on which that work was performed, and the duration of
275	that work; and
276	3. Be for a term of at least 1 year.
277	
278	The hourly rate specified in the contract may not be increased
279	during the term of the contract. The home health agency may not
280	execute a subsequent contract with that physician which has an
281	increased hourly rate and covers any portion of the term that
282	was in the original contract.
283	<u>(i)</u> Gives remuneration to:
284	1. A physician, and the home health agency is in violation
285	of paragraph <u>(g)</u> <del>(h)</del> or paragraph <u>(h)</u> <del>(i)</del> ;
286	2. A member of the physician's office staff; or
287	3. An immediate family member of the physician,
288	
289	if the home health agency has received a patient referral in the
290	preceding 12 months from that physician or physician's office

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291	staff.
292	(j) <del>(k)</del> Fails to provide to the agency, upon request, copies
293	of all contracts with a medical director which were executed
294	within 5 years before the request.
295	(k)(1) Demonstrates a pattern of billing the Medicaid
296	program for services to Medicaid recipients which are medically
297	unnecessary as determined by a final order. A pattern may be
298	demonstrated by a showing of at least two such medically
299	unnecessary services within one Medicaid program integrity audit
300	period.
301	
302	Paragraphs (e) and (i) do not apply to or preclude Nothing in
303	paragraph (e) or paragraph (j) shall be interpreted as applying
304	to or precluding any discount, compensation, waiver of payment,
305	or payment practice permitted by 42 U.S.C. s. 1320a-7(b) or
306	regulations adopted thereunder, including 42 C.F.R. s. 1001.952
307	or s. 1395nn or regulations adopted thereunder.
308	(7) The agency shall impose a fine of \$50 per day against a
309	home health agency that fails to submit to the agency, within 15
310	days after the end of each calendar quarter, a written report
311	that includes the following data based on data as it existed on
312	the last day of the quarter:
313	(a) The number of patients receiving both home health
314	services from the home health agency and hospice services;
315	(b) The number of patients receiving home health services
316	from the home health agency;
317	(c) The number of insulin-dependent diabetic patients
318	receiving insulin-injection services from the home health
319	agency; and
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320	(d) The names and license numbers of nurses whose primary
321	job responsibility is to provide home health services to
322	patients and who received remuneration from the home health
323	agency in excess of \$25,000 during the calendar quarter.
324	Section 3. Paragraph (1) of subsection (4) of section
325	400.9905, Florida Statutes, is amended, and paragraph (m) is
326	added to that subsection, to read:
327	400.9905 Definitions
328	(4) "Clinic" means an entity at which health care services
329	are provided to individuals and which tenders charges for
330	reimbursement for such services, including a mobile clinic and a
331	portable equipment provider. For purposes of this part, the term
332	does not include and the licensure requirements of this part do
333	not apply to:
334	(l) Orthotic <u>,</u> <del>or</del> prosthetic <u>, pediatric cardiology, or</u>
335	perinatology clinical facilities or anesthesia clinical
336	facilities that are not otherwise exempt under paragraph (a) or
337	paragraph (k) and that are a publicly traded corporation or <del>that</del>
338	are wholly owned, directly or indirectly, by a publicly traded
339	corporation. As used in this paragraph, a publicly traded
340	corporation is a corporation that issues securities traded on an
341	exchange registered with the United States Securities and
342	Exchange Commission as a national securities exchange.
343	(m) Entities that are owned or controlled, directly or
344	indirectly, by a publicly traded entity that has \$100 million or
345	more, in the aggregate, in total annual revenues derived from
346	providing health care services by licensed health care
347	practitioners who are employed or contracted by an entity
348	described in this paragraph.

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588-03223-12 20121316c1 349 Section 4. Paragraph (i) of subsection (4) of section 350 409.221, Florida Statutes, is amended to read: 351 409.221 Consumer-directed care program.-352 (4) CONSUMER-DIRECTED CARE.-353 (i) Background screening requirements.-All persons who 354 render care under this section must undergo level 2 background 355 screening pursuant to chapter 435 and s. 408.809. The agency 356 shall, as allowable, reimburse consumer-employed caregivers for 357 the cost of conducting such background screening as required by 358 this section. For purposes of this section, a person who has 359 undergone screening, who is qualified for employment under this 360 section and applicable rule, and who has not been unemployed for 361 more than 90 days following such screening is not required to be 362 rescreened. Such person must attest under penalty of perjury to 363 not having been convicted of a disqualifying offense since 364 completing such screening.

Section 5. Paragraph (c) of subsection (3) of section 409.907, Florida Statutes, is amended, paragraph (k) is added to that subsection, and subsections (6), (7), and (8) of that section are amended, to read:

369 409.907 Medicaid provider agreements.-The agency may make 370 payments for medical assistance and related services rendered to 371 Medicaid recipients only to an individual or entity who has a 372 provider agreement in effect with the agency, who is performing 373 services or supplying goods in accordance with federal, state, 374 and local law, and who agrees that no person shall, on the 375 grounds of handicap, race, color, or national origin, or for any 376 other reason, be subjected to discrimination under any program 377 or activity for which the provider receives payment from the

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588-03223-12 20121316c1 378 agency. 379 (3) The provider agreement developed by the agency, in addition to the requirements specified in subsections (1) and 380 381 (2), shall require the provider to: 382 (c) Retain all medical and Medicaid-related records for 6 a 383 period of 5 years to satisfy all necessary inquiries by the 384 agency. 385 (k) Report a change in any principal of the provider, 386 including any officer, director, agent, managing employee, or 387 affiliated person, or any partner or shareholder who has an 388 ownership interest equal to 5 percent or more in the provider, 389 to the agency in writing no later than 30 days after the change 390 occurs. 391 (6) A Medicaid provider agreement may be revoked, at the 392 option of the agency, due to as the result of a change of 393 ownership of any facility, association, partnership, or other 394 entity named as the provider in the provider agreement. 395 (a) In the event of a change of ownership, the transferor 396 remains liable for all outstanding overpayments, administrative 397 fines, and any other moneys owed to the agency before the 398 effective date of the change of ownership. In addition to the 399 continuing liability of the transferor, The transferee is also 400 liable to the agency for all outstanding overpayments identified 401 by the agency on or before the effective date of the change of 402 ownership. For purposes of this subsection, the term 403 "outstanding overpayment" includes any amount identified in a preliminary audit report issued to the transferor by the agency 404 405 on or before the effective date of the change of ownership. In 406 the event of a change of ownership for a skilled nursing

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588-03223-12 20121316c1 407 facility or intermediate care facility, the Medicaid provider 408 agreement shall be assigned to the transferee if the transferee 409 meets all other Medicaid provider qualifications. In the event 410 of a change of ownership involving a skilled nursing facility 411 licensed under part II of chapter 400, liability for all 412 outstanding overpayments, administrative fines, and any moneys 413 owed to the agency before the effective date of the change of 414 ownership shall be determined in accordance with s. 400.179. 415 (b) At least 60 days before the anticipated date of the 416 change of ownership, the transferor must shall notify the agency 417 of the intended change of ownership and the transferee must 418 shall submit to the agency a Medicaid provider enrollment 419 application. If a change of ownership occurs without compliance 420 with the notice requirements of this subsection, the transferor 421 and transferee are shall be jointly and severally liable for all 422 overpayments, administrative fines, and other moneys due to the 423 agency, regardless of whether the agency identified the 424 overpayments, administrative fines, or other moneys before or 425 after the effective date of the change of ownership. The agency 426 may not approve a transferee's Medicaid provider enrollment 427 application if the transferee or transferor has not paid or 428 agreed in writing to a payment plan for all outstanding 429 overpayments, administrative fines, and other moneys due to the 430 agency. This subsection does not preclude the agency from 431 seeking any other legal or equitable remedies available to the 432 agency for the recovery of moneys owed to the Medicaid program. 433 In the event of a change of ownership involving a skilled 434 nursing facility licensed under part II of chapter 400, 435 liability for all outstanding overpayments, administrative

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436	fines, and any moneys owed to the agency before the effective
437	date of the change of ownership shall be determined in
438	accordance with s. 400.179 if the Medicaid provider enrollment
439	application for change of ownership is submitted before the
440	change of ownership.
441	(c) As used in this subsection, the term:
442	1. "Administrative fines" includes any amount identified in
443	a notice of a monetary penalty or fine which has been issued by
444	the agency or other regulatory or licensing agency that governs
445	the provider.
446	2. "Outstanding overpayment" includes any amount identified
447	in a preliminary audit report issued to the transferor by the
448	agency on or before the effective date of a change of ownership.
449	(7) <del>The agency may require,</del> As a condition of participating
450	in the Medicaid program and before entering into the provider
451	agreement, <u>the agency may require</u> <del>that</del> the provider <u>to</u> submit
452	information, in an initial and any required renewal
453	applications, concerning the professional, business, and
454	personal background of the provider and permit an onsite
455	inspection of the provider's service location by agency staff or
456	other personnel designated by the agency to perform this
457	function. Before entering into a provider agreement, the agency
458	<u>may</u> <del>shall</del> perform <u>an</u> <del>a random</del> onsite inspection <del>, within 60 days</del>
459	after receipt of a fully complete new provider's application, of
460	the provider's service location <del>prior to making its first</del>
461	payment to the provider for Medicaid services to determine the
462	applicant's ability to provide <del>the</del> services <u>in compliance with</u>
463	the Medicaid program and professional regulations that the
464	applicant is proposing to provide for Medicaid reimbursement.

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588-03223-12 20121316c1 465 The agency is not required to perform an onsite inspection of a 466 provider or program that is licensed by the agency, that 467 provides services under waiver programs for home and community-468 based services, or that is licensed as a medical foster home by the Department of Children and Family Services. As a continuing 469 condition of participation in the Medicaid program, a provider 470 471 must shall immediately notify the agency of any current or 472 pending bankruptcy filing. Before entering into the provider 473 agreement, or as a condition of continuing participation in the 474 Medicaid program, the agency may also require that Medicaid 475 providers reimbursed on a fee-for-services basis or fee schedule 476 basis that which is not cost-based, post a surety bond not to 477 exceed \$50,000 or the total amount billed by the provider to the 478 program during the current or most recent calendar year, 479 whichever is greater. For new providers, the amount of the surety bond shall be determined by the agency based on the 480 481 provider's estimate of its first year's billing. If the 482 provider's billing during the first year exceeds the bond 483 amount, the agency may require the provider to acquire an 484 additional bond equal to the actual billing level of the 485 provider. A provider's bond need shall not exceed \$50,000 if a 486 physician or group of physicians licensed under chapter 458, 487 chapter 459, or chapter 460 has a 50 percent or greater 488 ownership interest in the provider or if the provider is an 489 assisted living facility licensed under chapter 429. The bonds 490 permitted by this section are in addition to the bonds 491 referenced in s. 400.179(2)(d). If the provider is a corporation, partnership, association, or other entity, the 492 493 agency may require the provider to submit information concerning

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494 the background of that entity and of any principal of the 495 entity, including any partner or shareholder having an ownership 496 interest in the entity equal to 5 percent or greater, and any 497 treating provider who participates in or intends to participate 498 in Medicaid through the entity. The information must include:

(a) Proof of holding a valid license or operating
certificate, as applicable, if required by the state or local
jurisdiction in which the provider is located or if required by
the Federal Government.

503 (b) Information concerning any prior violation, fine, 504 suspension, termination, or other administrative action taken 505 under the Medicaid laws, rules, or regulations of this state or 506 of any other state or the Federal Government; any prior 507 violation of the laws, rules, or regulations relating to the 508 Medicare program; any prior violation of the rules or 509 regulations of any other public or private insurer; and any 510 prior violation of the laws, rules, or regulations of any 511 regulatory body of this or any other state.

(c) Full and accurate disclosure of any financial or ownership interest that the provider, or any principal, partner, or major shareholder thereof, may hold in any other Medicaid provider or health care related entity or any other entity that is licensed by the state to provide health or residential care and treatment to persons.

(d) If a group provider, identification of all members of
the group and attestation that all members of the group are
enrolled in or have applied to enroll in the Medicaid program.

521 (8) (a) Each provider, or each principal of the provider if 522 the provider is a corporation, partnership, association, or

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588-03223-12 20121316c1 523 other entity, seeking to participate in the Medicaid program 524 must submit a complete set of his or her fingerprints to the 525 agency for the purpose of conducting a criminal history record 526 check. Principals of the provider include any officer, director, 527 billing agent, managing employee, or affiliated person, or any 528 partner or shareholder who has an ownership interest equal to 5 529 percent or more in the provider. However, for a hospital 530 licensed under chapter 395 or a nursing home licensed under 531 chapter 400, principals of the provider are those who meet the 532 definition of a controlling interest under s. 408.803. A 533 director of a not-for-profit corporation or organization is not 534 a principal for purposes of a background investigation as required by this section if the director: serves solely in a 535 536 voluntary capacity for the corporation or organization, does not 537 regularly take part in the day-to-day operational decisions of 538 the corporation or organization, receives no remuneration from 539 the not-for-profit corporation or organization for his or her 540 service on the board of directors, has no financial interest in the not-for-profit corporation or organization, and has no 541 542 family members with a financial interest in the not-for-profit corporation or organization; and if the director submits an 543 544 affidavit, under penalty of perjury, to this effect to the 545 agency and the not-for-profit corporation or organization 546 submits an affidavit, under penalty of perjury, to this effect 547 to the agency as part of the corporation's or organization's 548 Medicaid provider agreement application.

549 <u>(a)</u> Notwithstanding the above, the agency may require a 550 background check for any person reasonably suspected by the 551 agency to have been convicted of a crime. This subsection does

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section are amended, to read:

588-03223-12 20121316c1 552 not apply to: 553 1. A hospital licensed under chapter 395; 554 2. A nursing home licensed under chapter 400; 555 3. A hospice licensed under chapter 400; 556 4. An assisted living facility licensed under chapter 429; 557 1.5. A unit of local government, except that requirements 558 of this subsection apply to nongovernmental providers and 559 entities contracting with the local government to provide Medicaid services. The actual cost of the state and national 560 561 criminal history record checks must be borne by the 562 nongovernmental provider or entity; or 563 2.6. Any business that derives more than 50 percent of its revenue from the sale of goods to the final consumer, and the 564 565 business or its controlling parent is required to file a form 10-K or other similar statement with the Securities and Exchange 566 567 Commission or has a net worth of \$50 million or more. 568 (b) Background screening shall be conducted in accordance 569 with chapter 435 and s. 408.809. The cost of the state and 570 national criminal record check shall be borne by the provider. 571 (c) Proof of compliance with the requirements of level 2 572 screening under chapter 435 conducted within 12 months before 573 the date the Medicaid provider application is submitted to the 574 agency fulfills the requirements of this subsection. 575 Section 6. Present paragraphs (e) and (f) of subsection (1) of section 409.913, Florida Statutes, are redesignated as 576 577 paragraphs (f) and (g), respectively, a new paragraph (e) is added to that subsection, and subsections (2), (9), (13), (15), 578 579 (16), (21), (22), (25), (28), (29), (30), and (31) of that

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CODING: Words stricken are deletions; words underlined are additions.

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588-03223-12 20121316c1 581 409.913 Oversight of the integrity of the Medicaid 582 program.-The agency shall operate a program to oversee the 583 activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive 584 585 behavior and neglect of recipients occur to the minimum extent 586 possible, and to recover overpayments and impose sanctions as 587 appropriate. Beginning January 1, 2003, and each year 588 thereafter, the agency and the Medicaid Fraud Control Unit of 589 the Department of Legal Affairs shall submit a joint report to 590 the Legislature documenting the effectiveness of the state's 591 efforts to control Medicaid fraud and abuse and to recover 592 Medicaid overpayments during the previous fiscal year. The 593 report must describe the number of cases opened and investigated 594 each year; the sources of the cases opened; the disposition of 595 the cases closed each year; the amount of overpayments alleged 596 in preliminary and final audit letters; the number and amount of 597 fines or penalties imposed; any reductions in overpayment 598 amounts negotiated in settlement agreements or by other means; 599 the amount of final agency determinations of overpayments; the 600 amount deducted from federal claiming as a result of 601 overpayments; the amount of overpayments recovered each year; 602 the amount of cost of investigation recovered each year; the 603 average length of time to collect from the time the case was 604 opened until the overpayment is paid in full; the amount 605 determined as uncollectible and the portion of the uncollectible 606 amount subsequently reclaimed from the Federal Government; the 607 number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and 608 609 abuse; and all costs associated with discovering and prosecuting

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588-03223-12 20121316c1 610 cases of Medicaid overpayments and making recoveries in such 611 cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from 612 613 enrolling in or reenrolling in the Medicaid program as a result 614 of documented Medicaid fraud and abuse and must include policy 615 recommendations necessary to prevent or recover overpayments and 616 changes necessary to prevent and detect Medicaid fraud. All 617 policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation 618 619 costs, estimated savings to the Medicaid program, and the return 620 on investment. The agency must submit the policy recommendations 621 and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. 622 623 The agency and the Medicaid Fraud Control Unit of the Department 624 of Legal Affairs each must include detailed unit-specific 625 performance standards, benchmarks, and metrics in the report, 626 including projected cost savings to the state Medicaid program 627 during the following fiscal year.

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(1) For the purposes of this section, the term:

(e) "Medicaid provider" or "provider" has the same meaning
 as provided in s. 409.901 and, for purposes of oversight of the
 integrity of the Medicaid program, also includes a participant
 in a Medicaid managed care provider network.

(2) The agency shall conduct, or cause to be conducted by
contract or otherwise, reviews, investigations, analyses,
audits, or any combination thereof, to determine possible fraud,
abuse, overpayment, or recipient neglect in the Medicaid program
and shall report the findings of any overpayments in audit
reports as appropriate. At least 5 percent of all audits <u>must</u>

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588-03223-12 20121316c1 639 shall be conducted on a random basis. As part of its ongoing 640 fraud detection activities, the agency shall identify and monitor, by contract or otherwise, patterns of overutilization 641 642 of Medicaid services based on state averages. The agency shall 643 track Medicaid provider prescription and billing patterns and 644 evaluate them against Medicaid medical necessity criteria and 645 coverage and limitation guidelines adopted by rule. Medical 646 necessity determination requires that service be consistent with symptoms or confirmed diagnosis of illness or injury under 647 648 treatment and not in excess of the patient's needs. The agency shall conduct reviews of provider exceptions to peer group norms 649 650 and shall, using statistical methodologies, provider profiling, 651 and analysis of billing patterns, detect and investigate 652 abnormal or unusual increases in billing or payment of claims 653 for Medicaid services and medically unnecessary provision of 654 services. The agency may review and analyze information from 655 sources other than enrolled Medicaid providers in conducting its 656 activities under this subsection.

657 (9) A Medicaid provider shall retain medical, professional, 658 financial, and business records pertaining to services and goods 659 furnished to a Medicaid recipient and billed to Medicaid for 6 a 660 period of 5 years after the date of furnishing such services or 661 goods. The agency may investigate, review, or analyze such 662 records, which must be made available during normal business 663 hours. However, 24-hour notice must be provided if patient 664 treatment would be disrupted. The provider is responsible for 665 furnishing to the agency, and keeping the agency informed of the 666 location of, the provider's Medicaid-related records. The 667 authority of the agency to obtain Medicaid-related records from

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668	a provider is neither curtailed nor limited during a period of
669	litigation between the agency and the provider.
670	(13) The agency shall <i>immediately</i> terminate participation
671	of a Medicaid provider in the Medicaid program and may seek
672	civil remedies or impose other administrative sanctions against
673	a Medicaid provider, if the provider or any principal, officer,
674	director, agent, managing employee, or affiliated person of the
675	provider, or any partner or shareholder having an ownership
676	interest in the provider equal to 5 percent or greater, <u>has been</u>
677	convicted of a criminal offense under federal law or the law of
678	any state relating to the practice of the provider's profession,
679	or an offense listed under s. 409.907(10), s. 408.809(4), or s.
680	<u>435.04(2)</u> has been:
681	(a) Convicted of a criminal offense related to the delivery
682	of any health care goods or services, including the performance
683	of management or administrative functions relating to the
684	delivery of health care goods or services;
685	(b) Convicted of a criminal offense under federal law or
686	the law of any state relating to the practice of the provider's
687	profession; or
688	(c) Found by a court of competent jurisdiction to have
689	neglected or physically abused a patient in connection with the
690	delivery of health care goods or services. If the agency
691	determines <u>that the</u> <del>a</del> provider did not participate or acquiesce
692	in <u>the</u> <del>an</del> offense <del>specified in paragraph (a), paragraph (b), or</del>
693	<del>paragraph (c)</del> , termination will not be imposed. If the agency
694	effects a termination under this subsection, the agency shall

695 issue an immediate final order pursuant to s. 120.569(2)(n).

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(15) The agency shall seek a remedy provided by law,

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588-03223-12 20121316c1 697 including, but not limited to, any remedy provided in 698 subsections (13) and (16) and s. 812.035, if: 699 (a) The provider's license has not been renewed, or has 700 been revoked, suspended, or terminated, for cause, by the 701 licensing agency of any state; 702 (b) The provider has failed to make available or has 703 refused access to Medicaid-related records to an auditor, 704 investigator, or other authorized employee or agent of the 705 agency, the Attorney General, a state attorney, or the Federal 706 Government; 707 (c) The provider has not furnished or has failed to make 708 available such Medicaid-related records as the agency has found 709 necessary to determine whether Medicaid payments are or were due 710 and the amounts thereof; 711 (d) The provider has failed to maintain medical records 712 made at the time of service, or prior to service if prior 713 authorization is required, demonstrating the necessity and 714 appropriateness of the goods or services rendered; 715 (e) The provider is not in compliance with provisions of 716 Medicaid provider publications that have been adopted by 717 reference as rules in the Florida Administrative Code; with provisions of state or federal laws, rules, or regulations; with 718 719 provisions of the provider agreement between the agency and the 720 provider; or with certifications found on claim forms or on 721 transmittal forms for electronically submitted claims that are 722 submitted by the provider or authorized representative, as such

(f) The provider or person who ordered, authorized, or prescribed the care, services, or supplies has furnished, or

provisions apply to the Medicaid program;

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allowable;

588-03223-12 20121316c1 726 ordered, or authorized the furnishing of  $\overline{r}$  goods or services to a recipient which are inappropriate, unnecessary, excessive, or 727 728 harmful to the recipient or are of inferior quality; (g) The provider has demonstrated a pattern of failure to 729 730 provide goods or services that are medically necessary; 731 (h) The provider or an authorized representative of the 732 provider, or a person who ordered, authorized, or prescribed the 733 goods or services, has submitted or caused to be submitted false 734 or a pattern of erroneous Medicaid claims; 735 (i) The provider or an authorized representative of the 736 provider, or a person who has ordered, authorized, or prescribed 737 the goods or services, has submitted or caused to be submitted a 738 Medicaid provider enrollment application, a request for prior 739 authorization for Medicaid services, a drug exception request, 740 or a Medicaid cost report that contains materially false or 741 incorrect information; 742 (j) The provider or an authorized representative of the 743 provider has collected from or billed a recipient or a 744 recipient's responsible party improperly for amounts that should 745 not have been so collected or billed by reason of the provider's 746 billing the Medicaid program for the same service; (k) The provider or an authorized representative of the 747 748 provider has included in a cost report costs that are not 749 allowable under a Florida Title XIX reimbursement plan $_{\tau}$  after 750 the provider or authorized representative had been advised in an 751 audit exit conference or audit report that the costs were not

(1) The provider is charged by information or indictment with fraudulent billing practices or any offense referenced in

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588-03223-12 20121316c1 755 subsection (13). The sanction applied for this reason is limited 756 to suspension of the provider's participation in the Medicaid 757 program for the duration of the indictment unless the provider 758 is found guilty pursuant to the information or indictment; 759 (m) The provider or a person who has ordered, authorized, 760 or prescribed the goods or services is found liable for 761 negligent practice resulting in death or injury to the 762 provider's patient; 763 (n) The provider fails to demonstrate that it had available 764 during a specific audit or review period sufficient quantities 765 of goods, or sufficient time in the case of services, to support 766 the provider's billings to the Medicaid program; 767 (o) The provider has failed to comply with the notice and 768 reporting requirements of s. 409.907; 769 (p) The agency has received reliable information of patient 770 abuse or neglect or of any act prohibited by s. 409.920; or 771 (q) The provider has failed to comply with an agreed-upon 772 repayment schedule. 773 774 A provider is subject to sanctions for violations of this 775 subsection as the result of actions or inactions of the 776 provider, or actions or inactions of any principal, officer, 777 director, agent, managing employee, or affiliated person of the 778 provider, or any partner or shareholder having an ownership 779 interest in the provider equal to 5 percent or greater, in which 780 the provider participated or acquiesced. (16) The agency shall impose any of the following sanctions 781 782 or disincentives on a provider or a person for any of the acts 783 described in subsection (15):

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(a) Suspension for a specific period of time of not more
than 1 year. Suspension <u>precludes</u> shall preclude participation
in the Medicaid program, which includes any action that results
in a claim for payment to the Medicaid program as a result of
furnishing, supervising a person who is furnishing, or causing a
person to furnish goods or services.

(b) Termination for a specific period of time of from more than 1 year to 20 years. Termination <u>precludes</u> shall preclude participation in the Medicaid program, which includes any action that results in a claim for payment to the Medicaid program as a result of furnishing, supervising a person who is furnishing, or causing a person to furnish goods or services.

796 (c) Imposition of a fine of up to \$5,000 for each 797 violation. Each day that an ongoing violation continues, such as 798 refusing to furnish Medicaid-related records or refusing access 799 to records, is considered, for the purposes of this section, to 800 be a separate violation. Each instance of improper billing of a 801 Medicaid recipient; each instance of including an unallowable 802 cost on a hospital or nursing home Medicaid cost report after 803 the provider or authorized representative has been advised in an 804 audit exit conference or previous audit report of the cost 805 unallowability; each instance of furnishing a Medicaid recipient 806 goods or professional services that are inappropriate or of 807 inferior quality as determined by competent peer judgment; each instance of knowingly submitting a materially false or erroneous 808 809 Medicaid provider enrollment application, request for prior 810 authorization for Medicaid services, drug exception request, or 811 cost report; each instance of inappropriate prescribing of drugs 812 for a Medicaid recipient as determined by competent peer

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813	judgment; and each false or erroneous Medicaid claim leading to
814	an overpayment to a provider is considered, for the purposes of
815	this section, to be a separate violation.
816	(d) Immediate suspension, if the agency has received
817	information of patient abuse or neglect or of any act prohibited
818	by s. 409.920. Upon suspension, the agency must issue an
819	immediate final order under s. 120.569(2)(n).
820	(e) A fine, not to exceed \$10,000, for a violation of
821	paragraph (15)(i).
822	(f) Imposition of liens against provider assets, including,
823	but not limited to, financial assets and real property, not to
824	exceed the amount of fines or recoveries sought, upon entry of
825	an order determining that such moneys are due or recoverable.
826	(g) Prepayment reviews of claims for a specified period of
827	time.
828	(h) Comprehensive followup reviews of providers every 6
829	months to ensure that they are billing Medicaid correctly.
830	(i) Corrective-action plans that <del>would</del> remain in effect <del>for</del>
831	<del>providers</del> for up to 3 years and that <u>are</u> <del>would be</del> monitored by
832	the agency every 6 months while in effect.
833	(j) Other remedies as permitted by law to effect the
834	recovery of a fine or overpayment.
835	
836	If a provider voluntarily relinquishes its Medicaid provider
837	number after receiving written notice that the agency is
838	conducting, or has conducted, an audit or investigation and the
839	sanction of suspension or termination will be imposed for
840	noncompliance discovered as a result of the audit or
841	investigation, the agency shall impose the sanction of

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588-03223-12 20121316c1 842 termination for cause against the provider. The Secretary of 843 Health Care Administration may make a determination that imposition of a sanction or disincentive is not in the best 844 845 interest of the Medicaid program, in which case a sanction or 846 disincentive may shall not be imposed. 847 (21) When making a determination that an overpayment has 848 occurred, the agency shall prepare and issue an audit report to 849 the provider showing the calculation of overpayments. The 850 agency's determination shall be based solely upon information 851 available to it before issuance of the audit report and, in the 852 case of documentation obtained to substantiate claims for 853 Medicaid reimbursement, based solely upon contemporaneous 854 records. 855 (22) The audit report, supported by agency work papers,

856 showing an overpayment to a provider constitutes evidence of the 857 overpayment. A provider may not present or elicit testimony, 858 either on direct examination or cross-examination in any court 859 or administrative proceeding, regarding the purchase or 860 acquisition by any means of drugs, goods, or supplies; sales or 861 divestment by any means of drugs, goods, or supplies; or 862 inventory of drugs, goods, or supplies, unless such acquisition, 863 sales, divestment, or inventory is documented by written 864 invoices, written inventory records, or other competent written 865 documentary evidence maintained in the normal course of the provider's business. Testimony or evidence that is not based 866 upon contemporaneous records or that was not furnished to the 867 868 agency within 21 days after the issuance of the audit report is 869 inadmissible in an administrative hearing on a Medicaid 870 overpayment or an administrative sanction. Notwithstanding the

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588-03223-12 20121316c1 871 applicable rules of discovery, all documentation to that will be 872 offered as evidence at an administrative hearing on a Medicaid 873 overpayment or an administrative sanction must be exchanged by 874 all parties at least 14 days before the administrative hearing 875 or must be excluded from consideration. 876 (25) (a) The agency shall withhold Medicaid payments, in 877 whole or in part, to a provider upon receipt of reliable 878 evidence that the circumstances giving rise to the need for a 879 withholding of payments involve fraud, willful 880 misrepresentation, or abuse under the Medicaid program, or a 881 crime committed while rendering goods or services to Medicaid 882 recipients. If it is determined that fraud, willful 883 misrepresentation, abuse, or a crime did not occur, the payments 884 withheld must be paid to the provider within 14 days after such 885 determination with interest at the rate of 10 percent a year. 886 Any money withheld in accordance with this paragraph shall be 887 placed in a suspended account, readily accessible to the agency, 888 so that any payment ultimately due the provider shall be made 889 within 14 days. 890 (b) The agency shall deny payment, or require repayment, if

(b) The agency shall deny payment, or require repayment, if the goods or services were furnished, supervised, or caused to be furnished by a person who has been suspended or terminated from the Medicaid program or Medicare program by the Federal Government or any state.

(c) Overpayments owed to the agency bear interest at the rate of 10 percent per year from the date of determination of the overpayment by the agency, and payment arrangements <u>regarding overpayments and fines</u> must be made <u>within 30 days</u> after the date of the final order and are not subject to further

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588-03223-12 20121316c1 900 appeal at the conclusion of legal proceedings. A provider who 901 does not enter into or adhere to an agreed-upon repayment 902 schedule may be terminated by the agency for nonpayment or 903 partial payment. 904 (d) The agency, upon entry of a final agency order, a judgment or order of a court of competent jurisdiction, or a 905 stipulation or settlement, may collect the moneys owed by all 906 907 means allowable by law, including, but not limited to, notifying 908 any fiscal intermediary of Medicare benefits that the state has 909 a superior right of payment. Upon receipt of such written 910 notification, the Medicare fiscal intermediary shall remit to 911 the state the sum claimed. 912 (e) The agency may institute amnesty programs to allow 913 Medicaid providers the opportunity to voluntarily repay 914 overpayments. The agency may adopt rules to administer such 915 programs. 916 (28) Venue for all Medicaid program integrity overpayment 917 cases lies shall lie in Leon County, at the discretion of the 918 agency. 919 (29) Notwithstanding other provisions of law, the agency and the Medicaid Fraud Control Unit of the Department of Legal 920 921 Affairs may review a person's or provider's Medicaid-related and non-Medicaid-related records in order to determine the total 922 923 output of a provider's practice to reconcile quantities of goods

924 or services billed to Medicaid with quantities of goods or 925 services used in the provider's total practice.

926 (30) The agency shall terminate a provider's participation
927 in the Medicaid program if the provider fails to reimburse an
928 overpayment or pay a fine that has been determined by final

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588-03223-12 20121316c1 929 order, not subject to further appeal, within 30 35 days after 930 the date of the final order, unless the provider and the agency 931 have entered into a repayment agreement. (31) If a provider requests an administrative hearing 932 933 pursuant to chapter 120, such hearing must be conducted within 934 90 days following assignment of an administrative law judge, 935 absent exceptionally good cause shown as determined by the 936 administrative law judge or hearing officer. Upon issuance of a 937 final order, the outstanding balance of the amount determined to 938 constitute the overpayment and fines is shall become due. If a 939 provider fails to make payments in full, fails to enter into a 940 satisfactory repayment plan, or fails to comply with the terms 941 of a repayment plan or settlement agreement, the agency shall 942 withhold medical assistance reimbursement payments for Medicaid 943 services until the amount due is paid in full. 944 Section 7. Subsection (8) of section 409.920, Florida 945 Statutes, is amended to read: 946 409.920 Medicaid provider fraud.-947 (8) A person who provides the state, any state agency, any 948 of the state's political subdivisions, or any agency of the 949 state's political subdivisions with information about fraud or 950 suspected fraudulent acts fraud by a Medicaid provider, 951 including a managed care organization, is immune from civil 952 liability for libel, slander, or any other relevant tort for 953 providing any the information about fraud or suspected 954 fraudulent acts, unless the person acted with knowledge that the 955 information was false or with reckless disregard for the truth or falsity of the information. For purposes of this subsection, 956 957 the term "fraudulent acts" includes actual or suspected fraud,

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958	abuse, or overpayment, including any fraud-related matters that
959	a provider or health plan is required to report to the agency or
960	a law enforcement agency. The immunity from civil liability
961	extends to reports of fraudulent acts conveyed to the agency in
962	any manner, including any forum and with any audience as
963	directed by the agency, and includes all discussions subsequent
964	to the report and subsequent inquiries from the agency, unless
965	the person acted with knowledge that the information was false
966	or with reckless disregard for the truth or falsity of the
967	information.
968	Section 8. Paragraph (c) of subsection (2) of section
969	409.967, Florida Statutes, is amended to read:
970	409.967 Managed care plan accountability
971	(2) The agency shall establish such contract requirements
972	as are necessary for the operation of the statewide managed care
973	program. In addition to any other provisions the agency may deem
974	necessary, the contract must require:
975	(c) Access
976	1. <u>Providers.—</u> The agency shall establish specific standards
977	for the number, type, and regional distribution of providers in
978	managed care plan networks to ensure access to care for both
979	adults and children. Each plan must maintain a regionwide
980	network of providers in sufficient numbers to meet the access
981	standards for specific medical services for all recipients
982	enrolled in the plan. The exclusive use of mail-order pharmacies
983	is may not be sufficient to meet network access standards.
984	Consistent with the standards established by the agency,
985	provider networks may include providers located outside the
986	region. A plan may contract with a new hospital facility before

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987	the date the hospital becomes operational if the hospital has
988	commenced construction, will be licensed and operational by
989	January 1, 2013, and a final order has issued in any civil or
990	administrative challenge. Each plan shall establish and maintain
991	an accurate and complete electronic database of contracted
992	providers, including information about licensure or
993	registration, locations and hours of operation, specialty
994	credentials and other certifications, specific performance
995	indicators, and such other information as the agency deems
996	necessary. The database must be available online to both the
997	agency and the public and have the capability to compare the
998	availability of providers to network adequacy standards and to
999	accept and display feedback from each provider's patients. Each
1000	plan shall submit quarterly reports to the agency identifying
1001	the number of enrollees assigned to each primary care provider.
1002	2. Prescribed drugs
1003	a. If establishing a prescribed drug formulary or preferred
1004	drug list, a managed care plan must:
1005	(I) Provide a broad range of therapeutic options for the
1006	treatment of disease states consistent with the general needs of
1007	an outpatient population. Whenever feasible, the formulary or
1008	preferred drug list should include at least two products in a
1009	therapeutic class;
1010	(II) Include coverage via prior authorization for each drug
1011	newly approved by the federal Food and Drug Administration until
1012	the plan's Pharmaceutical and Therapeutics Committee reviews
1013	such drug for inclusion on the formulary. The timing of the
1014	formulary review must comply with s. 409.91195; and
1015	(III) Provide a response within 24 hours after receipt of

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588-03223-12 20121316c1 1016 all necessary information from the medical provider for a 1017 request for prior authorization and provide a procedure for 1018 escalating a delayed prior authorization request to the pharmacy 1019 management team for resolution or to override other medical 1020 management tools. 1021 b. Each managed care plan shall must publish any prescribed 1022 drug formulary or preferred drug list on the plan's website in a 1023 manner that is accessible to and searchable by enrollees and 1024 providers. The plan must update the list within 24 hours after 1025 making a change. Each plan must ensure that the prior 1026 authorization process for prescribed drugs is readily accessible 1027 to health care providers, including posting appropriate contact 1028 information on its website and providing timely responses to 1029 providers. 1030 c. The managed care plan must continue to permit an 1031 enrollee who was receiving a prescription drug that was on the 1032 plan's formulary and subsequently removed or changed to continue 1033 to receive that drug if the provider submits a written request 1034 that demonstrates that the drug is medically necessary, and the 1035 enrollee meets clinical criteria to receive the drug. 1036 d. A managed care plan that imposes a step-therapy or a 1037 fail-first protocol must do so in accordance with the following: 1038 (I) If prescribed drugs for the treatment of a medical 1039 condition are restricted for use by the plan through a step-1040 therapy or fail-first protocol, the plan must provide the 1041 prescriber with access to a clear and convenient process to 1042 expeditiously request a prior authorization that includes a 1043 procedure for escalation to the pharmacy management team if not 1044 resolved in a timely manner.

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1045	(II) Escalation to the pharmacy management team must be
1046	expeditiously granted by the plan if the prescriber can submit
1047	appropriate and complete medical documentation to the plan that
1048	the preferred treatment required under the step-therapy or fail-
1049	first protocol:
1050	(A) Has been ineffective in the treatment of the enrollee's
1051	disease or medical condition;
1052	(B) Is reasonably expected to be ineffective based on the
1053	known relevant physical or mental characteristics and medical
1054	history of the enrollee and known characteristics of the drug
1055	regimen; or
1056	(C) Will cause or will likely cause an adverse reaction or
1057	other physical harm to the enrollee.
1058	(III) The pharmacy management team shall work directly with
1059	the medical provider to bring the prior-authorization request to
1060	a clinically appropriate, cost-effective, and timely resolution.
1061	e. For enrollees Medicaid recipients diagnosed with
1062	hemophilia who have been prescribed anti-hemophilic-factor
1063	replacement products, the agency shall provide for those
1064	products and hemophilia overlay services through the agency's
1065	hemophilia disease management program.
1066	3. Prior authorization
1067	a. Each managed care plan must ensure that the prior
1068	authorization process for prescribed drugs is readily accessible
1069	to health care providers, including posting appropriate contact
1070	information on its website and providing timely responses to
1071	providers.
1072	b. If a drug, determined to be medically necessary and
1073	prescribed for an enrollee by a physician using sound clinical

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1074	judgment, is subject to prior authorization and approved, the
1075	managed care plan must provide for sufficient refills to
1076	complete the duration of the prescription. If the medication is
1077	still clinically appropriate for ongoing therapy after the
1078	initial prior authorization expires, the plan must provide a
1079	process of expedited review to evaluate ongoing therapy.
1080	c. If a prescribed drug requires prior authorization, the
1081	managed care plan shall reimburse the pharmacist for dispensing
1082	a 72-hour supply of oral maintenance medications to the enrollee
1083	and process the prior authorization request. Dispensing a 72-
1084	hour supply must be consistent with laws that govern pharmacy
1085	practice and controlled substances. The managed care plan shall
1086	process all prior authorization requests in as timely a manner
1087	as possible.
1088	d. <del>3.</del> Managed care plans, and their fiscal agents or
1089	intermediaries, must accept prior authorization requests for
1090	prescribed drugs any service electronically.
1091	Section 9. Subsection (11) is added to section 429.23,
1092	Florida Statutes, to read:
1093	429.23 Internal risk management and quality assurance
1094	program; adverse incidents and reporting requirements
1095	(11) The agency shall annually submit a report to the
1096	Legislature on adverse incident reports by assisted living
1097	facilities. The report must include the following information
1098	arranged by county:
1099	(a) A total number of adverse incidents;
1100	(b) A listing, by category, of the type of adverse
1101	incidents occurring within each category and the type of staff
1102	involved;

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1103	(c) A listing, by category, of the types of injuries, if
1104	any, and the number of injuries occurring within each category;
1105	(d) Types of liability claims filed based on an adverse
1106	incident report or reportable injury; and
1107	(e) Disciplinary action taken against staff, categorized by
1108	the type of staff involved.
1109	Section 10. Present subsections (9), (10), and (11) of
1110	section 429.26, Florida Statutes, are renumbered as subsections
1111	(12), (13), and (14), respectively, and new subsections (9),
1112	(10), and (11) are added to that section, to read:
1113	429.26 Appropriateness of placements; examinations of
1114	residents
1115	(9) If, at any time after admission to a facility, agency
1116	personnel question whether a resident needs care beyond that
1117	which the facility is licensed to provide, the agency may
1118	require the resident to be physically examined by a licensed
1119	physician, licensed physician assistant, or certified nurse
1120	practitioner. To the extent possible, the examination must be
1121	performed by the resident's preferred physician, physician
1122	assistant, or nurse practitioner and paid for by the resident
1123	with personal funds, except as provided in s. 429.18(2). This
1124	subsection does not preclude the agency from imposing sanctions
1125	for violations of subsection (1).
1126	(a) Following examination, the examining physician,
1127	physician assistant, or nurse practitioner shall complete and
1128	sign a medical form provided by the agency. The completed
1129	medical form must be submitted to the agency within 30 days
1130	after the date the facility owner or administrator was notified
1131	by the agency that a physical examination is required.

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1132	(b) A medical review team designated by the agency shall
1133	determine whether the resident is appropriately residing in the
1134	facility based on the completed medical form and, if necessary,
1135	consultation with the physician, physician assistant, or nurse
1136	practitioner who performed the examination. Members of the
1137	medical review team making the determination may not include the
1138	agency personnel who initially questioned the appropriateness of
1139	the resident's placement. The medical review team shall base its
1140	decision on a comprehensive review of the resident's physical
1141	and functional status. A determination that the resident's
1142	placement is not appropriate is final and binding upon the
1143	facility and the resident.
1144	(c) A resident who is determined by the medical review team
1145	to be inappropriately residing in a facility shall be given 30
1146	days' written notice to relocate by the owner or administrator,
1147	unless the resident's continued residence in the facility
1148	presents an imminent danger to the health, safety, or welfare of
1149	the resident or a substantial probability exists that death or
1150	serious physical harm to the resident would result if the
1151	resident is allowed to remain in the facility.
1152	(10) If a mental health resident appears to have needs in
1153	addition to those identified in the community living support
1154	plan, the agency may require an evaluation by a mental health
1155	professional, as determined by the Department of Children and
1156	Family Services.
1157	(11) A facility may not be required to retain a resident
1158	who requires more services or care than the facility is able to
1159	provide in accordance with its policies and criteria for
1160	admission and continued residency.

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588-03223-12 20121316c1 1161 Section 11. Effective July 1, 2012, section 456.0635, 1162 Florida Statutes, is amended to read: 456.0635 Health care Medicaid fraud; disqualification for 1163 1164 license, certificate, or registration.-1165 (1) Health care Medicaid fraud in the practice of a health 1166 care profession is prohibited. 1167 (2) Each board under within the jurisdiction of the department, or the department if there is no board, shall refuse 1168 to admit a candidate to an any examination and refuse to issue 1169 1170 or renew a license, certificate, or registration to an any applicant if the candidate or applicant or any principal, 1171 1172 officer, agent, managing employee, or affiliated person of the 1173 applicant, has been: 1174 (a) Has been convicted of, or entered a plea of guilty or 1175 nolo contendere to, regardless of adjudication, a felony under 1176 chapter 409, chapter 817, or chapter 893, or a similar felony 1177 offense committed in another state or jurisdiction, unless the 1178 candidate or applicant has successfully completed a drug court 1179 program for that felony and provides proof that the plea has 1180 been withdrawn or the charges have been dismissed. Any such 1181 conviction or plea shall exclude the applicant or candidate from 1182 licensure, examination, certification, or registration 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and 1183 any subsequent period of probation for such conviction or plea 1184 1185 pleas ended: more than 15 years prior to the date of the 1186 application; 1187 1. For felonies of the first or second degree, more than 15 1188 years before the date of application.

1189

2. For felonies of the third degree, more than 10 years

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1190	before the date of application, except for felonies of the third
1191	degree under s. 893.13(6)(a).
1192	3. For felonies of the third degree under s. 893.13(6)(a),
1193	more than 5 years before the date of application.
1194	(b) Has been convicted of, or entered a plea of guilty or
1195	nolo contendere to, regardless of adjudication, a felony under
1196	21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396, unless the
1197	sentence and any subsequent period of probation for such
1198	conviction or plea ended more than 15 years before the date of
1199	the application.
1200	<u>(c) (b)</u> Has been terminated for cause from the Florida
1201	Medicaid program pursuant to s. 409.913, unless the <u>candidate or</u>
1202	applicant has been in good standing with the Florida Medicaid
1203	program for the most recent 5 years. $\dot{\cdot}$
1204	(d) (c) Has been terminated for cause, pursuant to the
1205	appeals procedures established by the state <del>or Federal</del>
1206	Government, from any other state Medicaid program or the federal
1207	Medicare program, unless the candidate or applicant has been in
1208	good standing with <u>that</u> <del>a</del> state Medicaid program <del>or the federal</del>
1209	Medicare program for the most recent 5 years and the termination
1210	occurred at least 20 years <u>before</u> <del>prior to</del> the date of the
1211	application.
1212	(e) Is currently listed on the United States Department of
1213	Health and Human Services Office of Inspector General's List of
1214	Excluded Individuals and Entities.
1215	
1216	This subsection does not apply to candidates or applicants for
1217	initial licensure or certification who were enrolled in an
1218	educational or training program on or before July 1, 2009, which

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1219	was recognized by a board or, if there is no board, recognized
1220	by the department, and who applied for licensure after July 1,
1221	2012.
1222	(3) The department shall refuse to renew a license,
1223	certificate, or registration of any applicant if the applicant
1224	or any principal, officer, agent, managing employee, or
1225	affiliated person of the applicant:
1226	(a) Has been convicted of, or entered a plea of guilty or
1227	nolo contendere to, regardless of adjudication, a felony under
1228	chapter 409, chapter 817, or chapter 893, or a similar felony
1229	offense committed in another state or jurisdiction, unless the
1230	applicant is currently enrolled in a drug court program that
1231	allows the withdrawal of the plea for that felony upon
1232	successful completion of that program. Any such conviction or
1233	plea excludes the applicant or candidate from licensure,
1234	examination, certification, or registration unless the sentence
1235	and any subsequent period of probation for such conviction or
1236	plea ended:
1237	1. For felonies of the first or second degree, more than 15
1238	years before the date of application.
1239	2. For felonies of the third degree, more than 10 years
1240	before the date of application, except for felonies of the third
1241	degree under s. 893.13(6)(a).
1242	3. For felonies of the third degree under s. 893.13(6)(a),
1243	more than 5 years before the date of application.
1244	(b) Has been convicted of, or entered a plea of guilty or
1245	nolo contendere to, regardless of adjudication, a felony under
1246	21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1,
1247	2009, unless the sentence and any subsequent period of probation

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1248	for such conviction or plea ended more than 15 years before the
1249	date of the application.
1250	(c) Has been terminated for cause from the Florida Medicaid
1251	program pursuant to s. 409.913, unless the applicant has been in
1252	good standing with the Florida Medicaid program for the most
1253	recent 5 years.
1254	(d) Has been terminated for cause, pursuant to the appeals
1255	procedures established by the state, from any other state
1256	Medicaid program, unless the applicant has been in good standing
1257	with that state Medicaid program for the most recent 5 years and
1258	the termination occurred at least 20 years before the date of
1259	the application.
1260	(e) Is currently listed on the United States Department of
1261	Health and Human Services Office of Inspector General's List of
1262	Excluded Individuals and Entities.
1263	(4)(3) Licensed health care practitioners shall report
1264	allegations of <u>health care</u> Medicaid fraud to the department,
1265	regardless of the practice setting in which the alleged <u>health</u>
1266	care Medicaid fraud occurred.
1267	(5)(4) The acceptance by a licensing authority of a
1268	<u>licensee's</u> candidate's relinquishment of a license which is
1269	offered in response to or anticipation of the filing of
1270	administrative charges alleging <u>health care</u> <del>Medicaid</del> fraud or
1271	similar charges constitutes the permanent revocation of the
1272	license.
1273	Section 12. Effective July 1, 2012, present subsections
1274	(14) and (15) of section 456.036, Florida Statutes, are
1275	renumbered as subsections (15) and (16), respectively, and a new
1276	subsection (14) is added to that section, to read:

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1277	456.036 Licenses; active and inactive status; delinquency
1278	(14) A person who has been denied license renewal,
1279	certification, or registration under s. 456.0635(3) may regain
1280	licensure, certification, or registration only by meeting the
1281	qualifications and completing the application process for
1282	initial licensure as defined by the board, or the department if
1283	there is no board. However, a person who was denied renewal of
1284	licensure, certification, or registration under s. 24 of chapter
1285	2009-223, Laws of Florida, between July 1, 2009, and June 30,
1286	2012, is not required to retake and pass examinations applicable
1287	for initial licensure, certification, or registration.
1288	Section 13. Subsection (1) of section 456.074, Florida
1289	Statutes, is amended to read:
1290	456.074 Certain health care practitioners; immediate
1291	suspension of license
1292	(1) The department shall issue an emergency order
1293	suspending the license of any person licensed under chapter 458,
1294	chapter 459, chapter 460, chapter 461, chapter 462, chapter 463,
1295	chapter 464, chapter 465, chapter 466, or chapter 484 who pleads
1296	guilty to, is convicted or found guilty of, or who enters a plea
1297	of nolo contendere to, regardless of adjudication <del>, to</del> :
1298	(a) A felony under chapter 409, chapter 817, or chapter 893
1299	or under 21 U.S.C. ss. 801-970 or <del>under</del> 42 U.S.C. ss. 1395-1396;
1300	or
1301	(b) A misdemeanor or felony under 18 U.S.C. s. 669, ss.
1302	285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s.
1303	1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b <del>, relating to the</del>
1304	Medicaid program.
1305	Section 14. Subsection (3) of section 458.309, Florida

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588-03223-12 20121316c1 1306 Statutes, is amended to read: 1307 458.309 Rulemaking authority.-1308 (3) A physician All physicians who performs liposuction 1309 procedures in which more than 1,000 cubic centimeters of 1310 supernatant fat is removed, perform level 2 procedures lasting 1311 more than 5 minutes, and all level 3 surgical procedures in an 1312 office setting must register the office with the department 1313 unless that office is licensed as a facility under <del>pursuant to</del> chapter 395. The department shall inspect the physician's office 1314 1315 annually unless the office is accredited by a nationally 1316 recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs 1317 1318 for registration and inspection or accreditation shall be paid 1319 by the person seeking to register and operate the office setting 1320 in which office surgery is performed. 1321 Section 15. Subsection (2) of section 459.005, Florida 1322 Statutes, is amended to read: 1323 459.005 Rulemaking authority.-(2) A physician All physicians who performs liposuction 1324 1325 procedures in which more than 1,000 cubic centimeters of 1326 supernatant fat is removed, perform level 2 procedures lasting 1327 more than 5 minutes, and all level 3 surgical procedures in an 1328 office setting must register the office with the department 1329 unless that office is licensed as a facility under pursuant to 1330 chapter 395. The department shall inspect the physician's office 1331 annually unless the office is accredited by a nationally 1332 recognized accrediting agency or an accrediting organization 1333 subsequently approved by the Board of Osteopathic Medicine. The 1334 actual costs for registration and inspection or accreditation

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588-03223-12 20121316c1 1335 shall be paid by the person seeking to register and operate the 1336 office setting in which office surgery is performed. Section 16. Subsections (3), (4), and (5) of section 1337 1338 463.002, Florida Statutes, are amended to read: 1339 463.002 Definitions.-As used in this chapter, the term: 1340 (3) (a) "Licensed practitioner" means a person who is a 1341 primary health care provider licensed to engage in the practice 1342 of optometry under the authority of this chapter. (b) A licensed practitioner who is not a certified 1343 1344 optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not 1345 1346 a Certified Optometrist, and I am not able to prescribe topical 1347 ocular pharmaceutical agents." 1348 (c) All practitioners initially licensed after July 1, 1349 1993, must be certified optometrists. 1350 (4) "Certified optometrist" means a licensed practitioner 1351 authorized by the board to administer and prescribe topical 1352 ocular pharmaceutical agents. (5) "Optometry" means the diagnosis of conditions of the 1353 1354 human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of 1355 1356 topical ocular pharmaceutical agents, for the purpose of 1357 determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the 1358 1359 human eyes and their appendages; and the prescribing and 1360 employment of lenses, prisms, frames, mountings, contact lenses, 1361 orthoptic exercises, light frequencies, and any other means or 1362 methods, including topical ocular pharmaceutical agents, for the 1363 correction, remedy, or relief of any insufficiencies or abnormal

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588-03223-12 20121316c1 1364 conditions of the human eyes and their appendages. 1365 Section 17. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read: 1366 1367 463.005 Authority of the board.-1368 (1) The Board of Optometry has authority to adopt rules 1369 pursuant to ss. 120.536(1) and 120.54 to implement the 1370 provisions of this chapter conferring duties upon it. Such rules 1371 shall include, but not be limited to, rules relating to: 1372 (g) Administration and prescription of topical ocular 1373 pharmaceutical agents. 1374 Section 18. Section 463.0055, Florida Statutes, is amended 1375 to read: 1376 463.0055 Administration and prescription of topical ocular 1377 pharmaceutical agents; committee.-1378 (1) (a) Certified optometrists may administer and prescribe 1379 topical ocular pharmaceutical agents as provided in this section 1380 for the diagnosis and treatment of ocular conditions of the 1381 human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not 1382 1383 certified may use topically applied anesthetics solely for the 1384 purpose of glaucoma examinations  $\tau$  but is otherwise prohibited 1385 from administering or prescribing topical ocular pharmaceutical 1386 agents. 1387 (b) Before a certified optometrist may administer or 1388 prescribe oral ocular pharmaceutical agents, the certified 1389 optometrist must complete a course and subsequent examination on 1390 general and ocular pharmacology which have a particular emphasis 1391 on the ingestion of oral pharmaceutical agents and the side 1392 effects of those agents. For certified optometrists licensed

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588-03223-12 20121316c1 1393 before January 1, 1990, the course shall consist of 50 contact 1394 hours and 25 of those hours shall be Internet-based. For 1395 certified optometrists licensed on or after January 1, 1990, the 1396 course shall consist of 20 contact hours and 10 of those hours 1397 shall be Internet-based. The first course and examination shall 1398 be presented by January 1, 2013, and shall thereafter be 1399 administered at least annually. The Florida Medical Association and the Florida Optometric Association shall jointly develop and 1400 1401 administer a course and examination for such purpose and jointly 1402 determine the site or sites for the course and examination.

1403 (2) (a) There is hereby created a committee composed of two 1404 certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified 1405 1406 ophthalmologists licensed pursuant to chapter 458 or chapter 1407 459, appointed by the Board of Medicine, and one additional 1408 person with a doctorate degree in pharmacology who is not 1409 licensed pursuant to chapter 458, chapter 459, or this chapter, 1410 appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or 1411 1412 modifications of a formulary of topical ocular pharmaceutical 1413 agents for administration and prescription by certified 1414 optometrists and shall provide to the board advisory opinions 1415 and recommendations on such requests. The formulary of topical ocular pharmaceutical agents shall consist of those topical 1416 1417 ocular pharmaceutical agents that are appropriate to treat and 1418 diagnose ocular diseases and disorders and that which the 1419 certified optometrist is qualified to use in the practice of 1420 optometry. The board shall establish, add to, delete from, or 1421 modify the formulary by rule. Notwithstanding any provision of

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588-03223-12 20121316c1 1422 chapter 120 to the contrary, the formulary rule shall become 1423 effective 60 days from the date it is filed with the Secretary 1424 of State. 1425 (b) The topical formulary may be added to, deleted from, or 1426 modified according to the procedure described in paragraph (a). 1427 Any person who requests an addition, deletion, or modification 1428 of an authorized topical ocular pharmaceutical agent shall have 1429 the burden of proof to show cause why such addition, deletion, 1430 or modification should be made. 1431 (c) The State Surgeon General shall have standing to 1432 challenge any rule or proposed rule of the board pursuant to s. 1433 120.56. In addition to challenges for any invalid exercise of 1434 delegated legislative authority, the administrative law judge, 1435 upon such a challenge by the State Surgeon General, may declare 1436 all or part of a rule or proposed rule invalid if it: 1437 1. Does not protect the public from any significant and 1438 discernible harm or damages; 1439 2. Unreasonably restricts competition or the availability 1440 of professional services in the state or in a significant part 1441 of the state; or 3. Unnecessarily increases the cost of professional 1442 1443 services without a corresponding or equivalent public benefit. 1444 1445 However, there shall not be created a presumption of the 1446 existence of any of the conditions cited in this subsection in 1447 the event that the rule or proposed rule is challenged. 1448 (d) Upon adoption of the topical formulary required by this 1449 section, and upon each addition, deletion, or modification to 1450 the topical formulary, the board shall mail a copy of the

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1451	amended topical formulary to each certified optometrist and to
1452	each pharmacy licensed by the state.
1453	(3) In addition to the formulary of topical ocular
1454	pharmaceutical agents in subsection (2), there is created a
1455	statutory formulary of oral pharmaceutical agents, which include
1456	the following agents:
1457	(a) The following analgesics, or their generic or
1458	therapeutic equivalents, which may not be administered or
1459	prescribed for more than 72 hours without consultation with a
1460	physician licensed under chapter 458 or chapter 459 who is
1461	skilled in diseases of the eye:
1462	1. Tramadol hydrochloride.
1463	2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
1464	(b) The following antibiotics, or their generic or
1465	therapeutic equivalents:
1466	1. Amoxicillin.
1467	2. Azithromycin.
1468	3. Ciprofloxacin.
1469	4. Dicloxacillin.
1470	5. Doxycycline.
1471	6. Keflex.
1472	7. Minocycline.
1473	(c) The following antivirals, or their generic or
1474	therapeutic equivalents:
1475	1. Acyclovir.
1476	2. Famciclovir.
1477	3. Valacyclovir.
1478	(d) The following oral anti-glaucoma agents, or their
1479	generic or therapeutic equivalents, which may not be

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1480	administered or prescribed for more than 72 hours without
1481	consultation with a physician licensed under chapter 458 or
1482	chapter 459 who is skilled in diseases of the eye:
1483	1. Acetazolamide.
1484	2. Methazolamide.
1485	
1486	Any oral pharmaceutical agent listed in the statutory formulary
1487	set forth in this subsection which is subsequently determined by
1488	the United States Food and Drug Administration to be unsafe for
1489	administration or prescription shall be considered to have been
1490	deleted from the formulary of oral pharmaceutical agents. The
1491	oral pharmaceutical agents on the statutory formulary set forth
1492	in this subsection may not otherwise be deleted by the board,
1493	the department, or the State Surgeon General.
1494	(4) (3) A certified optometrist shall be issued a prescriber
1495	number by the board. Any prescription written by a certified
1496	optometrist for a <del>topical ocular</del> pharmaceutical agent pursuant
1497	to this section shall have the prescriber number printed
1498	thereon.
1499	Section 19. Subsection (3) of section 463.0057, Florida
1500	Statutes, is amended to read:
1501	463.0057 Optometric faculty certificate
1502	(3) The holder of a faculty certificate may engage in the
1503	practice of optometry as permitted by this section $_{m{ au}}$ but may not
1504	administer or prescribe <del>topical</del> ocular pharmaceutical agents
1505	unless the certificateholder has satisfied the requirements of
1506	<u>ss. 463.0055(1)(b) and <del>s.</del> 463.006(1)(b)4. and 5.</u>
1507	Section 20. Subsections (2) and (3) of section 463.006,
1508	Florida Statutes, are amended to read:

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1509	463.006 Licensure and certification by examination
1510	(2) The examination shall consist of the appropriate
1511	subjects, including applicable state laws and rules and general
1512	and ocular pharmacology with emphasis on the <u>use</u> topical
1513	application and side effects of ocular pharmaceutical agents.
1514	The board may by rule substitute a national examination as part
1515	or all of the examination and may by rule offer a practical
1516	examination in addition to the written examination.
1517	(3) Each applicant who successfully passes the examination
1518	and otherwise meets the requirements of this chapter is entitled
1519	to be licensed as a practitioner and to be certified to
1520	administer and prescribe <del>topical ocular</del> pharmaceutical agents in
1521	the diagnosis and treatment of ocular conditions.
1522	Section 21. Subsections (1) and (2) of section 463.0135,
1523	Florida Statutes, are amended, and subsection (10) is added to
1524	that section, to read:
1525	463.0135 Standards of practice
1526	(1) A licensed practitioner shall provide that degree of
1527	care which conforms to that level of care provided by medical
1528	practitioners in the same or similar communities. <u>A certified</u>
1529	optometrist shall administer and prescribe oral ocular
1530	pharmaceutical agents in a manner consistent with applicable
1531	preferred practice patterns of the American Academy of
1532	<u>Ophthalmology.</u> A licensed practitioner shall advise or assist
1533	her or his patient in obtaining further care when the service of
1534	another health care practitioner is required.
1535	(2) A licensed practitioner diagnosing angle closure,
1536	neovascular, infantile, or congenital forms of glaucoma shall
1537	promptly and without unreasonable delay refer the patient to a

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1538	physician skilled in diseases of the eye and licensed under
1539	chapter 458 or chapter 459. In addition, a licensed practitioner
1540	shall timely refer any patient who experiences progressive
1541	glaucoma due to failed pharmaceutical intervention to a
1542	physician who is skilled in diseases of the eye and licensed
1543	under chapter 458 or chapter 459.
1544	(10) Comanagement of postoperative care shall be conducted
1545	pursuant to an established protocol that governs the
1546	relationship between the operating surgeon and the optometrist.
1547	The patient shall be informed that either physician will be
1548	available for emergency care throughout the postoperative
1549	period, and the patient shall consent in writing to the
1550	comanagement relationship.
1551	Section 22. Subsections (3) and (4) of section 463.014,
1552	Florida Statutes, are amended to read:
1553	463.014 Certain acts prohibited
1554	(3) Prescribing, ordering, dispensing, administering,
1555	supplying, selling, or giving any <del>systemic</del> drugs <u>for the purpose</u>
1556	of treating a systemic disease by a licensed practitioner is
1557	prohibited. However, a certified optometrist is permitted to use
1558	commonly accepted means or methods to immediately address
1559	incidents of anaphylaxis.
1560	(4) Surgery of any kind, including the use of lasers, is
1561	expressly prohibited. For purposes of this subsection, the term
1562	"surgery" means a procedure using an instrument, including
1563	lasers, scalpels, or needles, in which human tissue is cut,
1564	burned, or vaporized by incision, injection, ultrasound, laser,
1565	or radiation. The term includes procedures using instruments
1566	that require closing by suturing, clamping, or another such

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1567	device. Certified optometrists may remove superficial foreign
1568	bodies. For the purposes of this subsection, the term
1569	"superficial foreign bodies" means any foreign matter that is
1570	embedded in the conjunctiva or cornea but which has not
1571	penetrated the globe.
1572	Section 23. Section 463.0141, Florida Statutes, is created
1573	to read:
1574	463.0141 Reports of adverse incidents in the practice of
1575	optometry
1576	(1) Any adverse incident that occurs on or after January 1,
1577	2013, in the practice of optometry must be reported to the
1578	department in the accordance with this section.
1579	(2) The required notification to the department must be
1580	submitted in writing by certified mail and postmarked within 15
1581	days after the occurrence of the adverse incident.
1582	(3) For purposes of notification to the department, the
1583	term "adverse incident," as used in this section, means an event
1584	that is associated in whole or in part with the prescribing of
1585	an oral ocular pharmaceutical agent and that results in one of
1586	the following:
1587	(a) Any condition that requires the transfer of a patient
1588	to a hospital licensed under chapter 395;
1589	(b) Any condition that requires the patient to obtain care
1590	from a physician licensed under chapter 458 or chapter 459,
1591	other than a referral or a consultation required under this
1592	chapter;
1593	(c) Permanent physical injury to the patient;
1594	(d) Partial or complete permanent loss of sight by the
1595	patient; or

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588-03223-12 20121316c1 1596 (e) Death of the patient. 1597 (4) The department shall review each incident and determine 1598 whether it potentially involved conduct by the licensed 1599 practitioner which may be subject to disciplinary action, in 1600 which case s. 456.073 applies. Disciplinary action, if any, 1601 shall be taken by the board. 1602 Section 24. Subsection (1) of section 483.035, Florida 1603 Statutes, is amended to read: 1604 483.035 Clinical laboratories operated by practitioners for 1605 exclusive use; licensure and regulation.-1606 (1) A clinical laboratory operated by one or more 1607 practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, 1608 1609 exclusively in connection with the diagnosis and treatment of 1610 their own patients, must be licensed under this part and must 1611 comply with the provisions of this part, except that the agency 1612 shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, 1613 and for construction standards relating to the licensure and 1614 1615 operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory 1616 1617 Improvement Amendments of 1988 and the federal regulations 1618 adopted thereunder. 1619 Section 25. Subsection (7) of section 483.041, Florida 1620 Statutes, is amended to read: 1621 483.041 Definitions.-As used in this part, the term: 1622 (7) "Licensed practitioner" means a physician licensed 1623 under chapter 458, chapter 459, chapter 460, or chapter 461, or 1624 chapter 463; a dentist licensed under chapter 466; a person

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588-03223-12 20121316c1 1625 licensed under chapter 462; or an advanced registered nurse 1626 practitioner licensed under part I of chapter 464; or a duly 1627 licensed practitioner from another state licensed under similar 1628 statutes who orders examinations on materials or specimens for 1629 nonresidents of the State of Florida, but who reside in the same 1630 state as the requesting licensed practitioner. 1631 Section 26. Subsection (5) of section 483.181, Florida 1632 Statutes, is amended to read: 483.181 Acceptance, collection, identification, and 1633 1634 examination of specimens.-1635 (5) A clinical laboratory licensed under this part must 1636 accept a human specimen submitted for examination by a 1637 practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or 1638 1639 chapter 466, if the specimen and test are the type performed by 1640 the clinical laboratory. A clinical laboratory may only refuse a 1641 specimen based upon a history of nonpayment for services by the 1642 practitioner. A clinical laboratory shall not charge different 1643 prices for tests based upon the chapter under which a 1644 practitioner submitting a specimen for testing is licensed. 1645 Section 27. Paragraph (a) of subsection (54) of section 1646 499.003, Florida Statutes, is amended to read: 1647 499.003 Definitions of terms used in this part.-As used in 1648 this part, the term: 1649 (54) "Wholesale distribution" means distribution of 1650 prescription drugs to persons other than a consumer or patient, 1651 but does not include: 1652 (a) Any of the following activities, which is not a 1653 violation of s. 499.005(21) if such activity is conducted in

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1654 accordance with s. 499.01(2)(g):

1655 1. The purchase or other acquisition by a hospital or other 1656 health care entity that is a member of a group purchasing 1657 organization of a prescription drug for its own use from the 1658 group purchasing organization or from other hospitals or health 1659 care entities that are members of that organization.

1660 2. The sale, purchase, or trade of a prescription drug or 1661 an offer to sell, purchase, or trade a prescription drug by a 1662 charitable organization described in s. 501(c)(3) of the 1663 Internal Revenue Code of 1986, as amended and revised, to a 1664 nonprofit affiliate of the organization to the extent otherwise 1665 permitted by law.

1666 3. The sale, purchase, or trade of a prescription drug or 1667 an offer to sell, purchase, or trade a prescription drug among 1668 hospitals or other health care entities that are under common 1669 control. For purposes of this subparagraph, "common control" 1670 means the power to direct or cause the direction of the 1671 management and policies of a person or an organization, whether 1672 by ownership of stock, by voting rights, by contract, or 1673 otherwise.

1674 4. The sale, purchase, trade, or other transfer of a
1675 prescription drug from or for any federal, state, or local
1676 government agency or any entity eligible to purchase
1677 prescription drugs at public health services prices pursuant to
1678 Pub. L. No. 102-585, s. 602 to a contract provider or its
1679 subcontractor for eligible patients of the agency or entity
1680 under the following conditions:

1681a. The agency or entity must obtain written authorization1682for the sale, purchase, trade, or other transfer of a

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588-03223-12 20121316c1 1683 prescription drug under this subparagraph from the State Surgeon 1684 General or his or her designee. 1685 b. The contract provider or subcontractor must be 1686 authorized by law to administer or dispense prescription drugs. 1687 c. In the case of a subcontractor, the agency or entity 1688 must be a party to and execute the subcontract. 1689 d. A contract provider or subcontractor must maintain 1690 separate and apart from other prescription drug inventory any 1691 prescription drugs of the agency or entity in its possession. 1692 d.e. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement 1693 1694 or transfer of all the prescription drugs belonging to the 1695 agency or entity, including, but not limited to, the records of 1696 receipt and disposition of prescription drugs. Each contractor 1697 and subcontractor dispensing or administering these drugs must 1698 maintain and produce records documenting the dispensing or 1699 administration. Records that are required to be maintained 1700 include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or 1701 1702 administered by patient identifier, which must be submitted to 1703 the agency or entity quarterly. e.f. The contract provider or subcontractor may administer 1704 1705 or dispense the prescription drugs only to the eligible patients 1706 of the agency or entity or must return the prescription drugs 1707 for or to the agency or entity. The contract provider or 1708 subcontractor must require proof from each person seeking to 1709 fill a prescription or obtain treatment that the person is an 1710 eligible patient of the agency or entity and must, at a minimum,

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maintain a copy of this proof as part of the records of the

588-03223-12 20121316c1 1712 contractor or subcontractor required under sub-subparagraph e. 1713 f.g. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract 1714 1715 provider and subcontractor and all records pertaining to 1716 prescription drugs subject to this subparagraph shall be subject 1717 to inspection by the agency or entity. All records relating to 1718 prescription drugs of a manufacturer under this subparagraph 1719 shall be subject to audit by the manufacturer of those drugs, 1720 without identifying individual patient information. 1721 Section 28. Subsection (4) of section 766.102, Florida 1722 Statutes, is amended to read: 1723 766.102 Medical negligence; standards of recovery; expert 1724 witness.-1725 (4) (a) The Legislature is cognizant of the changing trends 1726 and techniques for the delivery of health care in this state and 1727 the discretion that is inherent in the diagnosis, care, and 1728 treatment of patients by different health care providers. The 1729 failure of a health care provider to order, perform, or 1730 administer supplemental diagnostic tests is shall not be 1731 actionable if the health care provider acted in good faith and 1732 with due regard for the prevailing professional standard of 1733 care. 1734 (b) The claimant has the burden of proving by clear and 1735 convincing evidence that the alleged actions of the health care 1736 provider represent a breach of the prevailing professional 1737 standard of care in an action for damages based on death or 1738 personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or 1739 1740 administer supplemental diagnostic tests.

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588-03223-12 20121316c1 1741 Section 29. Paragraph (b) of subsection (6) of section 1742 766.106, Florida Statutes, is amended to read: 1743 766.106 Notice before filing action for medical negligence; 1744 presuit screening period; offers for admission of liability and 1745 for arbitration; informal discovery; review.-1746 (6) INFORMAL DISCOVERY.-1747 (b) Informal discovery may be used by a party to obtain 1748 unsworn statements, the production of documents or things, and physical and mental examinations, and ex parte interviews, as 1749 1750 follows: 1751 1. Unsworn statements. - Any party may require other parties 1752 to appear for the taking of an unsworn statement. Such 1753 statements may be used only for the purpose of presuit screening 1754 and are not discoverable or admissible in any civil action for 1755 any purpose by any party. A party desiring to take the unsworn 1756 statement of any party must give reasonable notice in writing to 1757 all parties. The notice must state the time and place for taking 1758 the statement and the name and address of the party to be 1759 examined. Unless otherwise impractical, the examination of any 1760 party must be done at the same time by all other parties. Any 1761 party may be represented by counsel at the taking of an unsworn 1762 statement. An unsworn statement may be recorded electronically, 1763 stenographically, or on videotape. The taking of unsworn 1764 statements is subject to the provisions of the Florida Rules of 1765 Civil Procedure and may be terminated for abuses.

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1766 2. Documents or things.-Any party may request discovery of 1767 documents or things. The documents or things must be produced, 1768 at the expense of the requesting party, within 20 days after the 1769 date of receipt of the request. A party is required to produce

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588-03223-12 20121316c1 1770 discoverable documents or things within that party's possession 1771 or control. Medical records shall be produced as provided in s. 1772 766.204. 1773 3. Physical and mental examinations.-A prospective 1774 defendant may require an injured claimant to appear for 1775 examination by an appropriate health care provider. The 1776 prospective defendant shall give reasonable notice in writing to 1777 all parties as to the time and place for examination. Unless 1778 otherwise impractical, a claimant is required to submit to only 1779 one examination on behalf of all potential defendants. The 1780 practicality of a single examination must be determined by the

1781 nature of the claimant's condition, as it relates to the 1782 liability of each prospective defendant. Such examination report 1783 is available to the parties and their attorneys upon payment of 1784 the reasonable cost of reproduction and may be used only for the 1785 purpose of presuit screening. Otherwise, such examination report 1786 is confidential and exempt from the provisions of s. 119.07(1) 1787 and s. 24(a), Art. I of the State Constitution.

4. Written questions.—Any party may request answers to
written questions, the number of which may not exceed 30,
including subparts. A response must be made within 20 days after
receipt of the questions.

5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn

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1799	statements from a claimant's treating physicians. Reasonable
1800	notice and opportunity to be heard must be given to the claimant
1801	or the claimant's legal representative before taking unsworn
1802	statements. The claimant or claimant's legal representative has
1803	the right to attend the taking of such unsworn statements.
1804	6. Ex parte interviews of treating health care providersA
1805	prospective defendant or his or her legal representative may
1806	interview the claimant's treating health care providers without
1807	the presence of the claimant or the claimant's legal
1808	representative. If a prospective defendant or his or her legal
1809	representative intends to interview a claimant's health care
1810	providers, the prospective defendant must provide the claimant
1811	with notice of such interview at least 10 days before the date
1812	of the interview.
1813	Section 30. Section 766.1091, Florida Statutes, is created
1814	to read:
1815	766.1091 Voluntary binding arbitration; damages
1816	(1) A health care provider licensed under chapter 458,
1817	chapter 459, chapter 463, or chapter 466; any entity owned in
1818	whole or in part by a health care provider licensed under
1819	chapter 458, chapter 459, chapter 463, or chapter 466; or any
1820	health care clinic licensed under part X of chapter 400, and a
1821	patient or prospective patient, may agree in writing to submit
1822	to arbitration any claim for medical negligence which may
1823	currently exist or may accrue in the future and would otherwise
1824	be brought pursuant to this chapter. Any arbitration agreement
1825	entered into pursuant to this section shall be governed by
1826	chapter 682.
1827	(2) Any arbitration agreement entered into pursuant to

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1828	subsection (1) may contain a provision that limits the available
1829	damages in an arbitration award.
1830	Section 31. Subsection (21) of section 893.02, Florida
1831	Statutes, is amended to read:
1832	893.02 Definitions.—The following words and phrases as used
1833	in this chapter shall have the following meanings, unless the
1834	context otherwise requires:
1835	(21) "Practitioner" means a physician licensed pursuant to
1836	chapter 458, a dentist licensed pursuant to chapter 466, a
1837	veterinarian licensed pursuant to chapter 474, an osteopathic
1838	physician licensed pursuant to chapter 459, a naturopath
1839	licensed pursuant to chapter 462, <u>a certified optometrist</u>
1840	licensed under chapter 463, or a podiatric physician licensed
1841	pursuant to chapter 461, provided such practitioner holds a
1842	valid federal controlled substance registry number.
1843	Section 32. Subsection (1) of section 893.05, Florida
1844	Statutes, is amended to read:
1845	893.05 Practitioners and persons administering controlled
1846	substances in their absence
1847	(1) A practitioner, in good faith and in the course of his
1848	or her professional practice only, may prescribe, administer,
1849	dispense, mix, or otherwise prepare a controlled substance, or
1850	the practitioner may cause the same to be administered by a
1851	licensed nurse or an intern practitioner under his or her
1852	direction and supervision only. A veterinarian may so prescribe,
1853	administer, dispense, mix, or prepare a controlled substance for
1854	use on animals only $_{m{ au}}$ and may cause it to be administered by an
1855	assistant or orderly under the veterinarian's direction and
1856	supervision only. <u>A certified optometrist licensed under chapter</u>

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1857	463 may not administer or prescribe pharmaceutical agents in
1858	Schedule I or Schedule II of the Florida Comprehensive Drug
1859	Abuse Prevention and Control Act.
1860	Section 33. The Agency for Health Care Administration shall
1861	prepare a report within 18 months after the implementation of an
1862	expansion of managed care to new populations or the provision of
1863	new items and services. The agency shall post a draft of the
1864	report on its website and provide an opportunity for public
1865	comment. The final report shall be submitted to the Legislature,
1866	along with a description of the process for public input. The
1867	report must include an assessment of:
1868	(1) The impact of managed care on patient access to care,
1869	including an evaluation of any new barriers to the use of
1870	services and prescription drugs, created by the use of medical
1871	management or cost-containment tools.
1872	(2) The impact of the increased managed care expansion on
1873	the utilization of services, quality of care, and patient
1874	outcomes.
1875	(3) The use of prior authorization and other utilization
1876	management tools, including an assessment of whether these tools
1877	pose an undue administrative burden for health care providers or
1878	create barriers to needed care.
1879	Section 34. Except as otherwise expressly provided in this
1880	act, this act shall take effect upon becoming a law.

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