

By the Committee on Health Policy; and Senator Bean

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1 A bill to be entitled
2 An act relating to Medicaid; amending s. 402.81, F.S.;
3 deleting a requirement for the Agency for Health Care
4 Administration to submit an annual report to the
5 Legislature on the operation of the pharmaceutical
6 expense assistance program; amending s. 409.815, F.S.;
7 conforming a provision to changes made by the act;
8 amending s. 409.908, F.S.; revising the method for
9 determining prescribed drug provider reimbursements;
10 deleting a requirement for the agency to implement
11 certain fees for prescribed medicines; deleting
12 authorization for the agency to increase certain
13 dispensing fees by certain amounts; reenacting and
14 amending s. 409.91195, F.S., relating to the Medicaid
15 Pharmaceutical and Therapeutics Committee; deleting a
16 requirement for the agency to ensure that the
17 committee reviews certain drugs under certain
18 circumstances; designating the agency, rather than the
19 Department of Children and Families, as the
20 administrator for certain hearings; amending s.
21 409.912, F.S.; requiring the agency to establish
22 certain procedures related to prior authorization
23 requests rather than prior consultation requests;
24 revising the method for determining prescribed drug
25 provider reimbursements; deleting a requirement for
26 the agency to expand home delivery of pharmacy
27 products; deleting a dosage limitation on certain
28 drugs; deleting a requirement for the agency to submit
29 certain quarterly reports to the Governor and the

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30 Legislature; repealing s. 409.91213, F.S., relating to
31 quarterly progress reports and annual reports;
32 amending s. 409.913, F.S.; revising the definitions of
33 the terms "medical necessity" and "medically
34 necessary" to provide an exception for behavior
35 analysis services determinations; requiring that
36 determinations be based on information available at
37 the time goods or services are requested, rather than
38 at the time such goods or services are provided;
39 repealing s. 765.53, F.S., relating to the Organ
40 Transplant Advisory Council; providing an effective
41 date.

42
43 Be It Enacted by the Legislature of the State of Florida:

44
45 Section 1. Subsection (4) of section 402.81, Florida
46 Statutes, is amended to read:

47 402.81 Pharmaceutical expense assistance.—

48 (4) ADMINISTRATION.—The agency shall administer the
49 pharmaceutical expense assistance program ~~shall be administered~~
50 ~~by the agency,~~ in collaboration with the Department of Elderly
51 Affairs and the Department of Children and Families. ~~By January~~
52 ~~1 of each year, the agency shall report to the Legislature on~~
53 ~~the operation of the program. The report shall include~~
54 ~~information on the number of individuals served, use rates, and~~
55 ~~expenditures under the program.~~

56 Section 2. Paragraph (e) of subsection (2) of section
57 409.815, Florida Statutes, is amended to read:

58 409.815 Health benefits coverage; limitations.—

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59 (2) BENCHMARK BENEFITS.—In order for health benefits
60 coverage to qualify for premium assistance payments for an
61 eligible child under ss. 409.810-409.821, the health benefits
62 coverage, except for coverage under Medicaid and Medikids, must
63 include the following minimum benefits, as medically necessary.

64 (e) *Organ transplantation services*.—Covered services
65 include pretransplant, transplant, and postdischarge services
66 and treatment of complications after transplantation for
67 transplants deemed necessary and appropriate within the
68 guidelines set by the ~~Organ Transplant Advisory Council under s.~~
69 ~~765.53~~ or the Bone Marrow Transplant Advisory Panel under s.
70 627.4236.

71 Section 3. Subsection (14) of section 409.908, Florida
72 Statutes, is amended to read:

73 409.908 Reimbursement of Medicaid providers.—Subject to
74 specific appropriations, the agency shall reimburse Medicaid
75 providers, in accordance with state and federal law, according
76 to methodologies set forth in the rules of the agency and in
77 policy manuals and handbooks incorporated by reference therein.
78 These methodologies may include fee schedules, reimbursement
79 methods based on cost reporting, negotiated fees, competitive
80 bidding pursuant to s. 287.057, and other mechanisms the agency
81 considers efficient and effective for purchasing services or
82 goods on behalf of recipients. If a provider is reimbursed based
83 on cost reporting and submits a cost report late and that cost
84 report would have been used to set a lower reimbursement rate
85 for a rate semester, then the provider's rate for that semester
86 shall be retroactively calculated using the new cost report, and
87 full payment at the recalculated rate shall be effected

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88 retroactively. Medicare-granted extensions for filing cost
89 reports, if applicable, shall also apply to Medicaid cost
90 reports. Payment for Medicaid compensable services made on
91 behalf of Medicaid eligible persons is subject to the
92 availability of moneys and any limitations or directions
93 provided for in the General Appropriations Act or chapter 216.
94 Further, nothing in this section shall be construed to prevent
95 or limit the agency from adjusting fees, reimbursement rates,
96 lengths of stay, number of visits, or number of services, or
97 making any other adjustments necessary to comply with the
98 availability of moneys and any limitations or directions
99 provided for in the General Appropriations Act, provided the
100 adjustment is consistent with legislative intent.

101 (14) A provider of prescribed drugs shall be reimbursed in
102 an amount not to exceed the lesser of the actual acquisition
103 cost based on the Centers for Medicare and Medicaid Services
104 National Average Drug Acquisition Cost pricing files plus a
105 professional dispensing fee, the wholesale acquisition cost plus
106 a professional dispensing fee, the state maximum allowable cost
107 plus a professional dispensing fee, or the usual and customary
108 charge billed by the provider ~~the least of the amount billed by~~
109 ~~the provider, the provider's usual and customary charge, or the~~
110 ~~Medicaid maximum allowable fee established by the agency, plus a~~
111 ~~dispensing fee. The Medicaid maximum allowable fee for~~
112 ~~ingredient cost must be based on the lowest of: the average~~
113 ~~wholesale price (AWP) minus 16.4 percent, the wholesaler~~
114 ~~acquisition cost (WAC) plus 1.5 percent, the federal upper limit~~
115 ~~(FUL), the state maximum allowable cost (SMAC), or the usual and~~
116 ~~customary (UAC) charge billed by the provider.~~

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117 (a) Medicaid providers must dispense generic drugs if
118 available at lower cost and the agency has not determined that
119 the branded product is more cost-effective, unless the
120 prescriber has requested and received approval to require the
121 branded product.

122 ~~(b) The agency shall implement a variable dispensing fee~~
123 ~~for prescribed medicines while ensuring continued access for~~
124 ~~Medicaid recipients. The variable dispensing fee may be based~~
125 ~~upon, but not limited to, either or both the volume of~~
126 ~~prescriptions dispensed by a specific pharmacy provider, the~~
127 ~~volume of prescriptions dispensed to an individual recipient,~~
128 ~~and dispensing of preferred drug list products.~~

129 ~~(c) The agency may increase the pharmacy dispensing fee~~
130 ~~authorized by statute and in the General Appropriations Act by~~
131 ~~\$.50 for the dispensing of a Medicaid preferred drug list~~
132 ~~product and reduce the pharmacy dispensing fee by \$.50 for the~~
133 ~~dispensing of a Medicaid product that is not included on the~~
134 ~~preferred drug list.~~

135 ~~(d)~~ The agency may establish a supplemental pharmaceutical
136 dispensing fee to be paid to providers returning unused unit-
137 dose packaged medications to stock and crediting the Medicaid
138 program for the ingredient cost of those medications if the
139 ingredient costs to be credited exceed the value of the
140 supplemental dispensing fee.

141 (c) ~~(e)~~ The agency may limit reimbursement for prescribed
142 medicine in order to comply with any limitations or directions
143 provided in the General Appropriations Act, which may include
144 implementing a prospective or concurrent utilization review
145 program.

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146 Section 4. Subsections (9) and (11) of section 409.91195,
147 Florida Statutes, are amended, and subsection (4) of that
148 section is reenacted for the purpose of incorporating the
149 amendment made by this act to section 409.912, Florida Statutes,
150 in a reference thereto, to read:

151 409.91195 Medicaid Pharmaceutical and Therapeutics
152 Committee.—There is created a Medicaid Pharmaceutical and
153 Therapeutics Committee within the agency for the purpose of
154 developing a Medicaid preferred drug list.

155 (4) Upon recommendation of the committee, the agency shall
156 adopt a preferred drug list as described in s. 409.912(5). To
157 the extent feasible, the committee shall review all drug classes
158 included on the preferred drug list every 12 months, and may
159 recommend additions to and deletions from the preferred drug
160 list, such that the preferred drug list provides for medically
161 appropriate drug therapies for Medicaid patients which achieve
162 cost savings contained in the General Appropriations Act.

163 ~~(9) Upon timely notice, the agency shall ensure that any~~
164 ~~therapeutic class of drugs which includes a drug that has been~~
165 ~~removed from distribution to the public by its manufacturer or~~
166 ~~the United States Food and Drug Administration or has been~~
167 ~~required to carry a black box warning label by the United States~~
168 ~~Food and Drug Administration because of safety concerns is~~
169 ~~reviewed by the committee at the next regularly scheduled~~
170 ~~meeting. After such review, the committee must recommend whether~~
171 ~~to retain the therapeutic class of drugs or subcategories of~~
172 ~~drugs within a therapeutic class on the preferred drug list and~~
173 ~~whether to institute prior authorization requirements necessary~~
174 ~~to ensure patient safety.~~

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175 ~~(10)(11)~~ Medicaid recipients may appeal agency preferred
176 drug formulary decisions using the Medicaid fair hearing process
177 administered by the Agency for Health Care Administration
178 ~~Department of Children and Families.~~

179 Section 5. Paragraphs (a) and (c) of subsection (5) of
180 section 409.912, Florida Statutes, are amended to read:

181 409.912 Cost-effective purchasing of health care.—The
182 agency shall purchase goods and services for Medicaid recipients
183 in the most cost-effective manner consistent with the delivery
184 of quality medical care. To ensure that medical services are
185 effectively utilized, the agency may, in any case, require a
186 confirmation or second physician's opinion of the correct
187 diagnosis for purposes of authorizing future services under the
188 Medicaid program. This section does not restrict access to
189 emergency services or poststabilization care services as defined
190 in 42 C.F.R. s. 438.114. Such confirmation or second opinion
191 shall be rendered in a manner approved by the agency. The agency
192 shall maximize the use of prepaid per capita and prepaid
193 aggregate fixed-sum basis services when appropriate and other
194 alternative service delivery and reimbursement methodologies,
195 including competitive bidding pursuant to s. 287.057, designed
196 to facilitate the cost-effective purchase of a case-managed
197 continuum of care. The agency shall also require providers to
198 minimize the exposure of recipients to the need for acute
199 inpatient, custodial, and other institutional care and the
200 inappropriate or unnecessary use of high-cost services. The
201 agency shall contract with a vendor to monitor and evaluate the
202 clinical practice patterns of providers in order to identify
203 trends that are outside the normal practice patterns of a

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204 provider's professional peers or the national guidelines of a
205 provider's professional association. The vendor must be able to
206 provide information and counseling to a provider whose practice
207 patterns are outside the norms, in consultation with the agency,
208 to improve patient care and reduce inappropriate utilization.
209 The agency may mandate prior authorization, drug therapy
210 management, or disease management participation for certain
211 populations of Medicaid beneficiaries, certain drug classes, or
212 particular drugs to prevent fraud, abuse, overuse, and possible
213 dangerous drug interactions. The Pharmaceutical and Therapeutics
214 Committee shall make recommendations to the agency on drugs for
215 which prior authorization is required. The agency shall inform
216 the Pharmaceutical and Therapeutics Committee of its decisions
217 regarding drugs subject to prior authorization. The agency is
218 authorized to limit the entities it contracts with or enrolls as
219 Medicaid providers by developing a provider network through
220 provider credentialing. The agency may competitively bid single-
221 source-provider contracts if procurement of goods or services
222 results in demonstrated cost savings to the state without
223 limiting access to care. The agency may limit its network based
224 on the assessment of beneficiary access to care, provider
225 availability, provider quality standards, time and distance
226 standards for access to care, the cultural competence of the
227 provider network, demographic characteristics of Medicaid
228 beneficiaries, practice and provider-to-beneficiary standards,
229 appointment wait times, beneficiary use of services, provider
230 turnover, provider profiling, provider licensure history,
231 previous program integrity investigations and findings, peer
232 review, provider Medicaid policy and billing compliance records,

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233 clinical and medical record audits, and other factors. Providers
234 are not entitled to enrollment in the Medicaid provider network.
235 The agency shall determine instances in which allowing Medicaid
236 beneficiaries to purchase durable medical equipment and other
237 goods is less expensive to the Medicaid program than long-term
238 rental of the equipment or goods. The agency may establish rules
239 to facilitate purchases in lieu of long-term rentals in order to
240 protect against fraud and abuse in the Medicaid program as
241 defined in s. 409.913. The agency may seek federal waivers
242 necessary to administer these policies.

243 (5) (a) The agency shall implement a Medicaid prescribed-
244 drug spending-control program that includes the following
245 components:

246 1. A Medicaid preferred drug list, which shall be a listing
247 of cost-effective therapeutic options recommended by the
248 Medicaid Pharmacy and Therapeutics Committee established
249 pursuant to s. 409.91195 and adopted by the agency for each
250 therapeutic class on the preferred drug list. At the discretion
251 of the committee, and when feasible, the preferred drug list
252 should include at least two products in a therapeutic class. The
253 agency may post the preferred drug list and updates to the list
254 on an Internet website without following the rulemaking
255 procedures of chapter 120. Antiretroviral agents are excluded
256 from the preferred drug list. The agency shall also limit the
257 amount of a prescribed drug dispensed to no more than a 34-day
258 supply unless the drug products' smallest marketed package is
259 greater than a 34-day supply, or the drug is determined by the
260 agency to be a maintenance drug in which case a 100-day maximum
261 supply may be authorized. The agency may seek any federal

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262 waivers necessary to implement these cost-control programs and
263 to continue participation in the federal Medicaid rebate
264 program, or alternatively to negotiate state-only manufacturer
265 rebates. The agency may adopt rules to administer this
266 subparagraph. The agency shall continue to provide unlimited
267 contraceptive drugs and items. The agency must establish
268 procedures to ensure that:

269 a. There is a response to a request for prior authorization
270 ~~consultation~~ by telephone or other telecommunication device
271 within 24 hours after receipt of a request for prior
272 authorization ~~consultation~~; and

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

276 2. A provider of prescribed drugs is reimbursed in an
277 amount not to exceed the lesser of the actual acquisition cost
278 based on the Centers for Medicare and Medicaid Services National
279 Average Drug Acquisition Cost pricing files plus a professional
280 dispensing fee, the wholesale acquisition cost plus a
281 professional dispensing fee, the state maximum allowable cost
282 plus a professional dispensing fee, or the usual and customary
283 charge billed by the provider ~~Reimbursement to pharmacies for~~
284 ~~Medicaid prescribed drugs shall be set at the lowest of: the~~
285 ~~average wholesale price (AWP) minus 16.4 percent, the wholesaler~~
286 ~~acquisition cost (WAC) plus 1.5 percent, the federal upper limit~~
287 ~~(FUL), the state maximum allowable cost (SMAC), or the usual and~~
288 ~~eustomary (UAC) charge billed by the provider.~~

289 3. The agency shall develop and implement a process for
290 managing the drug therapies of Medicaid recipients who are using

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291 significant numbers of prescribed drugs each month. The
292 management process may include, but is not limited to,
293 comprehensive, physician-directed medical-record reviews, claims
294 analyses, and case evaluations to determine the medical
295 necessity and appropriateness of a patient's treatment plan and
296 drug therapies. The agency may contract with a private
297 organization to provide drug-program-management services. The
298 Medicaid drug benefit management program shall include
299 initiatives to manage drug therapies for HIV/AIDS patients,
300 patients using 20 or more unique prescriptions in a 180-day
301 period, and the top 1,000 patients in annual spending. The
302 agency shall enroll any Medicaid recipient in the drug benefit
303 management program if he or she meets the specifications of this
304 provision and is not enrolled in a Medicaid health maintenance
305 organization.

306 4. The agency may limit the size of its pharmacy network
307 based on need, competitive bidding, price negotiations,
308 credentialing, or similar criteria. The agency shall give
309 special consideration to rural areas in determining the size and
310 location of pharmacies included in the Medicaid pharmacy
311 network. A pharmacy credentialing process may include criteria
312 such as a pharmacy's full-service status, location, size,
313 patient educational programs, patient consultation, disease
314 management services, and other characteristics. The agency may
315 impose a moratorium on Medicaid pharmacy enrollment if it is
316 determined that it has a sufficient number of Medicaid-
317 participating providers. The agency must allow dispensing
318 practitioners to participate as a part of the Medicaid pharmacy
319 network regardless of the practitioner's proximity to any other

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320 entity that is dispensing prescription drugs under the Medicaid
321 program. A dispensing practitioner must meet all credentialing
322 requirements applicable to his or her practice, as determined by
323 the agency.

324 5. The agency shall develop and implement a program that
325 requires Medicaid practitioners who issue written prescriptions
326 for medicinal drugs to use a counterfeit-proof prescription pad
327 for Medicaid prescriptions. The agency shall require the use of
328 standardized counterfeit-proof prescription pads by prescribers
329 who issue written prescriptions for Medicaid recipients. The
330 agency may implement the program in targeted geographic areas or
331 statewide.

332 6. The agency may enter into arrangements that require
333 manufacturers of generic drugs prescribed to Medicaid recipients
334 to provide rebates of at least 15.1 percent of the average
335 manufacturer price for the manufacturer's generic products.
336 These arrangements shall require that if a generic-drug
337 manufacturer pays federal rebates for Medicaid-reimbursed drugs
338 at a level below 15.1 percent, the manufacturer must provide a
339 supplemental rebate to the state in an amount necessary to
340 achieve a 15.1-percent rebate level.

341 7. The agency may establish a preferred drug list as
342 described in this subsection, and, pursuant to the establishment
343 of such preferred drug list, negotiate supplemental rebates from
344 manufacturers that are in addition to those required by Title
345 XIX of the Social Security Act and at no less than 14 percent of
346 the average manufacturer price as defined in 42 U.S.C. s. 1936
347 on the last day of a quarter unless the federal or supplemental
348 rebate, or both, equals or exceeds 29 percent. There is no upper

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349 limit on the supplemental rebates the agency may negotiate. The
350 agency may determine that specific products, brand-name or
351 generic, are competitive at lower rebate percentages. Agreement
352 to pay the minimum supplemental rebate percentage guarantees a
353 manufacturer that the Medicaid Pharmaceutical and Therapeutics
354 Committee will consider a product for inclusion on the preferred
355 drug list. However, a pharmaceutical manufacturer is not
356 guaranteed placement on the preferred drug list by simply paying
357 the minimum supplemental rebate. Agency decisions will be made
358 on the clinical efficacy of a drug and recommendations of the
359 Medicaid Pharmaceutical and Therapeutics Committee, as well as
360 the price of competing products minus federal and state rebates.
361 The agency may contract with an outside agency or contractor to
362 conduct negotiations for supplemental rebates. For the purposes
363 of this section, the term "supplemental rebates" means cash
364 rebates. Value-added programs as a substitution for supplemental
365 rebates are prohibited. The agency may seek any federal waivers
366 to implement this initiative.

367 8.a. ~~The agency shall expand home delivery of pharmacy~~
368 ~~products. The agency may amend the state plan and issue a~~
369 ~~procurement, as necessary, in order to implement this program.~~
370 ~~The procurements must include agreements with a pharmacy or~~
371 ~~pharmacies located in the state to provide mail order delivery~~
372 ~~services at no cost to the recipients who elect to receive home~~
373 ~~delivery of pharmacy products. The procurement must focus on~~
374 ~~servicing recipients with chronic diseases for which pharmacy~~
375 ~~expenditures represent a significant portion of Medicaid~~
376 ~~pharmacy expenditures or which impact a significant portion of~~
377 ~~the Medicaid population. The agency may seek and implement any~~

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378 ~~federal waivers necessary to implement this subparagraph.~~

379 ~~9. The agency shall limit to one dose per month any drug~~
380 ~~prescribed to treat erectile dysfunction.~~

381 ~~10.a.~~ The agency may implement a Medicaid behavioral drug
382 management system. The agency may contract with a vendor that
383 has experience in operating behavioral drug management systems
384 to implement this program. The agency may seek federal waivers
385 to implement this program.

386 b. The agency, in conjunction with the Department of
387 Children and Families, may implement the Medicaid behavioral
388 drug management system that is designed to improve the quality
389 of care and behavioral health prescribing practices based on
390 best practice guidelines, improve patient adherence to
391 medication plans, reduce clinical risk, and lower prescribed
392 drug costs and the rate of inappropriate spending on Medicaid
393 behavioral drugs. The program may include the following
394 elements:

395 (I) Provide for the development and adoption of best
396 practice guidelines for behavioral health-related drugs such as
397 antipsychotics, antidepressants, and medications for treating
398 bipolar disorders and other behavioral conditions; translate
399 them into practice; review behavioral health prescribers and
400 compare their prescribing patterns to a number of indicators
401 that are based on national standards; and determine deviations
402 from best practice guidelines.

403 (II) Implement processes for providing feedback to and
404 educating prescribers using best practice educational materials
405 and peer-to-peer consultation.

406 (III) Assess Medicaid beneficiaries who are outliers in

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407 their use of behavioral health drugs with regard to the numbers
408 and types of drugs taken, drug dosages, combination drug
409 therapies, and other indicators of improper use of behavioral
410 health drugs.

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

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

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

420 (VII) Disseminate electronic and published materials.

421 (VIII) Hold statewide and regional conferences.

422 (IX) Implement a disease management program with a model
423 quality-based medication component for severely mentally ill
424 individuals and emotionally disturbed children who are high
425 users of care.

426 ~~9.11.~~ The agency shall implement a Medicaid prescription
427 drug management system.

428 a. The agency may contract with a vendor that has
429 experience in operating prescription drug management systems in
430 order to implement this system. Any management system that is
431 implemented in accordance with this subparagraph must rely on
432 cooperation between physicians and pharmacists to determine
433 appropriate practice patterns and clinical guidelines to improve
434 the prescribing, dispensing, and use of drugs in the Medicaid
435 program. The agency may seek federal waivers to implement this

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436 program.

437 b. The drug management system must be designed to improve
438 the quality of care and prescribing practices based on best
439 practice guidelines, improve patient adherence to medication
440 plans, reduce clinical risk, and lower prescribed drug costs and
441 the rate of inappropriate spending on Medicaid prescription
442 drugs. The program must:

443 (I) Provide for the adoption of best practice guidelines
444 for the prescribing and use of drugs in the Medicaid program,
445 including translating best practice guidelines into practice;
446 reviewing prescriber patterns and comparing them to indicators
447 that are based on national standards and practice patterns of
448 clinical peers in their community, statewide, and nationally;
449 and determine deviations from best practice guidelines.

450 (II) Implement processes for providing feedback to and
451 educating prescribers using best practice educational materials
452 and peer-to-peer consultation.

453 (III) Assess Medicaid recipients who are outliers in their
454 use of a single or multiple prescription drugs with regard to
455 the numbers and types of drugs taken, drug dosages, combination
456 drug therapies, and other indicators of improper use of
457 prescription drugs.

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

462 10.12. The agency may contract for drug rebate
463 administration, including, but not limited to, calculating
464 rebate amounts, invoicing manufacturers, negotiating disputes

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465 with manufacturers, and maintaining a database of rebate
466 collections.

467 ~~11.13.~~ The agency may specify the preferred daily dosing
468 form or strength for the purpose of promoting best practices
469 with regard to the prescribing of certain drugs as specified in
470 the General Appropriations Act and ensuring cost-effective
471 prescribing practices.

472 ~~12.14.~~ The agency may require prior authorization for
473 Medicaid-covered prescribed drugs. The agency may prior-
474 authorize the use of a product:

- 475 a. For an indication not approved in labeling;
476 b. To comply with certain clinical guidelines; or
477 c. If the product has the potential for overuse, misuse, or
478 abuse.

479

480 The agency may require the prescribing professional to provide
481 information about the rationale and supporting medical evidence
482 for the use of a drug. The agency shall post prior
483 authorization, step-edit criteria and protocol, and updates to
484 the list of drugs that are subject to prior authorization on the
485 agency's Internet website within 21 days after the prior
486 authorization and step-edit criteria and protocol and updates
487 are approved by the agency. For purposes of this subparagraph,
488 the term "step-edit" means an automatic electronic review of
489 certain medications subject to prior authorization.

490 ~~13.15.~~ The agency, in conjunction with the Pharmaceutical
491 and Therapeutics Committee, may require age-related prior
492 authorizations for certain prescribed drugs. The agency may
493 preauthorize the use of a drug for a recipient who may not meet

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494 the age requirement or may exceed the length of therapy for use
495 of this product as recommended by the manufacturer and approved
496 by the Food and Drug Administration. Prior authorization may
497 require the prescribing professional to provide information
498 about the rationale and supporting medical evidence for the use
499 of a drug.

500 ~~14.16.~~ The agency shall implement a step-therapy prior
501 authorization approval process for medications excluded from the
502 preferred drug list. Medications listed on the preferred drug
503 list must be used within the previous 12 months before the
504 alternative medications that are not listed. The step-therapy
505 prior authorization may require the prescriber to use the
506 medications of a similar drug class or for a similar medical
507 indication unless contraindicated in the Food and Drug
508 Administration labeling. The trial period between the specified
509 steps may vary according to the medical indication. The step-
510 therapy approval process shall be developed in accordance with
511 the committee as stated in s. 409.91195(7) and (8). A drug
512 product may be approved without meeting the step-therapy prior
513 authorization criteria if the prescribing physician provides the
514 agency with additional written medical or clinical documentation
515 that the product is medically necessary because:

516 a. There is not a drug on the preferred drug list to treat
517 the disease or medical condition which is an acceptable clinical
518 alternative;

519 b. The alternatives have been ineffective in the treatment
520 of the beneficiary's disease; or

521 c. Based on historic evidence and known characteristics of
522 the patient and the drug, the drug is likely to be ineffective,

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523 or the number of doses have been ineffective.

524

525 The agency shall work with the physician to determine the best
526 alternative for the patient. The agency may adopt rules waiving
527 the requirements for written clinical documentation for specific
528 drugs in limited clinical situations.

529 15.17. The agency shall implement a return and reuse
530 program for drugs dispensed by pharmacies to institutional
531 recipients, which includes payment of a \$5 restocking fee for
532 the implementation and operation of the program. The return and
533 reuse program shall be implemented electronically and in a
534 manner that promotes efficiency. The program must permit a
535 pharmacy to exclude drugs from the program if it is not
536 practical or cost-effective for the drug to be included and must
537 provide for the return to inventory of drugs that cannot be
538 credited or returned in a cost-effective manner. The agency
539 shall determine if the program has reduced the amount of
540 Medicaid prescription drugs which are destroyed on an annual
541 basis and if there are additional ways to ensure more
542 prescription drugs are not destroyed which could safely be
543 reused.

544 ~~(c) The agency shall submit quarterly reports to the~~
545 ~~Governor, the President of the Senate, and the Speaker of the~~
546 ~~House of Representatives which must include, but need not be~~
547 ~~limited to, the progress made in implementing this subsection~~
548 ~~and its effect on Medicaid prescribed drug expenditures.~~

549 Section 6. Section 409.91213, Florida Statutes, is
550 repealed.

551 Section 7. Paragraph (d) of subsection (1) of section

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552 409.913, Florida Statutes, is amended to read:

553 409.913 Oversight of the integrity of the Medicaid
554 program.—The agency shall operate a program to oversee the
555 activities of Florida Medicaid recipients, and providers and
556 their representatives, to ensure that fraudulent and abusive
557 behavior and neglect of recipients occur to the minimum extent
558 possible, and to recover overpayments and impose sanctions as
559 appropriate. Each January 15, the agency and the Medicaid Fraud
560 Control Unit of the Department of Legal Affairs shall submit a
561 report to the Legislature documenting the effectiveness of the
562 state's efforts to control Medicaid fraud and abuse and to
563 recover Medicaid overpayments during the previous fiscal year.
564 The report must describe the number of cases opened and
565 investigated each year; the sources of the cases opened; the
566 disposition of the cases closed each year; the amount of
567 overpayments alleged in preliminary and final audit letters; the
568 number and amount of fines or penalties imposed; any reductions
569 in overpayment amounts negotiated in settlement agreements or by
570 other means; the amount of final agency determinations of
571 overpayments; the amount deducted from federal claiming as a
572 result of overpayments; the amount of overpayments recovered
573 each year; the amount of cost of investigation recovered each
574 year; the average length of time to collect from the time the
575 case was opened until the overpayment is paid in full; the
576 amount determined as uncollectible and the portion of the
577 uncollectible amount subsequently reclaimed from the Federal
578 Government; the number of providers, by type, that are
579 terminated from participation in the Medicaid program as a
580 result of fraud and abuse; and all costs associated with

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581 discovering and prosecuting cases of Medicaid overpayments and
582 making recoveries in such cases. The report must also document
583 actions taken to prevent overpayments and the number of
584 providers prevented from enrolling in or reenrolling in the
585 Medicaid program as a result of documented Medicaid fraud and
586 abuse and must include policy recommendations necessary to
587 prevent or recover overpayments and changes necessary to prevent
588 and detect Medicaid fraud. All policy recommendations in the
589 report must include a detailed fiscal analysis, including, but
590 not limited to, implementation costs, estimated savings to the
591 Medicaid program, and the return on investment. The agency must
592 submit the policy recommendations and fiscal analyses in the
593 report to the appropriate estimating conference, pursuant to s.
594 216.137, by February 15 of each year. The agency and the
595 Medicaid Fraud Control Unit of the Department of Legal Affairs
596 each must include detailed unit-specific performance standards,
597 benchmarks, and metrics in the report, including projected cost
598 savings to the state Medicaid program during the following
599 fiscal year.

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

601 (d) "Medical necessity" or "medically necessary" means any
602 goods or services necessary to palliate the effects of a
603 terminal condition, or to prevent, diagnose, correct, cure,
604 alleviate, or preclude deterioration of a condition that
605 threatens life, causes pain or suffering, or results in illness
606 or infirmity, which goods or services are provided in accordance
607 with generally accepted standards of medical practice. For
608 purposes of determining Medicaid reimbursement, the agency is
609 the final arbiter of medical necessity. Determinations of

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610 medical necessity must be made by a licensed physician employed
611 by or under contract with the agency, except for behavior
612 analysis services, which may be determined by a licensed
613 physician or a doctoral-level board-certified behavior analyst.
614 Determinations ~~and~~ must be based upon information available at
615 the time the goods or services are requested ~~provided~~.

616 Section 8. Section 765.53, Florida Statutes, is repealed.

617 Section 9. This act shall take effect July 1, 2021.