§2837-F. Off-label use of prescription drugs for cancer

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Medically accepted indication" includes any use of a drug that has been approved by the federal Food and Drug Administration and includes another use of the drug if that use is supported by one or more citations in the standard reference compendia or if the insurer involved, based upon guidance provided by the federal Department of Health and Human Services Medicare program pursuant to 42 United States Code, Section 1395x(t), determines that that use is medically accepted based on supportive clinical evidence in peer-reviewed medical literature. [PL 1997, c. 701, §3 (NEW).]

B. "Off-label use" means the prescription and use of drugs for medically accepted indications other than those stated in the labeling approved by the federal Food and Drug Administration. [PL 1997, c. 701, §3 (NEW).]

C. "Peer-reviewed medical literature" means scientific studies published in at least 2 articles from major peer-reviewed medical journals that present data that supports the proposed off-label use as generally safe and effective. [PL 1997, c. 701, §3 (NEW).]

D. "Standard reference compendia" means:

(1) The United States Pharmacopeia Drug Information or information published by its successor organization; or

(2) The American Hospital Formulary Service Drug Information or information published by its successor organization. [PL 1997, c. 701, §3 (NEW).]

[PL 1997, c. 701, §3 (NEW).]

2. Required coverage for off-label use. All group insurance policies and contracts that provide coverage for prescription drugs must provide coverage for off-label use in accordance with the following.

A. Group insurance policies and contracts that provide coverage for prescription drugs may not exclude coverage of any such drug used for the treatment of cancer for a medically accepted indication on the grounds that the drug has not been approved by the federal Food and Drug Administration for that indication, as long as that use of that drug is a medically accepted indication for the treatment of cancer. [PL 1997, c. 701, §3 (NEW).]

B. Coverage of a drug required by this subsection also includes medically necessary services associated with the administration of the drug. [PL 1997, c. 701, §3 (NEW).]

C. This subsection may not be construed to require coverage for a drug when the federal Food and Drug Administration has determined its use to be contraindicated for treatment of the current indication. [PL 1997, c. 701, §3 (NEW).]

D. A drug use that is covered pursuant to paragraph A may not be denied coverage based on a "medical necessity" requirement except for a reason that is unrelated to the legal status of the drug use. [PL 1997, c. 701, §3 (NEW).]

E. A contract that provides coverage of a drug as required by this subsection may contain provisions for maximum benefits and coinsurance and reasonable limitations, deductibles and exclusions to the same extent that these provisions are applicable to coverage of all prescription drugs and are not inconsistent with the requirements of this subsection. [PL 1997, c. 701, §3 (NEW).]

[PL 1997, c. 701, §3 (NEW).]

3. Application. The requirements of this section apply to all policies, contracts and certificates executed, delivered, issued for delivery, continued or renewed in this State on or after January 1, 1999. For purposes of this section, all contracts are deemed to be renewed no later than the next yearly anniversary of the contract date.

[PL 1997, c. 701, §3 (NEW).]

REVISOR'S NOTE: §2837-F. Coverage for prostate cancer screening (As enacted by PL 1997, c. 754, §3 is REALLOCATED TO TITLE 24-A, SECTION 2837-H)

SECTION HISTORY

RR 1997, c. 2, §52 (RAL). PL 1997, c. 701, §3 (NEW). PL 1997, c. 754, §3 (NEW).