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HCFA Threatens Access to Chemotherapy: Key Leaders Meet to Discuss How to Best Respond

by Don Jewler

Oncology society presidents and officers from forty states, leaders from major national cancer organizations, and representatives from key government agencies, such as the National Cancer Institute, the Food and Drug Administration, and the Health Care Financing Administration, gathered in McLean, Va., for ACCC's sixth annual Oncology Presidents' Retreat, held January 30-31, 1998. The meeting was sponsored by Ortho Biotech Inc. and Eli Lilly and Company.

Heated and lengthy discussion centered around ways to respond quickly, forcefully, and in a united manner to a new threat to cancer care delivery: the Health Care Financing Administration's proposed regulations to implement the 1993 amendments to the Stark law (also known as Stark II). That law prohibits physicians from referring patients to a designated health service from which the physician is receiving remuneration, unless one of the exceptions applies. HCFA's regulations (as published in the January 9, 1998, *Federal Register*) define remuneration to include discounts received on the purchase of drugs, including chemotherapy agents. Thus, physicians would be guilty of "fraud and abuse" if they did not effectively pass the discounted acquisition cost to the payer and/or patient. This restriction on allowing any margin on pharmaceuticals would effectively destroy the office-based provision of cancer treatment in the United States.

Don Jewler is ACCC publications director.

ACCC Executive Director Lee E. Mortenson, D.P.A., gave a "State of the Union" address to the assembly, underscoring the need to move from this "retreat" to an "offensive" posture over the next few weeks. Outlining an aggressive campaign to educate congressmen, senators, physicians, and the public, Mortenson stressed the importance of grassroots activity arising from the state and local level. "We are dealing with a potentially rapid, and catastrophic, transformation of the delivery of cancer care in this country, resulting from a seemingly minor change in drug reimbursement."

Many of the oncologists in attendance voiced concerns that if the provision remains in the final rule, it would have serious repercussions on the availability and continuity of cancer care.

"In the Phoenix area there is no other arena besides the physician's office in which to provide chemotherapy—except the Veterans Affairs Hospital. Our hospitals are not geared to provide chemotherapy. It would bring chemotherapy to a halt," said David K. King, M.D., a medical oncologist and chair of ACCC's Reimbursement Committee.

"We would lose three-fourths of our oncology nurses.... How many medication errors would result in an overburdened system?," questioned Cary A. Presant, M.D., F.A.C.P., president of the Medical Oncology Association of Southern California.

"Our hospitals do not have the facilities available to take on the extra patients," said Gregory Parker, M.D., president of the Oklahoma Society of Clinical Oncology.

Others argued that the regulations pose serious restrictions on patient access to chemotherapy, regardless of setting. "It's an issue of access," said ACCC Treasurer Margaret A. Riley, M.N., R.N., C.N.A.A. "Hospitals could respond by providing outpatient chemotherapy. Hospitals have been mandated by JCAHO and ACoS to provide many unreimbursed services for oncology program certification and to comply with policies and procedures, which are not applicable to physician office practices. Hospitals have been underpaid by DRGs for oncology services. Cost shifting in pharmacies to pay for unreimbursed services occurs in hospitals, just as in physician offices. The problem is that if cost shifting is not allowed in office settings, it may also be threatened in hospital settings. But patient access to care is the ultimate threat."

To counter the perceived threats, Daniel Rosenblum, M.D., chairman of the Clinical Practice Committee of the American Society of Hematology, presented a grassroots letter that he hoped meeting attendees would deliver to their patients, who in turn would write HCFA and members of Congress. Rosenblum's message urged HCFA to conform to the spirit and intention of the Stark II ruling. "The law was intended to prevent fraud and abuse. The law was not intended to make some medical specialties unprofitable and undesirable by forcing its practitioners to operate at a loss. The law was not intended to prevent oncologists from giving chemotherapy in their offices."

Rep. William M. Thomas (R-Calif.), chairman of the Health Subcommittee of the House Ways and Means Committee and Rep. Bill Archer (R-Tex.), chairman of the full House Ways and Means Committee, are key players on the issue of Medicare reimbursement. Rep. Archer's legislative assistant,

Andrew A. Shore, told meeting attendees that access to quality cancer care is one of Archer's top priorities, and that Archer will not view lightly HCFA's proposed interpretation of Stark II.

HCFA MUMBLES AND STUMBLES

HCFA was represented at the Oncology Presidents' Retreat by Grant Bagley, M.D., J.D., Director for Coverage and Analysis Group in HCFA's Office of Clinical Standards and Quality. He was besieged by questions relating to the denial of coverage by certain Medicare medical directors for some widely accepted drug indications. Bagley agreed there should be less variation in policy on the local level, and that HCFA needs to have a consistent national policy in place. However, he was unclear how HCFA plans to rein in a few carriers, such as those in Mississippi and South Carolina, who are denying coverage for certain compendia-approved off-label uses and even for the labeled uses of GCSF. His responses both angered and confused meeting attendees.

"We need to find a way that we can follow some good scientific thinking, and not say we will use the FDA label this day, and we'll use off-label stuff this day," said Bagley. "Let's base it on the clinical science....

"I'd like to elevate the dialogue and say let's forget about the technicalities of what the FDA label says and what it's approved for or not...., " Bagley proposed. "To say that an FDA approval will automatically lead to payment because the FDA knows what they are doing leads us pretty far astray at times, very far astray at times."

"I'm not quite sure how it leads you astray," responded FDA's Susan Flamm Honig, M.D., who chastised Bagley with a lesson on FDA's rigorous review process. Honig is a medical reviewer with FDA's Division of Oncology Drug Products.

NCI's Robert E. Wittes, M.D., also responded to Bagley's remarks.

"I find much of your response incomprehensible," said Wittes. "It doesn't sound reasonable when you bemoan the lack of evidence as a basis for coverage decisions in view of your own agency's past history." Wittes is deputy director, Extramural Science, and director, Division of Cancer Treatment and Diagnosis at the National Cancer Institute.

These criticisms of HCFA come at a time when the agency as a whole is having difficulty coping with the increasing demands placed on it. A recent General Accounting Office report, for example, stated: "Substantial program growth and greater responsibilities appear to be outstripping [HCFA's] capacity to manage its existing workload." At the same time, the report noted that almost 40 percent of the organization has turned over in the past five years, and many more managers and experienced technical staff members are eligible to retire soon.

...The Balanced Budget Act of 1997 also has significant and substantial effects on reimbursement for ambulatory and home health services.

LEGISLATIVE MATTERS

Although nationwide Medicare managed care is only about 13 percent, the Balanced Budget Act of 1997 contains several items that will have long-term consequences for converting Medicare to a managed care system, according to legislative analyst Randy L. Teach, Ph.D., with Mulberry Row Enterprises in Arlington, Va.

"The managed care program in this legislation holds the potential for significant growth in Medicare managed care." According to Teach, this is the latest milestone in the gradual "federal assumption of responsibility for regulation of health insurance in the United States."

Teach advised that with significant growth in government-supported managed care products, "physicians need to be owners (with authority, responsibility, and accountability) and not receivers (subcontractors), experiencing diminishing revenue streams." New legislation establishes a payment floor of $367 per beneficiary, which may be very attractive on the surface, but is fraught with clinical and financial danger to the provider. Adjusting the provider reimbursement formula to a single conversion factor based on a primary care physician's practice will have a largely negative effect on those procedure-based policies, such as medical oncology, said Teach.

To encourage migration into these managed care plans, the budget proposal guarantees that if beneficiaries choose to disenroll from a managed care plan, they can renew or reacquire their Medigap insurance at their previous premium. "So, it allows Medicare beneficiaries to take a chance, enroll in managed care, and see if they like it without the economic penalty on the backside," said Teach.

Expansion of Medicare benefits to the under-65 population would attract an underinsured and unhealthy population, said Teach, resulting in significant expansion of the most costly groups in Medicare. A potential ripple effect could be employer "encouragement" of these newly enfranchised employees to disenroll from their expensive commercial plans into the expanded Medicare managed care safety net. Hospitals and providers would subsequently be saddled with those more resource-intensive patients now covered under a capitated reimbursement system.

The Balanced Budget Act of 1997 also has significant and substantial effects on reimbursement for ambulatory and home health services. Currently, hospital ambulatory services are 30 to 50 percent more expensive than similarly provided physician office-based services. The 1999 government mandate to implement a prospective payment system for outpatient hospital services may decrease hospital ambulatory reimbursement 20 to 30 percent (including a 10 percent "stand by" allowance). According

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IN THE NEWS

REQUEST FOR PROPOSALS

Applications for the 1998 ACCORD Grants for health outcomes research studies are now available. The ACCORD (A Company-wide Commitment to Outcomes Research and Development) Grants program, funded by Hoechst Marion Roussel, encourages health outcomes research projects in the following therapeutic areas: oncology, cardiovascular disease, neurosciences, respiratory diseases, endocrinology, rheumatology, and infectious diseases.

ACCORD Grant proposals are evaluated on a variety of criteria, including scientific merit and contribution to the health care system and to society. To be eligible, research must advance knowledge in health outcomes research or investigate health outcomes research issues related to a specific therapeutic domain or product, or a specific therapeutic domain or product compared to another intervention. Grant recipients are selected by a panel of experts in health outcomes research, including members of an external advisory board. The final selections are made by Hoechst Marion Roussel.

Applications for 1998 ACCORD Grants may be requested by calling 800-867-7001. The deadline for completed applications is May 1, 1998. Grants will be awarded in October 1998. Amounts range from $5,000 to $100,000.

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to Teach, the intent is to bring ambulatory hospital payments in line with physician office practices.

Moving home health, the largest single area of Medicare growth, to Part B of the trust fund should allow for more money to be available at the state level. However, expect increasingly restrictive referral enforcement to be placed on hospital owned and controlled home health agencies, Teach said.

Finally, Teach urged all physician practices to draw up a compliance plan to evaluate Medicare and Medicaid billing. "It is a smart insurance policy, no matter how small you are. Seventy-five percent of grievances are brought by whistle blowers in physicians' offices. It takes just one disgruntled employee to result in a major problem. You can be hit with substantial fines and penalties."

Last year, Congress vastly increased HCFA's resources for fraud control. Up to $440 million is available this year to investigate fraud, and the amount is scheduled to grow to $720 million by the year 2003. Stark II allows the Inspector General's office and the Justice Department to keep all funds they recover. "This means they have an unlimited amount of money to do these investigations," said Teach, who noted that he didn't believe any practice—regardless of size—was immune from scrutiny.

PROFESSIONAL OPPORTUNITIES