



## Pre-Election Update

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To cite this article: Jamie Young (1998) Pre-Election Update, *Oncology Issues*, 13:4, 11-11, DOI: [10.1080/10463356.1998.11904758](https://doi.org/10.1080/10463356.1998.11904758)

To link to this article: <https://doi.org/10.1080/10463356.1998.11904758>



Published online: 18 Oct 2017.



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## Pre-election Update

by Jamie Young

**S**ummer is in full swing in an even numbered year, which means that almost all state legislatures are quiet places as members return home to prepare for the November elections. This year has again produced thousands of bills relating to health care issues and, for oncology, has yielded several more off-label laws and new requirements for coverage of clinical trials.

**Augusta.** Effective January 1, 1999, Maine law assures that insurers cannot exclude coverage for off-label uses of FDA-approved drugs to treat cancer, HIV, or AIDS that are recognized in one of the two compendia or medically accepted based on supportive clinical evidence in peer-reviewed medical literature, as defined in the bill. L.D. 2068 was supported by the Maine Medical Association, ACCC, and the Northern New England Clinical Oncology Society, especially society member Dr. Ronald Carroll of Portland who worked closely with Senate President Mark Lawrence, the bill's sponsor, and the Joint Standing Committee on Banking and Insurance. The bill was signed into law by Gov. Angus S. King, Jr., on April 3, 1998.

**Frankfort.** Effective July 15, 1998, Kentucky law requires coverage of off-label indications of FDA-approved drugs for the treatment

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of cancer when the off-label use is recognized as effective for the treatment of that indication in one of the standard reference compendia or in the medical literature. H.B. 618 was approved by Gov. Paul E. Patton on April 9.

**Lincoln.** Five years after the initial bill was introduced, Nebraska's unicameral legislature became the thirty-first state to pass off-label drug legislation when Gov. Ben Nelson signed L.B. 1162 into law. Freshman Sen. Deborah Suttle introduced L.B. 849 in January of last year but worked with Sen. David Landis to have the bill folded into his L.B. 1162. Section 81 of the lengthy bill is devoted to the off-label provisions. The bill is limited to off-label uses of drugs used in the treatment of cancer and HIV/AIDS. Last year, the Banking, Commerce, and Insurance Committee took testimony on the legislation, including proponent testimony on behalf of ACCC and the Nebraska Oncology Society (NOS). The insurance industry was uniformly opposed to the bill at that time but negotiations over the past year led to an agreement. NOS President Dr. Joseph Verdirame was instrumental in shaping the language.

### CLINICAL TRIALS TALLY

Also included in the tally of legislative victories for cancer patients and their families in 1998 is clinical trials legislation passed in both Georgia and Maryland. Prior to this year only Rhode Island had enacted such legislation. As expected, Georgia's Gov. Zell

Miller signed S.B. 603 into law shortly after the bill was approved unanimously by both the House and Senate. As of July 1, 1998, the legislation requires that insurers cover the costs of routine care, such as doctors' visits and blood tests, for children with cancer who are enrolled in approved clinical trials (as defined in the bill). Supporters testified that despite data showing higher survival rates for children treated on a study versus those who are not, participation in pediatric cancer clinical trials has dropped from 95 percent less than 10 years ago to 60 percent because many insurers refuse to cover routine care. Many of the bill's supporters plan to return to the legislature next year to broaden the law to cover adult cancer patients.

Maryland is the second state this year to enact legislation requiring insurers, including managed care plans, to cover the patient care costs of clinical trials. In fact, the Maryland law is broader than that of Georgia and Rhode Island because it applies to all cancer patients in all phases of trials and also covers other life-threatening conditions. S.B. 137, introduced by Sen. Thomas Bromwell, was approved overwhelmingly in both the Senate and House and was signed by Gov. Parris Glendening on April 28. The new law takes effect on January 1, 1999, and applies to all policies issued on or after that date. Any policy in effect before that date must comply with the bill's requirements by January 1, 2000.

Clinical trials legislation remains pending in Illinois, New York and Pennsylvania. ■