SENATE, No. 492 STATE OF NEW JERSEY 218th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2018 SESSION

Sponsored by: Senator JOSEPH F. VITALE District 19 (Middlesex) Senator JAMES BEACH District 6 (Burlington and Camden)

Co-Sponsored by: Senators Diegnan and Gopal

SYNOPSIS

Requires continued coverage of prescription drugs for certain medical conditions.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



(Sponsorship Updated As Of: 6/26/2018)

AN ACT concerning prescription drug coverage for certain medical

conditions and supplementing various parts of the statutory law.

4 **BE IT ENACTED** by the Senate and General Assembly of the State 5 of New Jersey: 6 7 1. a. As used in this section: 8 "Complex or chronic medical condition" means a physical, 9 behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or 10 11 undertreated. 12 "Rare disease" means any disease or condition that affects less 13 than 200,000 persons in the United States. 14 b. Every group or individual hospital service corporation 15 contract delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State, on or after the 16 17 effective date of this act, which provides for pharmacy services, 18 prescription drugs, or for participation in a prescription drug plan 19 shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if: 20 (1) the drug was previously covered by the contract for a 21 22 medical condition or disease of the covered person; and 23 (2) the prescribing provider continues to prescribe the drug for 24 the medical condition or disease, provided that the drug is 25 appropriately prescribed and neither of the following has occurred: 26 (a) the United States Food and Drug Administration has issued a 27 notice, guidance, warning, announcement, or any other statement 28 about the drug which calls into question the clinical safety of the 29 drug; or 30 (b) the manufacturer of the drug has notified the United States 31 Food and Drug Administration of any manufacturing 32 discontinuance or potential discontinuance as required by 21 U.S.C. 33 s.356c. 34 c. With respect to a drug for a covered person with a complex 35 or chronic medical condition or a rare disease which meets the 36 conditions of subsection b. of this section, except during open 37 enrollment periods, a group or individual hospital service 38 corporation contract shall not: 39 (1) set forth limitations on maximum coverage of prescription 40 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 group or individual hospital service corporation uses a formulary with tiers. 45

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47 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

6 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 amedical 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:

32 (1) set forth limitations on maximum coverage of prescription33 drug benefits;

34 (2) subject the covered person to increased out-of-pocket costs;35 or

36 (3) move a drug for a covered person to a more restrictive tier, if
37 the group or individual medical service corporation uses a
38 formulary with tiers.

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3. a. As used in this section:

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

45 "Rare disease" means any disease or condition that affects less46 than 200,000 persons in the United States.

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

issuance or renewal in this State, on or after the effective date of 1 2 this act, which provides for pharmacy services, prescription drugs, 3 or for participation in a prescription drug plan shall continue to 4 cover a drug for a covered person with a complex or chronic 5 medical condition or a rare disease if: (1) the drug was previously covered by the contract for a 6 7 medical condition or disease of the covered person; and 8 (2) the prescribing provider continues to prescribe the drug for 9 the medical condition or disease, provided that the drug is 10 appropriately prescribed and neither of the following has occurred: (a) the United States Food and Drug Administration has issued a 11 12 notice, guidance, warning, announcement, or any other statement 13 about the drug which calls into question the clinical safety of the 14 drug; or 15 (b) the manufacturer of the drug has notified the United States Administration 16 Food Drug of any manufacturing and 17 discontinuance or potential discontinuance as required by 21 U.S.C. 18 s.356c. 19 c. With respect to a drug for a covered person with a complex 20 or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open 21 22 enrollment periods, a group or individual health service corporation 23 contract shall not: 24 (1) set forth limitations on maximum coverage of prescription 25 drug benefits; 26 (2) subject the covered person to increased out-of-pocket costs; 27 or 28 (3) move a drug for a covered person to a more restrictive tier, if 29 the group or individual health service corporation uses a formulary 30 with tiers. 31 32 4. a. As used in this section: "Complex or chronic medical condition" means a physical, 33 34 behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or 35 36 undertreated. 37 "Rare disease" means any disease or condition that affects less 38 than 200,000 persons in the United States. 39 b. Every individual health insurance policy or contract delivered, issued, executed or renewed in this State, or approved for 40 41 issuance or renewal in this State, on or after the effective date of 42 this act, which provides for pharmacy services, prescription drugs, 43 or for participation in a prescription drug plan shall continue to 44 cover a drug for a covered person with a complex or chronic 45 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

2 the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred: 4 (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 Administration of any manufacturing and Drug 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 14 conditions of subsection b. of this section, except during open 15 enrollment periods, an individual health insurance policy or 16 contract shall not: (1) set forth limitations on maximum coverage of prescription 18 drug benefits; (2) subject the covered person to increased out-of-pocket costs; 20 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. 24 5. a. As used in this section: "Complex or chronic medical condition" means a physical, 26 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 30 than 200,000 persons in the United States. b. Every group health insurance policy or contract delivered, issued, executed or renewed in this State, or approved for issuance 34 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: 39 (1) the drug was previously covered by the policy or contract for 40 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 43 appropriately prescribed and neither of the following has occurred: 44 (a) the United States Food and Drug Administration has issued a 45 notice, guidance, warning, announcement, or any other statement about the drug which calls into question the clinical safety of the drug; or

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(b) the manufacturer of the drug has notified the United States 1 2 Administration manufacturing Food and Drug of any 3 discontinuance or potential discontinuance as required by 21 U.S.C. 4 s.356c. 5 c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the 6 7 conditions of subsection b. of this section, except during open 8 enrollment periods, a group health insurance policy or contract shall not: 9 10 (1) set forth limitations on maximum coverage of prescription 11 drug benefits; 12 (2) subject the covered person to increased out-of-pocket costs; 13 or 14 (3) move a drug for a covered person to a more restrictive tier, if 15 the group health insurance policy or contract uses a formulary with 16 tiers. 17 6. a. As used in this section: 18 "Complex or chronic medical condition" means a physical, 19 behavioral, or developmental condition that does not have a known 20 cure or that can be severely debilitating or fatal if left untreated or 21 22 undertreated. 23 "Rare disease" means any disease or condition that affects less 24 than 200,000 persons in the United States. 25 b. Every certificate of authority to establish and operate a health maintenance organization issued, continued or renewed in 26 this State, or approved for issuance or renewal in this State, on or 27 28 after the effective date of this act, which provides for pharmacy 29 services, prescription drugs, or for participation in a prescription 30 drug plan shall continue to cover a drug for a covered person with a complex or chronic medical condition or a rare disease if: 31 32 (1) the drug was previously covered by the enrollee agreement 33 for a medical condition or disease of the covered person; and 34 (2) the prescribing provider continues to prescribe the drug for 35 the medical condition or disease, provided that the drug is 36 appropriately prescribed and neither of the following has occurred: 37 (a) the United States Food and Drug Administration has issued a 38 notice, guidance, warning, announcement, or any other statement 39 about the drug which calls into question the clinical safety of the 40 drug; or 41 (b) the manufacturer of the drug has notified the United States 42 Administration Food and Drug of any manufacturing 43 discontinuance or potential discontinuance as required by 21 U.S.C. 44 s.356c. 45 With respect to a drug for a covered person with a complex c. 46 or chronic medical condition or a rare disease which meets the 47 conditions of subsection b. of this section, except during open enrollment periods, an enrollee agreement shall not: 48

(1) set forth limitations on maximum coverage of prescription 1 2 drug benefits; 3 (2) subject the covered person to increased out-of-pocket costs; 4 or 5 (3) move a drug for a covered person to a more restrictive tier, if 6 the enrollee agreement uses a formulary with tiers. 7 8 7. a. As used in this section: "Complex or chronic medical condition" means a physical, 9 behavioral, or developmental condition that does not have a known 10 cure or that can be severely debilitating or fatal if left untreated or 11 12 undertreated. 13 "Rare disease" means any disease or condition that affects less 14 than 200,000 persons in the United States. 15 b. Every individual health benefits plan delivered, issued, executed or renewed in this State, or approved for issuance or 16 renewal in this State, on or after the effective date of this act, which 17 18 provides for pharmacy services, prescription drugs, or for 19 participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical 20 condition or a rare disease if: 21 22 (1) the drug was previously covered by the plan for a medical 23 condition or disease of the covered person; and (2) the prescribing provider continues to prescribe the drug for 24 25 the medical condition or disease, provided that the drug is 26 appropriately prescribed and neither of the following has occurred: 27 (a) the United States Food and Drug Administration has issued a 28 notice, guidance, warning, announcement, or any other statement 29 about the drug which calls into question the clinical safety of the 30 drug; or (b) the manufacturer of the drug has notified the United States 31 32 Administration of Food and Drug any manufacturing discontinuance or potential discontinuance as required by 21 U.S.C. 33 34 s.356c. 35 c. With respect to a drug for a covered person with a complex 36 or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open 37 enrollment periods, an individual health benefits plan shall not: 38 39 (1) set forth limitations on maximum coverage of prescription 40 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 the individual health benefits plan uses a formulary with tiers. 44 45 46 8. a. As used in this section: "Complex or chronic medical condition" means a physical, 47 behavioral, or developmental condition that does not have a known 48

cure or that can be severely debilitating or fatal if left untreated or

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undertreated.

3 "Rare disease" means any disease or condition that affects less 4 than 200,000 persons in the United States. 5 b. Every small employer health benefits plan delivered, issued, executed or renewed in this State, or approved for issuance or 6 7 renewal in this State, on or after the effective date of this act, which 8 provides for pharmacy services, prescription drugs, or for 9 participation in a prescription drug plan shall continue to cover a drug for a covered person with a complex or chronic medical 10 11 condition or a rare disease if: 12 (1) the drug was previously covered by the plan for a medical 13 condition or disease of the covered person; and 14 (2) the prescribing provider continues to prescribe the drug for 15 the medical condition or disease, provided that the drug is appropriately prescribed and neither of the following has occurred: 16 17 (a) the United States Food and Drug Administration has issued a 18 notice, guidance, warning, announcement, or any other statement 19 about the drug which calls into question the clinical safety of the 20 drug; or (b) the manufacturer of the drug has notified the United States 21 22 Food Administration of any manufacturing and Drug 23 discontinuance or potential discontinuance as required by 21 U.S.C. 24 s.356c. 25 c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the 26 conditions of subsection b. of this section, except during open 27 28 enrollment periods, a small employer health benefits plan shall not: (1) set forth limitations on maximum coverage of prescription 29 30 drug benefits; 31 (2) subject the covered person to increased out-of-pocket costs; 32 or 33 (3) move a drug for a covered person to a more restrictive tier, if 34 the small employer health benefits plan uses a formulary with tiers. 35 36 9. a. As used in this section: "Complex or chronic medical condition" means a physical, 37 behavioral, or developmental condition that does not have a known 38 39 cure or that can be severely debilitating or fatal if left untreated or 40 undertreated. 41 "Rare disease" means any disease or condition that affects less 42 than 200,000 persons in the United States. 43 b. Every prepaid prescription service organization contract delivered, issued, executed or renewed in this State, or approved for 44 45 issuance or renewal in this State, on or after the effective date of 46 this act, shall continue to cover a drug for a covered person with a

47 complex or chronic medical condition or a rare disease if:

(1) the drug was previously covered by the contract for a 1 2 medical condition or disease of the covered person; and 3 (2) the prescribing provider continues to prescribe the drug for 4 the medical condition or disease, provided that the drug is 5 appropriately prescribed and neither of the following has occurred: (a) the United States Food and Drug Administration has issued a 6 7 notice, guidance, warning, announcement, or any other statement 8 about the drug which calls into question the clinical safety of the 9 drug; or 10 (b) the manufacturer of the drug has notified the United States Administration 11 Food and Drug of any manufacturing 12 discontinuance or potential discontinuance as required by 21 U.S.C. 13 s.356c. 14 c. With respect to a drug for a covered person with a complex 15 or chronic medical condition or a rare disease which meets the conditions of subsection b. of this section, except during open 16 17 enrollment periods, the prepaid prescription contract shall not: 18 (1) set forth limitations on maximum coverage of prescription 19 drug benefits; 20 (2) subject the covered person to increased out-of-pocket costs; 21 or 22 (3) move a drug for a covered person to a more restrictive tier, if 23 the prepaid prescription service organization uses a formulary with 24 tiers. 25 26 10. a. As used in this section: 27 "Complex or chronic medical condition" means a physical, 28 behavioral, or developmental condition that does not have a known 29 cure or that can be severely debilitating or fatal if left untreated or 30 undertreated. "Rare disease" means any disease or condition that affects less 31 32 than 200,000 persons in the United States. 33 b. The State Health Benefits Commission shall ensure that 34 every contract purchased by the State Health Benefits Program on or after the effective date of this act, which provides for pharmacy 35 36 services, prescription drugs, or for participation in a prescription 37 drug plan shall continue to cover a drug for a covered person with a 38 complex or chronic medical condition or a rare disease if: 39 (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and 40 41 (2) the prescribing provider continues to prescribe the drug for 42 the medical condition or disease, provided that the drug is 43 appropriately prescribed and neither of the following has occurred: 44 (a) the United States Food and Drug Administration has issued a 45 notice, guidance, warning, announcement, or any other statement 46 about the drug which calls into question the clinical safety of the 47 drug; or

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(b) the manufacturer of the drug has notified the United States 1 2 Administration Food and Drug of any manufacturing 3 discontinuance or potential discontinuance as required by 21 U.S.C. 4 s.356c. 5 c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the 6 7 conditions of subsection b. of this section, except during open 8 enrollment periods, the State Health Benefits Program shall not: 9 (1) set forth limitations on maximum coverage of prescription 10 drug benefits; (2) subject the covered person to increased out-of-pocket costs; 11 12 or 13 (3) move a drug for a covered person to a more restrictive tier, if 14 the State Health Benefits Program uses a formulary with tiers. 15 11. a. As used in this section: 16 17 "Complex or chronic medical condition" means a physical, 18 behavioral, or developmental condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or 19 undertreated. 20 "Rare disease" means any disease or condition that affects less 21 22 than 200,000 persons in the United States. 23 b. The School Employees' Health Benefits Commission shall 24 ensure that every contract purchased by the School Employees' 25 Health Benefits Program on or after the effective date of this act, 26 which provides for pharmacy services, prescription drugs, or for 27 participation in a prescription drug plan shall continue to cover a 28 drug for a covered person with a complex or chronic medical 29 condition or a rare disease if: 30 (1) the drug was previously covered by the contract for a medical condition or disease of the covered person; and 31 32 (2) the prescribing provider continues to prescribe the drug for 33 the medical condition or disease, provided that the drug is 34 appropriately prescribed and neither of the following has occurred: 35 (a) the United States Food and Drug Administration has issued a 36 notice, guidance, warning, announcement, or any other statement 37 about the drug which calls into question the clinical safety of the 38 drug; or 39 (b) the manufacturer of the drug has notified the United States Administration 40 Food and Drug of any manufacturing 41 discontinuance or potential discontinuance as required by 21 U.S.C. 42 s.356c. 43 c. With respect to a drug for a covered person with a complex or chronic medical condition or a rare disease which meets the 44 45 conditions of subsection b. of this section, except during open 46 enrollment periods, the School Employees' Health Benefits

47 Program shall not:

(1) set forth limitations on maximum coverage of prescription 1 2 drug benefits; 3 (2) subject the covered person to increased out-of-pocket costs; 4 or 5 (3) move a drug for a covered person to a more restrictive tier, if the School Employees' Health Benefits Program uses a formulary 6 7 with tiers. 8 9 12. This act shall take effect on the 90th day next following 10 enactment. 11 12 **STATEMENT** 13 14 This bill requires health insurance carriers to provide continued 15 coverage of prescription drugs for covered persons diagnosed with a complex or chronic medical condition or a rare disease. 16 17 The bill defines "complex or chronic medical condition" as a 18 physical, behavioral, or developmental condition that does not have 19 a known cure or that can be severely debilitating or fatal if left untreated or undertreated. "Rare disease" is defined as any disease 20 or condition that affects less than 200,000 persons in the United 21 22 States. 23 This bill requires hospital, medical and health service 24 corporations, commercial insurers. health maintenance 25 organizations, health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health 26 27 Benefits Programs, prepaid prescription service organizations, and 28 plans provided by the State Health Benefits Commission and the 29 School Employees' Health Benefits Commission to provide 30 continued coverage of a prescription drug prescribed for a complex or chronic medical condition or rare disease when the drug: (1) was 31 32 previously covered by the carrier; and (2) the prescribing provider 33 continues to prescribe the drug for the medical condition or disease, 34 provided the drug is appropriately prescribed, and neither of the 35 following has occurred: 36 the United States Food and Drug Administration has • 37 issued a notice, guidance, warning, announcement, or any 38 other statement about the drug which calls into question 39 the clinical safety of the drug; or 40 the manufacturer of the drug has notified the United 41 States Food and Drug Administration of any 42 manufacturing discontinuance or potential discontinuance 43 as required by 21 U.S.C. s.356c. 44 The bill further provides that a carrier shall not set forth 45 limitations on maximum coverage of prescription drug benefits; subject the covered person to increased out-of-pocket costs; or 46 47 move a drug for a covered person to a more restrictive tier, if the 48 carrier uses a formulary with tiers.