

STATE OF NEW YORK

9115

IN ASSEMBLY

January 21, 2020

Introduced by M. of A. M. L. MILLER -- read once and referred to the Committee on Insurance

AN ACT to amend the insurance law and the public health law, in relation to off-label drug usage

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. The insurance law is amended by adding a new section 3114
2 to read as follows:

3 § 3114. Off-label drug usage. (a) As used in this section, the follow-
4 ing terms shall have the following meanings:

5 (1) "Medical literature" means published scientific studies published
6 in any peer-reviewed national professional journal.

7 (2) "Standard reference compendia" means:

8 (A) The United States Pharmacopeia Drug Information;

9 (B) The American Medical Association Drug Evaluations;

10 (C) The American Hospital Formulary Service Drug Information;

11 (D) The National Comprehensive Cancer Network Drugs and Biologics
12 Compendium;

13 (E) The Thomson Micromedex DrugDex; or

14 (F) The Gold Standard/Elsevier Clinical Pharmacology.

15 (b) (1) Any contract or other arrangement entered into by a health
16 insurer offering health insurance under this chapter that provides
17 coverage for drugs shall exclude coverage of any such drug for a partic-
18 ular indication on the ground that the drug has not been approved by the
19 United States food and drug administration for that indication, if the
20 drug is recognized for treatment of the indication in one of the stand-
21 ard reference compendia, in the medical literature or has been success-
22 fully used for treatment previously by the insured for the same indi-
23 cation; provided, however, that nothing in this section shall be
24 construed to authorize the commissioner of health to approve any drug or
25 direct any person that issues an insurance policy to make payments for
26 the drug for a particular indication unless the drug is recognized for
27 treatment of the indication in one of the standard reference compendia,

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 in the medical literature or has been successfully used for treatment
2 previously by the insured for the same indication.

3 (2) Any coverage of a drug required by this section shall also include
4 medically necessary services associated with the administration of the
5 drug.

6 (3) This section shall not be construed to alter existing law with
7 regard to provisions limiting the coverage of drugs that have not been
8 approved by the United States food and drug administration.

9 (4) This section shall not be construed to require coverage for any
10 drug when the United States food and drug administration has determined
11 its use to be contra-indicated.

12 (5) This section shall not be construed to require coverage for exper-
13 imental drugs not otherwise approved for any indication by the United
14 States food and drug administration.

15 (6) Any dispute about coverage for off-label uses brought to the
16 commissioner of health shall be resolved by the appropriate grievance
17 process authorized by the department.

18 (7) The commissioner of health shall have the authority to direct any
19 person who issues an insurance policy to make payments required by this
20 section.

21 § 2. Subdivision 4 of section 280-a of the public health law is renum-
22 bered subdivision 5 and a new subdivision 4 is added to read as follows:

23 4. (a) No pharmacy benefit manager shall exclude coverage of any such
24 drug for a particular indication on the ground that the drug has not
25 been approved by the United States food and drug administration for that
26 indication, if the drug is recognized for treatment of the indication in
27 one of the standard reference compendia, in the medical literature or
28 has been successfully used for treatment previously by the insured for
29 the same indication; provided, however, that nothing in this subdivision
30 shall be construed to authorize the commissioner to approve any drug or
31 direct any pharmacy benefit manager to make payments for the drug for a
32 particular indication unless the drug is recognized for treatment of the
33 indication in one of the standard reference compendia, in the medical
34 literature or has been successfully used for treatment previously by the
35 insured for the same indication.

36 (b) Any coverage of a drug required by this subdivision shall also
37 include medically necessary services associated with the administration
38 of the drug.

39 (c) This subdivision shall not be construed to alter existing law with
40 regard to provisions limiting the coverage of drugs that have not been
41 approved by the United States food and drug administration.

42 (d) This subdivision shall not be construed to require coverage for
43 any drug when the United States food and drug administration has deter-
44 mined its use to be contra-indicated.

45 (e) This subdivision shall not be construed to require coverage for
46 experimental drugs not otherwise approved for any indication by the
47 United States food and drug administration.

48 (f) Any dispute about coverage for off-label uses brought to the
49 commissioner shall be resolved by the appropriate grievance process
50 authorized by the department.

51 (g) The commissioner shall have the authority to direct any pharmacy
52 benefit manager to make payments required by this subdivision.

53 (h) As used in this subdivision, the following terms shall have the
54 following meanings:

55 (1) "Medical literature" means published scientific studies published
56 in any peer-reviewed national professional journal.

1 (2) "Standard reference compendia" means:

2 (A) The United States Pharmacopeia Drug Information;

3 (B) The American Medical Association Drug Evaluations;

4 (C) The American Hospital Formulary Service Drug Information;

5 (D) The National Comprehensive Cancer Network Drugs and Biologics
6 Compendium;

7 (E) The Thomson Micromedex DrugDex; or

8 (F) The Gold Standard/Elsevier Clinical Pharmacology.

9 § 3. This act shall take effect on the ninetieth day after it shall
10 have become a law and shall apply to insurance policies issued, amended,
11 or renewed on or after such effective date.