

State payer mandates to cover cancer trials offer heterogeneous protection for patients

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A 2001 federal law mandates care for Medicare-eligible patients enrolled in clinical trials; however, only 25 state laws cover clinical-trial related medical costs for non-Medicare patients, and these offer less protection than the federal law. A lawyer explains these findings in a special article published online March 2 in the *Journal of the National Cancer Institute*.

In the United States, participants' costs for routine care and complications from [cancer clinical trials](#) are covered by Medicare because of a 2001 [Medical Coverage](#) Determination. People not covered by Medicare, however, depend on state insurance mandates with respect to coverage. Few publications have examined state laws regarding insurance coverage for costs of cancer clinical trials, and none have addressed whether such provisions promote scientific and ethical quality.

To address these issues, Patrick L. Taylor, J.D., of the Children's Hospital Boston and Harvard Medical School, reviewed legal data from three nationwide cancer trial databases and from similar databases in each state. State mandates were reviewed for requirements to assure trials' scientific and ethical soundness, whom they covered and omitted, scope, and coverage for participants' research-related injuries in addition to routine care costs.

Taylor found that only 25 states had enacted legislation concerning coverage of cancer clinical trial costs. Among these, most did not expressly require unbiased scientific review or ethical review. About

half of them required coverage of only certain kinds of trials, under certain conditions, and very few required publication of results.

"For science and ethics to matter in practice, there will need to be closer, more exact communication between legislators and diverse members of the oncology community, including clinical researchers, on essential policy elements....," the author writes.

There appears to be much room for legislative improvements both to help patients and to improve research, the author adds.

More information: jnci.oxfordjournals.org

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