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To cite this article: Jamie Young (1993) Medicare and Cancer Coverage, *Oncology Issues*, 8:3, 6-7, DOI: [10.1080/10463356.1993.11904424](https://doi.org/10.1080/10463356.1993.11904424)

To link to this article: <https://doi.org/10.1080/10463356.1993.11904424>



Published online: 18 Oct 2017.



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The Medicare Cancer Coverage Improvement Act has been reintroduced in Congress by the same sponsors of last year's bills. Senator Jay Rockefeller (D-W.V.) and Representative Sander Levin (D-Mich.) have filed S. 821 and H.R. 1787, respectively. Similar legislation last year resulted in one of the provisions being included in other legislation that was ultimately vetoed by President Bush.

The bills seek to assure Medicare coverage of off-label drugs by requiring coverage when the use of an FDA-approved anticancer drug is included in one of the three major medical compendia or is supported by the peer-reviewed medical literature. When this criteria is met, that use would be considered a medically accepted indication and would then be covered by Medicare. A second provision of the legislation addresses oral drugs. It would cover certain self-administered anticancer drugs by extending coverage for oral anticancer drugs that contain the same active ingredient as an injection that would be given to the patient in the physician's office. The third major provision calls for the Department of Health and Human Services to study the effects of covering patient care costs associated with clinical trials of new cancer therapies and to develop criteria for such coverage. The study would be due two years after the bill becomes effective.

Although S. 821 and H.R. 1787 have been introduced, they are not likely to be considered as single, stand-alone pieces of legislation. Already, the language of the proposal has been lifted and inserted into the Medicare Budget Reconciliation legislation. This omnibus legislation contains numerous items

in addition to the Medicare Cancer Coverage Improvement Act. While the House versions of the reconciliation bill include the Medicare Cancer Coverage Improvement Act, the Senate version does not, largely because of a rule that will not allow zero-budget items to be included in budget bills. The reason for this type of rule is to prevent legislation from being loaded up with items not germane to the original subject matter of the bill. Unfortunately, in this circumstance, the Medicare Cancer Coverage Improvement Act is considered not to have a budgetary impact and should therefore not be permitted to be included in a budget bill. This could prove to be a fatal sticking point as the two bodies seek to reach compromise language. At the time of this writing, it is unclear as to whether Congress will finish the work on this legislation prior to its August recess. If not, the matter will be taken up when Congress returns in the fall.

A TAXING PROPOSITION

The Coalition on Smoking OR Health, consisting primarily of the American Heart Association, the American Lung Association, and the American Cancer Society, continues to push hard for a \$2-3 increase in the federal excise tax on cigarettes. Senator Bill Bradley (D-N.J.) and Representative Mike Andrews (D-Tex.) have introduced bills that would raise the tax to a total of \$1 per pack. However, Congress is waiting on the White House to unveil its health care reform package before moving on this item, as well as many others. According to the Coalition, its discussions with the Clinton Administration have not met with any resistance to the general concept of a cigarette tax increase within the context of health care reform. They are not aware, though, of what level of increase will be recommended

by the Administration's plan. Incremental increases, possibly indexed to inflation, are one scenario. Overall, the ACCC continues to be supportive of these efforts and is working with the American Society of Clinical Oncology and other groups to see that it becomes a reality.



Oklahoma City

Ongoing conversations with legislative leaders in Oklahoma proved fruitful as off-label drug language was added in May to existing legislation already under consideration. The definition of the compendia was different than in the ACCC model bill but still included the U.S. Pharmacopeial Convention's *Drug Information*. The full Oklahoma legislature approved the conference committee report, and on May 26 Governor David Walters signed the bill into law. It takes effect on September 1, 1993. ACCC worked closely with members of our Industry Advisory Council and Charles Nash, M.D., president of the Oklahoma Society of Clinical Oncology.



Indianapolis

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

Under new Indiana Chapter 27-8-20 insurance policies or health maintenance contracts that are entered into or renewed with employers or individuals that become effective after June 30, 1993, are required to cover off-label drugs

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used in the treatment of cancer. The newly enacted state law provides that no private insurer who provides coverage for prescription drugs shall exclude coverage of any such drug used for the treatment of cancer on the grounds that the off-label use of the drug has not been approved by the FDA for that indication. However, the drug must be recognized for the treatment of such indication in one of the standard reference compendia or in the peer-reviewed medical literature. Standard reference compendium is defined as *Drug Information* by The United States Pharmacopeial Convention, Inc.; The American Medical Association's *Drug Evaluations*; and *The American Hospital Formulary Service Drug Information*, published by the American Society of Hospital Pharmacists. However, if no listing appears, the drug may still meet the requirements of the law if it is recommended for that particular type of cancer and found to be safe and effective in formal clinical studies, the results of which have been published in a peer-reviewed professional medical journal published in either the United States or Great Britain.

Although procedural problems in Indiana developed on the original bill, expectations were that it would be amended into another insurance-related bill. What happened was that the language of HB 1270 was placed into another insurance-related bill during conference committee negotiations. That bill was reported to the House and Senate on the very last day of regular session. The Senate approved the report, but the House failed to act on it based on the recommendation of a staff member of the Governor's office. That recommendation had to do with ongoing budget considerations and the mistaken belief that this bill would provide leverage to bring the Senate Repub-

licans to an agreement on the budget. In other words, the bill that now included the off-label drug provision was being held political hostage.

The last day came and went without the report being approved. That event necessitated working to assure the bill was taken up during the special session that was called to finalize the budget. Literally no one was opposed to the off-label language, and the issue attracted a good deal of media interest heading into the special session. A rally was organized at the Statehouse for the supporters of the bill. The end result was that widespread public support led to an agreement to include off-label in the budget bill. The inclusion turned out to be one of the few things the legislature and the governor could agree on.

A great deal of gratitude is owed to our ACCC members; Robert T. Woodburn, M.D., president of the Indiana Medical Oncology Society and his members; the Indiana Division of the American Cancer Society; and members of ACCC's Industry Advisory Council. It was a total team effort that got the job done!



Trenton

On June 14 the New Jersey State Senate Commerce Committee heard testimony from Jamie Young, ACCC Director of Public Policy and Mark Pascal, M.D., President of the New Jersey Oncology Society, supporting Senate Bill 1631, that state's version of the ACCC model bill. Amendments were adopted that delete the creation of the medical expert panel. This was negotiated and had been agreed upon by members of the insurance industry leading to the removal of any opposition to the bill. As a result, the committee voted unanimously to approve the bill. On June 28, the bill was

approved by the full Senate, also by a unanimous vote. Hearings are expected in the House this fall after the elections in November. The outlook appears good for this bill to become law this year.



Raleigh

Through the efforts of the North Carolina Oncology Society and ACCC, Senate Bill 935 has been introduced by State Senator Ted Kaplan. On May 12, the bill was amended into Senate Bill 622 on the Senate floor and approved by a vote of 48-0. The legislation now goes to the House Insurance Committee for further consideration.



Columbus

At the request of Dale Cowan, M.D., president of the Ohio/West Virginia Oncology Society, ACCC worked with the society to introduce legislation in Ohio. As a result, Senate Bill 157 was filed, which requires off-label uses of cancer drugs to be reimbursed when recognized in the three compendia or peer-reviewed literature. State Senator Grace Drake, chairperson of the Senate Health and Human Services Committee, is the bill's sponsor. ACCC and the state oncology society are working together to solicit support from other groups and have added the Ohio Division of the American Cancer Society and the Ohio State Medical Association to the list of supporters. Although the bill has received a hearing, two subsequent committee meetings were canceled due to lengthy Senate floor sessions. The Ohio General Assembly has recessed until the fall when hearings should resume. Several large insurers have thus far expressed little interest in opposing the bill. ■