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**Insurance and Real Estate Committee**
**February 20, 2013**
**American Cancer Society Cancer Action Network Testimony**

**SB 857 (RAISED) AN ACT CONCERNING THE USE OF STEP THERAPY FOR AND OFF-LABEL PRESCRIBING OF PRESCRIPTION DRUGS.**

When a patient is prescribed an expensive or risky, branded drug, a payer may determine that the patient will not be allowed coverage on that drug until other, less expensive or less risky protocols have been tried, first. If it works well for the patient, then no more steps are needed. However, if the patient does not have the desired outcomes with the first drug, then a second drug, the next least expensive or risky drug in the same class, will be tried until the patient takes a drug that is effective and costs the least amount of money.

The rationale behind this "step therapy" is that it enables patients to receive medications in a cost effective manner, while reducing waste, error and unnecessary drug use. However, this can lead to delays in proper treatment as well as unnecessary discomfort to the patients themselves and potential increased costs in the form of unplanned emergency room, doctor visits or other health complications.

Two years ago, the Legislature approved a prohibition against the practice of step therapy for pain medications. SB 857 would expand this prohibition to include all therapeutic areas, not just pain management.

An additional issue related to treatment is the practice of "Off Label Prescribing." New uses of older generic medications are sometimes found and there is often medical evidence to support the new use. However the makers of the drugs have not put them through the formal, lengthy, and often costly studies required by the FDA to officially approve the drug for new uses.

The FDA does not regulate the practice of medicine. In general, once the FDA approves a drug, licensed doctors can use it for any purpose they consider medically appropriate. Off-label use can vary greatly from one doctor to another. It depends on the doctor's preferences, knowledge, and past patient experiences.

One of the biggest problems related to widespread off-label use is the lack of information about how to best use the drug beyond what was approved. One of the most reliable and easy-to-find sources of information available to health professionals, caregivers, and patients is the drug label. But the label can only contain the information that has been approved by the FDA, and it does not mention off-label uses.

The medical literature reports clinical trials, including those that are not part of the FDA approval process. This is the main source of off-label use information, although treatment guidelines may also offer options that include off-label use. Treatment guidelines are based on information from medical literature, including clinical trials, and recommend standard ways to treat certain diseases.

Lack of information on off-label drug use and outcomes may also put patients at a higher risk for medication errors, side effects, and unwanted drug reactions. It is important that the patient and doctor talk about the possible risks of using the drug and weigh them against the possible benefits.

SB 857 would prohibit policies from requiring, as a condition of coverage, the use of any prescription drug for a condition for which the drug has not ben approved by the FDA unless a patient's treating health care provider has prescribed the drug.

We are supportive of this measure because we view the physician-patient decision-making process as a critical component of proper care and prefer to avoid policies that may not be in the patient's best interest in that regard.

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