Maryland Bill Proposes Mandated Clinical Trial Coverage

A bill that would mandate the most comprehensive insurance coverage for clinical trials anywhere in the United States is expected to be brought to the Maryland Legislature this month. It would mandate that insurers provide coverage for people enrolled in approved clinical trials for cancer and other “life-threatening conditions.”

The bill, sponsored in the Senate by Sen. Thomas L. Bromwell (D) and in the House by Delegate Carolyn Krysiak (D), is expected to pass into law as it has garnered the support of the Maryland Association of Health Maintenance Organizations (MAHMO). The insurance industry trade association’s opposition helped defeat a similar bill last year. The industry feared that it would end up spending too much on what it considered to be many expensive and unreliable experimental techniques that could have unknown side effects.

Educational Push

Barry Meisenberg, M.D., director of hematology and oncology at the University of Maryland Hospital, Baltimore, said that the support of MAHMO came after an extensive education effort by both Martin Abeloff, M.D., director of the Johns Hopkins Oncology Center, and himself on the importance of clinical trials to medicine.

“We made the point that medical progress would grind to a standstill in a few years without clinical trials,” said Meisenberg. The rate of accrual in clinical trials is low and research physicians have cited a lack of coverage by insurers as a major contributing factor.

No coverage of clinical trials “is a disservice to cancer patients, number one,” Abeloff said. “It’s clearly a barrier not only to entering patients into clinical trials but to their development as well.” Abeloff said that the opportunity to explain away some misunderstandings about clinical trials and open a real dialogue with HMOs was an important step.

Meisenberg said they had to educate the HMOs that coverage of clinical trials is not an either/or proposition. “It’s not ‘clinical trials or no therapy,’” Meisenberg pointed out. If a patient with a life-threatening disease can’t afford to enter a clinical trial due to a lack of insurance, Meisenberg said, that patient is going to use the conventional therapy that the insurance already does cover. It will still cost the insurers money, although the costs of taking care of a patient in a clinical trial are not necessarily higher.

“We gave them tangible examples of some clinical trials which have led to lower costs. Like 6 months of breast cancer adjuvant therapy instead of 12; 5 years of tamoxifen instead of 10.”

Dr. Martin Abeloff

Thomas Barbera, President of MAHMO, said that it seemed there was strong sentiment for this type of bill in the legislature, and MAHMO took the opportunity to work with the proponents of the legislation to craft something that would accommodate MAHMO’s concerns.

“It was a long process,” Barbera said, “[and] not an easy process.” Barbera said it was fair to say that a large part of the negotiation process was educational. “Big ideas don’t pass in 1 year,” he said. “They take time to digest and fully understand. The time spent educating MAHMO’s members proved very fruitful.”

That willingness to be educated was an important step, according to Meisenberg. “They understand that when faced with a life-threatening disease, people will demand” this kind of coverage, he said.

The proposed law will fund clinical trials approved by one of the National Institutes of Health, or an NIH-sponsored cooperative group or center, the federal Department of Veterans Affairs, the U.S. Food and Drug Administration in cases of an investigational new drug application, and trials conducted by academic medical centers.

Patient care will be insured for trials of either treatment or palliative intent. Phase I to phase IV cancer clinical trials would be covered. For other “life-threatening conditions,” phase II to phase IV clinical trials will be covered and coverage of phase I trials would be on a case-by-case basis.

Breaking the Ice

“It helps to have one state break the ice,” Meisenberg said. He expects that the success in Maryland will provide a certain comfort level for future legislation like this elsewhere. If insurers in Maryland, home of the NIH and the FDA, don’t go out of business, he said, others will be less likely to oppose such legislation in the future.
There has been a push nationwide for coverage of clinical trials, with the most success coming in the area of cancer. The National Cancer Institute has forged partnerships with health plans in the Midwest, and with government health plans run by the Department of Defense and the Department of Veteran’s Affairs to cover cancer clinical trials. Rhode Island has a law that mandates coverage of cancer trials and Vice President Al Gore recently announced a 3-year demonstration project, dependent on the tobacco settlement, providing Medicare coverage of patient care costs for cancer clinical trials sponsored by the NIH. Maryland’s law would be the first to include trials concerning other life-threatening diseases.

— Laurent Castellucci

Awards, Appointments, Announcements

The Raymond Bourgine Award, presented once a year during the International Congress on Anti-Cancer Treatment, was given this year to Richard D. Klausner, M.D., at the eighth annual congress in Paris. The award recognizes exceptional scientific achievements. Klausner is director of the U.S. National Cancer Institute, and during the award ceremony at Paris City Hall, he received the Gold Medal of Paris, one of the city’s highest honors, from the Mayor of Paris.

Mayer Honored

The American Physical Therapy Association’s Oncology Section presented its 1998 Debra Flomenhoft Humanitarian Award to Deborah Mayer for her “notable contributions to oncology rehabilitation and physical therapy.” Mayer, a former member of the National Cancer Advisory Board and a current member of the National Cancer Institute’s Board of Scientific Advisors, works through Cancer Counseling and Education Services, South Easton, Mass., to help individuals and families deal with cancer-related issues and consults with organizations on issues related to improved cancer care.

New Positions for Bishop

President Clinton last month nominated J. Michael Bishop, M.D., as chair of the National Cancer Advisory Board. Earlier in February, Bishop was named chancellor of the University of California, San Francisco. Bishop, who has been a member of the NCAB since 1994, succeeds Barbara K. Rimer, Dr.P.H., as chair. She resigned from the board to become director of the National Cancer Institute’s new Division of Cancer Control and Population Science.

A Nobel laureate, Bishop will be the eighth person to lead UCSF in its 134-year history. In that position, he succeeds Haile T. Debas, M.D., dean of the UCSF School of Medicine, who became chancellor in July 1997, but planned to serve as chancellor no longer than a year. Bishop’s appointment is effective July 1.

AACR Honors Wynder

The American Association for Cancer Research, Philadelphia, will present the 1998 American Cancer Society Award for Research Excellence in Cancer Epidemiology and Prevention to Ernst L. Wynder, M.D., president of the American Health Foundation in New York. The award, to be presented in New Orleans on April 1 at the annual AACR meeting, recognizes Wynder’s “pioneering work toward establishing the relationship between smoking and lung cancer.”

Lane Nominated for OSTP

President Clinton announced his intention to nominate Neal F. Lane, Ph.D., as director of the White House Office of Science and Technology Policy. Lane has been director of the National Science Foundation, Washington, D.C., an independent federal agency that provides support for research and education in science, mathematics, engineering, and technology.

Lane will succeed John H. Gibbons, Ph.D., who is resigning after more than 5 years in the post. The director of OSTP also serves as assistant to the president for science and technology, advises the president in all areas of science and technology policy, and coordinates such programs across the federal government.

Gabrilove Named

The Mount Sinai Medical Center, New York, appointed Janice L. Gabrilove, M.D., as professor and chief of the Division of Neoplastic Diseases in the Depart-