Kansas) to verify insurance reimbursement issues with the business office before opening a trial. "If it's likely that patients will not receive reimbursement, we may not open a trial or we will raise the issue with a study sponsor to find a means of implementing a trial locally," says Marge Good, RNT, BSN, MPH, OCN, Manager of the Wichita CCOP. "We work very closely with business/insurance staff, maintaining open communication with the hope of preventing reimbursement issues for patients registered to trials."

Currently, 23 states have laws or special agreements regarding reimbursement for cancer clinical trials (see table "Clinical Trials Covered in State Laws and Cooperative Agreements" online at www.jopasco.org). Wisconsin is the state to most recently adopt legislation that mandates reimbursement for patient-care costs in a clinical trial, and two CTPA recipients played primary roles in getting the law passed. Both Marshfield Clinic and Green Bay Oncology (Green Bay, Wisconsin) lobbied extensively in favor of Bill 617, and physicians in both practices are quick to acknowledge the leadership of the University of Wisconsin-Madison. "It's difficult as a single person to bring about such a change," says Thomas Saphner, MD, of Green Bay Oncology. "We fell into rank behind a good leader, and I think a good state university system is key for such an effort." The bill was signed into law on March 24, 2006, and became effective on November 1, 2006.

Marshfield Clinic conducted a Web search to collect data on insurance coverage for clinical trials in various states, and Tarit Banerjee, MD, of the clinic, wrote a resolution for the Wisconsin State Medical Society (Madison, Wisconsin). "Over the course of months, we collected data regarding the number of insurance denials we received, the number and type of clinical trials we have open, and the number of enrollees, and we shared this information with our state representatives in support of the bill," says Banerjee.

Saphner notes, "Before this bill, if you offered a patient a trial and they called his or her insurance company and did not get complete assurance, the patient went into total fear. Now, we can tell Medicaid patients that coverage is guaranteed, and we can tell anybody who has routine health insurance within Wisconsin that costs are covered." He adds that passage of the bill led to a "banner year for accrual."

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Mandated Clinical Trial Coverage Varies Across States

Whether a third-party carrier will provide reimbursement to patients for clinical trials participation is often uncertain. As a result, the prospect of paying for trial participation out of pocket may prevent patients with cancer from enrolling onto a trial, even though it may provide the best treatment option. Despite the benefits of clinical trials, attempts to federally mandate coverage of clinical trial–related costs have not been successful. Efforts in state legislatures have been more successful with clinical trials legislation. As of November 2006, 20 states have clinical trials coverage laws (Table 1). In addition, insurers in Georgia, Michigan, and New Jersey have signed agreements to voluntarily cover the costs of clinical trials. In Ohio, the primary health plan for state employees has agreed to reimburse covered individuals for participating in a clinical trial.

Medicare began coverage of clinical trials in late 2000, providing reimbursement for all trial items and services, except the following: the investigational item or service itself, items and services provided solely to satisfy data collection and analysis needs, and items and services usually provided free of charge by the trial sponsor. In July 2006, the Centers for Medicaid & Medicare Services (CMS) issued a notice that it is reconsidering this coverage policy. It is unlikely that CMS will rescind coverage, but it does intend to address issues that have arisen with implementation, such as the definitions of routine care and research costs, the registering of clinical trials, removal of the self-certification process, and federal oversight of trials exempt from the Food and Drug Administration investigational new drug review. ASCO submitted comments in response to CMS' July 2006 notice

Table 1. States With Clinical Trials Coverage Laws*

Arizona	Nevada
California	New Hampshire
Connecticut	New Mexico
Delaware	North Carolina
Georgia†	Rhode Island
Louisiana	Tennessee
Maine	Vermont
Maryland	Virginia
Massachusetts	West Virginia
Missouri	Wisconsin

* Illinois had a state law effective January 1, 2000, but it expired on January 1, 2003, and has not been renewed.
† Georgia's state law (requiring coverage only for pediatric cancer trials) is less comprehensive than its cooperative agreement.

and submitted additional information to a December 2006 Medicare Coverage Advisory Committee meeting. (Both sets of comments are available by contacting cancerresearch@asco.org.) [*Editor's note: See the November 2006 issue of the* Journal of Oncology Practice *for articles on "Navigating the Clinical Trial Billing Maze" on page 280 and "Developing an Effective and Compliant Plan for Billing Clinical Trials" on page 265.*]

The state laws differ in the types of trials covered with respect to phase and disease (cancer only or life-threatening diseases), as well as whether the trial addresses prevention, treatment, palliation, or early detection. Specific trial-related costs and other criteria also vary across laws and agreements. Oncologists should check with the relevant laws in their own states to better understand coverage requirements. More detailed information on the state laws can be found online at www.jopasco.org.

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