

26 Association in the Diagnostic and Statistical Manual of Mental
 27 Disorders, Fifth Edition:

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

30 (b) Depression in childhood or adolescence.

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

33 (d) Obsessive-compulsive disorders.

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

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

38 (g) Schizophrenia.

39 Section 2. Paragraph (a) of subsection (5) of section
 40 409.912, Florida Statutes, is amended to read:

41 409.912 Cost-effective purchasing of health care.—The
 42 agency shall purchase goods and services for Medicaid recipients
 43 in the most cost-effective manner consistent with the delivery
 44 of quality medical care. To ensure that medical services are
 45 effectively utilized, the agency may, in any case, require a
 46 confirmation or second physician's opinion of the correct
 47 diagnosis for purposes of authorizing future services under the
 48 Medicaid program. This section does not restrict access to
 49 emergency services or poststabilization care services as defined
 50 in 42 C.F.R. s. 438.114. Such confirmation or second opinion

51 shall be rendered in a manner approved by the agency. The agency
52 shall maximize the use of prepaid per capita and prepaid
53 aggregate fixed-sum basis services when appropriate and other
54 alternative service delivery and reimbursement methodologies,
55 including competitive bidding pursuant to s. 287.057, designed
56 to facilitate the cost-effective purchase of a case-managed
57 continuum of care. The agency shall also require providers to
58 minimize the exposure of recipients to the need for acute
59 inpatient, custodial, and other institutional care and the
60 inappropriate or unnecessary use of high-cost services. The
61 agency shall contract with a vendor to monitor and evaluate the
62 clinical practice patterns of providers in order to identify
63 trends that are outside the normal practice patterns of a
64 provider's professional peers or the national guidelines of a
65 provider's professional association. The vendor must be able to
66 provide information and counseling to a provider whose practice
67 patterns are outside the norms, in consultation with the agency,
68 to improve patient care and reduce inappropriate utilization.
69 The agency may mandate prior authorization, drug therapy
70 management, or disease management participation for certain
71 populations of Medicaid beneficiaries, certain drug classes, or
72 particular drugs to prevent fraud, abuse, overuse, and possible
73 dangerous drug interactions. The Pharmaceutical and Therapeutics
74 Committee shall make recommendations to the agency on drugs for
75 which prior authorization is required. The agency shall inform

76 | the Pharmaceutical and Therapeutics Committee of its decisions
77 | regarding drugs subject to prior authorization. The agency is
78 | authorized to limit the entities it contracts with or enrolls as
79 | Medicaid providers by developing a provider network through
80 | provider credentialing. The agency may competitively bid single-
81 | source-provider contracts if procurement of goods or services
82 | results in demonstrated cost savings to the state without
83 | limiting access to care. The agency may limit its network based
84 | on the assessment of beneficiary access to care, provider
85 | availability, provider quality standards, time and distance
86 | standards for access to care, the cultural competence of the
87 | provider network, demographic characteristics of Medicaid
88 | beneficiaries, practice and provider-to-beneficiary standards,
89 | appointment wait times, beneficiary use of services, provider
90 | turnover, provider profiling, provider licensure history,
91 | previous program integrity investigations and findings, peer
92 | review, provider Medicaid policy and billing compliance records,
93 | clinical and medical record audits, and other factors. Providers
94 | are not entitled to enrollment in the Medicaid provider network.
95 | The agency shall determine instances in which allowing Medicaid
96 | beneficiaries to purchase durable medical equipment and other
97 | goods is less expensive to the Medicaid program than long-term
98 | rental of the equipment or goods. The agency may establish rules
99 | to facilitate purchases in lieu of long-term rentals in order to
100 | protect against fraud and abuse in the Medicaid program as

101 defined in s. 409.913. The agency may seek federal waivers
102 necessary to administer these policies.

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

106 1. A Medicaid preferred drug list, which shall be a
107 listing of cost-effective therapeutic options recommended by the
108 Medicaid Pharmacy and Therapeutics Committee established
109 pursuant to s. 409.91195 and adopted by the agency for each
110 therapeutic class on the preferred drug list. At the discretion
111 of the committee, and when feasible, the preferred drug list
112 should include at least two products in a therapeutic class. The
113 agency may post the preferred drug list and updates to the list
114 on an Internet website without following the rulemaking
115 procedures of chapter 120. Antiretroviral agents are excluded
116 from the preferred drug list. The agency shall also limit the
117 amount of a prescribed drug dispensed to no more than a 34-day
118 supply unless the drug products' smallest marketed package is
119 greater than a 34-day supply, or the drug is determined by the
120 agency to be a maintenance drug in which case a 100-day maximum
121 supply may be authorized. The agency may seek any federal
122 waivers necessary to implement these cost-control programs and
123 to continue participation in the federal Medicaid rebate
124 program, or alternatively to negotiate state-only manufacturer
125 rebates. The agency may adopt rules to administer this

126 subparagraph. The agency shall continue to provide unlimited
127 contraceptive drugs and items. The agency must establish
128 procedures to ensure that:

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

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

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

144 3. The agency shall develop and implement a process for
145 managing the drug therapies of Medicaid recipients who are using
146 significant numbers of prescribed drugs each month. The
147 management process may include, but is not limited to,
148 comprehensive, physician-directed medical-record reviews, claims
149 analyses, and case evaluations to determine the medical
150 necessity and appropriateness of a patient's treatment plan and

151 drug therapies. The agency may contract with a private
152 organization to provide drug-program-management services. The
153 Medicaid drug benefit management program shall include
154 initiatives to manage drug therapies for HIV/AIDS patients,
155 patients using 20 or more unique prescriptions in a 180-day
156 period, and the top 1,000 patients in annual spending. The
157 agency shall enroll any Medicaid recipient in the drug benefit
158 management program if he or she meets the specifications of this
159 provision and is not enrolled in a Medicaid health maintenance
160 organization.

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

176 program. A dispensing practitioner must meet all credentialing
 177 requirements applicable to his or her practice, as determined by
 178 the agency.

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

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

196 7. The agency may establish a preferred drug list as
 197 described in this subsection, and, pursuant to the establishment
 198 of such preferred drug list, negotiate supplemental rebates from
 199 manufacturers that are in addition to those required by Title
 200 XIX of the Social Security Act and at no less than 14 percent of

201 the average manufacturer price as defined in 42 U.S.C. s. 1936
202 on the last day of a quarter unless the federal or supplemental
203 rebate, or both, equals or exceeds 29 percent. There is no upper
204 limit on the supplemental rebates the agency may negotiate. The
205 agency may determine that specific products, brand-name or
206 generic, are competitive at lower rebate percentages. Agreement
207 to pay the minimum supplemental rebate percentage guarantees a
208 manufacturer that the Medicaid Pharmaceutical and Therapeutics
209 Committee will consider a product for inclusion on the preferred
210 drug list. However, a pharmaceutical manufacturer is not
211 guaranteed placement on the preferred drug list by simply paying
212 the minimum supplemental rebate. Agency decisions will be made
213 on the clinical efficacy of a drug and recommendations of the
214 Medicaid Pharmaceutical and Therapeutics Committee, as well as
215 the price of competing products minus federal and state rebates.
216 The agency may contract with an outside agency or contractor to
217 conduct negotiations for supplemental rebates. For the purposes
218 of this section, the term "supplemental rebates" means cash
219 rebates. Value-added programs as a substitution for supplemental
220 rebates are prohibited. The agency may seek any federal waivers
221 to implement this initiative.

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

226 | to implement this program.

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

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

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

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

251 health drugs.

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

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

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

261 (VII) Disseminate electronic and published materials.

262 (VIII) Hold statewide and regional conferences.

263 (IX) Implement a disease management program with a model
264 quality-based medication component for severely mentally ill
265 individuals and emotionally disturbed children who are high
266 users of care.

267 9. The agency shall implement a Medicaid prescription drug
268 management system.

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

276 program. The agency may seek federal waivers to implement this
277 program.

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

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

291 (II) Implement processes for providing feedback to and
292 educating prescribers using best practice educational materials
293 and peer-to-peer consultation.

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

299 (IV) Alert prescribers to recipients who fail to refill
300 prescriptions in a timely fashion, are prescribed multiple drugs

301 that may be redundant or contraindicated, or may have other
302 potential medication problems.

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

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

313 12. The agency may require prior authorization for
314 Medicaid-covered prescribed drugs. The agency may prior-
315 authorize the use of a product:

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

320
321 The agency may require the prescribing professional to provide
322 information about the rationale and supporting medical evidence
323 for the use of a drug. The agency shall post prior
324 authorization, step-edit criteria and protocol, and updates to
325 the list of drugs that are subject to prior authorization on the

326 agency's Internet website within 21 days after the prior
327 authorization and step-edit criteria and protocol and updates
328 are approved by the agency. For purposes of this subparagraph,
329 the term "step-edit" means an automatic electronic review of
330 certain medications subject to prior authorization.

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

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

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

359 a. There is not a drug on the preferred drug list to treat
360 the disease or medical condition which is an acceptable clinical
361 alternative;

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

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

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

373
374 The agency shall work with the physician to determine the best
375 alternative for the patient. The agency may adopt rules waiving

376 the requirements for written clinical documentation for specific
377 drugs in limited clinical situations.

378 15. The agency shall implement a return and reuse program
379 for drugs dispensed by pharmacies to institutional recipients,
380 which includes payment of a \$5 restocking fee for the
381 implementation and operation of the program. The return and
382 reuse program shall be implemented electronically and in a
383 manner that promotes efficiency. The program must permit a
384 pharmacy to exclude drugs from the program if it is not
385 practical or cost-effective for the drug to be included and must
386 provide for the return to inventory of drugs that cannot be
387 credited or returned in a cost-effective manner. The agency
388 shall determine if the program has reduced the amount of
389 Medicaid prescription drugs which are destroyed on an annual
390 basis and if there are additional ways to ensure more
391 prescription drugs are not destroyed which could safely be
392 reused.

393 Section 3. Paragraph (a) of subsection (20) of section
394 409.910, Florida Statutes, is amended to read:

395 409.910 Responsibility for payments on behalf of Medicaid-
396 eligible persons when other parties are liable.-

397 (20) (a) Entities providing health insurance as defined in
398 s. 624.603, health maintenance organizations and prepaid health
399 clinics as defined in chapter 641, and, on behalf of their
400 clients, third-party administrators, pharmacy benefits managers,

401 and any other third parties, as defined in s. 409.901(28) ~~s.~~
 402 ~~409.901(27)~~, which are legally responsible for payment of a
 403 claim for a health care item or service as a condition of doing
 404 business in this ~~the~~ state or providing coverage to residents of
 405 this state, shall provide such records and information as are
 406 necessary to accomplish the purpose of this section, unless such
 407 requirement results in an unreasonable burden.

408 Section 4. The Agency for Health Care Administration is
 409 directed to include the rate impact of this act in the Medicaid
 410 managed medical assistance program and long-term care managed
 411 care program rates that become effective on October 1, 2023.

412 Section 5. This act shall take effect October 1, 2023.