

By Senator Harrell

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1 A bill to be entitled
2 An act relating to step-therapy protocols; amending s.
3 409.901, F.S.; defining the term "serious mental
4 illness"; amending s. 409.912, F.S.; requiring the
5 Agency for Health Care Administration to approve drug
6 products for Medicaid recipients for the treatment of
7 serious mental illness without step-therapy prior
8 authorization under certain circumstances; amending s.
9 409.910, F.S.; conforming a cross-reference; directing
10 the agency to include rate impacts resulting from the
11 act in certain rates that become effective on a
12 specified date; providing an effective date.

13
14 Be It Enacted by the Legislature of the State of Florida:

15
16 Section 1. Present subsections (27) and (28) of section
17 409.901, Florida Statutes, are redesignated as subsections (28)
18 and (29), respectively, and a new subsection (27) is added to
19 that section, to read:

20 409.901 Definitions; ss. 409.901-409.920.—As used in ss.
21 409.901-409.920, except as otherwise specifically provided, the
22 term:

23 (27) "Serious mental illness" means any of the following
24 psychiatric disorders as defined by the American Psychiatric
25 Association in the Diagnostic and Statistical Manual of Mental
26 Disorders, Fifth Edition:

27 (a) Bipolar disorders, including hypomanic, manic,
28 depressive, and mixed-feature episodes.

29 (b) Depression in childhood or adolescence.

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30 (c) Major depressive disorders, including single and
31 recurrent depressive episodes.

32 (d) Obsessive-compulsive disorders.

33 (e) Paranoid personality disorder or other psychotic
34 disorders.

35 (f) Schizoaffective disorders, including bipolar or
36 depressive symptoms.

37 (g) Schizophrenia.

38 Section 2. Paragraph (a) of subsection (5) of section
39 409.912, Florida Statutes, is amended to read:

40 409.912 Cost-effective purchasing of health care.—The
41 agency shall purchase goods and services for Medicaid recipients
42 in the most cost-effective manner consistent with the delivery
43 of quality medical care. To ensure that medical services are
44 effectively utilized, the agency may, in any case, require a
45 confirmation or second physician's opinion of the correct
46 diagnosis for purposes of authorizing future services under the
47 Medicaid program. This section does not restrict access to
48 emergency services or poststabilization care services as defined
49 in 42 C.F.R. s. 438.114. Such confirmation or second opinion
50 shall be rendered in a manner approved by the agency. The agency
51 shall maximize the use of prepaid per capita and prepaid
52 aggregate fixed-sum basis services when appropriate and other
53 alternative service delivery and reimbursement methodologies,
54 including competitive bidding pursuant to s. 287.057, designed
55 to facilitate the cost-effective purchase of a case-managed
56 continuum of care. The agency shall also require providers to
57 minimize the exposure of recipients to the need for acute
58 inpatient, custodial, and other institutional care and the

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59 inappropriate or unnecessary use of high-cost services. The
60 agency shall contract with a vendor to monitor and evaluate the
61 clinical practice patterns of providers in order to identify
62 trends that are outside the normal practice patterns of a
63 provider's professional peers or the national guidelines of a
64 provider's professional association. The vendor must be able to
65 provide information and counseling to a provider whose practice
66 patterns are outside the norms, in consultation with the agency,
67 to improve patient care and reduce inappropriate utilization.
68 The agency may mandate prior authorization, drug therapy
69 management, or disease management participation for certain
70 populations of Medicaid beneficiaries, certain drug classes, or
71 particular drugs to prevent fraud, abuse, overuse, and possible
72 dangerous drug interactions. The Pharmaceutical and Therapeutics
73 Committee shall make recommendations to the agency on drugs for
74 which prior authorization is required. The agency shall inform
75 the Pharmaceutical and Therapeutics Committee of its decisions
76 regarding drugs subject to prior authorization. The agency is
77 authorized to limit the entities it contracts with or enrolls as
78 Medicaid providers by developing a provider network through
79 provider credentialing. The agency may competitively bid single-
80 source-provider contracts if procurement of goods or services
81 results in demonstrated cost savings to the state without
82 limiting access to care. The agency may limit its network based
83 on the assessment of beneficiary access to care, provider
84 availability, provider quality standards, time and distance
85 standards for access to care, the cultural competence of the
86 provider network, demographic characteristics of Medicaid
87 beneficiaries, practice and provider-to-beneficiary standards,

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88 appointment wait times, beneficiary use of services, provider
89 turnover, provider profiling, provider licensure history,
90 previous program integrity investigations and findings, peer
91 review, provider Medicaid policy and billing compliance records,
92 clinical and medical record audits, and other factors. Providers
93 are not entitled to enrollment in the Medicaid provider network.
94 The agency shall determine instances in which allowing Medicaid
95 beneficiaries to purchase durable medical equipment and other
96 goods is less expensive to the Medicaid program than long-term
97 rental of the equipment or goods. The agency may establish rules
98 to facilitate purchases in lieu of long-term rentals in order to
99 protect against fraud and abuse in the Medicaid program as
100 defined in s. 409.913. The agency may seek federal waivers
101 necessary to administer these policies.

102 (5) (a) The agency shall implement a Medicaid prescribed-
103 drug spending-control program that includes the following
104 components:

105 1. A Medicaid preferred drug list, which shall be a listing
106 of cost-effective therapeutic options recommended by the
107 Medicaid Pharmacy and Therapeutics Committee established
108 pursuant to s. 409.91195 and adopted by the agency for each
109 therapeutic class on the preferred drug list. At the discretion
110 of the committee, and when feasible, the preferred drug list
111 should include at least two products in a therapeutic class. The
112 agency may post the preferred drug list and updates to the list
113 on an Internet website without following the rulemaking
114 procedures of chapter 120. Antiretroviral agents are excluded
115 from the preferred drug list. The agency shall also limit the
116 amount of a prescribed drug dispensed to no more than a 34-day

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117 supply unless the drug products' smallest marketed package is
118 greater than a 34-day supply, or the drug is determined by the
119 agency to be a maintenance drug in which case a 100-day maximum
120 supply may be authorized. The agency may seek any federal
121 waivers necessary to implement these cost-control programs and
122 to continue participation in the federal Medicaid rebate
123 program, or alternatively to negotiate state-only manufacturer
124 rebates. The agency may adopt rules to administer this
125 subparagraph. The agency shall continue to provide unlimited
126 contraceptive drugs and items. The agency must establish
127 procedures to ensure that:

128 a. There is a response to a request for prior authorization
129 by telephone or other telecommunication device within 24 hours
130 after receipt of a request for prior authorization; and

131 b. A 72-hour supply of the drug prescribed is provided in
132 an emergency or when the agency does not provide a response
133 within 24 hours as required by sub-subparagraph a.

134 2. A provider of prescribed drugs is reimbursed in an
135 amount not to exceed the lesser of the actual acquisition cost
136 based on the Centers for Medicare and Medicaid Services National
137 Average Drug Acquisition Cost pricing files plus a professional
138 dispensing fee, the wholesale acquisition cost plus a
139 professional dispensing fee, the state maximum allowable cost
140 plus a professional dispensing fee, or the usual and customary
141 charge billed by the provider.

142 3. The agency shall develop and implement a process for
143 managing the drug therapies of Medicaid recipients who are using
144 significant numbers of prescribed drugs each month. The
145 management process may include, but is not limited to,

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146 comprehensive, physician-directed medical-record reviews, claims
147 analyses, and case evaluations to determine the medical
148 necessity and appropriateness of a patient's treatment plan and
149 drug therapies. The agency may contract with a private
150 organization to provide drug-program-management services. The
151 Medicaid drug benefit management program shall include
152 initiatives to manage drug therapies for HIV/AIDS patients,
153 patients using 20 or more unique prescriptions in a 180-day
154 period, and the top 1,000 patients in annual spending. The
155 agency shall enroll any Medicaid recipient in the drug benefit
156 management program if he or she meets the specifications of this
157 provision and is not enrolled in a Medicaid health maintenance
158 organization.

159 4. The agency may limit the size of its pharmacy network
160 based on need, competitive bidding, price negotiations,
161 credentialing, or similar criteria. The agency shall give
162 special consideration to rural areas in determining the size and
163 location of pharmacies included in the Medicaid pharmacy
164 network. A pharmacy credentialing process may include criteria
165 such as a pharmacy's full-service status, location, size,
166 patient educational programs, patient consultation, disease
167 management services, and other characteristics. The agency may
168 impose a moratorium on Medicaid pharmacy enrollment if it is
169 determined that it has a sufficient number of Medicaid-
170 participating providers. The agency must allow dispensing
171 practitioners to participate as a part of the Medicaid pharmacy
172 network regardless of the practitioner's proximity to any other
173 entity that is dispensing prescription drugs under the Medicaid
174 program. A dispensing practitioner must meet all credentialing

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175 requirements applicable to his or her practice, as determined by
176 the agency.

177 5. The agency shall develop and implement a program that
178 requires Medicaid practitioners who issue written prescriptions
179 for medicinal drugs to use a counterfeit-proof prescription pad
180 for Medicaid prescriptions. The agency shall require the use of
181 standardized counterfeit-proof prescription pads by prescribers
182 who issue written prescriptions for Medicaid recipients. The
183 agency may implement the program in targeted geographic areas or
184 statewide.

185 6. The agency may enter into arrangements that require
186 manufacturers of generic drugs prescribed to Medicaid recipients
187 to provide rebates of at least 15.1 percent of the average
188 manufacturer price for the manufacturer's generic products.
189 These arrangements must ~~shall~~ require that if a generic-drug
190 manufacturer pays federal rebates for Medicaid-reimbursed drugs
191 at a level below 15.1 percent, the manufacturer must provide a
192 supplemental rebate to the state in an amount necessary to
193 achieve a 15.1-percent rebate level.

194 7. The agency may establish a preferred drug list as
195 described in this subsection, and, pursuant to the establishment
196 of such preferred drug list, negotiate supplemental rebates from
197 manufacturers that are in addition to those required by Title
198 XIX of the Social Security Act and at no less than 14 percent of
199 the average manufacturer price as defined in 42 U.S.C. s. 1936
200 on the last day of a quarter unless the federal or supplemental
201 rebate, or both, equals or exceeds 29 percent. There is no upper
202 limit on the supplemental rebates the agency may negotiate. The
203 agency may determine that specific products, brand-name or

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204 generic, are competitive at lower rebate percentages. Agreement
205 to pay the minimum supplemental rebate percentage guarantees a
206 manufacturer that the Medicaid Pharmaceutical and Therapeutics
207 Committee will consider a product for inclusion on the preferred
208 drug list. However, a pharmaceutical manufacturer is not
209 guaranteed placement on the preferred drug list by simply paying
210 the minimum supplemental rebate. Agency decisions will be made
211 on the clinical efficacy of a drug and recommendations of the
212 Medicaid Pharmaceutical and Therapeutics Committee, as well as
213 the price of competing products minus federal and state rebates.
214 The agency may contract with an outside agency or contractor to
215 conduct negotiations for supplemental rebates. For the purposes
216 of this section, the term "supplemental rebates" means cash
217 rebates. Value-added programs as a substitution for supplemental
218 rebates are prohibited. The agency may seek any federal waivers
219 to implement this initiative.

220 8.a. The agency may implement a Medicaid behavioral drug
221 management system. The agency may contract with a vendor that
222 has experience in operating behavioral drug management systems
223 to implement this program. The agency may seek federal waivers
224 to implement this program.

225 b. The agency, in conjunction with the Department of
226 Children and Families, may implement the Medicaid behavioral
227 drug management system that is designed to improve the quality
228 of care and behavioral health prescribing practices based on
229 best practice guidelines, improve patient adherence to
230 medication plans, reduce clinical risk, and lower prescribed
231 drug costs and the rate of inappropriate spending on Medicaid
232 behavioral drugs. The program may include the following

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233 elements:

234 (I) Provide for the development and adoption of best
235 practice guidelines for behavioral health-related drugs such as
236 antipsychotics, antidepressants, and medications for treating
237 bipolar disorders and other behavioral conditions; translate
238 them into practice; review behavioral health prescribers and
239 compare their prescribing patterns to a number of indicators
240 that are based on national standards; and determine deviations
241 from best practice guidelines.

242 (II) Implement processes for providing feedback to and
243 educating prescribers using best practice educational materials
244 and peer-to-peer consultation.

245 (III) Assess Medicaid beneficiaries who are outliers in
246 their use of behavioral health drugs with regard to the numbers
247 and types of drugs taken, drug dosages, combination drug
248 therapies, and other indicators of improper use of behavioral
249 health drugs.

250 (IV) Alert prescribers to patients who fail to refill
251 prescriptions in a timely fashion, are prescribed multiple same-
252 class behavioral health drugs, and may have other potential
253 medication problems.

254 (V) Track spending trends for behavioral health drugs and
255 deviation from best practice guidelines.

256 (VI) Use educational and technological approaches to
257 promote best practices, educate consumers, and train prescribers
258 in the use of practice guidelines.

259 (VII) Disseminate electronic and published materials.

260 (VIII) Hold statewide and regional conferences.

261 (IX) Implement a disease management program with a model

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262 quality-based medication component for severely mentally ill
263 individuals and emotionally disturbed children who are high
264 users of care.

265 9. The agency shall implement a Medicaid prescription drug
266 management system.

267 a. The agency may contract with a vendor that has
268 experience in operating prescription drug management systems in
269 order to implement this system. Any management system that is
270 implemented in accordance with this subparagraph must rely on
271 cooperation between physicians and pharmacists to determine
272 appropriate practice patterns and clinical guidelines to improve
273 the prescribing, dispensing, and use of drugs in the Medicaid
274 program. The agency may seek federal waivers to implement this
275 program.

276 b. The drug management system must be designed to improve
277 the quality of care and prescribing practices based on best
278 practice guidelines, improve patient adherence to medication
279 plans, reduce clinical risk, and lower prescribed drug costs and
280 the rate of inappropriate spending on Medicaid prescription
281 drugs. The program must:

282 (I) Provide for the adoption of best practice guidelines
283 for the prescribing and use of drugs in the Medicaid program,
284 including translating best practice guidelines into practice;
285 reviewing prescriber patterns and comparing them to indicators
286 that are based on national standards and practice patterns of
287 clinical peers in their community, statewide, and nationally;
288 and determine deviations from best practice guidelines.

289 (II) Implement processes for providing feedback to and
290 educating prescribers using best practice educational materials

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291 and peer-to-peer consultation.

292 (III) Assess Medicaid recipients who are outliers in their
293 use of a single or multiple prescription drugs with regard to
294 the numbers and types of drugs taken, drug dosages, combination
295 drug therapies, and other indicators of improper use of
296 prescription drugs.

297 (IV) Alert prescribers to recipients who fail to refill
298 prescriptions in a timely fashion, are prescribed multiple drugs
299 that may be redundant or contraindicated, or may have other
300 potential medication problems.

301 10. The agency may contract for drug rebate administration,
302 including, but not limited to, calculating rebate amounts,
303 invoicing manufacturers, negotiating disputes with
304 manufacturers, and maintaining a database of rebate collections.

305 11. The agency may specify the preferred daily dosing form
306 or strength for the purpose of promoting best practices with
307 regard to the prescribing of certain drugs as specified in the
308 General Appropriations Act and ensuring cost-effective
309 prescribing practices.

310 12. The agency may require prior authorization for
311 Medicaid-covered prescribed drugs. The agency may prior-
312 authorize the use of a product:

- 313 a. For an indication not approved in labeling;
314 b. To comply with certain clinical guidelines; or
315 c. If the product has the potential for overuse, misuse, or
316 abuse.

317

318 The agency may require the prescribing professional to provide
319 information about the rationale and supporting medical evidence

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320 for the use of a drug. The agency shall post prior
321 authorization, step-edit criteria and protocol, and updates to
322 the list of drugs that are subject to prior authorization on the
323 agency's Internet website within 21 days after the prior
324 authorization and step-edit criteria and protocol and updates
325 are approved by the agency. For purposes of this subparagraph,
326 the term "step-edit" means an automatic electronic review of
327 certain medications subject to prior authorization.

328 13. The agency, in conjunction with the Pharmaceutical and
329 Therapeutics Committee, may require age-related prior
330 authorizations for certain prescribed drugs. The agency may
331 preauthorize the use of a drug for a recipient who may not meet
332 the age requirement or may exceed the length of therapy for use
333 of this product as recommended by the manufacturer and approved
334 by the Food and Drug Administration. Prior authorization may
335 require the prescribing professional to provide information
336 about the rationale and supporting medical evidence for the use
337 of a drug.

338 14. The agency shall implement a step-therapy prior
339 authorization approval process for medications excluded from the
340 preferred drug list. Medications listed on the preferred drug
341 list must be used within the previous 12 months before the
342 alternative medications that are not listed. The step-therapy
343 prior authorization may require the prescriber to use the
344 medications of a similar drug class or for a similar medical
345 indication unless contraindicated in the Food and Drug
346 Administration labeling. The trial period between the specified
347 steps may vary according to the medical indication. The step-
348 therapy approval process must ~~shall~~ be developed in accordance

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349 with the committee as stated in s. 409.91195(7) and (8). A drug
350 product may be approved or, in the case of a drug product for
351 the treatment of a serious mental illness, must be approved
352 without meeting the step-therapy prior authorization criteria if
353 the prescribing physician provides the agency with additional
354 written medical or clinical documentation that the product is
355 medically necessary because:

356 a. There is not a drug on the preferred drug list to treat
357 the disease or medical condition which is an acceptable clinical
358 alternative;

359 b. The alternatives have been ineffective in the treatment
360 of the beneficiary's disease;

361 c. The drug product or medication of a similar drug class
362 is prescribed for the treatment of a serious mental illness
363 ~~schizophrenia or schizotypal or delusional disorders~~; prior
364 authorization has been granted previously for the prescribed
365 drug; and the medication was dispensed to the patient during the
366 previous 12 months; or

367 d. Based on historical evidence and known characteristics
368 of the patient and the drug, the drug is likely to be
369 ineffective, or the number of doses have been ineffective.

370

371 The agency shall work with the physician to determine the best
372 alternative for the patient. The agency may adopt rules waiving
373 the requirements for written clinical documentation for specific
374 drugs in limited clinical situations.

375 15. The agency shall implement a return and reuse program
376 for drugs dispensed by pharmacies to institutional recipients,
377 which includes payment of a \$5 restocking fee for the

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378 implementation and operation of the program. The return and
379 reuse program shall be implemented electronically and in a
380 manner that promotes efficiency. The program must permit a
381 pharmacy to exclude drugs from the program if it is not
382 practical or cost-effective for the drug to be included and must
383 provide for the return to inventory of drugs that cannot be
384 credited or returned in a cost-effective manner. The agency
385 shall determine if the program has reduced the amount of
386 Medicaid prescription drugs which are destroyed on an annual
387 basis and if there are additional ways to ensure more
388 prescription drugs are not destroyed which could safely be
389 reused.

390 Section 3. Paragraph (a) of subsection (20) of section
391 409.910, Florida Statutes, is amended to read:

392 409.910 Responsibility for payments on behalf of Medicaid-
393 eligible persons when other parties are liable.-

394 (20) (a) Entities providing health insurance as defined in
395 s. 624.603, health maintenance organizations and prepaid health
396 clinics as defined in chapter 641, and, on behalf of their
397 clients, third-party administrators, pharmacy benefits managers,
398 and any other third parties, as defined in s. 409.901(28) ~~s.~~
399 ~~409.901(27)~~, which are legally responsible for payment of a
400 claim for a health care item or service as a condition of doing
401 business in this ~~the~~ state or providing coverage to residents of
402 this state, shall provide such records and information as are
403 necessary to accomplish the purpose of this section, unless such
404 requirement results in an unreasonable burden.

405 Section 4. The Agency for Health Care Administration is
406 directed to include the rate impact of this act in the Medicaid

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407 managed medical assistance program and long-term care managed
408 care program rates that become effective on October 1, 2024.

409 Section 5. This act shall take effect October 1, 2024.