

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

26 | the dosage of certain drugs, and submit certain
 27 | quarterly reports to the Governor and Legislature;
 28 | repealing s. 409.91213, F.S., relating to quarterly
 29 | progress reports and annual reports; amending s.
 30 | 409.913, F.S.; revising the definition of the term
 31 | "medical necessity" or "medically necessary";
 32 | repealing s. 765.53, F.S., relating to the Organ
 33 | Transplant Advisory Council; amending s. 409.815,
 34 | F.S.; conforming a provision to changes made by the
 35 | act; providing an effective date.

36 |
 37 | Be It Enacted by the Legislature of the State of Florida:

38 |
 39 | Section 1. Subsection (4) of section 402.81, Florida
 40 | Statutes, is amended to read:

41 | 402.81 Pharmaceutical expense assistance.—

42 | (4) ADMINISTRATION.—The agency shall administer the
 43 | pharmaceutical expense assistance program ~~shall be administered~~
 44 | ~~by the agency,~~ in collaboration with the Department of Elderly
 45 | Affairs and the Department of Children and Families. ~~By January~~
 46 | ~~1 of each year, the agency shall report to the Legislature on~~
 47 | ~~the operation of the program. The report shall include~~
 48 | ~~information on the number of individuals served, use rates, and~~
 49 | ~~expenditures under the program.~~

50 | Section 2. Subsection (14) of section 409.908, Florida

51 Statutes, is amended to read:

52 409.908 Reimbursement of Medicaid providers.—Subject to
53 specific appropriations, the agency shall reimburse Medicaid
54 providers, in accordance with state and federal law, according
55 to methodologies set forth in the rules of the agency and in
56 policy manuals and handbooks incorporated by reference therein.
57 These methodologies may include fee schedules, reimbursement
58 methods based on cost reporting, negotiated fees, competitive
59 bidding pursuant to s. 287.057, and other mechanisms the agency
60 considers efficient and effective for purchasing services or
61 goods on behalf of recipients. If a provider is reimbursed based
62 on cost reporting and submits a cost report late and that cost
63 report would have been used to set a lower reimbursement rate
64 for a rate semester, then the provider's rate for that semester
65 shall be retroactively calculated using the new cost report, and
66 full payment at the recalculated rate shall be effected
67 retroactively. Medicare-granted extensions for filing cost
68 reports, if applicable, shall also apply to Medicaid cost
69 reports. Payment for Medicaid compensable services made on
70 behalf of Medicaid eligible persons is subject to the
71 availability of moneys and any limitations or directions
72 provided for in the General Appropriations Act or chapter 216.
73 Further, nothing in this section shall be construed to prevent
74 or limit the agency from adjusting fees, reimbursement rates,
75 lengths of stay, number of visits, or number of services, or

76 making any other adjustments necessary to comply with the
77 availability of moneys and any limitations or directions
78 provided for in the General Appropriations Act, provided the
79 adjustment is consistent with legislative intent.

80 (14) A provider of prescribed drugs shall be reimbursed in
81 an amount not to exceed the lesser of the actual acquisition
82 cost based on the Centers for Medicare and Medicaid Services
83 National Average Drug Acquisition Cost pricing files plus a
84 professional dispensing fee, the wholesale acquisition cost plus
85 a professional dispensing fee, the state maximum allowable cost
86 plus a professional dispensing fee, or the usual and customary
87 charge billed by the provider ~~the least of the amount billed by~~
88 ~~the provider, the provider's usual and customary charge, or the~~
89 ~~Medicaid maximum allowable fee established by the agency, plus a~~
90 ~~dispensing fee. The Medicaid maximum allowable fee for~~
91 ~~ingredient cost must be based on the lowest of: the average~~
92 ~~wholesale price (AWP) minus 16.4 percent, the wholesaler~~
93 ~~acquisition cost (WAC) plus 1.5 percent, the federal upper limit~~
94 ~~(FUL), the state maximum allowable cost (SMAC), or the usual and~~
95 ~~customary (UAC) charge billed by the provider.~~

96 (a) Medicaid providers must dispense generic drugs if
97 available at lower cost and the agency has not determined that
98 the branded product is more cost-effective, unless the
99 prescriber has requested and received approval to require the
100 branded product.

101 ~~(b) The agency shall implement a variable dispensing fee~~
102 ~~for prescribed medicines while ensuring continued access for~~
103 ~~Medicaid recipients. The variable dispensing fee may be based~~
104 ~~upon, but not limited to, either or both the volume of~~
105 ~~prescriptions dispensed by a specific pharmacy provider, the~~
106 ~~volume of prescriptions dispensed to an individual recipient,~~
107 ~~and dispensing of preferred drug list products.~~

108 ~~(c) The agency may increase the pharmacy dispensing fee~~
109 ~~authorized by statute and in the General Appropriations Act by~~
110 ~~\$0.50 for the dispensing of a Medicaid preferred drug list~~
111 ~~product and reduce the pharmacy dispensing fee by \$0.50 for the~~
112 ~~dispensing of a Medicaid product that is not included on the~~
113 ~~preferred drug list.~~

114 (b)~~(d)~~ The agency may establish a supplemental
115 pharmaceutical dispensing fee to be paid to providers returning
116 unused unit-dose packaged medications to stock and crediting the
117 Medicaid program for the ingredient cost of those medications if
118 the ingredient costs to be credited exceed the value of the
119 supplemental dispensing fee.

120 (c)~~(e)~~ The agency may limit reimbursement for prescribed
121 medicine in order to comply with any limitations or directions
122 provided in the General Appropriations Act, which may include
123 implementing a prospective or concurrent utilization review
124 program.

125 Section 3. Subsections (10) and (11) of section 409.91195,

126 Florida Statutes, are renumbered as subsections (9) and (10),
127 respectively, present subsections (9) and (11) of that section
128 are amended, and subsection (4) of that section is reenacted for
129 the purpose of incorporating the amendment made by this act to
130 section 409.912, Florida Statutes, to read:

131 409.91195 Medicaid Pharmaceutical and Therapeutics
132 Committee.—There is created a Medicaid Pharmaceutical and
133 Therapeutics Committee within the agency for the purpose of
134 developing a Medicaid preferred drug list.

135 (4) Upon recommendation of the committee, the agency shall
136 adopt a preferred drug list as described in s. 409.912(5). To
137 the extent feasible, the committee shall review all drug classes
138 included on the preferred drug list every 12 months, and may
139 recommend additions to and deletions from the preferred drug
140 list, such that the preferred drug list provides for medically
141 appropriate drug therapies for Medicaid patients which achieve
142 cost savings contained in the General Appropriations Act.

143 ~~(9) Upon timely notice, the agency shall ensure that any~~
144 ~~therapeutic class of drugs which includes a drug that has been~~
145 ~~removed from distribution to the public by its manufacturer or~~
146 ~~the United States Food and Drug Administration or has been~~
147 ~~required to carry a black box warning label by the United States~~
148 ~~Food and Drug Administration because of safety concerns is~~
149 ~~reviewed by the committee at the next regularly scheduled~~
150 ~~meeting. After such review, the committee must recommend whether~~

151 ~~to retain the therapeutic class of drugs or subcategories of~~
152 ~~drugs within a therapeutic class on the preferred drug list and~~
153 ~~whether to institute prior authorization requirements necessary~~
154 ~~to ensure patient safety.~~

155 (10)~~(11)~~ Medicaid recipients may appeal agency preferred
156 drug formulary decisions using the Medicaid fair hearing process
157 administered by the Agency for Health Care Administration
158 ~~Department of Children and Families.~~

159 Section 4. Paragraphs (a) and (c) of subsection (5) of
160 section 409.912, Florida Statutes, are amended to read:

161 409.912 Cost-effective purchasing of health care.—The
162 agency shall purchase goods and services for Medicaid recipients
163 in the most cost-effective manner consistent with the delivery
164 of quality medical care. To ensure that medical services are
165 effectively utilized, the agency may, in any case, require a
166 confirmation or second physician's opinion of the correct
167 diagnosis for purposes of authorizing future services under the
168 Medicaid program. This section does not restrict access to
169 emergency services or poststabilization care services as defined
170 in 42 C.F.R. s. 438.114. Such confirmation or second opinion
171 shall be rendered in a manner approved by the agency. The agency
172 shall maximize the use of prepaid per capita and prepaid
173 aggregate fixed-sum basis services when appropriate and other
174 alternative service delivery and reimbursement methodologies,
175 including competitive bidding pursuant to s. 287.057, designed

176 | to facilitate the cost-effective purchase of a case-managed
177 | continuum of care. The agency shall also require providers to
178 | minimize the exposure of recipients to the need for acute
179 | inpatient, custodial, and other institutional care and the
180 | inappropriate or unnecessary use of high-cost services. The
181 | agency shall contract with a vendor to monitor and evaluate the
182 | clinical practice patterns of providers in order to identify
183 | trends that are outside the normal practice patterns of a
184 | provider's professional peers or the national guidelines of a
185 | provider's professional association. The vendor must be able to
186 | provide information and counseling to a provider whose practice
187 | patterns are outside the norms, in consultation with the agency,
188 | to improve patient care and reduce inappropriate utilization.
189 | The agency may mandate prior authorization, drug therapy
190 | management, or disease management participation for certain
191 | populations of Medicaid beneficiaries, certain drug classes, or
192 | particular drugs to prevent fraud, abuse, overuse, and possible
193 | dangerous drug interactions. The Pharmaceutical and Therapeutics
194 | Committee shall make recommendations to the agency on drugs for
195 | which prior authorization is required. The agency shall inform
196 | the Pharmaceutical and Therapeutics Committee of its decisions
197 | regarding drugs subject to prior authorization. The agency is
198 | authorized to limit the entities it contracts with or enrolls as
199 | Medicaid providers by developing a provider network through
200 | provider credentialing. The agency may competitively bid single-

201 source-provider contracts if procurement of goods or services
202 results in demonstrated cost savings to the state without
203 limiting access to care. The agency may limit its network based
204 on the assessment of beneficiary access to care, provider
205 availability, provider quality standards, time and distance
206 standards for access to care, the cultural competence of the
207 provider network, demographic characteristics of Medicaid
208 beneficiaries, practice and provider-to-beneficiary standards,
209 appointment wait times, beneficiary use of services, provider
210 turnover, provider profiling, provider licensure history,
211 previous program integrity investigations and findings, peer
212 review, provider Medicaid policy and billing compliance records,
213 clinical and medical record audits, and other factors. Providers
214 are not entitled to enrollment in the Medicaid provider network.
215 The agency shall determine instances in which allowing Medicaid
216 beneficiaries to purchase durable medical equipment and other
217 goods is less expensive to the Medicaid program than long-term
218 rental of the equipment or goods. The agency may establish rules
219 to facilitate purchases in lieu of long-term rentals in order to
220 protect against fraud and abuse in the Medicaid program as
221 defined in s. 409.913. The agency may seek federal waivers
222 necessary to administer these policies.

223 (5) (a) The agency shall implement a Medicaid prescribed-
224 drug spending-control program that includes the following
225 components:

226 1. A Medicaid preferred drug list, which shall be a
227 listing of cost-effective therapeutic options recommended by the
228 Medicaid Pharmacy and Therapeutics Committee established
229 pursuant to s. 409.91195 and adopted by the agency for each
230 therapeutic class on the preferred drug list. At the discretion
231 of the committee, and when feasible, the preferred drug list
232 should include at least two products in a therapeutic class. The
233 agency may post the preferred drug list and updates to the list
234 on an Internet website without following the rulemaking
235 procedures of chapter 120. Antiretroviral agents are excluded
236 from the preferred drug list. The agency shall also limit the
237 amount of a prescribed drug dispensed to no more than a 34-day
238 supply unless the drug products' smallest marketed package is
239 greater than a 34-day supply, or the drug is determined by the
240 agency to be a maintenance drug in which case a 100-day maximum
241 supply may be authorized. The agency may seek any federal
242 waivers necessary to implement these cost-control programs and
243 to continue participation in the federal Medicaid rebate
244 program, or alternatively to negotiate state-only manufacturer
245 rebates. The agency may adopt rules to administer this
246 subparagraph. The agency shall continue to provide unlimited
247 contraceptive drugs and items. The agency must establish
248 procedures to ensure that:

249 a. There is a response to a request for prior
250 authorization ~~consultation~~ by telephone or other

251 telecommunication device within 24 hours after receipt of a
252 request for prior authorization ~~consultation~~; and

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

256 2. A provider of prescribed drugs is reimbursed in an
257 amount not to exceed the lesser of the actual acquisition cost
258 based on the Centers for Medicare and Medicaid Services National
259 Average Drug Acquisition Cost pricing files plus a professional
260 dispensing fee, the wholesale acquisition cost plus a
261 professional dispensing fee, the state maximum allowable cost
262 plus a professional dispensing fee, or the usual and customary
263 charge billed by the provider ~~Reimbursement to pharmacies for~~
264 ~~Medicaid prescribed drugs shall be set at the lowest of: the~~
265 ~~average wholesale price (AWP) minus 16.4 percent, the wholesaler~~
266 ~~acquisition cost (WAC) plus 1.5 percent, the federal upper limit~~
267 ~~(FUL), the state maximum allowable cost (SMAC), or the usual and~~
268 ~~eustomary (UAC) charge billed by the provider.~~

269 3. The agency shall develop and implement a process for
270 managing the drug therapies of Medicaid recipients who are using
271 significant numbers of prescribed drugs each month. The
272 management process may include, but is not limited to,
273 comprehensive, physician-directed medical-record reviews, claims
274 analyses, and case evaluations to determine the medical
275 necessity and appropriateness of a patient's treatment plan and

276 drug therapies. The agency may contract with a private
277 organization to provide drug-program-management services. The
278 Medicaid drug benefit management program shall include
279 initiatives to manage drug therapies for HIV/AIDS patients,
280 patients using 20 or more unique prescriptions in a 180-day
281 period, and the top 1,000 patients in annual spending. The
282 agency shall enroll any Medicaid recipient in the drug benefit
283 management program if he or she meets the specifications of this
284 provision and is not enrolled in a Medicaid health maintenance
285 organization.

286 4. The agency may limit the size of its pharmacy network
287 based on need, competitive bidding, price negotiations,
288 credentialing, or similar criteria. The agency shall give
289 special consideration to rural areas in determining the size and
290 location of pharmacies included in the Medicaid pharmacy
291 network. A pharmacy credentialing process may include criteria
292 such as a pharmacy's full-service status, location, size,
293 patient educational programs, patient consultation, disease
294 management services, and other characteristics. The agency may
295 impose a moratorium on Medicaid pharmacy enrollment if it is
296 determined that it has a sufficient number of Medicaid-
297 participating providers. The agency must allow dispensing
298 practitioners to participate as a part of the Medicaid pharmacy
299 network regardless of the practitioner's proximity to any other
300 entity that is dispensing prescription drugs under the Medicaid

301 program. A dispensing practitioner must meet all credentialing
302 requirements applicable to his or her practice, as determined by
303 the agency.

304 5. The agency shall develop and implement a program that
305 requires Medicaid practitioners who issue written prescriptions
306 for medicinal drugs to use a counterfeit-proof prescription pad
307 for Medicaid prescriptions. The agency shall require the use of
308 standardized counterfeit-proof prescription pads by prescribers
309 who issue written prescriptions for Medicaid recipients. The
310 agency may implement the program in targeted geographic areas or
311 statewide.

312 6. The agency may enter into arrangements that require
313 manufacturers of generic drugs prescribed to Medicaid recipients
314 to provide rebates of at least 15.1 percent of the average
315 manufacturer price for the manufacturer's generic products.
316 These arrangements shall require that if a generic-drug
317 manufacturer pays federal rebates for Medicaid-reimbursed drugs
318 at a level below 15.1 percent, the manufacturer must provide a
319 supplemental rebate to the state in an amount necessary to
320 achieve a 15.1-percent rebate level.

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

326 the average manufacturer price as defined in 42 U.S.C. s. 1936
327 on the last day of a quarter unless the federal or supplemental
328 rebate, or both, equals or exceeds 29 percent. There is no upper
329 limit on the supplemental rebates the agency may negotiate. The
330 agency may determine that specific products, brand-name or
331 generic, are competitive at lower rebate percentages. Agreement
332 to pay the minimum supplemental rebate percentage guarantees a
333 manufacturer that the Medicaid Pharmaceutical and Therapeutics
334 Committee will consider a product for inclusion on the preferred
335 drug list. However, a pharmaceutical manufacturer is not
336 guaranteed placement on the preferred drug list by simply paying
337 the minimum supplemental rebate. Agency decisions will be made
338 on the clinical efficacy of a drug and recommendations of the
339 Medicaid Pharmaceutical and Therapeutics Committee, as well as
340 the price of competing products minus federal and state rebates.
341 The agency may contract with an outside agency or contractor to
342 conduct negotiations for supplemental rebates. For the purposes
343 of this section, the term "supplemental rebates" means cash
344 rebates. Value-added programs as a substitution for supplemental
345 rebates are prohibited. The agency may seek any federal waivers
346 to implement this initiative.

347 ~~8. The agency shall expand home delivery of pharmacy~~
348 ~~products. The agency may amend the state plan and issue a~~
349 ~~procurement, as necessary, in order to implement this program.~~
350 ~~The procurements must include agreements with a pharmacy or~~

351 ~~pharmacies located in the state to provide mail order delivery~~
352 ~~services at no cost to the recipients who elect to receive home~~
353 ~~delivery of pharmacy products. The procurement must focus on~~
354 ~~servng recipients with chronic diseases for which pharmacy~~
355 ~~expenditures represent a significant portion of Medicaid~~
356 ~~pharmacy expenditures or which impact a significant portion of~~
357 ~~the Medicaid population. The agency may seek and implement any~~
358 ~~federal waivers necessary to implement this subparagraph.~~

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

361 8.a.10.a. The agency may implement a Medicaid behavioral
362 drug management system. The agency may contract with a vendor
363 that has experience in operating behavioral drug management
364 systems to implement this program. The agency may seek federal
365 waivers to implement this program.

366 b. The agency, in conjunction with the Department of
367 Children and Families, may implement the Medicaid behavioral
368 drug management system that is designed to improve the quality
369 of care and behavioral health prescribing practices based on
370 best practice guidelines, improve patient adherence to
371 medication plans, reduce clinical risk, and lower prescribed
372 drug costs and the rate of inappropriate spending on Medicaid
373 behavioral drugs. The program may include the following
374 elements:

375 (I) Provide for the development and adoption of best

376 practice guidelines for behavioral health-related drugs such as
377 antipsychotics, antidepressants, and medications for treating
378 bipolar disorders and other behavioral conditions; translate
379 them into practice; review behavioral health prescribers and
380 compare their prescribing patterns to a number of indicators
381 that are based on national standards; and determine deviations
382 from best practice guidelines.

383 (II) Implement processes for providing feedback to and
384 educating prescribers using best practice educational materials
385 and peer-to-peer consultation.

386 (III) Assess Medicaid beneficiaries who are outliers in
387 their use of behavioral health drugs with regard to the numbers
388 and types of drugs taken, drug dosages, combination drug
389 therapies, and other indicators of improper use of behavioral
390 health drugs.

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

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

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

400 (VII) Disseminate electronic and published materials.

401 (VIII) Hold statewide and regional conferences.

402 (IX) Implement a disease management program with a model
 403 quality-based medication component for severely mentally ill
 404 individuals and emotionally disturbed children who are high
 405 users of care.

406 9.11. The agency shall implement a Medicaid prescription
 407 drug management system.

408 a. The agency may contract with a vendor that has
 409 experience in operating prescription drug management systems in
 410 order to implement this system. Any management system that is
 411 implemented in accordance with this subparagraph must rely on
 412 cooperation between physicians and pharmacists to determine
 413 appropriate practice patterns and clinical guidelines to improve
 414 the prescribing, dispensing, and use of drugs in the Medicaid
 415 program. The agency may seek federal waivers to implement this
 416 program.

417 b. The drug management system must be designed to improve
 418 the quality of care and prescribing practices based on best
 419 practice guidelines, improve patient adherence to medication
 420 plans, reduce clinical risk, and lower prescribed drug costs and
 421 the rate of inappropriate spending on Medicaid prescription
 422 drugs. The program must:

423 (I) Provide for the adoption of best practice guidelines
 424 for the prescribing and use of drugs in the Medicaid program,
 425 including translating best practice guidelines into practice;

426 reviewing prescriber patterns and comparing them to indicators
427 that are based on national standards and practice patterns of
428 clinical peers in their community, statewide, and nationally;
429 and determine deviations from best practice guidelines.

430 (II) Implement processes for providing feedback to and
431 educating prescribers using best practice educational materials
432 and peer-to-peer consultation.

433 (III) Assess Medicaid recipients who are outliers in their
434 use of a single or multiple prescription drugs with regard to
435 the numbers and types of drugs taken, drug dosages, combination
436 drug therapies, and other indicators of improper use of
437 prescription drugs.

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

442 ~~10.12.~~ The agency may contract for drug rebate
443 administration, including, but not limited to, calculating
444 rebate amounts, invoicing manufacturers, negotiating disputes
445 with manufacturers, and maintaining a database of rebate
446 collections.

447 ~~11.13.~~ The agency may specify the preferred daily dosing
448 form or strength for the purpose of promoting best practices
449 with regard to the prescribing of certain drugs as specified in
450 the General Appropriations Act and ensuring cost-effective

451 prescribing practices.

452 ~~12.14.~~ The agency may require prior authorization for
453 Medicaid-covered prescribed drugs. The agency may prior-
454 authorize the use of a product:

- 455 a. For an indication not approved in labeling;
456 b. To comply with certain clinical guidelines; or
457 c. If the product has the potential for overuse, misuse,
458 or abuse.

459

460 The agency may require the prescribing professional to provide
461 information about the rationale and supporting medical evidence
462 for the use of a drug. The agency shall post prior
463 authorization, step-edit criteria and protocol, and updates to
464 the list of drugs that are subject to prior authorization on the
465 agency's Internet website within 21 days after the prior
466 authorization and step-edit criteria and protocol and updates
467 are approved by the agency. For purposes of this subparagraph,
468 the term "step-edit" means an automatic electronic review of
469 certain medications subject to prior authorization.

470 ~~13.15.~~ The agency, in conjunction with the Pharmaceutical
471 and Therapeutics Committee, may require age-related prior
472 authorizations for certain prescribed drugs. The agency may
473 preauthorize the use of a drug for a recipient who may not meet
474 the age requirement or may exceed the length of therapy for use
475 of this product as recommended by the manufacturer and approved

476 by the Food and Drug Administration. Prior authorization may
477 require the prescribing professional to provide information
478 about the rationale and supporting medical evidence for the use
479 of a drug.

480 ~~14.16.~~ The agency shall implement a step-therapy prior
481 authorization approval process for medications excluded from the
482 preferred drug list. Medications listed on the preferred drug
483 list must be used within the previous 12 months before the
484 alternative medications that are not listed. The step-therapy
485 prior authorization may require the prescriber to use the
486 medications of a similar drug class or for a similar medical
487 indication unless contraindicated in the Food and Drug
488 Administration labeling. The trial period between the specified
489 steps may vary according to the medical indication. The step-
490 therapy approval process shall be developed in accordance with
491 the committee as stated in s. 409.91195(7) and (8). A drug
492 product may be approved without meeting the step-therapy prior
493 authorization criteria if the prescribing physician provides the
494 agency with additional written medical or clinical documentation
495 that the product is medically necessary because:

496 a. There is not a drug on the preferred drug list to treat
497 the disease or medical condition which is an acceptable clinical
498 alternative;

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

501 c. Based on historic evidence and known characteristics of
502 the patient and the drug, the drug is likely to be ineffective,
503 or the number of doses have been ineffective.

504

505 The agency shall work with the physician to determine the best
506 alternative for the patient. The agency may adopt rules waiving
507 the requirements for written clinical documentation for specific
508 drugs in limited clinical situations.

509 15.17. The agency shall implement a return and reuse
510 program for drugs dispensed by pharmacies to institutional
511 recipients, which includes payment of a \$5 restocking fee for
512 the implementation and operation of the program. The return and
513 reuse program shall be implemented electronically and in a
514 manner that promotes efficiency. The program must permit a
515 pharmacy to exclude drugs from the program if it is not
516 practical or cost-effective for the drug to be included and must
517 provide for the return to inventory of drugs that cannot be
518 credited or returned in a cost-effective manner. The agency
519 shall determine if the program has reduced the amount of
520 Medicaid prescription drugs which are destroyed on an annual
521 basis and if there are additional ways to ensure more
522 prescription drugs are not destroyed which could safely be
523 reused.

524 ~~(c) The agency shall submit quarterly reports to the~~
525 ~~Governor, the President of the Senate, and the Speaker of the~~

526 ~~House of Representatives which must include, but need not be~~
527 ~~limited to, the progress made in implementing this subsection~~
528 ~~and its effect on Medicaid prescribed drug expenditures.~~

529 Section 5. Section 409.91213, Florida Statutes, is
530 repealed.

531 Section 6. Paragraph (d) of subsection (1) of section
532 409.913, Florida Statutes, is amended to read:

533 409.913 Oversight of the integrity of the Medicaid
534 program.—The agency shall operate a program to oversee the
535 activities of Florida Medicaid recipients, and providers and
536 their representatives, to ensure that fraudulent and abusive
537 behavior and neglect of recipients occur to the minimum extent
538 possible, and to recover overpayments and impose sanctions as
539 appropriate. Each January 15, the agency and the Medicaid Fraud
540 Control Unit of the Department of Legal Affairs shall submit a
541 report to the Legislature documenting the effectiveness of the
542 state's efforts to control Medicaid fraud and abuse and to
543 recover Medicaid overpayments during the previous fiscal year.
544 The report must describe the number of cases opened and
545 investigated each year; the sources of the cases opened; the
546 disposition of the cases closed each year; the amount of
547 overpayments alleged in preliminary and final audit letters; the
548 number and amount of fines or penalties imposed; any reductions
549 in overpayment amounts negotiated in settlement agreements or by
550 other means; the amount of final agency determinations of

551 overpayments; the amount deducted from federal claiming as a
552 result of overpayments; the amount of overpayments recovered
553 each year; the amount of cost of investigation recovered each
554 year; the average length of time to collect from the time the
555 case was opened until the overpayment is paid in full; the
556 amount determined as uncollectible and the portion of the
557 uncollectible amount subsequently reclaimed from the Federal
558 Government; the number of providers, by type, that are
559 terminated from participation in the Medicaid program as a
560 result of fraud and abuse; and all costs associated with
561 discovering and prosecuting cases of Medicaid overpayments and
562 making recoveries in such cases. The report must also document
563 actions taken to prevent overpayments and the number of
564 providers prevented from enrolling in or reenrolling in the
565 Medicaid program as a result of documented Medicaid fraud and
566 abuse and must include policy recommendations necessary to
567 prevent or recover overpayments and changes necessary to prevent
568 and detect Medicaid fraud. All policy recommendations in the
569 report must include a detailed fiscal analysis, including, but
570 not limited to, implementation costs, estimated savings to the
571 Medicaid program, and the return on investment. The agency must
572 submit the policy recommendations and fiscal analyses in the
573 report to the appropriate estimating conference, pursuant to s.
574 216.137, by February 15 of each year. The agency and the
575 Medicaid Fraud Control Unit of the Department of Legal Affairs

576 each must include detailed unit-specific performance standards,
577 benchmarks, and metrics in the report, including projected cost
578 savings to the state Medicaid program during the following
579 fiscal year.

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

581 (d) "Medical necessity" or "medically necessary" means any
582 goods or services necessary to palliate the effects of a
583 terminal condition, or to prevent, diagnose, correct, cure,
584 alleviate, or preclude deterioration of a condition that
585 threatens life, causes pain or suffering, or results in illness
586 or infirmity, which goods or services are provided in accordance
587 with generally accepted standards of medical practice. For
588 purposes of determining Medicaid reimbursement, the agency is
589 the final arbiter of medical necessity. Determinations of
590 medical necessity must be made by a licensed physician employed
591 by or under contract with the agency, except for behavior
592 analysis services, which may be determined by either a licensed
593 physician or a doctoral-level board-certified behavior analyst.
594 Determinations ~~and~~ must be based upon information available at
595 the time the goods or services are requested ~~provided~~.

596 Section 7. Section 765.53, Florida Statutes, is repealed.

597 Section 8. Paragraph (e) of subsection (2) of section
598 409.815, Florida Statutes, is amended to read:

599 409.815 Health benefits coverage; limitations.—

600 (2) BENCHMARK BENEFITS.—In order for health benefits

601 coverage to qualify for premium assistance payments for an
602 eligible child under ss. 409.810-409.821, the health benefits
603 coverage, except for coverage under Medicaid and Medikids, must
604 include the following minimum benefits, as medically necessary.

605 (e) Organ transplantation services.—Covered services
606 include pretransplant, transplant, and postdischarge services
607 and treatment of complications after transplantation for
608 transplants deemed necessary and appropriate within the
609 guidelines set by ~~the Organ Transplant Advisory Council under s.~~
610 ~~765.53~~ or the Bone Marrow Transplant Advisory Panel under s.
611 627.4236.

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