



1997 Off-Label Drug Scorecard

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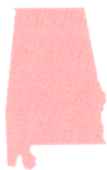
by Jamie Young

Last year was a very productive year with regard to ACCC off-label drug legislation. Seven additional states (Louisiana, Mississippi, Missouri, New Mexico, North Dakota, Oregon, and Tennessee) either enacted new laws or adopted administrative rules to ensure cancer patients access to off-label uses of FDA-approved drugs. A number of other states considered legislation but did not pass a bill (Minnesota, Nebraska, Nevada, Pennsylvania, and Vermont). One state, Virginia, amended its original law to broaden coverage of off-label uses. In 1998 legislation is expected to be introduced in Colorado, Kentucky, Maine, Minnesota, Nebraska, New Hampshire, Pennsylvania, Vermont, and Wisconsin.

As an annual feature of "Capitol Comments," this 1997 off-label scorecard lists the twenty-seven states that now have laws in place. Copies of each of these laws are available through the ACCC Columbus office.

MONTGOMERY

On May 6, 1994, Gov. James E. Folsom, Jr., signed Senate Bill (S.B.) 103 into law. The bill took effect immediately upon the governor's signature. The law 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.

LITTLE ROCK

Arkansas became the eighteenth state to pass off-label drug legislation into law when Gov. Jim Guy Tucker signed S.B. 816 on April 12, 1995. Effective July 28, 1995, the law requires coverage of off-label uses of FDA-approved cancer drugs when the off-label use is recognized as safe and effective for treatment of that specific type of cancer in any of the three compendia or two articles from major peer-reviewed professional medical journals. Two amendments were added to the bill that differentiate it from most other off-label laws. They state that the law shall not be construed to require coverage for experimental or investigational drugs as defined by the insurance policy, nor shall the law be construed to require coverage for experimental or investigational dosage or application of a drug, as defined by the insurance policy.



SACRAMENTO

Gov. Pete Wilson signed Assembly Bill 1985 into law in September 1992. This law took effect on January 1, 1993, and applies to drugs used in the treatment of life-threatening illnesses, not just cancer drugs.



HARTFORD

On May 27, 1994, Gov. Lowell P. Weicker, Jr., signed into law a bill assuring access to off-label uses of anti-cancer drugs for the citizens of Connecticut. File #88 (S.B. 249), which took effect on October 1, 1994, 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.



TALLAHASSEE

Effective July 1, 1995, Florida law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer when the off-label use is recognized by one of the three compendia or peer-reviewed medical literature as safe and effective.



ATLANTA

House Bill (H.B.) 741 was signed into law by Gov. Zell Miller on April 7, 1993, and took effect on July 1, 1993. The bill applies only to cancer drugs.



SPRINGFIELD

S.B. 1533 was signed by Gov. Jim Edgar on September 1, 1992. The Illinois off-label law took effect January 1, 1993.



INDIANAPOLIS

On June 30, 1993, the Indiana legislature voted in special session to override Gov. Evan Bayh's



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

*As of January 1, 1996, the American Medical Association stopped publishing its *Drug Evaluations*. AMA transferred its *Drug Evaluations*' files to the United States Pharmacopeial Convention, Inc. USP is in the process of reviewing AMA's material.

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veto of H.B. 1001, the state budget bill. Included in the bill was a provision for coverage of off-label drugs used to treat cancer. The law took effect immediately.

BATON ROUGE

Effective August 15, 1997, Louisiana law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer when the off-label use is recognized in one of the compendia or in the medical literature. S.B. 722 was amended in the Senate to narrow the definition of peer-reviewed medical literature using language provided by ACCC. The bill was also amended on the House floor to exempt individually underwritten specified disease policies from the bill's provisions.



ANNAPOLIS

Maryland Gov. William Donald Schaefer signed H.B. 1222 into law on May 26, 1994. The law, which took effect on October 1, 1994, is broadly written. It 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. Corrective legislation was passed in 1995 to amend the law to include health maintenance organizations which were inadvertently excluded from the original law.



BOSTON

On July 10, 1994, Gov. 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 medical literature.

LANSING

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



JACKSON

Effective July 1, 1997, Mississippi law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer when the off-label use is recognized by either of the two compendia or in the medical literature as safe and effective. S.B. No. 2589 was signed into law by Gov. Kirk Fordice on March 25, 1997.



JEFFERSON CITY

H.B. 335, a managed care reform package, was signed by Gov. Mel Carnahan on June 25, 1997. The new law, which took effect on August 28, includes a section requiring insurers to cover off-label uses of FDA-approved drugs when those uses are recognized in the compendia or peer-reviewed medical literature. Two stand-alone off-label bills were also introduced and passed by various committees but were shelved in favor of H.B. 335.



TRENTON

On December 23, 1993, Gov. James Florio signed S.B. 1631 into law, which took effect in June of the following year. The law 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. The law applies to cancer drugs only.



SANTA FE

A New Mexico Department of Insurance regulation regarding "HMO Regulation/Patient Protection," which included off-label language, was adopted and took effect on March 14, 1997. The regulation states, "No managed health care plan that provides coverage of prescription drugs as a basic or supplemental service shall limit or exclude coverage for any drug approved by the U.S. FDA on the basis that the drug has not been approved for the treatment of a particular indication for which the drug has been prescribed, provided that the drug has been recognized as safe and effective in: a) one or more of the standard reference compendia, including the *AMA Drug Evaluations*, the *American Hospital Formulary Service Drug Information*, and *Drug Information for the Healthcare Provider*."



RALEIGH

The legislature ratified S.B. 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 the peer-reviewed medical literature.



BISMARCK

Effective August 1, 1997, North Dakota law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer or any other condi-



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tion when the off-label use is recognized by either of the two compendia or in the medical literature as safe and effective. H.B. 1428 was signed by Gov. Edward T. Schafer on March 25, 1997.

COLUMBUS

On May 11, 1994, Gov. George Voinovich signed S.B. 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. Two years later, in February 1996, Gov. Voinovich signed S.B. 107 into law, expanding the off-label provisions of the original law to drugs used for all illnesses. 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 for purposes of the state law.

OKLAHOMA CITY

On May 26, 1993, Gov. David Walters signed into law S.B. 106, which included off-label drug language. The law took effect on September 1, 1993.

SALEM

Effective October 4, 1997, Oregon law requires coverage of off-label indications of FDA-approved drugs for the treatment of cancer or any other condition when the off-label use is recognized as effective for the treatment of that indication by the Health Resources Commission. S.B. 312 was signed into law by Gov. John Kitzhaber on July 23.

This law is different than the other twenty-six states in two ways. First, it places the responsibility for determining the effectiveness of the drug for off-label uses to the existing Health Resources Commission. In doing so, the law includes the usual list of compendia and medical literature with one exception. The list of compendia also includes *Drug Facts and Comparisons*, which was requested by BC/BS of Oregon.

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 peer-reviewed medical literature as safe and effective.

COLUMBIA

On May 29, 1996, South Carolina became twentieth state to pass off-label drug legislation when Gov. David Beasley signed H.B. 4585 into law. The law incorporated the language negotiated by ACCC, the pharmaceutical industry, and the South Carolina Alliance for Managed Care. While the law applies only to cancer drugs, it does follow the ACCC model legislation in that it relies on the three compendia and the medical literature to substantiate off-label uses that must be covered by insurers. The new law took effect 120 days following the governor's signature.

NASHVILLE

After two previous attempts, legislation was also enacted in Tennessee in 1997. H.B. 772 was signed into law on May 27, 1997, by Gov. Don Sundquist and took effect on July 1, 1997. H.B. 772 was drafted broadly and applies to off-label uses of all drugs when recommended in the com-

pendia, the peer-reviewed medical literature, or by the Commissioner of Commerce and Insurance. The bill also includes language to establish a medical expert panel.

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 Gov. George Allen on April 6, 1994.

In 1997 Sen. Jane Woods introduced legislation (S.B. 1164) to expand the current off-label law as well as other services to state employees and retired state employees. In addition, the language of the bill used portions of the National Association of Insurance Commissioner's (NAIC) model off-label bill that defines the medical literature as those publications adhering to the International Committee of Medical Journal Editors Uniform Requirements for Manuscripts. ACCC's attempts to amend the bill to include the list of journals used in the Medicare program were rejected. The bill was approved in mid-February and was signed into law by the governor.

OLYMPIA

The Washington State Commissioner of Insurance, Deborah Senn, 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. The law became effective January 1, 1995.