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6

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Clinical Trials and Drive-Thru Mastectomies

by Jamie Young

oth Congress and the state legislatures have been cranking up the legislative process this spring to a level of activity on cancer-related issues that has not been matched in recent memory.

On February 27, U.S. Senators Jay Rockefeller (D-W.V.) and Connie Mack (R-Fla.) reintroduced bipartisan legislation that would initiate a five-year demonstration project in which Medicare recipients enrolled in cancer clinical trials would have their routine patient care costs covered. The bill currently has twenty-four of their Senate colleagues listed as cosponsors.

ACCC was present at a congressional luncheon briefing on S. 381, The Medicare Cancer Clinical Trial Coverage Act of 1997, a few days prior to the official introduction of the legislation. Speakers at the well-attended luncheon, in addition to the senators themselves, included cancer patient advocates and cancer researchers who shared their knowledge of the success and opportunities in cancer research and treatment.

Under the bill, which will be considered by the Senate Finance Committee, Medicare would cover "routine patient care costs," including physician charges, hospital costs, and routine diagnostic tests. These costs would otherwise be covered under Medicare if the patient were not participating in a clinical trial. The cost of investigational drugs or devices would continue to be covered by the research sponsor, as would research costs such as data collection and analysis. Similar legislation is expected to

Jamie Young is ACCC director for state societies and government relations. be introduced in the House of Representatives by Congresswoman Nancy L. Johnson (R-Conn.).

At the recent ACCC Governmental Affairs Forum, held during the Association's 23rd Annual National Meeting in Washington, D.C., Mark Smith of Senator Mack's office stressed the importance of S. 381. He encouraged ACCC members to contact their elected representatives and to invite their legislators to tour our cancer centers to learn first hand about cancer care and clinical research.

DRIVE-THRU MASTECTOMIES

In addition to clinical research, there has been a tidal wave of legislation on the issue of outpatient, or "drive-thru," mastectomies at both the state and federal levels. Last year twenty-nine states enacted laws seeking to curb "drivethru deliveries" by mandating that insurers pay for at least fortyeight hours of inpatient care for mothers and newborns, according to the National Conference of State Legislatures. This year, the outpatient mastectomy issue has generated more than eighty bills in thirty-two states.

U.S. Senator Thomas A. Daschle (D-S.D.) has introduced The Breast Cancer Patient Protection Act (S. 143) on the federal level. It would guarantee that women can spend at least forty-eight hours in the hospital after a mastectomy. It is modeled after last year's unanimously supported bill to end "drive-thru deliveries." Identical legislation (H.R. 135) has been introduced in the House by Representative Rosa DeLauro (D-Conn.), John Dingell (D-Mich.), and Marge Roukema (R-N.J.).

The bills leave the decision up to the patient and her doctor, but require insurers to pay for at least forty-eight hours of hospitalization for a mastectomy, and a minimum of twenty-four hours for lymph node removals. By setting a floor of at least forty-eight hours of coverage, the bill establishes a clear and reliable standard while leaving the final decision up to the patient and her doctor.

Another related issue has also begun to receive attention but is as yet the subject of less legislation. Seventeen states have legislation introduced to mandate coverage of reconstructive surgery after mastectomy. In Congress Senators Daschle and Edward Kennedy (D-Mass.) will also be introducing a bill for coverage of breast reconstruction surgery.

In March the ACCC Governmental Affairs Committee, under leadership from its new chair Edward L. Braud, M.D., unanimously agreed to lend ACCC's support to both issues at the congressional level. The decision was supported by the ACCC Board of Trustees.

ERISA UPDATE

Until recently states had no jurisdiction over health benefits offered by businesses that insure themselves, even when a worker registers a complaint with the state insurance commissioner. This is because self-insurers come under the umbrella of the federal Employee Retirement Income Security Act, known as ERISA. ERISA compliance is monitored by the U.S. Department of Labor.

According to an article in the March 1997 issue of *Governing* magazine, this situation is beginning to change. In January Oklahoma signed a "first-of-itskind agreement with the federal *continued on page 8* government that allows the state to be the Labor Department's eyes, ears, and initial enforcer," according to the article.

The Oklahoma Department of Insurance now has authorization to probe employers on complaints brought to their attention. The department can demand explanations from employers under threat of subpoenas that could be used by federal officials.

The Oklahoma insurance commissioner described the current scenario as one where companies ignored the state when it tried to investigate. As a result, the state initiated discussions with the Labor Department, which led to the two-year agreement.

As reported in *Governing*, the kinds of investigations Insurance Commissioner John Crawford has in mind, are "those for complaints like the one from a woman who was undergoing chemotherapy treatments for cancer when her employer terminated her benefits," Crawford said. "All we could do was say we were sorry and refer her to the Department of Labor. Now we have the authority to intervene."

ACCC's executive offices are often contacted by cancer survivors and their physicians about coverage issues. The most difficult questions to answer are those involving selfinsured plans, which lack accountability and regulatory authority to intervene. This agreement may serve as a prototype to duplicate elsewhere as we strive to assure quality cancer care for our patients.

HOME PAGES: STATE LEGISLATURES

At right are state legislative websites that allow the public access to listings of health care bills and other useful information. As with most things in cyberspace, the quality and quantity of information varies greatly from one site to the next.

STATE	ADDRESS
Alabama	www.asc.edu/archives/legislat/legislat.html
Alaska	www.state.ak.us/local/akpages/LEGISLATURE/home.htm
Arizona	www.azleg.state.az.us
Arkansas	www.uark.edu/~govninfo/PAGES/LEGISLATIVE/index.html
California	www.leginfo.ca.gov
Colorado	www.state.co.us/gov_dir/stateleg.html
Connecticut	www.state.ct.us/government.htm#Legislative_Branch
Delaware	www.state.de.us/govern/statlegi.htm
Florida	www.leg.state.fl.us
Georgia	www.state.ga.us/Senate OR www.state.ga.us/House
Hawaii	www.hawaii.gov/lcsd/leg/leg.html
Idaho	www.state.id.us/legislat/legislat.html
Illinois	www.state.il.us/CMS/HP0040.HTM
Indiana	www.state.in.us/acin/lga/index.html
Iowa	www.legis.state.ia.us
Kansas	www.ink.org/ink-index.cgi?type=byserv&which=legislative
Kentucky	www.lrc.state.ky.us/home.htm
Louisiana	www.house.state.la.us OR www.senate.state.la.us
Maine	www.state.me.us/legis/opla/homepage.htm
Maryland	mlis.state.md.us
Massachusetts	www.magnet.state.ma.us/legis/legis.htm
Michigan	info.migov.state.mi.us/legislature.html
Minnesota	www.leg.state.mn.us
Mississippi	www.ls.state.ms.us
Missouri	www.house.state.mo.us/gahome.htm
Montana	www.mt.gov/leg/branch/branch.htm
Nebraska	unicam1.lcs.state.ne.us
Nevada	No home page
New Hampshire	www.state.nh.us/gencourt/gencourt.htm
New Jersey	www.njleg.state.nj.us
New Mexico	www.nm.org/legislature
New York	assembly.state.ny.us OR www.senate.state.ny.us
North Carolina	www.legislature.state.nc.us
North Dakota	www.state.nd.us/lr
Ohio	www.odn.ohio.gov/ohio/index-le.htmlx
Oklahoma	www.lsb.state.ok.us
Oregon	www.leg.state.or.us
Pennsylvania	www.pasen.gov
Rhode Island	www.rilin.state.ri.us
South Carolina	www.lpitr.state.sc.us
South Dakota	www.state.sd.us/state/legis/lrc/lrc.htm
Tennessee	No home page
Texas	www.state.tx.us/leg/info.html
Utah	www.le.state.ut.us
Vermont	www.leg.state.vt.us
Virginia	legis.state.va.us
Washington	leg.wa.gov
West Virginia	www.state.wv.us/elected
Wisconsin	badger.state.wi.us/agencies/wilis
Wyoming	legisweb.state.wy.us