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Two Worlds Collide

Medical Technology and Oncology Reimbursement—Who Will Pay?

By Cara Egan and Donald Jewler

The battle lines have been drawn: On one side is the federal government, with its mandate to cut costs and restrict reimbursement to hospitals and physicians providing oncology care. On the other side are the patients' desire for, and providers' responsibility to administer, the most advanced forms of oncology treatment. This conflict was the central theme of the Association of Community Cancer Centers' 15th Annual Oncology Economics Conference held September 16-19, 1998, in Seattle, Wash. The tremendous technological advances of recent years—from advanced treatment planning in radiation oncology to the use of monoclonal antibodies to treat metastatic breast cancer—are currently juxtaposed with a number of proposed regulations from the Health Care Financing Administration that aim to significantly restrict reimbursement for these and other oncology services. Stark II, changes in physician practice expense, and APCs all have the potential to threaten oncology care in the outpatient setting. Presentations centered around ways to respond quickly, forcefully, and in a united manner to these threats.

APCs AND CHEMOTHERAPY

ACCC Executive Director Lee Mortenson, D.P.A., was upfront about what federal regulation is doing to oncology care. "The war on cancer has shifted to the war on *cancer patients*," he said. "HCFA is rationing the level of care we provide to patients based on cost."

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Mortenson was referring to the Health Care Financing Administration's anticipated implementation of ambulatory payment classifications or APCs, which are due to take effect shortly after January 1, 2000.

"HCFA's proposed reimbursement formulas for pharmaceuticals will pay hospitals from 40 to 60 percent less than it costs the hospital to purchase drugs used in administering chemotherapy," Mortenson explained. "Based on HCFA's own study of ten comprehensive cancer centers, those centers that exclusively treat patients with cancer can expect up to a 29 percent decline in their total outpatient revenues."

These regulations are being proposed at a time when a significant number of new, innovative cancer agents are being made available to patients. However, the prohibitive expense of administering newer, more promising treatments without adequate reimbursement may force hospitals to use drugs that are older and less costly.

In addition, the new regulations do not include any direct reimbursement for supportive care drugs, such as anti-nausea drugs. "HCFA has decided that supportive therapies will be offered to patients 'free of charge,'" Mortenson quipped.

The burden of reimbursement for cancer services is being shifted to patients, while the federal contribution drops precipitously. Under the current system, Medicare patients are expected to contribute co-payments of 20 percent. Under the proposed system, Medicare patients will be expected to contribute a higher percentage, in many cases as much as 55 percent.

"Hospitals better make sure they are receiving 100 percent of their patient co-payments, because the federal government will contribute as little as $16 but no more than $71 to the total payment for any cancer therapy, including supportive care drugs, in the hospital outpatient setting," Mortenson said. Currently, Medicare covers bad debt from unreimbursed co-pays, but under this rule, bad debt restrictions will become increasingly stringent.

HCFA has indicated that it hopes to apply this reimbursement scheme to private practice offices. If that happens, Mortenson remarked, "Cancer patients will not be able to get these drugs anywhere."

Speaking at a separate session, Jennifer Edwards, manager of physician practice development at ELM Services, Inc., in Rockville, Md., presented attendees a model for computing the impact of APCs at their institutions. She highlighted two facilities, both of which expect more than a $1 million drop in federal payments due to APCs. "These hospitals would be reimbursed well below their actual costs of acquiring the drugs," stated Edwards, who advised hospitals to first accurately assess their current level of drug reimbursement before embarking on an APC study.

E. Strode Weaver, F.A.C.H.E., M.H.S.A., M.B.A., administrator of the Tumor Institute at Swedish Medical Center in Seattle, Wash., offered his suggestions to attendees. "Over the next month, your hospital administrator will ask you how APCs are going to affect your institution," Weaver said. "You'll look like a champion if you can tell him or her exactly how great a hit your institution will take from APCs."

Calculating that "hit" is a laborious process because finding good

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data can be difficult, Weaver cautioned. While someone in your institution's drug purchasing department can tell you how much a particular drug is costing you now, your costs won't add up unless the J code unit of dosing is reconciled with the actual acquisition unit of the drug, he said. Other key areas to explore include your institution's current levels of volume and billing, as well as the Medicare cost report, which will show exactly what the pharmacy is currently reimbursed for chemotherapy drugs.

The comment period for the APC regulations originally scheduled to close November 9, 1998, was extended until January 8, 1999. ACCC strongly encouraged the oncology community to respond to HCFA by this deadline with letters explaining the devastating effect of APCs on programs providing oncology care as well as the patients they serve.

CHANGES IN RADIATION ONCOLOGY

In the same session, Mortenson outlined the serious consequences of another proposed HCFA regulation that could potentially cut technical fees for radiation therapy by 24 percent. If enacted as written, regulatory changes to the physician fee schedule would have the potential to shut down up to 50 percent of all radiation oncology centers in the United States, according to an ACCC study.

The study involved a series of *pro forma* for a standard radiation oncology center reflecting HCFA's proposals. (The methodology for this study is detailed in "Radiation Oncology: HCFA's Proposed Changes to Practice Expense Regulations," by Mortenson and White, *Oncology Issues,* September/October, Vol. 13 No. 5.)

The ACCC study, in conjunction with ELM Services, Inc., examined a variety of scenarios based on Medicare mix and number of patients treated per day. "In the best case scenarios, centers with 50 or 60 percent Medicare patients and up to 35 patients per day would have been unable to generate a sufficient rate of return to stay open over a five-year period," Mortenson reported.

Similarly, a joint study by the American Society for Therapeutic Radiology and Oncology (ASTRO), the American College of Radiology (ACR), and the American College of Radiation Oncology found that the median cost per hour for radiation oncology is $370—5.5 times greater than what HCFA is currently reimbursing, according to Paul E. Wallner, D.O., F.A.C.R., speaking at the same session. Wallner is a member of ACR's Committee on Economics Commission on Radiation Oncology and ASTRO's Clinical Practice Committee.

Fortunately, at press time it appears that HCFA's final revisions to the physician fee schedule will diminish the negative impact for radiation oncology centers. In the final regulations published the first week of November, the relative values for many radiation oncology codes are much higher than those originally proposed. As with Stark II regulations, it appears that a coordinated response by the oncology community, led by ACCC, significantly influenced HCFA's ultimate ruling.

Nevertheless, institutions should be prepared for change, whether in the form of APCs or other future regulations, advised Bette Snyder, R.T.T., M.B.A., project manager for the VARiS system at Varian Oncology Systems in Palo Alto, Calif.

"As the saying goes, 'If you're not riding the wave of change, you'll find yourself beneath it,'" Snyder told attendees at the Radiation Oncology Special Interest Group session. She compared the current environment with her experience as a director of patient case management at New York Hospital–Cornell Medical Center during the time of DRG implementation. "Our hospital took a very aggressive stand on how we were going to handle that type of dramatic reimbursement change. As a result, we were successful when other hospitals experienced tremendous financial difficulty."

An institution cannot accurately determine how much it stands to lose in radiation oncology without knowing its current costs, Snyder pointed out. Once costs are determined, a radiation oncology department should begin streamlining processes and trimming expenses. Synder recommended performing patterns of care and benchmarking analyses to develop a baseline upon which to compare future improvements. "If you don't benchmark, how do you know things will improve?" questioned Snyder.

Snyder also suggested enlisting the help of department staff in trimming costs. "Let your staff know what's happening with reimbursement. Let them know what things cost," Snyder said. "They have great ideas, and when they know the costs of supplies they use every day, they'll create solutions for containing them."

ASSESSING THE VALUE OF NEW TECHNOLOGIES

Despite today's restrictive reimbursement environment, many institutions are moving forward with investments in new technologies, which have the potential to ultimately reduce a program's operating costs in the future. In addition to contributing to the bottom line, these technologies also provide intangible benefits to a program, such as a reputation for delivering cutting-edge care and putting the patient first. These new technologies continue to expand the definition of what comprehensive cancer care is, in the eyes of patients, providers, and payers.

John R. Russell, M.D., a radiation oncologist at Mobile Infirmary Medical Center in Mobile, Ala., related his program's experience in initiating its transperineal ultrasound-directed prostate seed implant program. The decision to embark on such a program was based on a combination of data and demographics. "For the first time we have promising data on 10-year outcomes," said Russell, referring to the recent results of 10-year patient outcomes published by co-presenter Haakon Ragde, M.D., chief of brachytherapy at Northwest Hospital in Seattle, Wash., and the first physician to perform the transperineal ultrasound technique in the United States. "We've also

seen heightened interest among the general population; at Mobile Infirmary, our patients demanded this service," Russell stated.

To date, more than fifty patients have undergone prostate seed implant with transperineal ultrasound at Mobile Infirmary. Over the past year the hospital has seen a 20 percent increase in prostate patients overall. However, patients electing primary external beam irradiation have declined by one-third. These numbers point to one of the more sensitive disadvantages to the program, i.e., the success of the prostate seed program may mean a potential decline in surgical and irradiation hospital revenue.

Ironically, Russell believes that cuts to the Medicare physician fee schedule will ultimately drive a renewed interest in seed implant. Despite hefty start-up costs, institutions have shown that prostate seed implantation can be provided more cost effectively than external beam and surgical techniques while delivering similar outcomes. With radiation oncology facilities facing severe cuts, prostate seed implant may be worth investigating, Russell said. (For more on Mobile Infirmary's prostate seed implantation program, see "Prostate Brachytherapy: Establishing a Competitive Modality," page 20.)

In some cases, institutions invest serious dollars in innovative programs with the knowledge that any reimbursement will be limited at best. Cancer risk assessment programs, for example, offer the latest in genetic information, counseling, and testing to patients at high risk of developing the disease. However, most institutions shoulder the majority of program costs in an effort to respond to a defined patient need, according to Ellen R. Knell, Ph.D., director of medical genetics at the Los Angeles Oncologic Institute in Los Angeles, Calif. Knell spoke at one of three Administrator Special Interest Group sessions.

"I do not know of any program in the country operating a cost-effective risk assessment program," Knell said. These programs operate more from an institution's need to serve its patients at high risk, she said. The success of the risk assessment program is instead measured by its indirect positive outcomes. "Such a program has the potential to attract new patients to your cancer program," Knell stated.

...In time most patients and providers, and eventually payers, will recognize cancer risk assessment as a core component of comprehensive cancer services.

Knell cited studies that show that the extensive counseling involved in risk assessment leads to improved patient compliance with screening and/or treatment recommendations. Knell expects that in time most patients and providers, and eventually payers, will recognize cancer risk assessment as a core component of comprehensive cancer services.

STARK II: NOW WHAT?

In early 1998 the oncology community issued a powerful response to HCFA's proposed regulations to implement the 1993 amendments to the Stark law (also known as Stark II). Under HCFA's interpretation, oncologists would be guilty of "fraud and abuse" if they did not effectively pass the discounted acquisition cost of chemotherapy drugs to the payer and/or patient.

As a result of the oncology community's massive letter-writing campaign against Stark II, HCFA is reconsidering its position. "The rules are under revision, but they are going to come," cautioned James L. Wade III, M.D., F.A.C.P., president, Cancer Care Specialists of Central Illinois in Decatur. Wade raised alarms about HCFA's plans to impose specific restrictions on chemotherapy coding that prevent medical oncologists from billing for both an office visit as well as a chemotherapy treatment on the same day. For example, physicians would no longer be able to bill Medicare for the combination of a minimal office visit (99211) coupled with chemotherapy by IV-push technique (96408). "One or both codes would be kicked out, even though the two codes involve separate and distinct pieces of work that your staff or your pharmacist must go through."

Such a code edit comes to a $27.8 million loss per year to oncology practices, according to Wade. "When you factor in the fact that the new Medicare fee schedule includes $17 million in cuts for chemotherapy administration (from 1997 to 1999), the loss expands to a $44 million hit to oncology practices."

Wade noted that there have been substantially fewer cases billed to Medicare from 1996 to 1997. "One begins to wonder if this is because people aren't getting treated any more," he said. When Medicare does implement these new code edits, the volume of chemotherapy services billed to Medicare will drop even further. Although part of the explanation for the decline in Medicare-billed services from 1996 to 1997 may be patient enrollment in Medicare HMOs, it is also likely that fewer patients are being referred to an oncologist for their cancer treatment, according to Wade.

There will be at least some consideration of a legislative fix in 1999, according to Alan K. Parver, a partner with Powell, Goldstein, Frazer & Murphy LLP, in Washington, D.C., and president of the National Alliance for Infusion Therapy. "It could be some revisions to Stark or a global change to it." He cautioned, however, that the issues of

overutilization and reimbursement will not go away and that a global change might well be worse than the current regulations. According to Parver, Congressman Pete Stark (D-Calif.) is asking the Institute of Medicare to study alternatives to the Stark regulations to see if a less intrusive way of addressing the issues can be found.

According to Kathleen Smith, R.N., B.S., C.N.N., former health policy associate for the Oncology Nursing Society and currently the vice president for government affairs for Fresenius Medical Care North America, the oncology community must come to understand what she terms "the dual sides of HCFA." On one side, HCFA is responsible to Medicare beneficiaries and in that role the agency must ensure that the beneficiaries receive the best possible care. On the other hand, the agency acts as fiscal stewards of the Medicare program. "HCFA's watchdog role sometimes causes clashes not only with the oncology community but within the agency itself," Smith explained.

This is important to remember, added Smith, in light of the oncology community's opposition to Stark II and other recent HCFA regulations. Referring to the more than 20,000 letters that HCFA received from the oncology community about Stark II, Smith said, "They got our message." Perhaps more important than the sheer number of letters was the power of a consistent message. "HCFA heard the same [reports about Stark II] from different sectors of the cancer community and that reinforced the message."

Oncology professionals need to recognize that the techniques they have honed in advocating for patients in the clinical setting lend themselves well to lobbying on behalf of patients in the public policy forum, according to Smith. "'Lobbying' is not a special technique that you need to learn. Lobbying is a natural transition from what you do all day."

Smith offered several examples of how oncology professionals can become more involved in public policy:

- *Know who your legislators are.* The blue pages in the telephone book contains information on both local and federal legislators. Listings are also available on the Internet, with direct links to e-mail addresses.
- *Build a relationship.* Your representatives in Congress could belong to your church or local civic organizations. Make an effort to get to know them, or at least develop a relationship with one of their local offices, which are located throughout representatives' districts.
- *Offer yourself as a resource.* This places you in a more powerful position, according to Smith. "You are offering your expertise; you don't appear as if you are asking for anything."
- *Know your issues.* Regularly voice your opinion on issues coming up for vote. Be very clear what you want your legislators to do and have the data to support what you want.

According to Smith, oncology professionals are in a unique position to influence national policy, no matter where in the country they may live. After all, legislators and bureucrats are just as likely to be affected by cancer as anyone, she said. Smith advised attendees to position themselves as oncology experts, and then expect to be treated as such. "You don't have to live or work in Washington to have your voice heard," Smith asserted.

SPECIAL INTEREST GROUP (SIG) ROUND-UP

Administrator SIG. Three sessions were offered.

- "Setting up a Genetic Testing Program" was presented by Ellen R. Knell, Ph.D., director of medical genetics at the Los Angeles Oncologic Institute in Los Angeles. Dr. Knell provided an overview of the programmatic and administrative requirements for operating a risk assessment program. (See page 37.)
- "Setting up a Prostate Seed Implant Program: Programmatic and Financial Hurdles." Haakon Ragde, M.D., chief of brachytherapy at Northwest Hospital in Seattle, Wash., and John R. Russell, M.D., a radiation oncologist at Mobile Infirmary Medical Center in Mobile, Ala., discussed the viability of a prostate seed implant program in light of recently published results of 10-year survival data. (See page 37.)
- "The Future of Medical Informatics–The NCI Clinical Trials System" was led by Col. John Silva, M.D., U.S.A.F., director of the Office of Informatics at the National Cancer Institute in Bethesda, Md. Col. Silva presented an overview of the development and implementation of a national cancer informatics infrastructure to re-engineer cancer clinical research.

Community Research/ CCOP SIG. James L. Wade III, M.D., F.A.C.P., president of Cancer Care Specialists in Decatur, Ill., and a member of the NCI Clinical Trials Committee, reported on the Committee's initiatives to improve NCI clinical trial design. Initiatives include initiation of the Clinical Trials Management Unit and a national network of NCI-registered investigators.

Medical Director SIG. Kathleen M. Miner, M.B.A., managing director at SG Cowen Securities in Boston, Mass., provided an overview of the stock performance of several leading cancer specialty organizations.

Nursing SIG. Kathleen Smith, R.N., C.N.N., former health policy associate for the Oncology Nursing Society shared her insights on the public policy arena and suggested ways in which all members of the oncology community can influence policy and legislation affecting oncology care.

Radiation Oncology SIG. Bette Snyder, R.T.T., M.B.A., product manager of VARiS for Varian Oncology Systems in Palo Alto, Calif., led a discussion of how to cut costs while maximizing revenue in the radiation oncology department. (See page 36.)