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A bill to be entitled
An act relating to health care; amending s. 395.0191, F.S.; defining terms; requiring a certain percent of surgical assistants or surgical technologists employed or contracting with a hospital to be certified; providing exceptions; amending s. 395.003, F.S.; revising provisions relating to the provision of cardiovascular services by a hospital; amending s. 400.235, F.S.; revising the criteria for recognition as a Gold Seal Program nursing home facility; amending s. 394.9082, F.S.; requiring the Department of Children and Families to develop standards and protocols for the collection, storage, transmittal, and analysis of utilization data from public receiving facilities; defining the term "public receiving facility"; requiring the department to require compliance by managing entities by a specified date; requiring a managing entity to require public receiving facilities in its provider network to submit certain data within specified timeframes; requiring managing entities to reconcile data to ensure accuracy; requiring managing entities to submit certain data to the department within specified timeframes; requiring the department to create a statewide database; requiring the department to adopt rules; requiring the department to submit an annual report to the Governor and the Legislature; providing that implementation is subject to specific appropriations; amending s. 409.967, F.S.; revising

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contract requirements for Medicaid managed care programs; providing requirements for plans establishing a drug formulary or preferred drug list; requiring the use of a standardized prior authorization form; providing requirements for the form and for the availability and submission of the form; requiring a pharmacy benefits manager to use and accept the form under certain circumstances; establishing a process for providers to override certain treatment restrictions; providing requirements for approval of such overrides; providing an exception to the override protocol in certain circumstances; amending s. 465.189, F.S.; authorizing a pharmacist to administer meningococcal and shingles vaccines; creating s. 627.42392, F.S.; requiring health insurers to use a standardized prior authorization form; providing requirements for the form and for the availability and submission of the form; requiring a pharmacy benefits manager to use and accept the form under certain circumstances; providing an exemption; creating s. 627.42393, F.S.; establishing a process for providers to override certain treatment restrictions; providing requirements for approval of such overrides; providing an exception to the override protocol in certain circumstances; providing an exemption; amending s. 627.6131, F.S.; prohibiting an insurer from retroactively denying a claim in certain circumstances; amending s. 627.6471, F.S.; requiring insurers to post preferred provider information on a

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59 website; specifying that changes to such a website
60 must be made within a certain time; amending s.
61 627.6515, F.S.; applying provisions relating to prior
62 authorization and override protocols to out-of-state
63 groups; amending s. 641.3155, F.S.; prohibiting a
64 health maintenance organization from retroactively
65 denying a claim in certain circumstances; creating s.
66 641.393, F.S.; requiring the use of a standardized
67 prior authorization form by a health maintenance
68 organization; providing requirements for the
69 availability and submission of the form; requiring a
70 pharmacy benefits manager to use and accept the form
71 under certain circumstances; providing an exemption;
72 creating s. 641.394, F.S.; establishing a process for
73 providers to override certain treatment restrictions;
74 providing requirements for approval of such overrides;
75 providing an exception to the override protocol in
76 certain circumstances; providing an exemption;
77 amending s. 395.4001, F.S.; conforming cross-
78 references; amending s. 395.401, F.S.; limiting trauma
79 service fees to a certain amount; providing for future
80 expiration; conforming a cross-reference; amending s.
81 395.402, F.S.; requiring the Department of Health to
82 convene the Florida Trauma System Plan Advisory
83 Council by a specified date; requiring the advisory
84 council to review the Trauma System Consultation
85 Report and make recommendations to the Legislature by
86 a specified date; authorizing the advisory council to
87 make recommendations to the State Surgeon General;

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designating the membership of the advisory council;
amending s. 395.4025, F.S.; deleting a provision
relating to the procedure for protesting an
application decision by the department; conforming
cross-references; authorizing certain provisional and
verified trauma centers to continue operating and to
apply for renewal; restricting the department from
verifying, designating, or provisionally approving
hospitals as trauma centers; providing for future
expiration; providing effective dates.

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

Section 1. Present subsections (1) through (10) of section
395.0191, Florida Statutes, are redesignated as subsections (2)
through (11), respectively, present subsection (6) is amended,
and a new subsection (1) and subsection (12) are added to that
section, to read:

395.0191 Staff membership and clinical privileges.—

(1) As used in this section, the term:

(a) "Certified surgical assistant" means a surgical
assistant who maintains a valid and active certification under
one of the following designations:

1. Certified surgical first assistant, from the National
Board of Surgical Technology and Surgical Assisting.

2. Certified surgical assistant, from the National Surgical
Assistant Association.

3. Surgical assistant-certified, from the American Board of
Surgical Assistants.

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117 (b) "Certified surgical technologist" means a surgical
118 technologist who maintains a valid and active certification as a
119 certified surgical technologist from the National Board of
120 Surgical Technology and Surgical Assisting.

121 (c) "Surgeon" means a health care practitioner as defined
122 in s. 456.001 whose scope of practice includes performing
123 surgery and who is listed as the primary surgeon in the
124 operative record.

125 (d) "Surgical assistant" means a person who provides aid in
126 exposure, hemostasis, closures, and other intraoperative
127 technical functions and who assists the surgeon in performing a
128 safe operation with optimal results for the patient.

129 (e) "Surgical technologist" means a person whose duties
130 include, but are not limited to, maintaining sterility during a
131 surgical procedure, handling and ensuring the availability of
132 necessary equipment and supplies, and maintaining visibility of
133 the operative site to ensure that the operating room environment
134 is safe, that proper equipment is available, and that the
135 operative procedure is conducted efficiently.

136 (7)(6) Upon the written request of the applicant, a ~~any~~
137 licensed facility that has denied staff membership or clinical
138 privileges to an ~~any~~ applicant specified in subsection (2) ~~(1)~~
139 or subsection (3) ~~(2)~~ shall, within 30 days of such request,
140 provide the applicant with the reasons for such denial in
141 writing. A denial of staff membership or clinical privileges to
142 an ~~any~~ applicant shall be submitted, in writing, to the
143 applicant's respective licensing board.

144 (12) (a) At least 50 percent of the surgical assistants that
145 a facility employs or contracts must be certified surgical

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146 assistants.

147 (b) At least 50 percent of the surgical technologists that
148 a facility employs or contracts must be certified surgical
149 technologists.

150 (c) Paragraphs (a) and (b) do not apply to:

151 1. A person who has completed an appropriate training
152 program for surgical technology in any branch of the Armed
153 Forces or reserve component of the Armed Forces.

154 2. A person who was employed or contracted to perform the
155 duties of a surgical technologist or surgical assistant before
156 July 1, 2014.

157 3. A health care practitioner as defined in s. 456.001 or a
158 student if the duties performed by the practitioner or the
159 student are within the scope of the practitioner's or the
160 student's training and practice.

161 4. A person enrolled in a surgical technology or surgical
162 assisting training program accredited by the Commission on
163 Accreditation of Allied Health Education Programs, the
164 Accrediting Bureau of Health Education Schools, or other
165 accrediting body recognized by the United States Department of
166 Education on July 1, 2014. A person may practice as a surgical
167 technologist or a surgical assistant for 2 years after
168 completing such training program before he or she is required to
169 meet the criteria in paragraph (a).

170 Section 2. Paragraph (a) of subsection (6) of section
171 395.003, Florida Statutes, is amended to read:

172 395.003 Licensure; denial, suspension, and revocation.—

173 (6) (a) A specialty hospital may not provide any service or
174 regularly serve any population group beyond those services or

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175 groups specified in its license. A ~~specialty-licensed children's~~
176 hospital that is authorized to provide pediatric cardiac
177 catheterization and pediatric open-heart surgery services may
178 provide cardiovascular service to adults who, as children, were
179 previously served by the hospital for congenital heart disease,
180 or to ~~these~~ patients who are referred only for a specialized
181 procedure ~~only~~ for congenital heart disease by an adult
182 hospital, without obtaining additional licensure as a provider
183 of adult cardiovascular services. The agency may request
184 documentation as needed to support patient selection and
185 treatment. This subsection does not apply to a specialty-
186 licensed children's hospital that is already licensed to provide
187 adult cardiovascular services.

188 Section 3. Paragraph (f) of subsection (5) of section
189 400.235, Florida Statutes, is amended to read:

190 400.235 Nursing home quality and licensure status; Gold
191 Seal Program.—

192 (5) Facilities must meet the following additional criteria
193 for recognition as a Gold Seal Program facility:

194 (f) Had no evidence of unresolved, verified complaints
195 generated through an outstanding record regarding the number and
196 types of substantiated complaints reported to the State Long-
197 Term Care Ombudsman Program Council within the 30 months
198 preceding application for the program.

199
200 A facility assigned a conditional licensure status may not
201 qualify for consideration for the Gold Seal Program until after
202 it has operated for 30 months with no class I or class II
203 deficiencies and has completed a regularly scheduled relicensure

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204 survey.

205 Section 4. Present subsections (10) and (11) of section
206 394.9082, Florida Statutes, are redesignated as subsections (11)
207 and (12), respectively, and a new subsection (10) is added to
208 that section, to read:

209 394.9082 Behavioral health managing entities.—

210 (10) CRISIS STABILIZATION SERVICES UTILIZATION DATABASE.—

211 The department shall develop, implement, and maintain standards
212 under which a managing entity shall collect utilization data
213 from all public receiving facilities situated within its
214 geographic service area. As used in this subsection, the term
215 “public receiving facility” means an entity that meets the
216 licensure requirements of and is designated by the department to
217 operate as a public receiving facility under s. 394.875 and that
218 is operating as a licensed crisis stabilization unit.

219 (a) The department shall develop standards and protocols
220 for managing entities and public receiving facilities to be used
221 for data collection, storage, transmittal, and analysis. The
222 standards and protocols must allow for compatibility of data and
223 data transmittal between public receiving facilities, managing
224 entities, and the department for the implementation and
225 requirements of this subsection. The department shall require
226 managing entities contracted under this section to comply with
227 this subsection by August 1, 2014.

228 (b) A managing entity shall require a public receiving
229 facility within its provider network to submit data, in real
230 time or at least daily, to the managing entity for:

231 1. All admissions and discharges of clients receiving
232 public receiving facility services who qualify as indigent, as

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defined in s. 394.4787; and

2. Current active census of total licensed beds, the number of beds purchased by the department, the number of clients qualifying as indigent occupying those beds, and the total number of unoccupied licensed beds regardless of funding.

(c) A managing entity shall require a public receiving facility within its provider network to submit data, on a monthly basis, to the managing entity that aggregates the daily data submitted under paragraph (b). The managing entity shall reconcile the data in the monthly submission to the data received by the managing entity under paragraph (b) to check for consistency. If the monthly aggregate data submitted by a public receiving facility under this paragraph is inconsistent with the daily data submitted under paragraph (b), the managing entity shall consult with the public receiving facility to make corrections as necessary to ensure accurate data.

(d) A managing entity shall require a public receiving facility within its provider network to submit data, on an annual basis, to the managing entity that aggregates the data submitted and reconciled under paragraph (c). The managing entity shall reconcile the data in the annual submission to the data received and reconciled by the managing entity under paragraph (c) to check for consistency. If the annual aggregate data submitted by a public receiving facility under this paragraph is inconsistent with the data received and reconciled under paragraph (c), the managing entity shall consult with the public receiving facility to make corrections as necessary to ensure accurate data.

(e) After ensuring accurate data under paragraphs (c) and

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(d), the managing entity shall submit the data to the department on a monthly and annual basis. The department shall create a statewide database for the data described under paragraph (b) and submitted under this paragraph for the purpose of analyzing the payments for and the use of crisis stabilization services funded by the Baker Act on a statewide basis and on an individual public receiving facility basis.

(f) The department shall adopt rules to administer this subsection.

(g) The department shall submit a report by January 31, 2015, and annually thereafter, to the Governor, the President of the Senate, and the Speaker of the House of Representatives which provides details on the implementation of this subsection, including the status of the data collection process and a detailed analysis of the data collected under this subsection.

(h) The implementation of this subsection is subject to specific appropriations provided to the department in the General Appropriations Act.

Section 5. Paragraph (c) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) Access.—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and

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children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge. Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to ~~both~~ the agency and the public and have the capability of comparing ~~to compare~~ the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2. If establishing a prescribed drug formulary or preferred drug list, a managed care plan shall:

a. Provide a broad range of therapeutic options for the treatment of disease states which are consistent with the general needs of an outpatient population. If feasible, the

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320 formulary or preferred drug list must include at least two
321 products in a therapeutic class.

322 ~~b. Each managed care plan must~~ Publish the any prescribed
323 drug formulary or preferred drug list on the plan's website in a
324 manner that is accessible to and searchable by enrollees and
325 providers. The plan shall ~~must~~ update the list within 24 hours
326 after making a change. ~~Each plan must ensure that the prior~~
327 ~~authorization process for prescribed drugs is readily accessible~~
328 ~~to health care providers, including posting appropriate contact~~
329 ~~information on its website and providing timely responses to~~
330 ~~providers.~~

331 3. For enrollees ~~Medicaid recipients~~ diagnosed with
332 hemophilia who have been prescribed anti-hemophilic-factor
333 replacement products, the agency shall provide for those
334 products and hemophilia overlay services through the agency's
335 hemophilia disease management program.

336 ~~3. Managed care plans, and their fiscal agents or~~
337 ~~intermediaries, must accept prior authorization requests for any~~
338 ~~service electronically.~~

339 4. Notwithstanding any other law, in order to establish
340 uniformity in the submission of prior authorization forms,
341 effective January 1, 2015, a managed care plan shall use a
342 single standardized form for obtaining prior authorization for a
343 medical procedure, course of treatment, or prescription drug
344 benefit. The form may not exceed two pages in length, excluding
345 any instructions or guiding documentation.

346 a. The managed care plan shall make the form available
347 electronically and online to practitioners. The prescribing
348 provider may electronically submit the completed prior

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349 authorization form to the managed care plan.

350 b. If the managed care plan contracts with a pharmacy
351 benefits manager to perform prior authorization services for a
352 medical procedure, course of treatment, or prescription drug
353 benefit, the pharmacy benefits manager must use and accept the
354 standardized prior authorization form.

355 c. A completed prior authorization request submitted by a
356 health care provider using the standardized prior authorization
357 form is deemed approved upon receipt by the managed care plan
358 unless the managed care plan responds otherwise within 3
359 business days.

360 5. If medications for the treatment of a medical condition
361 are restricted for use by a managed care plan by a step-therapy
362 or fail-first protocol, the prescribing provider must have
363 access to a clear and convenient process to request an override
364 of the protocol from the managed care plan.

365 a. The managed care plan shall grant an override within 72
366 hours if the prescribing provider documents that:

367 (I) Based on sound clinical evidence, the preferred
368 treatment required under the step-therapy or fail-first protocol
369 has been ineffective in the treatment of the enrollee's disease
370 or medical condition; or

371 (II) Based on sound clinical evidence or medical and
372 scientific evidence, the preferred treatment required under the
373 step-therapy or fail-first protocol:

374 (A) Is expected or is likely to be ineffective based on
375 known relevant physical or mental characteristics of the
376 enrollee and known characteristics of the drug regimen; or

377 (B) Will cause or will likely cause an adverse reaction or

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378 other physical harm to the enrollee.

379 b. If the prescribing provider allows the enrollee to enter
380 the step-therapy or fail-first protocol recommended by the
381 managed care plan, the duration of the step-therapy or fail-
382 first protocol may not exceed the customary period for use of
383 the medication if the prescribing provider demonstrates such
384 treatment to be clinically ineffective. If the managed care plan
385 can, through sound clinical evidence, demonstrate that the
386 originally prescribed medication is likely to require more than
387 the customary period to provide any relief or amelioration to
388 the enrollee, the step-therapy or fail-first protocol may be
389 extended for an additional period, but no longer than the
390 original customary period for use of the medication.
391 Notwithstanding this provision, a step-therapy or fail-first
392 protocol shall be terminated if the prescribing provider
393 determines that the enrollee is having an adverse reaction or is
394 suffering from other physical harm resulting from the use of the
395 medication.

396 Section 6. Subsections (1) and (2) of section 465.189,
397 Florida Statutes, are amended to read:

398 465.189 Administration of vaccines and epinephrine
399 autoinjection.—

400 (1) In accordance with guidelines of the Centers for
401 Disease Control and Prevention for each recommended immunization
402 or vaccine, a pharmacist may administer the following vaccines
403 to an adult within the framework of an established protocol
404 under a supervising physician licensed under chapter 458 or
405 chapter 459:

406 (a) Influenza vaccine.

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(b) Pneumococcal vaccine.

(c) Meningococcal vaccine.

(d) Shingles vaccine.

~~(2) In accordance with guidelines of the Centers for Disease Control and Prevention, a pharmacist may administer the shingles vaccine within the framework of an established protocol and pursuant to a written or electronic prescription issued to the patient by a physician licensed under chapter 458 or chapter 459.~~

Section 7. Section 627.42392, Florida Statutes, is created to read:

627.42392 Prior authorization.—

(1) Notwithstanding any other law, in order to establish uniformity in the submission of prior authorization forms, effective January 1, 2015, a health insurer that delivers, issues for delivery, renews, amends, or continues an individual or group health insurance policy in this state, including a policy issued to a small employer as defined in s. 627.6699, shall use a single standardized form for obtaining prior authorization for a medical procedure, course of treatment, or prescription drug benefit. The form may not exceed two pages in length, excluding any instructions or guiding documentation.

(a) The health insurer shall make the form available electronically and online to practitioners. The prescribing provider may submit the completed prior authorization form electronically to the health insurer.

(b) If the health insurer contracts with a pharmacy benefits manager to perform prior authorization services for a medical procedure, course of treatment, or prescription drug

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benefit, the pharmacy benefits manager must use and accept the standardized prior authorization form.

(c) A completed prior authorization request submitted by a health care provider using the standardized prior authorization form is deemed approved upon receipt by the health insurer unless the health insurer responds otherwise within 3 business days.

(2) This section does not apply to a grandfathered health plan as defined in s. 627.402.

Section 8. Section 627.42393, Florida Statutes, is created to read:

627.42393 Medication protocol override.—If an individual or group health insurance policy, including a policy issued by a small employer as defined in s. 627.6699, restricts medications for the treatment of a medical condition by a step-therapy or fail-first protocol, the prescribing provider must have access to a clear and convenient process to request an override of the protocol from the health insurer.

(1) The health insurer shall authorize an override of the protocol within 72 hours if the prescribing provider documents that:

(a) Based on sound clinical evidence, the preferred treatment required under the step-therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or

(b) Based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:

1. Is expected or is likely to be ineffective based on

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known relevant physical or mental characteristics of the insured
and known characteristics of the drug regimen; or

2. Will cause or is likely to cause an adverse reaction or
other physical harm to the insured.

(2) If the prescribing provider allows the insured to enter
the step-therapy or fail-first protocol recommended by the
health insurer, the duration of the step-therapy or fail-first
protocol may not exceed the customary period for use of the
medication if the prescribing provider demonstrates such
treatment to be clinically ineffective. If the health insurer
can, through sound clinical evidence, demonstrate that the
originally prescribed medication is likely to require more than
the customary period for such medication to provide any relief
or amelioration to the insured, the step-therapy or fail-first
protocol may be extended for an additional period of time, but
no longer than the original customary period for the medication.
Notwithstanding this provision, a step-therapy or fail-first
protocol shall be terminated if the prescribing provider
determines that the insured is having an adverse reaction or is
suffering from other physical harm resulting from the use of the
medication.

(3) This section does not apply to grandfathered health
plans, as defined in s. 627.402.

Section 9. Subsection (11) of section 627.6131, Florida
Statutes, is amended to read:

627.6131 Payment of claims.—

(11) A health insurer may not retroactively deny a claim
because of insured ineligibility:

(a) More than 1 year after the date of payment of the

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claim; or

(b) If, under a policy compliant with the federal Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, and the regulations adopted pursuant to those acts, the health insurer verified the eligibility of the insured at the time of treatment and provided an authorization number, unless, at the time eligibility was verified, the provider was notified that the insured was delinquent in paying the premium.

Section 10. Subsection (2) of section 627.6471, Florida Statutes, is amended to read:

627.6471 Contracts for reduced rates of payment; limitations; coinsurance and deductibles.—

(2) An ~~Any~~ insurer issuing a policy of health insurance in this state, ~~which insurance~~ includes coverage for the services of a preferred provider shall, ~~must~~ provide each policyholder and certificateholder with a current list of preferred providers, shall ~~and must~~ make the list available for public inspection during regular business hours at the principal office of the insurer within the state, and shall post a link to the list of preferred providers on the home page of the insurer's website. Changes to the list of preferred providers must be reflected on the insurer's website within 24 hours.

Section 11. Paragraph (c) of subsection (2) of section 627.6515, Florida Statutes, is amended to read:

627.6515 Out-of-state groups.—

(2) Except as otherwise provided in this part, this part does not apply to a group health insurance policy issued or delivered outside this state under which a resident of this

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state is provided coverage if:

(c) The policy provides the benefits specified in ss. 627.419, 627.42392, 627.42393, 627.6574, 627.6575, 627.6579, 627.6612, 627.66121, 627.66122, 627.6613, 627.667, 627.6675, 627.6691, and 627.66911, and complies with the requirements of s. 627.66996.

Section 12. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(10) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility:

(a) More than 1 year after the date of payment of the claim; or

(b) If, under a policy in compliance with the federal Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, and the regulations adopted pursuant to those acts, the health maintenance organization verified the eligibility of the subscriber at the time of treatment and provided an authorization number, unless, at the time eligibility was verified, the provider was notified that the subscriber was delinquent in paying the premium.

Section 13. Section 641.393, Florida Statutes, is created to read:

641.393 Prior authorization.—Notwithstanding any other law, in order to establish uniformity in the submission of prior authorization forms, effective January 1, 2015, a health maintenance organization shall use a single standardized form for obtaining prior authorization for prescription drug

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benefits. The form may not exceed two pages in length, excluding any instructions or guiding documentation.

(1) A health maintenance organization shall make the form available electronically and online to practitioners. A health care provider may electronically submit the completed form to the health maintenance organization.

(2) If a health maintenance organization contracts with a pharmacy benefits manager to perform prior authorization services for prescription drug benefits, the pharmacy benefits manager must use and accept the standardized prior authorization form.

(3) A completed prior authorization request submitted by a health care provider using the standardized prior authorization form required under this section is deemed approved upon receipt by the health maintenance organization unless the health maintenance organization responds otherwise within 3 business days.

(4) This section does not apply to grandfathered health plans, as defined in s. 627.402.

Section 14. Section 641.394, Florida Statutes, is created to read:

641.394 Medication protocol override.—If a health maintenance organization contract restricts medications for the treatment of a medical condition by a step-therapy or fail-first protocol, the prescribing provider shall have access to a clear and convenient process to request an override of the protocol from the health maintenance organization.

(1) The health maintenance organization shall grant an override within 72 hours if the prescribing provider documents

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that:

(a) Based on sound clinical evidence, the preferred treatment required under the step-therapy or fail-first protocol has been ineffective in the treatment of the subscriber's disease or medical condition; or

(b) Based on sound clinical evidence or medical and scientific evidence, the preferred treatment required under the step-therapy or fail-first protocol:

1. Is expected or is likely to be ineffective based on known relevant physical or mental characteristics of the subscriber and known characteristics of the drug regimen; or

2. Will cause or is likely to cause an adverse reaction or other physical harm to the subscriber.

(2) If the prescribing provider allows the subscriber to enter the step-therapy or fail-first protocol recommended by the health maintenance organization, the duration of the step-therapy or fail-first protocol may not exceed the customary period for use of the medication if the prescribing provider demonstrates such treatment to be clinically ineffective. If the health maintenance organization can, through sound clinical evidence, demonstrate that the originally prescribed medication is likely to require more than the customary period to provide any relief or amelioration to the subscriber, the step-therapy or fail-first protocol may be extended for an additional period, but no longer than the original customary period for use of the medication. Notwithstanding this provision, a step-therapy or fail-first protocol shall be terminated if the prescribing provider determines that the subscriber is having an adverse reaction or is suffering from other physical harm resulting from

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the use of the medication.

(3) This section does not apply to grandfathered health plans, as defined in s. 627.402.

Section 15. Effective upon this act becoming a law, paragraph (a) of subsection (7) and subsection (14) of section 395.4001, Florida Statutes, are amended to read:

395.4001 Definitions.—As used in this part, the term:

(7) "Level II trauma center" means a trauma center that:

(a) Is verified by the department to be in substantial compliance with Level II trauma center standards and ~~has been~~ approved by the department to operate as a Level II trauma center or is designated pursuant to s. 395.4025(13) ~~s. 395.4025(14)~~.

(14) "Trauma center" means a hospital that has been verified by the department to be in substantial compliance with ~~the requirements in~~ s. 395.4025 and has been approved by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or is designated by the department as a Level II trauma center pursuant to s. 395.4025(13) ~~s. 395.4025(14)~~.

Section 16. Effective upon this act becoming a law, present paragraphs (k) through (o) of subsection (1) of section 395.401, Florida Statutes, are redesignated as paragraphs (l) through (p), respectively, a new paragraph (k) is added to that subsection, and present paragraph (k) of that subsection is amended, to read:

395.401 Trauma services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal.—

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639 (k) A hospital operating a trauma center may not charge a
640 trauma activation fee greater than \$15,000. This paragraph
641 expires on July 1, 2015.

642 (1)(k) A ~~It is unlawful for any~~ hospital or other facility
643 may not ~~to~~ hold itself out as a trauma center unless it has been
644 so verified or designated pursuant to s. 395.4025(13) ~~s.~~
645 395.4025(14).

646 Section 17. Effective upon this act becoming a law,
647 subsection (5) is added to section 395.402, Florida Statutes, to
648 read:

649 395.402 Trauma service areas; number and location of trauma
650 centers.—

651 (5) By October 1, 2014, the department must convene the
652 Florida Trauma System Plan Advisory Council in order to review
653 the Trauma System Consultation Report issued by the American
654 College of Surgeons Committee on Trauma dated February 2-5,
655 2013. Based on this review, the advisory council must submit
656 recommendations, including recommended statutory changes, to the
657 President of the Senate and the Speaker of the House of
658 Representatives by February 1, 2015. The advisory council may
659 make recommendations to the State Surgeon General regarding the
660 continuing development of the state trauma system. The advisory
661 council shall consist of nine representatives of an inclusive
662 trauma system appointed by the State Surgeon General as follows:

663 (a) A trauma patient, or a family member of a trauma
664 patient, who has sustained and recovered from severe injuries;

665 (b) A member of the Florida Committee on Trauma;

666 (c) A member of the Association of Florida Trauma
667 Coordinators;

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668 (d) A chief executive officer of a nontrauma acute care
669 hospital who is a member of the Florida Hospital Association;

670 (e) A member of the Florida Emergency Medical Services
671 Advisory Council;

672 (f) A member of the Florida Injury Prevention Advisory
673 Council;

674 (g) A member of the Brain and Spinal Cord Injury Program
675 Advisory Council;

676 (h) A member of the Florida Chamber of Commerce; and

677 (i) A member of the Florida Health Insurance Advisory
678 Board.

679 Section 18. Effective upon this act becoming a law, present
680 subsections (8) through (12) of section 395.4025, Florida
681 Statutes, are redesignated as subsections (7) through (11),
682 respectively, paragraph (d) of subsection (2) and present
683 subsection (7) of that section are amended, present subsections
684 (13) and (14) of that section are redesignated as subsections
685 (12) and (13), respectively, and amended, and a new subsection
686 (14) and subsection (15) are added to that section, to read:

687 395.4025 Trauma centers; selection; quality assurance;
688 records.—

689 (2)

690 (d)1. Notwithstanding other provisions in this section, the
691 department may grant up to an additional 18 months to a hospital
692 applicant that is unable to meet all requirements as provided in
693 paragraph (c) at the time of application if the number of
694 applicants in the service area in which the applicant is located
695 is equal to or less than the service area allocation, as
696 provided by rule of the department. An applicant that is granted

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697 additional time under ~~pursuant to~~ this paragraph shall submit a
698 plan for departmental approval which includes timelines and
699 activities that the applicant proposes to complete in order to
700 meet application requirements. An ~~Any~~ applicant that
701 demonstrates an ongoing effort to complete the activities within
702 the timelines outlined in the plan shall be included in the
703 number of trauma centers at such time that the department has
704 conducted a provisional review of the application and has
705 determined that the application is complete and that the
706 hospital has the critical elements required for a trauma center.

707 2. Timeframes provided in subsections (1)-(7) ~~(1)-(8)~~ shall
708 be stayed until the department determines that the application
709 is complete and that the hospital has the critical elements
710 required for a trauma center.

711 ~~(7) Any hospital that wishes to protest a decision made by~~
712 ~~the department based on the department's preliminary or in-depth~~
713 ~~review of applications or on the recommendations of the site~~
714 ~~visit review team pursuant to this section shall proceed as~~
715 ~~provided in chapter 120. Hearings held under this subsection~~
716 ~~shall be conducted in the same manner as provided in ss. 120.569~~
717 ~~and 120.57. Cases filed under chapter 120 may combine all~~
718 ~~disputes between parties.~~

719 (12) ~~(13)~~ The department may adopt, by rule, the procedures
720 and process by which it will select trauma centers. Such
721 procedures and process must be used in annually selecting trauma
722 centers and must be consistent with subsections (1)-(7) ~~(1)-(8)~~
723 except in those situations in which it is in the best interest
724 of, and mutually agreed to by, all applicants within a service
725 area and the department to reduce the timeframes.

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726 ~~(13)-(14)~~ Notwithstanding the procedures established
727 pursuant to subsections (1)-(12) ~~(1) through (13)~~, hospitals
728 located in areas with limited access to trauma center services
729 shall be designated by the department as Level II trauma centers
730 based on documentation of a valid certificate of trauma center
731 verification from the American College of Surgeons. Areas with
732 limited access to trauma center services are defined by the
733 following criteria:

734 (a) The hospital is located in a trauma service area with a
735 population greater than 600,000 persons but a population density
736 of less than 225 persons per square mile;

737 (b) The hospital is located in a county with no verified
738 trauma center; and

739 (c) The hospital is located at least 15 miles or 20 minutes
740 travel time by ground transport from the nearest verified trauma
741 center.

742 (14) Notwithstanding any other law, a hospital designated
743 as a provisional or verified as a Level I, Level II, or
744 pediatric trauma center after the enactment of chapter 2004-259,
745 Laws of Florida, whose approval has not been revoked may
746 continue to operate at the same trauma center level as a Level
747 I, Level II, or pediatric trauma center until the approval
748 period in subsection (6) expires, as long as the hospital
749 continues to meet the other requirements of part II of this
750 chapter related to trauma center standards and patient outcomes.
751 Any hospital that meets the requirements of this section is
752 eligible for renewal of its 7-year approval period pursuant to
753 subsection (6).

754 (15) The department may not verify, designate, or

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755 provisionally approve any hospital to operate as a trauma center
756 through the procedures established in subsections (1)-(13). This
757 subsection expires July 1, 2015.

758 Section 19. Except as otherwise expressly provided in this
759 act and except for this section, which shall take effect upon
760 becoming a law, this act shall take effect July 1, 2014.