

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.

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

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 and must be based upon~~  
592 ~~information available at the time the goods or services are~~  
593 ~~provided.~~

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 Section 765.53, Florida Statutes, is repealed.

595 Section 8. Paragraph (e) of subsection (2) of section  
596 409.815, Florida Statutes, is amended to read:

597 409.815 Health benefits coverage; limitations.—

598 (2) BENCHMARK BENEFITS.—In order for health benefits  
599 coverage to qualify for premium assistance payments for an  
600 eligible child under ss. 409.810-409.821, the health benefits



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601 coverage, except for coverage under Medicaid and Medikids, must  
602 include the following minimum benefits, as medically necessary.

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

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