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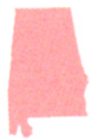
Off-Label Drug Scorecard

by Jamie Young

The ACCC offices receive regular phone calls from our members and other interested parties seeking information on states that have passed off-label drug legislation. Below is a summary of the laws in place in those 17 states. Special information regarding clinical trials legislation is indicated where legislative action has occurred or is under consideration. Copies of each of these laws are available through the ACCC Columbus office.

MONTGOMERY



On May 6, 1994, Governor James E. Folsom, Jr., signed Senate Bill 103 into law. The law, which took immediate effect, applies to off-label uses of drugs recognized for the treatment of life-threatening illnesses such as cancer, AIDS, and heart disease when those uses are indicated in one of the three compendia (the American Medical Association's *Drug Evaluations,* the United States Pharmacopeia's *Drug Information,* and the American Society of Hospital Pharmacists' *AHFS Drug Information*), the medical literature, or by the Commissioner of Insurance.

SACRAMENTO

Governor Pete Wilson signed Assembly Bill 1985 into law in September 1992. Effective January 1, 1993, the law applies to drugs used in the treatment of life-threatening illnesses, not just cancer drugs.

Clinical trials legislation S. 1816, authored by Senator Art Torres, was vetoed by Governor Wilson late last year at the urging of the insurance industry. The bill would have required insurers to pay for the patient care costs of clinical trials.

Jamie Young is ACCC Director for State Societies and Government Relations.

HARTFORD

On May 27, 1994, Connecticut Governor Lowell P. Weicker, Jr., signed into law a bill assuring access to off-label uses of anti-cancer drugs for the state citizens, effective October 1, 1994. File #88 (Senate Bill 249) requires the use of the three compendia to guide reimbursement decisions but does not have provisions for a medical expert panel or use of the peer-reviewed medical literature.

ATLANTA

House Bill 741, sponsored by State Representative Butch Parrish, was signed into law by Governor Zell Miller on April 7, 1993. Effective July 1, 1993, the bill applies only to cancer drugs.

SPRINGFIELD

Senate Bill 1533 was signed by Governor Jim Edgar on September 1, 1992. The Illinois off-label law took effect January 1, 1993.

This year the ACCC is working with the Illinois Medical Oncology Society, an ACCC state chapter, to seek passage of legislation that would include provisions for coverage of patient care costs of clinical trials.

INDIANAPOLIS

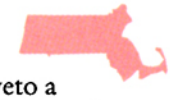
On June 30, 1993, the Indiana legislature voted in special session to override Gov. Evan Bayh's veto of HB 1001, the state budget bill. Included in that 500-plus page measure was a provision for coverage of off-label drugs used to treat cancer. The law took effect immediately.

ANNAPOLIS

Maryland Governor William Donald Schaefer signed House Bill 1222 into law on May 26, 1994. This broadly written law, which took effect on October 1, 1994, applies to off-label uses supported in any of the three compendia or the medical literature for any FDA-approved drug for any disease. It also creates a medical expert panel to assist with disputes that may arise between providers and insurers.

However, due to a drafting oversight, the law does not include health maintenance organizations. Corrective legislation, House Bill 351, has been filed to extend the provisions of the current law to HMOs.

BOSTON



On July 10, 1994, Governor William Weld chose not to veto a portion of the state budget that extended the off-label provisions of the existing state law for cancer patients to those being treated with drugs for HIV/AIDS related conditions. Like the original law signed in early 1993, it applies when the off-label use is recognized as appropriate by one of the three compendia or by medical literature.

In addition, the Massachusetts Society of Clinical Oncology, an ACCC state chapter, has inquired about assistance in introducing clinical trials legislation in 1995.

LANSING

Michigan was the first state to enact off-label drug legislation, although it does not utilize the three compendia provisions as have all the subsequent states. House Bill 4078, which applies to cancer drugs only, became effective on July 1, 1989.

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with the Texas Oncology Professional Association. Many larger hospitals have full-time staff assigned to monitor these developments.

THE RIGHT STEPS

A number of administrative or operational steps are essential if one is to be prepared for managed care:

- Develop a cost accounting system. Costs cannot be managed until they are known. A cost accounting system that identifies the costs of tests and routine care is essential.

- Initiate a clinical resource management program. One must be able to describe, monitor, and influence the patterns of care. Patterns of care need to be monitored across all sites of care, not just in the inpatient setting. Physician office care, subacute care, home care, and extended care all contribute to the total cost.

- Obtain physician commitment. Do not confuse those physicians who are philosophically ready to participate in resource management with those who actually accomplish it. Profiles should be developed for all physicians and physician groups, and the data shared with them. Physicians do not like being monitored by "outsiders," but most will cooperate when provided meaningful comparative data on their practice patterns.

- Provide education. Thriving in a managed care environment requires new talents. Understanding the intricacies of capitation and its reverse logic is not easy. A hospital's choices are to educate or recruit, and since knowledgeable people are in short supply and expensive, education may be the most cost-effective option.

This is perhaps the most exciting period in the evolution of health care delivery in this century. Hospitals will remain a critically important part of that system. Those who recognize that the hospital is only *one* part will be best positioned to deal with the future.

REFERENCES

[1] Office of the Department of Health & Human Services. *Health, United States, 1993*, compiled by the National Center for Health Statistics, Centers for Disease Control and Prevention (CDC), 1994.

CAPITOL COMMENTS

(continued from page 6)

TRENTON

On December 23, 1993, Governor James Florio signed Senate Bill 1631 into law, which took effect in June 1994. This particular piece of legislation is broadly written and applies to all diseases.

ALBANY

New York became the second state with off-label drug legislation when Chapter 853 became effective on January 1, 1991. It applies to cancer drugs only.

RALEIGH

The legislature ratified Senate Bill 622 in July 1993. The bill took effect in October and applies to contracts entered into on or after January 1, 1994. It does not contain language requiring the use of peer-reviewed medical literature.

COLUMBUS

On May 11, 1994, Ohio Governor George Voinovich signed Senate Bill 157 into law. Effective August 10, 1994, the law dictates that no private insurer providing coverage for prescription drugs shall exclude coverage of any such cancer drug on the grounds that the off-label use of the drug has not been approved by the FDA for that indication, provided, however, that the drug is recognized for the treatment of such indication in one of the three compendia or in the medical literature.

OKLAHOMA CITY

On May 26, 1993, Governor David Walters signed into law Senate Bill 106, which included off-label drug language. It took effect on September 1, 1993.

PROVIDENCE

Effective July 12, 1994, Rhode Island law requires coverage of off-label indications of FDA-approved cancer drugs when the off-label use is recognized by one of the three compendia or in peer-reviewed medical literature as safe and effective.

In addition, Governor Bruce Sundlun formally signed S. 2623 into law on October 13, 1994. The law requires health insurers to provide coverage of new cancer therapies still under investigation. The law is limited to Phase III or IV clinical trials that have been approved by the NIH in cooperation with the NCI, CCOPs; the FDA in the form of an IND exemption; the Department of Veterans' Affairs; or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants. The proposed therapy must also have been reviewed and approved by a qualified institutional review board. The new law took effect on January 1, 1995, and sunsets on December 31, 1996.

RICHMOND

Effective July 1, 1994, Virginia law requires coverage of off-label indications of FDA-approved cancer drugs when the off-label use is recognized by one of the three compendia as safe and effective. The law was signed by Governor George Allen on April 6, 1994.

OLYMPIA

The Washington State Commissioner of Insurance, Deborah Senn, recently adopted administrative rules requiring Washington insurers to provide coverage of off-label uses of FDA-approved drugs when the use is recognized in one of the three compendia or in the peer-reviewed medical literature. The language of the rule, which has the force of law, has its roots in the ACCC model legislation. It became effective January 1, 1995.