THE ISSUES

New Bill Aims to Ensure Patient Access to Cancer Care

ACCC has been working with both Congress and the Centers for Medicare and Medicaid Services (CMS) to ensure that hospital outpatient departments receive adequate payments that cover the cost of delivering cancer care. The culmination of these efforts was legislation introduced by Representative Clay Shaw (R-Fla.) on Sept. 25, 2002. The Beneficiary Access to Cancer Act (H.R. 5450) incorporates many ACCC proposals to ensure patients continue to have access to vital treatments in hospital and outpatient departments.

In the short-term, H.R. 5450 helps guarantee that cancer care is adequately reimbursed by mandating that all drugs continue to be reimbursed at 95 percent of average wholesale price (AWP). Looking to the future, the legislation requires CMS to review its data and revise its methodology for converting hospital charges to hospital costs.

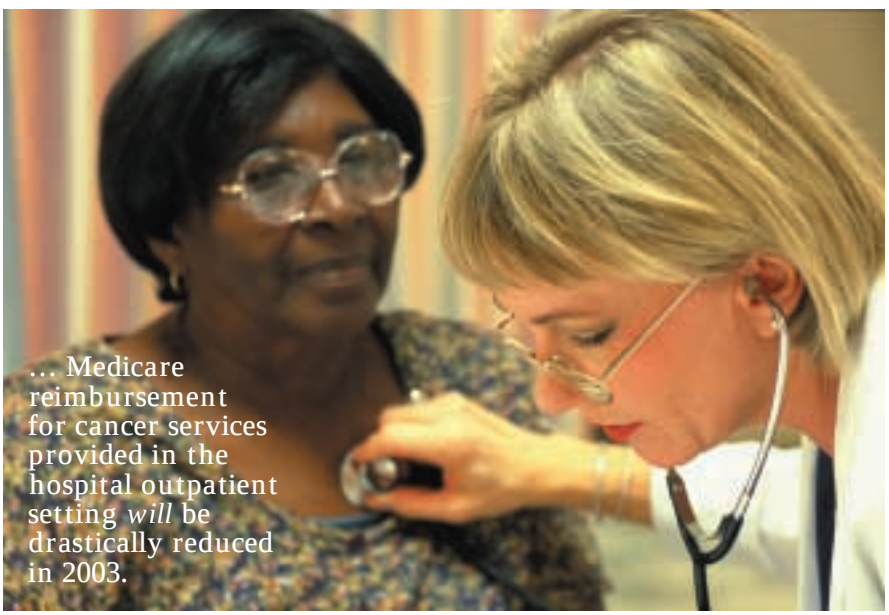
The legislation also calls for a study to evaluate the pharmacy service costs incurred by community cancer centers. Pharmacy costs are currently reimbursed through the drug payments, and if those payments are reduced in the future, pharmacy services will not be reimbursed. ACCC suggests either an increase in the drug payment in recognition of these costs or a new pharmacy payment that will adequately reimburse cancer centers so they can continue to deliver safe and appropriate care.

While introducing H.R. 5450 is a victory for ACCC and its member institutions, the bill must be enacted into law in order to protect hospitals from the drastic cuts proposed by CMS on August 6, 2002 (*http://cms.hhs.gov/regulations/hopps/propcy2003.asp*). If nothing is done, these reductions will go into effect January 1, 2003, and Medicare reimbursement will fall far below hospital costs for cancer treatments.

These proposed reductions are just one of the many obstacles hospitals have faced during the "bumpy" transition to a new Medicare prospective payment system (PPS). When this new payment system went into effect, Congress mandated that cancer drugs be reimbursed at 95 percent of AWP. Congress mandated this payment rate would remain in effect for two to three years. During that time CMS would gather hospital data and use the data to determine a new payment rate for each drug. The two- to three-year period is now over, and in January 2003 hospital data must support a new payment rate for cancer drugs.

These new payment rates are problematic since hospital data are "sketchy" and the methodology applied to that data to reduce hospital charges to cost is inadequate. Specifically, the methodology, which uses a hospital-specific, department-specific, cost-to-charge ratio, does not account for variability in how hospitals mark up various drugs and services on their bills. The methodology inaccurately assumes that some "average" of the markup on inexpensive and very expensive drugs will be sufficient to cover hospital costs. Both the data and the methodology have already resulted in huge payment reductions for cancer drugs.

Further complicating the issue is CMS' proposal to "bundle" the reimbursement payments for drugs costing less than $150 per encounter into the administration payment for that drug. Not only is the $150 threshold arbitrary but, even worse,



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the agency's poor data have resulted in some expensive drugs being bundled incorrectly.

Bundling drugs means that neither CMS nor the hospitals will be able to track how much a specific drug is reimbursed and compare that figure to the actual purchase cost incurred by the hospital. The final result may mean that hospitals will have no incentive to appropriately code these drugs on their cost reports.

Even more alarming is the fact that, in most cases, CMS is proposing bundled payments (for the drug and administration) that are *lower* than what hospitals received for the administration payment alone last year.

Although about half of the drugs exceed the $150 per encounter and will continue to receive a separate payment for the drug and its administration, both payments have been reduced in CMS' proposal. In many cases, the drug payment has been reduced based on the poor data and methodology discussed above. ACCC has analyzed the proposed 2003 payment rates and found that some payments fall more than 40 percent below last year's reimbursement rates.

The bottom line is that Medicare reimbursement for cancer services provided in the hospital outpatient setting *will* be drastically reduced in 2003. ACCC, along with other concerned organizations, has submitted comments on CMS' proposal (*http://www.accccancer.org/news/accccomments.asp*). CMS will issue its final rates in November. While ACCC hopes that CMS will revise many of its cancer drug payment rates, work continues to ensure that Congress will be ready to act with H.R. 5450.

ACCC is partnering with other organizations in the cancer community, including the Oncology Nursing Society (ONS) and the Association of Oncology Social Work (AOSW), to ensure a "united" voice for cancer patients. Additionally, ACCC-member institutions have been asked to lend their support to the grassroots effort. Logging onto ACCC's web site (*www.accc-cancer.org*) regularly for updates and responding to its "Calls for Action" are critical.

ILLUSTRATION/GETTY IMAGES

JCAHO Announces Major Changes in Accreditation for 2004

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced Oct. 3, 2002, major changes to its accreditation process for health care organizations. Effective in January 2004, the new accreditation process will substantially reduce the number of existing Joint Commission standards, in turn easing the documentation burden, particularly for nursing staff. In addition, JCAHO will shift the basic ownership of the evaluation process to the accredited organization through a self-assessment process, use data from multiple sources to guide the outside accreditation survey, and allow the outside evaluation to be conducted in the context of tracking actual patient experiences. The self-assessment process will be supported by newly developed software that is expected to help ease the burden of the actual self-assessment.

An accredited organization will complete the self-assessment at the 18-month point in its three-year accreditation cycle, rating the level of compliance with all standards that are applicable. JCAHO will provide each hospital with access to a password-protected extranet site to complete the assessment. There will be no on-site surveyor visit at the 18-month point.

In the self-assessment, if an organization finds itself not compliant in any standards area, it must detail the corrective actions that it has taken or will take.

JCAHO's new initiative is entitled *Shared Visions—New Pathways.* "It shifts the paradigm from a focus on survey preparation to one of continuous operational improvement. In so doing, it enables the accreditation process to become more of a service than a commodity," said Russ Massaro, M.D., JCAHO's executive vice president for accreditation operations.

The goal is to increase the value and satisfaction with accreditation among accredited organizations and their professional staffs, while decreasing costs related to survey "ramp-up" and resource allocation.

The new process will focus more closely on operational improvement and organization-specific, critical patient care processes and systems, not rote assessment of standards compliance. In addition, JCAHO has implemented a strategic initiative to enhance the relevance of accreditation to physicians by better engaging them in the accreditation process. A Medical Staff Standards Review Task Force will identify meaningful roles for physicians in achieving and maintaining JCAHO accreditation for the organizations in which they provide care.

The October 2002 edition of JCAHO's official newsletter, *Perspectives*, takes an in-depth look at the new accreditation process and is available at *www.jcrinc.com/perspectives*.

Medicare Recipients Report Difficulties Finding Physicians

Over the last year, ACCC has maintained that reductions in reimbursement for both the physician and hospital outpatient department are threatening Medicare beneficiaries' access to vital care. A recent report (*www.medicarerights.org/FactSheet-AccessDocs.pdf*) on the financial impact of Medicare reimbursement

…three states reported that cuts in Medicare reimbursement were…why doctors were not accepting new Medicare patients.

on beneficiary access to care conducted by the Medicare Rights Center (MRC) confirms ACCC's concerns.

The MRC report, *Have People with Medicare Lost Access to Doctors?*, found that calls from beneficiaries having trouble finding a doctor who accepts new Medicare patients have increased in at least eight states in 2002 (Ariz., Mo., N.H., N. Mex., R.I., Tenn., Tex., and Va.). Of those eight states, the survey found that three states (N.H., N. Mex., and Tenn.) reported that cuts in Medicare reimbursement were specifically cited as the reason why doctors were not accepting new Medicare patients. Half of the states that did not report seeing an increase in beneficiary calls in 2002 did report that beneficiaries in their state had been struggling to find doctors prior to January 2002 and continue to do so today.

The 2002 reduction to the physician fee schedule was the main reason cited by the MRC for this crisis in beneficiary access. ACCC's concerns about the impact of these cuts on beneficiaries' access to cancer care were expressed in comments recently submitted to CMS on its proposed payment rates for 2003. Not only were the 2002 rates reduced by 5.4 percent, CMS predicts negative increases for the next three years, a possibility that may result in the 2005 conversion factor being lower than the 1993 conversion factor.

Currently, physician payments are calculated using the Sustainable Growth Rate (SGR) system, which resulted in the 5.4 percent decrease in this year's physician payments. ACCC recommended that CMS fix errors in the calculations of previous years. Because the SGR is cumulative, fixing these errors will result in an increase in the physician update.

Furthermore, ACCC suggested that CMS revise its assumptions about changes in physicians' behavior in response to the fee schedule. While CMS believes that physicians will increase the volume and intensity of their services to recover approximately 30 percent of any payment rate decrease, assuming that physicians could mitigate the impact of payment decreases by increasing their volume over three consecutive years is unrealistic.

Finally, ACCC urged CMS to include the cost of national coverage decisions, outpatient prescription drugs, and medical liability in the calculation of SGR. Without a change in the calculation of the physician fee schedule, ACCC is concerned that Medicare beneficiaries will have an increasingly difficult time accessing care.

Particularly alarming to ACCC is that the trend described in MRC's report is also occurring in the hospital outpatient setting. *The Washington Post* recently reported that the Mayo Clinic in Jacksonville, Fla., has decided that it will no longer accept Medicare as a result of cuts in Medicare reimbursement. ACCC has also heard from numerous member institutions that are exploring other options for cancer departments in their hospital outpatient departments because of reimbursement rates that fail to cover the costs of providing the care. If both physician offices and hospital outpatients departments are starting to close their doors to Medicare beneficiaries, where will these patients go for care?

Without action from either Congress or CMS, beneficiaries may have to travel outside their communities to access care or may choose to forgo treatment altogether. ACCC continues to work to educate Congress and CMS about this possible impeding crisis of beneficiary access to cancer care and pursue legislative and administrative reforms to address these problems.

Major Private Insurers Agree to Pay for Cryosurgery of the Prostate

Six large Blue Cross/Blue Shield (BC/BS) plans have developed positive coverage policies specific to cryosurgery of the prostate. BC/BS plans in California, Connecticut, New Jersey, Pennsylvania, North Carolina, and Nebraska have adopted formal coverage policies for cryoablation surgery for prostate cancer.

These six BC/BS plans now join four of the largest private insurers in the U.S. that have also published

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reimbursement codes for the treatment. Over the past 12 to 24 months, United Healthcare, AETNA/USHC, PacifiCare/Secure Horizons, and Humana have established coverage for the procedure. These plans constitute health coverage for more than 75 million Americans.

Mandatory Screening for Colon and Ovarian Cancer

The Senate recently approved legislation that would require all private health insurers in the United States to cover screening tests to detect colon cancer in people over age 50. In addition, the House also approved a resolution supporting research on and health insurance coverage of ovarian cancer screening tests.

Supporters of the Senate bill (S. 710) to cover colonoscopies and other tests to detect colon cancer pointed to scientific evidence that early diagnosis of colon cancer significantly increases survivorship. However, some senators argued that S.710 is just another mandate on insurers, contributing to the rise of insurance costs, and, potentially, increasing the number of uninsured Americans.

The House resolution (H. Con. Res. 385) instructs the Department of Health and Human Services (HHS) to support research on certain ovarian cancer screening tests. The legislation states that if research supports the effectiveness of tests as early detectors of ovarian cancer, then the House will support a requirement that federal health care programs and private insurance must cover these tests. While the resolution does not specifically name a test, promising results from early-stage research on Proteome Quest software, a test that looks for protein patterns in the blood, likely led to support for this resolution.

Press reports indicate that early-stage research on Proteome Quest, a simple finger prick test that can be done in conjunction with cholesterol screening, has been found very effective in identifying ovarian cancer. The expectation is that the test's easy administration could significantly increase screening for and early detection of ovarian cancer.

While neither of these actions change current research and insurance coverage laws yet, they do signal that Congress recognizes the role that early detection plays in effectively treating cancer and are willing to invest in early screening efforts. ACCC continues to work in conjunction with the cancer community to educate Congress on this issue.

IOM Releases Recommendations for Improving Patient Safety In Research

Broader federal oversight is needed to ensure that the health and well being of people enrolled in research studies are better protected, says a new report from the Institute of Medicine (IOM) of the National Academy of Sciences.

Congress should "require every organization conducting research with human subjects to do so under the authority of a research participant protection program, which would be subject to federal oversight," recommended the IOM committee that wrote the report. However, the committee still found that "ultimate responsibility for ensuring that the essential protections are in place and followed rests on the research organization's leadership."

The IOM report was commissioned following the death of an 18-year-old boy during a 1999 clinical study at the University of Pennsylvania. This case, along with incidents at other research centers, brought to public attention growing problems in human research studies, including conflicts of interest, inadequate monitoring and oversight, and insufficient communication with participants.

Universal standards in research studies do not exist; a fact that may explain why participants may not be consistently afforded basic protections (i.e., adequate information about risks, assurance that researchers do not have conflicts of interest), the report said.

IOM proposes a participant protection program that is a system of interdependent elements—the investigators, the institution, the staff that monitors safety and data collection, the boards that review the scientific and ethical integrity of proposed research, and the research sponsor—linked through explicit responsibilities for participant protection.

Institutional review boards (IRBs) should return to their focused role of reviewing ethical issues of proposed protocols, and leave the more complex issues (i.e., institutional risk management, regulatory compliance, evaluation of increasingly complex scientific issues, assessments of conflicts of interest) to be managed by other entities within IOM's proposed protection program.

To ensure that the entire protection system receives credible, expert advice, the IOM requests that Congress establish an independent, multidisciplinary, nonpartisan advisory body whose membership should include individuals who can provide the perspective of the research participant.

In addition, the IOM calls for "reasonable compensation to be provided to people who are harmed as a result of their participation in studies." While acknowledging that more data are needed on the extent to which illness and injury happen in studies, the committee recommended the immediate creation of a no-fault compensation system to provide injured participants or their survivors with quicker claim resolution. At the minimum, compensation should include the costs of medical care and rehabilitation and could be paid for either by the research organizations or, potentially, through a federal compensation program. Finally, the IOM called for a study on the burden of lost wages, and whether these lost wages should and can be compensated.

Read the full text of *Responsible Research: A Systems Approach to Protecting Research Participants* at *http://www.nap.edu.*