OFF-LABEL DRUG USE MODEL ACT

Table of Contents

Drafting Note: Each state should determine where the provisions of this model act should be incorporated into its statutory or regulatory scheme. For example, it might be appropriate to include these provisions in a state's Unfair Trade Practices Act.

Section 1. Purpose

In order to prevent unfair discrimination among insured persons in this state and to prohibit unfair competition among health carriers that include coverage for drugs as part of health benefit plans, standards for payment or reimbursement of costs associated with prescription drugs are required. Some health benefit plans deny payment for drugs that have been approved by the federal Food and Drug Administration (FDA) when the drugs are used for indications other than those stated in the labeling approved by the FDA (this use is hereinafter referred to as "off-label use") while other health benefit plans with similar drug coverage pay or reimburse for off-label use. Denial of payment or reimbursement for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for persons being treated for life-threatening illnesses. In addition, drugs for off-label use may provide efficacious treatment at a lower cost.

Drafting Note: States may want to consider utilizing the term "lawfully marketed to be prescribed for at least one indication" instead of the term "approved by the FDA" in this section and throughout this model. States that elect to utilize the term "lawfully marketed to be prescribed for at least one indication" may also want to define the term "prescribed" to be limited to the lawful prescriptive authority of the state.

Section 2. Scope

This Act applies to all health benefit plans that are issued, amended, delivered or renewed on or after the effective date of this Act and provide coverage for drugs, and to all persons making determinations regarding payment of reimbursement for prescription drugs under these health benefit plans.

Drafting Note: States that have appropriate statutory authority may wish to consider framing this model as a regulation rather than as an Act.

Section 3. Definitions

A. "Commissioner" means the commissioner of insurance.

Drafting Note: Insert the title of the chief insurance regulatory official wherever the term "commissioner" appears.

B. "Drug" or "drugs" means any substance prescribed by a licensed health care provider acting within the scope of the provider's license and that is intended for use in the diagnosis, mitigation, treatment or prevention of disease that is taken by mouth; injected into a muscle, the skin, a blood vessel or cavity of the body; applied to the skin; or otherwise assimilated by the body. The term includes only those substances that are approved by the FDA for at least one indication.

C. "FDA" means the federal Food and Drug Administration.

D. "Health benefit plan" means a risk transferring contract entered into to provide, deliver, arrange for, pay for or reimburse the cost of health care services.

E. "Health carrier" means a person that contracts or offers to contract on a risk assuming basis to provide, deliver, arrange for, pay for, or reimburse any of the cost of health care services unless the person assuming the risk is accepting the risk from a duly licensed health carrier.

F. "Peer-reviewed medical literature" means a published scientific study in a journal or other publication in which original manuscripts have been published only after having been critically reviewed for scientific accuracy, validity and reliability by unbiased independent experts, and that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.

G. "Standard reference compendia" means:

(1) The American Hospital Formulary Service-Drug Information;

(2) The American Medical Association Drug Evaluation; or

(3) The United States Pharmacopoeia-Drug Information.

Section 4. Minimum Standards of Coverage

A. A health benefit plan that provides coverage for drugs shall provide for any drug prescribed to treat a covered indication so long as the drug has been approved by the FDA for at least one indication, if the drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature.

B. Coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.

C. This section shall not be construed to require coverage for a drug when the FDA has determined its use to be contra-indicated for treatment of the current indication.

D. A drug use that is covered by reason of Subsection A shall not be denied coverage based on a "medical necessity" requirement except for reasons that are unrelated to the legal status of the drug use.

E. The following drugs or services shall not be subject to coverage under Subsection A:

(1) Drugs that are used in research trials sponsored by their manufacturers or a government entity; or

(2) Drugs or services furnished in a research trial, if the sponsor of the research trial furnishes the drugs or services without charge to any participant in the research trial.

Drafting Note: Some states may wish to authorize the commissioner to appoint a panel of medical experts to review specific indications and make written recommendations for approval by the commissioner as to what drugs are recognized for treatment in substantially accepted peer-reviewed medical literature. States choosing to authorize this procedure would need to add language to Section 4A to include drugs recognized and approved by the commissioner through this peer-review panel process. States may wish to ensure that members of such panels have training in assessing new drugs or new usage of existing drugs, follow scientifically sound and objective protocols, and have no financial or other conflicts of interest. A review panel would be subject to the state administrative procedures and open meetings laws.

Section 5. Effective Date

This Act is effective on [insert date].

Chronological Summary of Action (all references are to the Proceedings of the NAIC)

1995 Proc. 2nd Quarter 2, 36, 552, 570, 573-574 (adopted).