# SENATE, No. 1128

# **STATE OF NEW JERSEY**

# 219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

Sponsored by: Senator JOSEPH F. VITALE District 19 (Middlesex)

### **SYNOPSIS**

Requires continued coverage of prescription drugs for certain medical conditions.

# **CURRENT VERSION OF TEXT**

As introduced.



**AN ACT** concerning prescription drug coverage for certain medical conditions and supplementing various parts of the statutory law.

**BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

- 1. a. As used in this section:
- "Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

"Rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

- b. Every group or individual hospital service corporation contract delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, a group or individual hospital service corporation contract shall not:
- (1) set forth limitations on maximum coverage of prescription drug benefits;
- (2) subject the covered person to increased out-of-pocket costs; or
- 43 (3) move a drug for a covered person to a more restrictive tier, if 44 the group or individual hospital service corporation uses a 45 formulary with tiers.

2. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

"Rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

- b. Every group or individual medical service corporation contract delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, a group or individual medical service corporation contract shall not:
- (1) set forth limitations on maximum coverage of prescription drug benefits;
- (2) subject the covered person to increased out-of-pocket costs; or
- (3) move a drug for a covered person to a more restrictive tier, if the group or individual medical service corporation uses a formulary with tiers.

3. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

"Rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

b. Every group or individual health service corporation contract delivered, issued, executed or renewed in this State, or approved for

- issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
  - (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and
  - (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
  - (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
  - (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
  - c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, a group or individual health service corporation contract shall not:
  - (1) set forth limitations on maximum coverage of prescription drug benefits;
  - (2) subject the covered person to increased out-of-pocket costs; or
  - (3) move a drug for a covered person to a more restrictive tier, if the group or individual health service corporation uses a formulary with tiers.

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4. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

- b. Every individual health insurance policy or contract delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- 46 (1) the drug was previously covered by the policy or contract for 47 a medical condition or disease of the covered person; and

- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, an individual health insurance policy or contract shall not:
- (1) set forth limitations on maximum coverage of prescription drug benefits;
- (2) subject the covered person to increased out-of-pocket costs; or
- (3) move a drug for a covered person to a more restrictive tier, if the individual health insurance policy or contract uses a formulary with tiers.

## 5. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

- b. Every group health insurance policy or contract delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the policy or contract for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or

- 1 (b) the manufacturer of the drug has notified the United States
  2 Food and Drug Administration of any manufacturing
  3 discontinuance or potential discontinuance as required by 21 U.S.C.
  4 s.356c.
  - c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, a group health insurance policy or contract shall not:
  - (1) set forth limitations on maximum coverage of prescription drug benefits;
  - (2) subject the covered person to increased out-of-pocket costs; or
  - (3) move a drug for a covered person to a more restrictive tier, if the group health insurance policy or contract uses a formulary with tiers.

#### 6. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

- b. Every certificate of authority to establish and operate a health maintenance organization issued, continued or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the enrollee agreement for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, an enrollee agreement shall not:

- 1 (1) set forth limitations on maximum coverage of prescription 2 drug benefits;
- 3 (2) subject the covered person to increased out-of-pocket costs; 4 or
  - (3) move a drug for a covered person to a more restrictive tier, if the enrollee agreement uses a formulary with tiers.

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#### 7. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

"Rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

- b. Every individual health benefits plan delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the plan for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
  - c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, an individual health benefits plan shall not:
- (1) set forth limitations on maximum coverage of prescription drug benefits;
- 41 (2) subject the covered person to increased out-of-pocket costs; 42 or
- 43 (3) move a drug for a covered person to a more restrictive tier, if 44 the individual health benefits plan uses a formulary with tiers.

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### 8. a. As used in this section:

47 "Complex or chronic medical condition" means a physical, 48 behavioral, or developmental condition that does not have a known 1 cure or that can be severely debilitating or fatal if left untreated or undertreated.

"Rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

- b. Every small employer health benefits plan delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the plan for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, a small employer health benefits plan shall not:
- (1) set forth limitations on maximum coverage of prescription drug benefits;
- (2) subject the covered person to increased out-of-pocket costs; or
  - (3) move a drug for a covered person to a more restrictive tier, if the small employer health benefits plan uses a formulary with tiers.

9. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

"Rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

b. Every prepaid prescription service organization contract delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the effective date of this act, shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:

- (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, the prepaid prescription contract shall not:
- (1) set forth limitations on maximum coverage of prescription drug benefits;
- (2) subject the covered person to increased out-of-pocket costs; or
- (3) move a drug for a covered person to a more restrictive tier, if the prepaid prescription service organization uses a formulary with tiers.

10. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

- b. The State Health Benefits Commission shall ensure that every contract purchased by the State Health Benefits Program on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or

- 1 (b) the manufacturer of the drug has notified the United States
  2 Food and Drug Administration of any manufacturing
  3 discontinuance or potential discontinuance as required by 21 U.S.C.
  4 s.356c.
  - c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, the State Health Benefits Program shall not:
  - (1) set forth limitations on maximum coverage of prescription drug benefits;
  - (2) subject the covered person to increased out-of-pocket costs; or
  - (3) move a drug for a covered person to a more restrictive tier, if the State Health Benefits Program uses a formulary with tiers.

16 11. a. As used in this section:

"Complex or chronic medical condition" means a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated.

- b. The School Employees' Health Benefits Commission shall ensure that every contract purchased by the School Employees' Health Benefits Program on or after the effective date of this act, which provides for pharmacy services, prescription drugs, or for participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if:
- (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and
- (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred:
- (a) the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- (b) the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.
- c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open enrollment periods, the School Employees' Health Benefits Program shall not:

- (1) set forth limitations on maximum coverage of prescription drug benefits;
- (2) subject the covered person to increased out-of-pocket costs; or
- (3) move a drug for a covered person to a more restrictive tier, if the School Employees' Health Benefits Program uses a formulary with tiers.

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12. This act shall take effect on the 90th day next following enactment.

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#### **STATEMENT**

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This bill requires health insurance carriers to provide continued coverage of prescription drugs for covered persons diagnosed with a complex or chronic medical condition or a rare disease.

The bill defines "complex or chronic medical condition" as a physical, behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated. "Rare disease" is defined as any disease or condition that affects less than 200,000 persons in the United States.

This bill requires hospital, medical and health service corporations, commercial insurers, health maintenance organizations, health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs, prepaid prescription service organizations, and plans provided by the State Health Benefits Commission and the School Employees' Health Benefits Commission to provide continued coverage of a prescription drug prescribed for a complex or chronic medical condition or rare disease when the drug: (1) was previously covered by the carrier; and (2) the prescribing provider continues to prescribe the drug for the medical condition or disease, provided the drug is appropriately prescribed, and neither of the following has occurred:

- the United States Food and Drug Administration has issued a notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or
- the manufacturer of the drug has notified the United States Food and Drug Administration of any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. s.356c.

The bill further provides that a carrier shall not set forth limitations on maximum coverage of prescription drug benefits; subject the covered person to increased out-of-pocket costs; or move a drug for a covered person to a more restrictive tier, if the carrier uses a formulary with tiers.