STATE OF NEW YORK

3935

2021-2022 Regular Sessions

IN ASSEMBLY

January 29, 2021

Introduced by M. of A. M. 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:

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

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

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

(2) "Standard reference compendia" means:

(A) The United States Pharmacopeia Drug Information;

(B) The American Medical Association Drug Evaluations;

(C) The American Hospital Formulary Service Drug Information;

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

(E) The Thomson Micromedex DrugDex; or

(F) The Gold Standard/Elsevier Clinical Pharmacology.

(b) (1) Any contract or other arrangement entered into by a health insurer offering health insurance under this chapter that provides coverage for drugs shall exclude coverage of any such drug for a particular indication on the ground that the drug has not been approved by the United States food and drug administration for that indication, if the drug is recognized for treatment of the indication in one of the standard reference compendia, in the medical literature or has been successfully used for treatment previously by the insured for the same indication; provided, however, that nothing in this section shall be construed to authorize the commissioner of health to approve any drug or direct any person that issues an insurance policy to make payments for

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

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the drug for a particular indication unless the drug is recognized for treatment of the indication in one of the standard reference compendia, in the medical literature or has been successfully used for treatment previously by the insured for the same indication.

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

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

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

(5) This section shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the United States food and drug administration.

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

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

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

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

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

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

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

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

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

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

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

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

(2) "Standard reference compendia" means:

(A) The United States Pharmacopeia Drug Information;

(B) The American Medical Association Drug Evaluations;

(C) The American Hospital Formulary Service Drug Information;

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

(E) The Thomson Micromedex DrugDex; or

(F) The Gold Standard/Elsevier Clinical Pharmacology.

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