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ACCC's 7th Annual Oncology Presidents' Retreat

Each year the Association of Community Cancer Centers hosts a diverse assembly of state oncology society presidents, national oncology leaders, federal officials, representatives of patient advocacy organizations, and members of industry to address issues of mutual concern in the care of patients with cancer. The Oncology Presidents' Retreat has historically provided a forum for consensus building across this multidisciplinary gathering.

Forty-five state oncology societies were represented at this year's retreat, held February 5, 1999, in McLean, Va. National organizations included the Oncology Nursing Society, the American Society of Clinical Oncology, the American College of Radiology, the American Society for Therapeutic Radiology and Oncology, and the American Society of Hematology, among others. A large contingency of patient advocacy organizations, including the Alliance for Lung Cancer Advocacy, the Center for Patient Advocacy, Cancer Care, Inc., and the National Coalition for Cancer Survivorship, were also in attendance. This year's retreat was sponsored by Ortho Biotech Inc. and Eli Lilly Company.

BUILDING AN APC CONSENSUS

Much discussion centered on the impact of Ambulatory Payment Classifications (APCs), part of the Health Care Financing Administration's (HCFA) planned outpatient prospective payment system (PPS). Within the entire health care community there is widespread agreement that APCs will deleteriously affect the delivery of oncology care in the hospital outpatient setting, particularly chemotherapy administration. As Lee E. Mortenson, D.P.A., explained, APCs will classify all chemotherapeutic agents into one of four payment classifications, with the newest, most advanced drugs grouped into the lowest category of reimbursement. Supportive therapies and other services such as whole blood for transfusion will be bundled into a single APC payment related to chemotherapy. Mortenson is ACCC executive director.

As it stands, the APC system would inadequately reimburse for any disease that is highly dependent on innovation. "The APC system will essentially make state-of-the-art therapies cost prohibitive," warned Mortenson. Unable to afford the latest therapy, and unwilling to provide less effective therapy, most hospital outpatient chemotherapy units would close as a likely result.

The problem is due in large part to the way in which the APC rates were calculated, according to presenter Linda Magno, managing director of policy development with the American Hospital Association. In calculating APC rates, HCFA excluded 97 percent of claims involving multiple procedures and/or drugs administered over multiple sessions, focusing primarily on those claims with only one procedure per day. As a result, the data sample did not accurately represent the typical activity in an outpatient chemotherapy unit, Magno said.

APCs have something for everyone to dislike, added Karen S. Fisher, J.D., R.Ph., assistant vice president in the Division of Health Care Affairs at the Association of American Medical Colleges. Fisher projects that major teaching hospitals (those with 100-plus residents) will suffer losses of at least 9.4 percent under APCs.

As Fisher explained, the APC rate is determined by the median cost of all procedures within a specified group. "Ideally, a hospital provides a mix of services in that APC group, and everything evens out," Fisher said. However, teaching hospitals, which tend to have a disproportionate share of more complex cases, will be unable to cost shift to compensate for major losses.

Teaching hospitals, like community hospitals, are concerned about how APCs will adapt to treatment innovation. For example, whenever a new technology or therapy is developed, "[will there be] an APC to accurately match those costs?" Fisher questioned. "If there is, then fine. But what happens if there isn't?" According to Fisher, such an inflexible reimbursement structure could very well inhibit the movement of services from the inpatient to the outpatient setting—a scenario that neither HCFA nor hospitals want to see. Fisher believes that new services would be better reimbursed using a cost-based methodology until there are actual data to support their inclusion in existing or newly created APCs.

There is growing momentum within the oncology community and among allied organizations for HCFA to carve out chemotherapy drugs from the APC system. However, when HCFA officials in attendance were questioned, they were somewhat vague. With the comment period on APCs still ongoing, officials were hesitant to make definitive statements about the future of APCs. However, Grant Bagley, M.D., J.D., director of the coverage and analysis group in the Office of Clinical Standards and Quality within the Health Care Financing Administration, did comment on HCFA's need to devise "national policies and priorities driven by those affected by them, beneficiaries and providers alike."

STREAMLINING CLINICAL TRIALS AND OFF-LABEL INDICATIONS

There are efforts at the federal level to improve efficiency of operations for the benefit of oncology providers and their patients,

according to representatives of the National Cancer Institute and the Food and Drug Administration. Attendees were briefed on new initiatives to improve both provider and patient access to the best cancer therapies available.

Susan Flamm Honig, M.D., medical reviewer within the Division of Oncology Drug Products at the Food and Drug Administration, detailed provisions of the FDA Modernization Act of 1997 designed to speed drug development and approval. Contributing to a more efficient drug development timeline are a reduction in the drug review process from twelve to ten months and a "fast track" to support more rapid development of drugs used in treating serious and life-threatening illness. By 2002, all drug review is expected to be conducted electronically.

The FDA is also concentrating on expanding indications of labeled drugs. "[Progress is] happening in oncology faster than industry can keep up with," stated Honig, who went on to explain how pharmaceutical corporations, pressured by patent limitations, may be hesitant in applying for new indications. As a result, the FDA has devised a set of policies intended to assist these corporations with dissemination of their off-label studies.

Similarly, the National Cancer Institute (NCI) is devising a clinical trials framework that combines technology and system reorganization to improve participation in the national clinical trials program. By decreasing the administrative burden of clinical trials, the NCI hopes to encourage physician involvement and thus increase patient accrual in the national clinical trials program.

This "user-friendly" approach is based on the concept of "idea generators," or investigators who are selected based on the best scientific concepts, with less emphasis on where those concepts were generated (i.e., the cooperative groups, cancer centers, community practice, or industry) according to Michaele Christian, M.D., associate director of the Cancer Therapy Evaluation Program at the NCI in Bethesda, Md.

Christian also outlined a number of projects designed to decrease administrative burden, including web-based data collection and a centralized Institutional Review Board. In addition, a clinical trials support unit is being designed to consolidate the many duplicative functions of the cooperative groups.

In the same vein, the American Society of Clinical Oncology is making its own contribution to the dialogue on improving the clinical trials system. The society is conducting a comprehensive study on the state of clinical trials in the United States as part of an initiative of ASCO president Allen Lichter, M.D. The study explores the attitudes, experiences, and barriers that physicians encounter in placing patients on clinical trials. "We all know the effect that fiscal constraints, time pressures, declining participation, and low accrual rates have on our ability to conduct clinical trials," stated Joseph S. Bailes, M.D., F.A.C.P., ASCO president-elect. "For the first time we will have a database to support what we already know."

Another component of the study is an assessment of the non-clinical costs of clinical trials participation. ASCO is in the process of compiling data from physician practices, freestanding centers, and 170 companies representing the pharmaceutical industry. According to Bailes, the study's results will enhance the debate on improving the clinical trials system.

INTERDISCIPLINARY SOCIETIES

There continues to be a high level of activity at the state oncology society level, with more states developing formal administrative mechanisms to support both legislative and programmatic initiatives. These societies are gaining more visibility across their respective states, in their legislatures, with their insurers, and within managed care organizations. At the same time many societies are reaching out to local chapters of the Oncology Nursing Society, Association of Oncology Social Work, and patient advocacy groups to broaden support for patient-related issues such as access to care and treatment denial.

Presentations by Peter R. Graze, M.D., of the Maryland Society of Clinical Oncology, Philip J. Stella, M.D., president of the Michigan Society of Hematology & Oncology, and Robert C. Kane, president of the Florida Society of Clinical Oncology revealed that state societies are reinventing the historically adversarial relationship between providers and payers, developing liaisons that are more consultative than confrontational. According to Kane, these efforts are all part of prioritizing patients' needs. "If we put the interests of the patients first, all the rest falls into line very easily."

Susan Flamm Honig, M.D., medical reviewer within the Division of Oncology Drug Products at the Food and Drug Administration, explains FDA efforts to expand off-label drug indications. Margaret A. Riley, M.N., R.N., C.N.A.A., ACCC president-elect, Robert Berenson, M.D., director of the Center for Health Plans and Providers within HCFA and Grant Bagley, M.D., director of the coverage and analysis group in HCFA's Office of Clinical Standards and Quality, look on.