

By Senator Gaetz

1-00098B-16

20161084__

1 A bill to be entitled
2 An act relating to health care protocols; providing a
3 short title; amending s. 409.967, F.S.; requiring a
4 managed care plan to establish a process by which a
5 prescribing physician may request an override of
6 certain restrictions in certain circumstances;
7 providing the circumstances under which an override
8 must be granted; defining the term "fail-first
9 protocol"; creating s. 627.6466, F.S.; requiring an
10 insurer to establish a process by which a prescribing
11 physician may request an override of certain
12 restrictions in certain circumstances; providing the
13 circumstances under which an override must be granted;
14 defining the term "fail-first protocol"; amending s.
15 641.31, F.S.; prohibiting a health maintenance
16 organization from requiring that a health care
17 provider use a clinical decision support system or a
18 laboratory benefits management program in certain
19 circumstances; defining terms; providing for
20 construction; creating s. 641.394, F.S.; requiring a
21 health maintenance organization to establish a process
22 by which a prescribing physician may request an
23 override of certain restrictions in certain
24 circumstances; providing the circumstances under which
25 an override must be granted; defining the term "fail-
26 first protocol"; providing an effective date.

27
28 Be It Enacted by the Legislature of the State of Florida:

29
30 Section 1. This act may be known as the "Right Medicine
31 Right Time Act."

32 Section 2. Paragraph (c) of subsection (2) of section

1-00098B-16

20161084__

33 409.967, Florida Statutes, is amended to read:

34 409.967 Managed care plan accountability.—

35 (2) The agency shall establish such contract requirements
36 as are necessary for the operation of the statewide managed care
37 program. In addition to any other provisions the agency may deem
38 necessary, the contract must require:

39 (c) Access.—

40 1. The agency shall establish specific standards for the
41 number, type, and regional distribution of providers in managed
42 care plan networks to ensure access to care for both adults and
43 children. Each plan must maintain a regionwide network of
44 providers in sufficient numbers to meet the access standards for
45 specific medical services for all recipients enrolled in the
46 plan. The exclusive use of mail-order pharmacies may not be
47 sufficient to meet network access standards. Consistent with the
48 standards established by the agency, provider networks may
49 include providers located outside the region. A plan may
50 contract with a new hospital facility before the date the
51 hospital becomes operational if the hospital has commenced
52 construction, will be licensed and operational by January 1,
53 2013, and a final order has issued in any civil or
54 administrative challenge. Each plan shall establish and maintain
55 an accurate and complete electronic database of contracted
56 providers, including information about licensure or
57 registration, locations and hours of operation, specialty
58 credentials and other certifications, specific performance
59 indicators, and such other information as the agency deems
60 necessary. The database must be available online to both the
61 agency and the public and have the capability to compare the

1-00098B-16

20161084__

62 availability of providers to network adequacy standards and to
63 accept and display feedback from each provider's patients. Each
64 plan shall submit quarterly reports to the agency identifying
65 the number of enrollees assigned to each primary care provider.

66 2.a. Each managed care plan must publish any prescribed
67 drug formulary or preferred drug list on the plan's website in a
68 manner that is accessible to and searchable by enrollees and
69 providers. The plan must update the list within 24 hours after
70 making a change. Each plan must ensure that the prior
71 authorization process for prescribed drugs is readily accessible
72 to health care providers, including posting appropriate contact
73 information on its website and providing timely responses to
74 providers. For Medicaid recipients diagnosed with hemophilia who
75 have been prescribed anti-hemophilic-factor replacement
76 products, the agency shall provide for those products and
77 hemophilia overlay services through the agency's hemophilia
78 disease management program.

79 b. If a managed care plan restricts the use of prescribed
80 drugs through a fail-first protocol, it must establish a clear
81 and convenient process that a prescribing physician may use to
82 request an override of the restriction from the managed care
83 plan. The managed care plan shall grant an override of the
84 protocol within 24 hours if:

85 (I) Based on sound clinical evidence, the prescribing
86 provider concludes that the preferred treatment required under
87 the fail-first protocol has been ineffective in the treatment of
88 the enrollee's disease or medical condition; or

89 (II) Based on sound clinical evidence or medical and
90 scientific evidence, the prescribing provider believes that the

1-00098B-16

20161084__

91 preferred treatment required under the fail-first protocol:

92 (A) Is likely to be ineffective given the known relevant
93 physical or mental characteristics and medical history of the
94 enrollee and the known characteristics of the drug regimen; or

95 (B) Will cause or is likely to cause an adverse reaction or
96 other physical harm to the enrollee.

97
98 If the prescribing provider follows the fail-first protocol
99 recommended by the managed care plan for an enrollee, the
100 duration of treatment under the fail-first protocol may not
101 exceed a period deemed appropriate by the prescribing provider.
102 Following such period, if the prescribing provider deems the
103 treatment provided under the protocol clinically ineffective,
104 the enrollee is entitled to receive the course of therapy that
105 the prescribing provider recommends, and the provider is not
106 required to seek approval of an override of the fail-first
107 protocol. As used in this subparagraph, the term "fail-first
108 protocol" means a prescription practice that begins medication
109 for a medical condition with the most cost-effective drug
110 therapy and progresses to other more costly or risky therapies
111 only if necessary.

112 3. Managed care plans, and their fiscal agents or
113 intermediaries, must accept prior authorization requests for any
114 service electronically.

115 4. Managed care plans serving children in the care and
116 custody of the Department of Children and Families shall ~~must~~
117 maintain complete medical, dental, and behavioral health
118 encounter information and participate in making such information
119 available to the department or the applicable contracted

1-00098B-16

20161084__

120 community-based care lead agency for use in providing
121 comprehensive and coordinated case management. The agency and
122 the department shall establish an interagency agreement to
123 provide guidance for the format, confidentiality, recipient,
124 scope, and method of information to be made available and the
125 deadlines for submission of the data. The scope of information
126 available to the department are ~~shall be~~ the data that managed
127 care plans are required to submit to the agency. The agency
128 shall determine the plan's compliance with standards for access
129 to medical, dental, and behavioral health services; the use of
130 medications; and followup on all medically necessary services
131 recommended as a result of early and periodic screening,
132 diagnosis, and treatment.

133 Section 3. Section 627.6466, Florida Statutes, is created
134 to read:

135 627.6466 Fail-first protocols.—If an insurer restricts the
136 use of prescribed drugs through a fail-first protocol, it must
137 establish a clear and convenient process that a prescribing
138 physician may use to request an override of the restriction from
139 the insurer. The insurer shall grant an override of the protocol
140 within 24 hours if:

141 (1) Based on sound clinical evidence, the prescribing
142 provider concludes that the preferred treatment required under
143 the fail-first protocol has been ineffective in the treatment of
144 the insured's disease or medical condition; or

145 (2) Based on sound clinical evidence or medical and
146 scientific evidence, the prescribing provider believes that the
147 preferred treatment required under the fail-first protocol:

148 (a) Is likely to be ineffective given the known relevant

1-00098B-16

20161084__

149 physical or mental characteristics and medical history of the
150 insured and the known characteristics of the drug regimen; or
151 (b) Will cause or is likely to cause an adverse reaction or
152 other physical harm to the insured.

153
154 If the prescribing provider follows the fail-first protocol
155 recommended by the insurer for an insured, the duration of
156 treatment under the fail-first protocol may not exceed a period
157 deemed appropriate by the prescribing provider. Following such
158 period, if the prescribing provider deems the treatment provided
159 under the protocol clinically ineffective, the insured is
160 entitled to receive the course of therapy that the prescribing
161 provider recommends, and the provider is not required to seek
162 approval of an override of the fail-first protocol. As used in
163 this section, the term "fail-first protocol" means a
164 prescription practice that begins medication for a medical
165 condition with the most cost-effective drug therapy and
166 progresses to other more costly or risky therapies only if
167 necessary.

168 Section 4. Subsection (44) is added to section 641.31,
169 Florida Statutes, to read:

170 641.31 Health maintenance contracts.—

171 (44) A health maintenance organization may not require a
172 health care provider, by contract with another health care
173 provider, a patient, or another individual or entity, to use a
174 clinical decision support system or a laboratory benefits
175 management program before the provider may order clinical
176 laboratory services or in an attempt to direct or limit the
177 provider's medical decisionmaking relating to the use of such

1-00098B-16

20161084__

178 services. This subsection may not be construed to prohibit any
179 prior authorization requirements that the health maintenance
180 organization may have regarding the provision of clinical
181 laboratory services. As used in this subsection, the term:

182 (a) "Clinical decision support system" means software
183 designed to direct or assist clinical decisionmaking by matching
184 the characteristics of an individual patient to a computerized
185 clinical knowledge base and providing patient-specific
186 assessments or recommendations based on the match.

187 (b) "Clinical laboratory services" means the examination of
188 fluids or other materials taken from the human body, which
189 examination is ordered by a health care provider for use in the
190 diagnosis, prevention, or treatment of a disease or in the
191 identification or assessment of a medical or physical condition.

192 (c) "Laboratory benefits management program" means a health
193 maintenance organization protocol that dictates or limits health
194 care provider decisionmaking relating to the use of clinical
195 laboratory services.

196 Section 5. Section 641.394, Florida Statutes, is created to
197 read:

198 641.394 Fail-first protocols.—If a health maintenance
199 organization restricts the use of prescribed drugs through a
200 fail-first protocol, it must establish a clear and convenient
201 process that a prescribing physician may use to request an
202 override of the restriction from the health maintenance
203 organization. The health maintenance organization shall grant an
204 override of the protocol within 24 hours if:

205 (1) Based on sound clinical evidence, the prescribing
206 provider concludes that the preferred treatment required under

1-00098B-16

20161084__

207 the fail-first protocol has been ineffective in the treatment of
208 the subscriber's disease or medical condition; or

209 (2) Based on sound clinical evidence or medical and
210 scientific evidence, the prescribing provider believes that the
211 preferred treatment required under the fail-first protocol:

212 (a) Is likely to be ineffective given the known relevant
213 physical or mental characteristics and medical history of the
214 subscriber and the known characteristics of the drug regimen; or

215 (b) Will cause or is likely to cause an adverse reaction or
216 other physical harm to the subscriber.

217
218 If the prescribing provider follows the fail-first protocol
219 recommended by the health maintenance organization for a
220 subscriber, the duration of treatment under the fail-first
221 protocol may not exceed a period deemed appropriate by the
222 prescribing provider. Following such period, if the prescribing
223 provider deems the treatment provided under the protocol
224 clinically ineffective, the subscriber is entitled to receive
225 the course of therapy that the prescribing provider recommends,
226 and the provider is not required to seek approval of an override
227 of the fail-first protocol. As used in this section, the term
228 "fail-first protocol" means a prescription practice that begins
229 medication for a medical condition with the most cost-effective
230 drug therapy and progresses to other more costly or risky
231 therapies only if necessary.

232 Section 6. This act shall take effect July 1, 2016.