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Minnesota Signs on to Off-Label Drug Legislation

by Jamie Young

After repeated attempts over the past five years, Minnesota has joined the ranks of the twenty-seven other states that have passed a version of the ACCC model off-label drug legislation. S.F. 1076, sponsored by State Senator Dallas Sams and cosponsored by State Representative Alice Hausman, was signed into law by Governor Arne Carlson on March 18, 1998. The law takes effect on January 1, 1999. The new Minnesota off-label law applies only to drugs used for the treatment of cancer and uses the standard reference compendia and the peer-reviewed medical literature for determining coverage of appropriate off-label uses.

S.F. 1076 was unanimously approved by both the Senate and House of Representatives—a stark contrast to the original bill introduced in 1993 that was steadfastly opposed by the insurance industry and unable to pass even the committee level. ACCC has worked continually since that time with the Minnesota Society of Clinical Oncology and many of its key physician members, local Oncology Nursing Society chapters, the Minnesota Division of the American Cancer Society, the Minneapolis Community Clinical Oncology Program (CCOP), the Minnesota Nurses Association, the Minnesota Medical Association, and the pharmaceutical industry to educate the Minnesota General Assembly and keep the issue alive.

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OFF-LABEL IN MAINE AND KENTUCKY

The Gopher State may soon be joined by others in passing off-label legislation this year. In Maine the Joint Standing Committee on Banking and Insurance recently approved bill L.D. 2068, sponsored by Senate President Mark Lawrence, after considering and adopting several amendments. The bill now awaits floor votes in both the House and Senate. The legislature was expected to adjourn by April 15 of this year.

The state's Bureau of Insurance mandates review and evaluation of proposed bills. The firm of William M. Mercer, Inc., of Boston conducted the review to study, as stipulated by Maine state law, the social and financial impact of the proposal and the medical efficacy of the procedure covered under the proposal. The report, delivered to the committee on March 3, made several findings "essential to balancing the societal, economic and medical impacts of L.D. 2068." The findings were:

- The proposed law impacts the health care of less than .4 percent of the residents of Maine.
- Premium increases needed to cover the mandated benefit range from zero to .6 percent, which equates to approximately $1.04 per member per month.
- Pharmacy benefit costs are increasing at a rate four to five times the medical component of the Consumer Price Index.
- Off-label use of prescription drugs is common practice and essential to the treatment of cancer and HIV/AIDS patients.
- FDA reform may expedite the approval of off-label uses. This would reduce the potential for claim denials.
- L.D. 2068 may limit pharmacy cost management. This would reduce the insurer's ability to control cost, according to the report.

In mid-February Kentucky State Representative Ruth Ann Palumbo introduced off-label legislation in the form of H.B. 618. The bill was approved by the House Health and Welfare Committee with amendments in early March. ACCC provided written testimony in support of the legislation as well as technical expertise in negotiations involving insurance industry proposed amendments. A bevy of additional amendments were worked out prior to the bill's approval on the House floor, resulting in a vote of 90-0 on March 16. The bill now applies only to drugs used to treat cancer and when the off-label use is recognized as safe and effective, based on scientific or medical criteria, in either of the two standard reference compendia or published scientific studies in peer-reviewed national professional journals. The bill also includes a provision to create a panel of five medical experts to review off-label uses not in the compendia or medical literature and to make recommendations to the Insurance Commissioner

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periodically and whenever there is a particular dispute about payment for the off-label drug use. The panel includes three medical oncologists and two other physicians recommended by the Kentucky Medical Association.

The bill has been forwarded to the Senate where approval is anticipated. The Kentucky Legislature meets only in even-numbered years and was expected to adjourn by April 15. In addition to ACCC, the bill is supported by the Kentucky Oncology Society, the Kentucky Medical Association, and the Kentucky Division of the American Cancer Society.

CLINICAL TRIALS LEGISLATION

Legislation to require insurers to provide coverage of the patient care costs of clinical trials has been reintroduced in Illinois by State Representative Judy Erwin. H.B. 3339 was heard by the House Health Care Access and Availability Committee on March 18 in Springfield. Dr. James L. Wade III, ACCC immediate past president, Dr. Edward Braud, chair of ACCC's Governmental Affairs Committee, and myself testified on behalf of the bill, as did Mary Lou Smith, president of the Board of Directors of the Y-ME National Breast Cancer Organization. The insurance industry and many employer groups continued to oppose the bill. Despite their opposition, the bill was approved by the committee 24-2. This year's version differs than previous versions in that the bill is limited to Phase II, III, and IV trials and includes a three-year sunset provision.

Similar legislation in Maryland has already been approved by the full Senate. S.B. 137, sponsored by State Senator Thomas Bromwell, was introduced in late January of this year. ACCC provided the sponsor with a letter of support at his request. Negotiations with the managed care industry recently resulted in what appears to be a compromise bill that will be supported by the Maryland Association of Health Maintenance Organizations. Senator Bromwell, who chairs the Senate Finance Committee, has stated that he believes the chances of passage are good. If the bill is enacted into law, Maryland would become only the second state (Rhode Island being the first) to pass such a bill.

Finally, clinical trials legislation in Georgia has moved quickly through the legislature and currently sits on Governor Zell Miller's desk for signature. S.B. 603, sponsored by State Senator Sonny Perdue, passed both the Senate and House unanimously in March. It differs from the aforementioned bills in one important way: S.B. 603 is limited to coverage of routine patient care costs for children enrolled in approved pediatric cancer clinical trials. ACCC provided technical assistance prior to the bill's introduction when a broader bill was envisioned. Passage of this legislation would represent an important victory for children with cancer and their families.