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Off-Label Interest Increases

by Jamie Young

The new year brings increased interest across the country in ACCC's model off-label drug legislation. This renewed interest is due in part to the overwhelming success of the model legislation in the past four years. Nineteen states now have such a law in place.

An additional boost in activity is being noted as a result of action taken late last year by the National Association of Insurance Commissioners (NAIC). Over the past two-and-a-half years the NAIC has been receiving comments from state insurance regulators and the general public, including ACCC and the American Society of Clinical Oncology (ASCO), through public hearings and the working group that NAIC had assigned to this issue. NAIC has now adopted a model act that seeks to prevent unfair discrimination among insured persons and to prohibit unfair competition among insurers that include coverage for drugs as part of health benefit plans. The Off-Label Drug Use Model Act was recommended by the NAIC Experimental Treatments Working Group. It is very similar to the ACCC model bill in that it uses the drug compendia and the peer-reviewed medical literature in making coverage determinations. It does not limit applicability to drugs used in the treatment of cancer.

The same working group is also beginning work on model legislation regarding insurance coverage for experimental treatments, referred to as "new health services." Support by NAIC is significant in that it represents suggested state legislation by the nation's state insurance commissioners.

Jamie Young is ACCC director for state societies and government relations.

FRANKFORT

In December I met with members of the Advocacy Committee of the American Cancer Society, Kentucky Division, to gain their support for introduction of off-label legislation in their state. Following a discussion of the issues, the committee voted to proceed with introducing the bill. The Kentucky legislature meets only every other year and is in session in 1996. The Kentucky Oncology Society and The Merle M. Mahr Cancer Center, an ACCC member institution in Madisonville, have also indicated support.

COLUMBUS

Senate Bill 107 is awaiting Gov. George Voinovich's signature into law. This bill, sponsored by State Senator Grace Drake, extends the original off-label drug law to drugs used to treat all diseases rather than just cancer. The ACCC Columbus office closely monitored this bill and worked with the sponsor, insurers, the pharmaceutical industry, and the Ohio/West Virginia Oncology Society to assure that the existing law was not weakened. Language suggested by ACCC was adopted into the bill to make certain that scientific literature used in conjunction with the Medicare law would be acceptable.

HARRISBURG

In November I spoke to the Pennsylvania Oncology Hematology Managers' Society about ACCC's model off-label drug legislation, including the issues and legislative strategy involved with introducing a bill. ACCC considers Pennsylvania to be a priority state for introduction of off-label drug legislation and anticipates considera-

tion of a bill by mid-year.

While attending this meeting, I had the good fortune to meet Pennsylvania State Senator Roy C. Afflerbach. Senator Afflerbach has introduced Senate Bill 1134, which requires third-party reimbursement of patient care costs associated with cancer clinical trials. The senator has been working on this issue for two years and drafted the legislation as a result of discussions with health care providers, the insurance industry, various government agencies, and the legislature. The "Cancer Clinical Trial Act" was announced at a press conference on November 30 last year. It has been assigned to the Senate Committee on Banking and Insurance for consideration. However, according to Sen. Afflerbach, prior to hearings in this committee it must be referred to the Health Care Cost Containment Council to obtain independently certified documentation that defines the social and financial impact and medical efficacy of the proposal. ACCC has pledged its support to the bill and urges our Pennsylvania members to contact the ACCC Columbus office or Senator Afflerbach's office in Harrisburg to assist in this effort.

COLUMBIA

Legislation, S. 716 sponsored by Senator John C. Land III, was introduced last year, but did not advance due to opposition by the South Carolina Alliance for Managed Care. A meeting has taken place among that group, the ACCC, and other interested parties in hopes of negotiating agreed-to language. Should agreement occur, and it appears likely that it can, the new off-label language will be inserted into the original bill during hearings this spring. ■