

## CHAPTER 2022-47

### House Bill No. 459

An act relating to step-therapy protocols; amending s. 627.42393, F.S.; revising the circumstances under which step-therapy protocols may not be required; defining terms; requiring health insurers to publish on their websites and provide to their insureds specified information; providing requirements for procedures for requests and appeals of denials of protocol exemptions; providing requirements for authorizations and denials of protocol exemption requests; authorizing health insurers to request specified documentation under certain circumstances; amending s. 641.31, F.S.; revising the circumstances under which step-therapy protocols may not be required; defining terms; requiring health maintenance organizations to publish on their websites and provide to their subscribers specified information; providing requirements for procedures for requests and appeals of denials of protocol exemptions; providing requirements for authorizations and denials of protocol exemption requests; authorizing health maintenance organizations to request specified documentation under certain circumstances; providing an effective date.

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

Section 1. Section 627.42393, Florida Statutes, is amended to read:

627.42393 Step-therapy protocol.—

(1)(2) As used in this section, the term:

(a) “Health coverage plan” means any of the following which is currently or was previously providing major medical or similar comprehensive coverage or benefits to the insured:

1.(a) A health insurer or health maintenance organization.

2.(b) A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.

3.(c) A multiple-employer welfare arrangement as defined in s. 624.437.

4.(d) A governmental entity providing a plan of self-insurance.

(b) “Protocol exemption” means a determination by a health insurer to authorize the use of another prescription drug, medical procedure, or course of treatment prescribed or recommended by the treating health care provider for the insured’s condition rather than the one specified by the health insurer’s step-therapy protocol.

(c) “Step-therapy protocol” means a written protocol that specifies the order in which certain prescription drugs, medical procedures, or courses of treatment must be used to treat an insured’s condition.

(2)(1) In addition to the protocol exemptions granted under subsection (3), a health insurer issuing a major medical individual or group policy may not require a step-therapy protocol under the policy for a covered prescription drug requested by an insured if:

(a) The insured has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

(b) The insured provides documentation originating from the health coverage plan that approved the prescription drug as described in paragraph (a) indicating that the health coverage plan paid for the drug on the insured’s behalf during the 90 days immediately before the request.

(3)(a) A health insurer shall publish on its website and provide to an insured in writing a procedure for the insured and his or her health care provider to request a protocol exemption or an appeal of the health insurer’s denial of a protocol exemption request. The procedure must include, at a minimum:

1. The manner in which the insured or health care provider may request a protocol exemption, including a form to request the protocol exemption.

2. The manner and timeframe in which the health insurer authorizes or denies a protocol exemption request, which must occur within a reasonable time.

3. The manner and timeframe in which the insured or health care provider may appeal the health insurer’s denial of a protocol exemption request.

(b) An authorization of a protocol exemption request must specify the approved prescription drug, medical procedure, or course of treatment. A denial of a protocol exemption request must include a written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure for appealing the health insurer’s denial.

(c) A health insurer may request relevant medical records in support of a protocol exemption request.

(4)(3) This section does not require a health insurer to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer does not otherwise cover.

Section 2. Subsection (46) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(46)~~(a)~~(b) As used in this subsection, the term:

1. “Health coverage plan” means any of the following which previously provided or is currently providing major medical or similar comprehensive coverage or benefits to the subscriber:

a.1. A health insurer or health maintenance organization.;

b.2. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.;

c.3. A multiple-employer welfare arrangement as defined in s. 624.437.;

d.4. A governmental entity providing a plan of self-insurance.

2. “Protocol exemption” means a determination by a health maintenance organization to authorize the use of another prescription drug, medical procedure, or course of treatment prescribed or recommended by the treating health care provider for the subscriber’s condition rather than the one specified by the health maintenance organization’s step-therapy protocol.

3. “Step-therapy protocol” means a written protocol that specifies the order in which certain prescription drugs, medical procedures, or courses of treatment must be used to treat a subscriber’s condition.

~~(b)(a)~~ In addition to the protocol exemptions granted under paragraph (c), a health maintenance organization issuing major medical coverage through an individual or group contract may not require a step-therapy protocol under the contract for a covered prescription drug requested by a subscriber if:

1. The subscriber has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

2. The subscriber provides documentation originating from the health coverage plan that approved the prescription drug as described in subparagraph 1. indicating that the health coverage plan paid for the drug on the subscriber’s behalf during the 90 days immediately before the request.

(c)1. A health maintenance organization shall publish on its website and provide to a subscriber in writing a procedure for the subscriber and his or her health care provider to request a protocol exemption or an appeal of the health maintenance organization’s denial of a protocol exemption request. The procedure must include, at a minimum:

a. The manner in which the subscriber or health care provider may request a protocol exemption, including a form to request the protocol exemption.

b. The manner and timeframe in which the health maintenance organization authorizes or denies a protocol exemption request, which must occur within a reasonable time.

c. The manner and timeframe in which the subscriber or health care provider may appeal the health maintenance organization’s denial of a protocol exemption request.

2. An authorization of a protocol exemption request must specify the approved prescription drug, medical procedure, or course of treatment. A denial of a protocol exemption request must include a written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure for appealing the health maintenance organization’s denial.

3. A health maintenance organization may request relevant medical records in support of a protocol exemption request.

~~(d)~~(e) This subsection does not require a health maintenance organization to add a drug to its prescription drug formulary or to cover a prescription drug that the health maintenance organization does not otherwise cover.

Section 3. This act shall take effect July 1, 2022.

Approved by the Governor April 6, 2022.

Filed in Office Secretary of State April 6, 2022.