1 A bill to be entitled 2 An act relating to health insurance restrictions on 3 prescription medication protocols; providing a short 4 title; amending s. 409.967, F.S., and creating ss. 5 627.6466 and 641.393, F.S.; requiring a Medicaid 6 managed care plan, an insurer, or a health maintenance 7 organization to allow a prescribing provider to request an override of a restriction on the use of 8 9 medication imposed through a step-therapy or fail-10 first protocol; requiring the plan, insurer, or health 11 maintenance organization to grant such override within 12 a specified timeframe under certain circumstances; 13 prohibiting the duration of a step-therapy or fail-14 first protocol from exceeding the time period 15 specified by the prescribing provider; providing that 16 an override is not required under certain 17 circumstances; providing an effective date. 18 19 Be It Enacted by the Legislature of the State of Florida: 20 21 Section 1. This act may be cited as the "Florida Patient 22 Protection Act." 23 Section 2. Paragraph (c) of subsection (2) of section 24 409.967, Florida Statutes, is amended to read: 25 409.967 Managed care plan accountability.-26 The agency shall establish such contract requirements (2)Page 1 of 8

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as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

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(c) Access.-

31 1. The agency shall establish specific standards for the 32 number, type, and regional distribution of providers in managed 33 care plan networks to ensure access to care for both adults and 34 children. Each plan must maintain a regionwide network of 35 providers in sufficient numbers to meet the access standards for 36 specific medical services for all recipients enrolled in the 37 plan. The exclusive use of mail-order pharmacies may not be 38 sufficient to meet network access standards. Consistent with the 39 standards established by the agency, provider networks may 40 include providers located outside the region. A plan may contract with a new hospital facility before the date the 41 42 hospital becomes operational if the hospital has commenced 43 construction, will be licensed and operational by January 1, 44 2013, and a final order has issued in any civil or administrative challenge. Each plan shall establish and maintain 45 46 an accurate and complete electronic database of contracted 47 providers, including information about licensure or 48 registration, locations and hours of operation, specialty 49 credentials and other certifications, specific performance indicators, and such other information as the agency deems 50 necessary. The database must be available online to both the 51 52 agency and the public and have the capability to compare the

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

57 2. Each managed care plan must publish any prescribed drug 58 formulary or preferred drug list on the plan's website in a 59 manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after 60 making a change. Each plan must ensure that the prior 61 62 authorization process for prescribed drugs is readily accessible 63 to health care providers, including posting appropriate contact 64 information on its website and providing timely responses to providers. For Medicaid recipients diagnosed with hemophilia who 65 66 have been prescribed anti-hemophilic-factor replacement 67 products, the agency shall provide for those products and 68 hemophilia overlay services through the agency's hemophilia 69 disease management program.

70 3. Managed care plans, and their fiscal agents or 71 intermediaries, must accept prior authorization requests for any 72 service electronically.

4. Managed care plans serving children in the care and custody of the Department of Children and Families must maintain complete medical, dental, and behavioral health encounter information and participate in making such information available to the department or the applicable contracted community-based care lead agency for use in providing comprehensive and

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79 coordinated case management. The agency and the department shall establish an interagency agreement to provide guidance for the format, confidentiality, recipient, scope, and method of information to be made available and the deadlines for submission of the data. The scope of information available to the department shall be the data that managed care plans are required to submit to the agency. The agency shall determine the plan's compliance with standards for access to medical, dental, and behavioral health services; the use of medications; and followup on all medically necessary services recommended as a result of early and periodic screening, diagnosis, and treatment.

91 5. If medication for the treatment of a medical condition is restricted for use by a managed care plan through a step-92 therapy or fail-first protocol, the prescribing provider shall 93 94 have access to a clear and convenient process to request an 95 override of such restriction from the managed care plan. The managed care plan shall grant an override of the protocol within 96 97 24 hours if: 98 a. The prescribing provider determines, based on sound 99 clinical evidence, that the preferred treatment required under 100 the step-therapy or fail-first protocol has been ineffective in 101 the treatment of the enrollee's disease or medical condition; or 102 The prescribing provider believes, based on sound b.

104 preferred treatment required under the step-therapy or fail-

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clinical evidence or medical and scientific evidence, that the

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105	<u>first protocol:</u>
106	(I) Is expected to, or is likely to, be ineffective given
107	the known relevant physical or mental characteristics and
108	medical history of the enrollee and the known characteristics of
109	the drug regimen; or
110	(II) Will cause, or is likely to cause, an adverse
111	reaction or other physical harm to the enrollee.
112	6. If the prescribing provider allows the enrollee to
113	enter the step-therapy or fail-first protocol recommended by the
114	managed care plan, the duration of the step-therapy or fail-
115	first protocol may not exceed a period deemed appropriate by the
116	prescribing provider. If the prescribing provider deems the
117	treatment clinically ineffective, the enrollee is entitled to
118	receive the recommended course of therapy without requiring the
119	prescribing provider to seek approval for an override of the
120	step-therapy or fail-first protocol.
121	Section 3. Section 627.6466, Florida Statutes, is created
122	to read:
123	627.6466 Fail-first protocolsIf medication for the
124	treatment of a medical condition is restricted for use by an
125	insurer through a step-therapy or fail-first protocol, the
126	prescribing provider shall have access to a clear and convenient
127	process to request an override of such restriction from the
128	insurer. The insurer shall grant an override of the protocol
129	within 24 hours if:
130	(1) The prescribing provider determines, based on sound
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131	clinical evidence, that the preferred treatment required under
132	the step-therapy or fail-first protocol has been ineffective in
133	the treatment of the insured's disease or medical condition; or
134	(2) The prescribing provider believes, based on sound
135	clinical evidence or medical and scientific evidence, that the
136	preferred treatment required under the step-therapy or fail-
137	first protocol:
138	(a) Is expected to, or is likely to, be ineffective given
139	the known relevant physical or mental characteristics and
140	medical history of the insured and the known characteristics of
141	the drug regimen; or
142	(b) Will cause, or is likely to cause, an adverse reaction
143	or other physical harm to the insured.
144	(3) If the prescribing provider allows the insured to
145	enter the step-therapy or fail-first protocol recommended by the
146	insurer, the duration of the step-therapy or fail-first protocol
147	may not exceed a period deemed appropriate by the prescribing
148	provider. If the prescribing provider deems the treatment
149	clinically ineffective, the insured is entitled to receive the
150	recommended course of therapy without requiring the prescribing
151	provider to seek approval for an override of the step-therapy or
152	fail-first protocol.
153	Section 4. Section 641.393, Florida Statutes, is created
154	to read:
155	641.393 Fail-first protocolsIf medication for the
156	treatment of a medical condition is restricted for use by a
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157 health maintenance organization through a step-therapy or fail-158 first protocol, the prescribing provider shall have access to a 159 clear and convenient process to request an override of such restriction from the organization. The health maintenance 160 161 organization shall grant an override of the protocol within 24 162 hours if: 163 (1) The prescribing provider determines, based on sound 164 clinical evidence, that the preferred treatment required under 165 the step-therapy or fail-first protocol has been ineffective in 166 the treatment of the subscriber's disease or medical condition; 167 or (2) 168 The prescribing provider believes, based on sound 169 clinical evidence or medical and scientific evidence, that the 170 preferred treatment required under the step-therapy or fail-171 first protocol: (a) 172 Is expected to, or is likely to, be ineffective given 173 the known relevant physical or mental characteristics and 174 medical history of the subscriber and the known characteristics 175 of the drug regimen; or 176 (b) Will cause, or is likely to cause, an adverse reaction 177 or other physical harm to the subscriber. 178 (3) If the prescribing provider allows the subscriber to 179 enter the step-therapy or fail-first protocol recommended by the 180 health maintenance organization, the duration of the step-181 therapy or fail-first protocol may not exceed a period deemed 182 appropriate by the prescribing provider. If the prescribing

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183 provider deems the treatment clinically ineffective, the 184 subscriber is entitled to receive the recommended course of 185 therapy without requiring the prescribing provider to seek 186 approval for an override of the step-therapy or fail-first 187 protocol. 188 Section 5. This act shall take effect July 1, 2016.

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