

FTR

Connecticut Oncology Association Testimony
Insurance and Real Estate Committee
Senate Bill No. 418
An Act Concerning Off-Label Prescription Drugs
March 3, 2015

Senator Crisco, Representative Megna, and members of the Insurance and Real Estate Committee, on behalf of the physicians of the Connecticut Oncology Association, I thank you for the opportunity to present this testimony to you today in support of Senate Bill 410 An Act Concerning Off-Label Prescription Drugs. This legislation will correct an older law from 1994 that has been previously outdated. The language of the prior CT Public Act No. 94-49, An Act Concerning Off-Label Drug Reimbursement for Cancer Treatment, was codified in 1994, and refers to specific references that private insurers should use when determining appropriate off-label choices for cancer treatment. The source for those 1994 references was the resources officially recognized by the federal government for the Medicare program at the time.

The references named in that 1994 CT law no longer match those accepted by the federal government for Medicare, and, in fact, some no longer exist. We strongly support the Senate Bill 418 because it will update and replace the current outdated law with references that do actually exist in today's world. However, we do also have a recommendation for a significant change to the language, to remove reference to the specific compendia – which are now outdated, and to replace that language with a reference to the compendia recognized in federal statutes for use with the Medicare program.

Why is off-label treatment common in cancer care?

Cancer treatment advances occur rapidly. The Federal Drug Administration (FDA) approves a drug for certain indications. Clinical trials and research is often published in peer-reviewed literature that extends the understanding of the role a drug may play in cancer treatment beyond the FDA indications. Within the cancer community, there is a process established for vetting with academic rigor and peer reviewed literature that may result in additional reference for a drug outside of the FDA indication. After review of peer-reviewed literature, those uses outside of the FDA indication may become part of a national Compendia of cancer drugs and their uses, and even to national guidelines for standard of care treatment, although still outside of the FDA indication.

What is the risk of not passing S B 418?

There are many reasons why a pharmaceutical manufacturer may choose not to seek additional formal FDA indications for cancer drug utility, and the medical and insurance community has recognized that there are appropriate resources that may vet appropriate off-label use for cancer treatments. The original 1994 CT law named the specific resources that the federal government recognized at the time as appropriate. Since then, market changes have resulted in changes to those resources. The letter of the law in CT dating from 1994 currently refers to resources that no longer exist or are no longer relevant. Should an insurer in the state of CT choose to refer to the language of the 1994 law as justification for denying coverage of treatment for a patient – that denial would be based upon a law that no longer reflects current standards of care. This leaves cancer patients in CT vulnerable to denial determinations because certain standard of care treatments can't be found on the resources mandated by the state.

Most other states have already passed updates correcting the outdated language of earlier off-label legislation that was similarly worded.

The Connecticut Oncology Association supports the passage of S B 418, but does suggest one more language change in the bill. The current proposed S B 418 provides for the addition of a reference to peer-reviewed medical literature generally recognized by the relevant medical community. We appreciate that. However, the reference to specific outdated resources still remains.

We would suggest that the following change occur as well. The Connecticut Oncology Association recommended changes are noted as ***underlined bolded italics*** in the following paragraph excerpted from the current proposed language for S B 418:

Sec. 2. Section 38a-518b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2016*):

(a) (1) Each group health insurance policy delivered, issued for delivery, renewed, amended or continued in this state, that provides coverage for [prescribed] prescription drugs approved by the federal Food and Drug Administration for treatment of [certain types of cancer or disabling or life-threatening chronic diseases] a covered condition, shall not exclude coverage of any such drug on the basis that such drug has been prescribed for the treatment of a [type of cancer or a disabling or life-threatening chronic disease] covered condition for which the drug has not been approved by the federal Food and Drug Administration, *provided the drug has been recognized as safe and effective for treatment of that covered condition in one or more of the standard medical reference compendia specified in division (B)(1) of this section adopted by the United States department of health and human services under 42 U.S.C.1395x (t)(2), as amended, or in peer reviewed medical literature generally recognized by the relevant medical community.* As used in this section, "peer-reviewed medical literature" means a published study in a journal or other publication in which original manuscripts have been critically reviewed for scientific accuracy, validity and reliability by unbiased international experts, and that has been determined by the International Committee of Medical Journal Editors to have met its 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 any health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society that delivers, issues for delivery, renews, amends or continues a health insurance policy in this state.

If you wish to name the specific current compendia recognized by CMS for Medicare, that reference is noted below, however, naming specific compendia in S B Bill 418 could result in this Bill also becoming outdated if those specific compendia change. By leaving the reference in S B 418 to those compendia recognized by CMS for Medicare, you will create an evergreen status for S B 418 that can transcend minor market changes and adjustments. The Connecticut Oncology Association would recommend that the paragraph change noted above stand alone in S B 418 and the specifics that follow not be included.

Additional specifics of CMS approved compendia, for reference only:

In the case of drugs used in an anti-cancer chemotherapeutic regimen, off-label uses are covered for a medically accepted indication as defined in the Medicare Benefit Policy Manual (CMS publication 100-2, Chapter 15, Section 50.4.5).

In order to meet the requirement that the use of the drug is reasonable and necessary for the treatment of disease, the drugs must be safe and effective. Drugs approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective when used for indications specified on the labeling. Therefore, Medicare pays for the use of a FDA-approved drug, if:

- *It was injected on or after the date of the FDA's approval;*
- *It is reasonable and necessary for the individual patient; and*
- *All other applicable coverage requirements are met.*

Indications: *A medically accepted indication, which is covered by National Government Services is one of the following:*

1. *An FDA approved, labeled indication or a use supported in the American Hospital Formulary Service Drug Information (AHFS-DI), NCCN Drugs and Biologics Compendium, Thomson Micromedex DrugDex® and Clinical Pharmacology as the acceptable compendia based on CMS' Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologics Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen);*
2. *Articles or Local Coverage Determinations (LCDs) published by National Government Services.*

Thank you for your consideration. We at the Connecticut Oncology Association have been encouraging this legislative change for several years and are very pleased that it is being considered in the 2015 Legislative Session.

Sincerely,

Dawn Holcombe
Executive Director, Connecticut Oncology Association

33 Woodmar Circle
South Windsor, CT 06074
dawnho@aol.com (main)
860-305-4510 (cell and main)
860-644-9119 (fax)