1 A bill to be entitled
2 An act relating to pharmacy benefits managers;
3 amending s. 409.975, F.S.; prohibiting a managed care
4 plan from contracting with a pharmacy benefits manager
5 to manage the prescription drug coverage provided
6 under the plan unless certain requirements are met;
7 creating s. 465.1863, F.S.; requiring pharmacy
8 benefits managers to register with the Board of
9 Pharmacy; providing application requirements;
10 requiring renewal; creating s. 465.1864, F.S.;
11 providing definitions; creating s. 465.1865, F.S.;
12 requiring specified duties of pharmacy benefits
13 managers; creating s. 465.1866, F.S.; requiring
14 pharmacy benefits managers to create a process to
15 appeal predetermined reimbursement costs; providing
16 deadlines for the appeals process; creating s.
17 465.1867, F.S.; providing rulemaking authority;
18 creating s. 465.1868, F.S.; providing penalties;
19 creating s. 465.1869, F.S.; providing definitions;
20 providing applicability; providing copayment
21 requirements; authorizing a pharmacy to dispense
22 specialty drugs under certain conditions; providing
23 requirements; providing notice requirements; providing
24 construction; authorizing specified complaints to be
25 filed with the Commissioner on Insurance Regulation;

26 providing an effective date.
27
28 Be It Enacted by the Legislature of the State of Florida:
29
30 Section 1. Subsection (1) of section 409.975, Florida
31 Statutes, is amended to read:
32 409.975 Managed care plan accountability.—In addition to
33 the requirements of s. 409.967, plans and providers
34 participating in the managed medical assistance program shall
35 comply with the requirements of this section.
36 (1) PROVIDER NETWORKS.—Managed care plans must develop and
37 maintain provider networks that meet the medical needs of their
38 enrollees in accordance with standards established pursuant to
39 s. 409.967(2)(c). Except as provided in this section, managed
40 care plans may limit the providers in their networks based on
41 credentials, quality indicators, and price.
42 (a) A managed care plan may not enter into a contract with
43 a pharmacy benefits manager (PBM) to manage the prescription
44 drug coverage provided under the plan or to control the costs of
45 the prescription drug coverage under such plan unless:
46 1. The contract prevents the PBM from requiring that a
47 plan enrollee use a retail pharmacy or other pharmacy entity
48 providing pharmacy services in which the PBM has an ownership
49 interest or which has an ownership interest in the PBM, or the
50 contract provides an incentive to a plan enrollee to encourage

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51 the enrollee to use a retail pharmacy, mail order pharmacy,
52 specialty pharmacy, or other pharmacy entity providing pharmacy
53 services in which the PBM has an ownership interest or which has
54 an ownership interest in the PBM, if the incentive is applicable
55 only to such pharmacies; and
56 2. The contract requires the PBM to update the maximum
57 allowable cost as defined by s. 465.1862(1)(a) every 7 calendar
58 days beginning on January 1 of each year, to accurately reflect
59 the market price of acquiring the drug.
60 (b) Plans must include all providers in the region which
61 ~~that~~ are classified by the agency as essential Medicaid
62 providers, unless the agency approves, in writing, an
63 alternative arrangement for securing the types of services
64 offered by the essential providers. Providers are essential for
65 serving Medicaid enrollees if they offer services that are not
66 available from any other provider within a reasonable access
67 standard, or if they provided a substantial share of the total
68 units of a particular service used by Medicaid patients within
69 the region during the last 3 years and the combined capacity of
70 other service providers in the region is insufficient to meet
71 the total needs of the Medicaid patients. The agency may not
72 classify physicians and other practitioners as essential
73 providers. The agency, at a minimum, shall determine which
74 providers in the following categories are essential Medicaid
75 providers:

76 1. Federally qualified health centers.
77 2. Statutory teaching hospitals as defined in s.
78 408.07(45).
79 3. Hospitals that are trauma centers as defined in s.
80 395.4001(14).
81 4. Hospitals located at least 25 miles from any other
82 hospital with similar services.
83
84 Managed care plans that have not contracted with all essential
85 providers in the region as of the first date of recipient
86 enrollment, or with whom an essential provider has terminated
87 its contract, must negotiate in good faith with such essential
88 providers for 1 year or until an agreement is reached, whichever
89 is first. Payments for services rendered by a nonparticipating
90 essential provider shall be made at the applicable Medicaid rate
91 as of the first day of the contract between the agency and the
92 plan. A rate schedule for all essential providers shall be
93 attached to the contract between the agency and the plan. After
94 1 year, managed care plans that are unable to contract with
95 essential providers shall notify the agency and propose an
96 alternative arrangement for securing the essential services for
97 Medicaid enrollees. The arrangement must rely on contracts with
98 other participating providers, regardless of whether those
99 providers are located within the same region as the
100 nonparticipating essential service provider. If the alternative

101 arrangement is approved by the agency, payments to
102 nonparticipating essential providers after the date of the
103 agency's approval shall equal 90 percent of the applicable
104 Medicaid rate. Except for payment for emergency services, if the
105 alternative arrangement is not approved by the agency, payment
106 to nonparticipating essential providers shall equal 110 percent
107 of the applicable Medicaid rate.
108 (c) ~~(b)~~ Certain providers are statewide resources and
109 essential providers for all managed care plans in all regions.
110 All managed care plans must include these essential providers in
111 their networks. Statewide essential providers include:
112 1. Faculty plans of Florida medical schools.
113 2. Regional perinatal intensive care centers as defined in
114 s. 383.16(2).
115 3. Hospitals licensed as specialty children's hospitals as
116 defined in s. 395.002(28).
117 4. Accredited and integrated systems serving medically
118 complex children which comprise separately licensed, but
119 commonly owned, health care providers delivering at least the
120 following services: medical group home, in-home and outpatient
121 nursing care and therapies, pharmacy services, durable medical
122 equipment, and Prescribed Pediatric Extended Care.
123
124 Managed care plans that have not contracted with all statewide
125 essential providers in all regions as of the first date of

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126 recipient enrollment must continue to negotiate in good faith.
127 Payments to physicians on the faculty of nonparticipating
128 Florida medical schools shall be made at the applicable Medicaid
129 rate. Payments for services rendered by regional perinatal
130 intensive care centers shall be made at the applicable Medicaid
131 rate as of the first day of the contract between the agency and
132 the plan. Except for payments for emergency services, payments
133 to nonparticipating specialty children's hospitals shall equal
134 the highest rate established by contract between that provider
135 and any other Medicaid managed care plan.
136 (d) ~~(c)~~ After 12 months of active participation in a plan's
137 network, the plan may exclude any essential provider from the
138 network for failure to meet quality or performance criteria. If
139 the plan excludes an essential provider from the plan, the plan
140 must provide written notice to all recipients who have chosen
141 that provider for care. The notice shall be provided at least 30
142 days before the effective date of the exclusion. For purposes of
143 this paragraph, the term "essential provider" includes providers
144 determined by the agency to be essential Medicaid providers
145 under paragraph (b) ~~(a)~~ and the statewide essential providers
146 specified in paragraph (c) ~~(b)~~.
147 (e) ~~(d)~~ The applicable Medicaid rates for emergency
148 services paid by a plan under this section to a provider with
149 which the plan does not have an active contract shall be
150 determined according to s. 409.967(2)(b).

151 (f) ~~(e)~~ Each managed care plan must ~~may~~ offer a network
152 contract to each home medical equipment and supplies provider in
153 the region which meets quality and fraud prevention and
154 detection standards established by the plan and which agrees to
155 accept the lowest price previously negotiated between the plan
156 and another such provider.
157 Section 2. Section 465.1863, Florida Statutes, is created
158 to read:
159 465.1863 Registration of pharmacy benefits managers
160 required.—
161 (1) To conduct business in this state, a pharmacy benefits
162 manager must register with the board and maintain annual renewal
163 of his or registration.
164 (2) A person seeking to register as a pharmacy benefits
165 manager shall submit an application to the board, on a form
166 adopted by rule of the board, which includes the following:
167 (a) The name, business address, phone number, and contact
168 person for the pharmacy benefits manager.
169 (b) Where applicable, the federal tax employer
170 identification number for the entity.
171 (c) A registration fee established by the board by rule.
172 (3) To annually renew registration, a pharmacy benefits
173 manager shall pay a renewal fee established by the board by
174 rule.
175 Section 3. Section 465.1864, Florida Statutes, is created

176 to read:
177 465.1864 Definitions.—As used in sections 465.1863-
178 465.1869, the term:
179 (1) "Claim" means a request from a pharmacy or pharmacist
180 to be reimbursed for the cost of filling or refilling a
181 prescription for a drug or for providing a medical supply or
182 service.
183 (2) "Insurer" means an entity licensed under chapter 624
184 which offers an individual health insurance policy or a group
185 health insurance policy, a preferred provider organization as
186 defined in s. 627.6471, an exclusive provider organization as
187 defined in s. 627.6472, a health maintenance organization
188 licensed under part I of chapter 641, or a prepaid limited
189 health service organization or discount plan organization
190 licensed under chapter 636.
191 (3) "List" means the list of drugs for which predetermined
192 reimbursement costs have been established, such as a maximum
193 allowable cost list or any other benchmark price list utilized
194 by the pharmacy benefits manager, and which list includes the
195 basis of the methodology and sources utilized to determine
196 multisource generic drug reimbursement amounts.
197 (4) "Multiple source drug" means a therapeutically
198 equivalent drug that is available from at least two
199 manufacturers.
200 (5) "Multisource generic drug" means a covered outpatient

201 prescription drug for which there is at least one other drug
202 product that is rated as therapeutically equivalent under the
203 United States Food and Drug Administration's most recent
204 publication of its "Approved Drug Products with Therapeutic
205 Equivalence Evaluations" (Orange Book), is pharmaceutically
206 equivalent or bioequivalent as determined by the United States
207 Food and Drug Administration, and is sold or marketed in the
208 state during the period.
209 (6) "Network pharmacy" means a retail drug establishment
210 licensed as a pharmacy that contracts with a pharmacy benefits
211 manager.
212 (7) "Pharmacy benefits manager" means a person or entity
213 doing business in this state which contracts to administer or
214 manage prescription drug benefits on behalf of a health
215 insurance plan, as defined in former s. 627.6482, to residents
216 of this state and that:
217 (a) Processes claims for prescription drugs or medical
218 supplies or provides retail network management for pharmacies or
219 pharmacists;
220 (b) Pays pharmacies or pharmacists for prescription drugs
221 or medical supplies; or
222 (c) Negotiates rebates with manufacturers for drugs paid
223 for or procured.
224 (8) Therapeutically equivalent" means a drug product of
225 the identical base or salt as the specific drug product

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226 prescribed with essentially the same efficacy and toxicity when
227 administered to an individual in the same dosage regimen.
228 Section 4. Section 465.1865, Florida Statutes, is created
229 to read:
230 465.1865 Duties of a pharmacy benefits manager.—
231 (1) A pharmacy benefits manager may not place a drug on a
232 list unless there are at least two multiple source drugs, or at
233 least one generic drug available from only one manufacturer,
234 generally available for purchase by a network pharmacy from a
235 national or regional manufacturer or wholesaler.
236 (2) A pharmacy benefits manager shall:
237 (a) Ensure that all drugs on a list are readily available
238 for purchase by a pharmacy in the state from a national or
239 regional manufacturer or wholesaler.
240 (b) Make available to each network pharmacy, at the
241 beginning of the term of a contract with such network pharmacy
242 and upon the renewal of such contract, the sources utilized to
243 determine the predetermined reimbursement costs for multisource
244 generic drugs.
245 (c) Upon request, make a list available to a network
246 pharmacy in a readily accessible and usable format.
247 (d) Update each list maintained by the pharmacy benefits
248 manager every seven business days and make such lists, including
249 all changes in the price of drugs, available to a network
250 pharmacy in a readily accessible and usable format.

251 (e) Ensure that dispensing fees are not included in the
252 calculation of the predetermined reimbursement costs for
253 multisource generic drugs.
254 Section 5. Section 465.1866, Florida Statutes, is created
255 to read:
256 465.1866 Appeals process.—A pharmacy benefits manager
257 shall establish a process by which a network pharmacy with fewer
258 than 15 retail locations in the state may appeal a predetermined
259 reimbursement cost for a multisource generic drug if the
260 reimbursement for the drug is less than the net amount that the
261 network pharmacy paid to the drug manufacturer or wholesaler.
262 (1) An appeal requested under this section must be
263 completed within 30 calendar days of the network pharmacy's
264 submission of its appeal. If, after 30 calendar days, the
265 network pharmacy has not received a decision on its appeal from
266 the pharmacy benefits manager, the appeal is deemed denied.
267 (2) The pharmacy benefits manager shall uphold an appeal
268 submitted by a network pharmacy if the pharmacy or pharmacist
269 can demonstrate that it is unable to purchase a therapeutically
270 equivalent drug product from a drug manufacturer or wholesaler
271 doing business in the state at the pharmacy benefits manager's
272 list price for such drug product.
273 (3) As part of the appeals process established under this
274 section, a pharmacy benefits manager must provide:
275 (a) A telephone number at which a network pharmacy may

276 contact the pharmacy benefits manager and speak with an
277 individual who is responsible for processing appeals.
278 (b) If an appeal is denied, the reason for the denial and
279 the national drug code of a drug that has been purchased by
280 other network pharmacies in the state at a price that is equal
281 to or less than the predetermined reimbursement cost for the
282 multisource generic drug.
283 (4) If an appeal is upheld, the pharmacy benefits manager
284 shall make a reasonable adjustment to the price no later than
285 one day after the date of determination.
286 (5) If an appeal is denied, or if the network pharmacy is
287 unsatisfied with the outcome of the appeal, the pharmacy or
288 pharmacist may dispute the decision and request review by the
289 board within 30 calendar days of receiving a decision.
290 (6) The board may render a binding decision in a dispute
291 between a pharmacy benefits manager and a pharmacy arising out
292 of an appeal under this section.
293 (a) After reviewing all relevant information in the
294 appeal, the board may direct the pharmacy benefits manager to
295 make an adjustment to the disputed claim, deny the appeal, or
296 take other action deemed fair and equitable.
297 (b) Upon the resolution of the dispute, the board shall
298 provide a copy of the final decision to both parties within 7
299 calendar days.
300 (c) The board may authorize the department to resolve

301 disputes under this subsection.
302 (7) This section applies only to a network pharmacy with
303 fewer than 15 retail locations in the state.
304 Section 6. Section 465.1867, Florida Statutes, is created
305 to read:
306 465.1867 Rulemaking authority.—The board may adopt rules
307 to implement and establish registration and renewal fees
308 sufficient for oversight of ss. 465.1863-465.1869.
309 Section 7. Section 465.1868, Florida Statutes, is created
310 to read:
311 465.1868 Penalties.—A pharmacy benefits manager that
312 knowingly and willfully misleads consumers or other businesses
313 or violates s. 465.1863, s. 465.1865, or s. 465.1866 commits an
314 unfair and deceptive trade practice, as prohibited by s.
315 501.204(1), and is subject to a civil penalty, pursuant to s.
316 501.2075, in the amount of $10,000 for each violation.
317 Section 8. Section 465.1869, Florida Statutes, is created
318 to read:
319 465.1869 Authority to dispense specialty drugs.—
320 (1) As used in this section, the term:
321 (a) "Complex or chronic medical condition" means a
322 physical, behavioral, or developmental condition that may have
323 no known cure, is progressive, or can be debilitating or fatal
324 if left untreated or undertreated. The term includes multiple
325 sclerosis, hepatitis C, and rheumatoid arthritis.

326 (b) "Managed care system" means a system of cost
327 containment methods that an insurer, a nonprofit health service
328 plan, or a health maintenance organization uses to review and
329 preauthorize drugs prescribed by a health care provider for a
330 covered individual to control utilization, quality, and claims.
331 (c) "Rare medical condition" means a disease or condition
332 that affects fewer than 200,000 individuals in the United States
333 or approximately 1 in 1,500 individuals worldwide. The term
334 includes cystic fibrosis, hemophilia, and multiple myeloma.
335 (d) "Specialty drug" means a prescription drug that:
336 1. Is prescribed for an individual with a complex or
337 chronic medical condition or a rare medical condition;
338 2. Costs $600 or more for up to a 30-day supply;
339 3. Is not typically stocked at retail pharmacies; and
340 4.a. Requires a difficult or unusual process of delivery
341 to the patient in the preparation, handling, storage, inventory,
342 or distribution of the drug; or
343 b. Requires enhanced patient education, management, or
344 support, beyond those required for traditional dispensing,
345 before or after administration of the drug.
346 (2) This section applies to:
347 (a) Insurers and nonprofit health service plans that
348 provide coverage for prescription drugs under individual, group,
349 or blanket health insurance policies or contracts that are
350 issued or delivered in the state; and

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351 (b) Health maintenance organizations that provide coverage
352 for prescription drugs under individual or group contracts that
353 are issued or delivered in the state.
354 (3)(a) Subject to paragraph (b), an entity subject to this
355 section may not impose a copayment or coinsurance requirement on
356 a covered specialty drug that exceeds $150 for up to a 30-day
357 supply of the specialty drug.
358 (b) On July 1 of each year, the limit on the copayment or
359 coinsurance requirement on a covered specialty drug shall
360 increase by a percentage equal to the percentage change from the
361 preceding year in the medical care component of the March
362 Consumer Price Index for All Urban Consumers, U.S. City Average,
363 from the U.S. Department of Labor, Bureau of Labor Statistics.
364 (4)(a) This section does not preclude an entity subject to
365 this section from requiring a covered specialty drug to be
366 obtained through:
367 1.a. A designated pharmacy or other source authorized
368 under chapter 465 to dispense or administer prescription drugs;
369 or
370 b. A pharmacy participating in the entity's provider
371 network, if the entity determines that the pharmacy:
372 (I) Is licensed under the chapter 465;
373 (II) Meets the entity's performance standards;
374 (III) Has in inventory or is able to readily obtain the
375 covered specialty drug from the manufacturer; and

376 (IV) Accepts the entity's network reimbursement rates.
377 (b) An entity subject to this section shall post its
378 performance standards on the entity's web site.
379 (5)(a) A pharmacy registered under s. 340B of the Public
380 Health Services Act may apply to be a designated pharmacy under
381 subparagraph (4)(a)1. for the purpose of enabling the pharmacy's
382 patients with HIV, AIDS, or hepatitis C to receive the copayment
383 or coinsurance maximum provided for in subsection (3) if:
384 1. The pharmacy is owned by a federally qualified health
385 center, as defined in 42 U.S.C. s. 254B;
386 2. The federally qualified health center provides
387 integrated and coordinated medical and pharmaceutical services
388 to patients with HIV, AIDS, or hepatitis C; and
389 3. The prescription drugs are covered specialty drugs for
390 the treatment of HIV, AIDS, or hepatitis C.
391 (b) An entity subject to this section may not unreasonably
392 withhold approval of a pharmacy's application under paragraph
393 (a).
394 (6)(a) An entity subject to this section that denies a
395 request of a pharmacy participating in the entity's network for
396 authorization to dispense a covered specialty drug shall notify
397 the pharmacy of the reason for the denial.
398 (b) The notice required under paragraph (a) must be in
399 writing and state the specific reason for the denial.
400 (7) This subsection does not prohibit a manufacturer from

401 establishing a limited distribution network for one or more of
402 manufacturer's specialty drugs.
403 (8) A determination by an entity subject to this section
404 that a prescription drug is not a specialty drug is considered a
405 denial under s. 627.6141.
406 (9) Complaints may be filed with the Commissioner of
407 Insurance Regulation under this subsection if the entity made
408 its determination that a prescription drug is not a specialty
409 drug on the basis that the prescription drug is not prescribed
410 for an individual with a complex or chronic medical condition or
411 a rare medical condition. For such complaints:
412 (a) The commissioner may seek advice from an independent
413 review organization or medical expert; and
414 (b) The expenses for any advice provided by an independent
415 review organization or medical expert shall be paid for as
416 follows:
417 1. The carrier that is the subject of the complaint is
418 responsible for paying the reasonable expenses of the
419 independent review organization or medical expert selected by
420 the commissioner in accordance with paragraph (a).
421 2. The independent review organization or medical expert
422 shall:
423 a. Present to the carrier for payment a detailed account
424 of the expenses incurred by the independent review organization
425 or medical expert; and

426 b. Provide a copy of the detailed account of expenses to
427 the commissioner.
428 Section 9. This act shall take effect July 1, 2018.

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