CONFERENCE COMMITTEE AMENDS CATASTROPHIC HEALTH BILL

On May 31st, the Joint Senate/House Conference Committee issued its proposed amended Medicare Catastrophic Coverage Act of 1988 (H.R. 2470)—a compromise between previous bills proposed by the House and the Senate. The amended act is expected to be approved by President Reagan.

ACCC was instrumental in the inclusion of specific drug compendia references that the Secretary of DHHS should consider when determining the appropriate utilization of drugs. The Joint Explanatory Statement of the Committee of Conference states that the standards established for the use of each covered outpatient drug must be based on "accepted medical practice." In establishing such standards, the Secretary is required to incorporate standards from one or more current authoritative compendia, as the Secretary may select. However, it goes on to say that "the conferees expect that included among the compendia the Secretary will consider for use are the United States Pharmacopoeia Dispensing Information, Volume 1; the American Medical Association's Drug Evaluations; and the American Hospital Formulary Service Drug Information."

At a critical juncture in committee negotiations, ACCC was asked to provide a key health counsel to the House Ways & Means Committee with information that expressed the Association's concern about reimbursement denials for non-FDA labeled drug indications and standard combination chemotherapy regimens. Prior to the ACCC's intervention, there was confusion on the Hill about the vital importance of citing specific compendia, rather than asking the Secretary to establish panels of his own.

Although the USPDI and the AMA's drug evaluations are not specifically mentioned in the amendment, their inclusion in the legislative intent portion of the conference amendment is "vital," says ACCC Executive Director, Lee E. Mortenson. "Without the specific compendia, it would be possible for the Secretary to fall back on FDA labeling as a method for identifying drugs for payment. This would have been a major setback to cancer care—one we were pleased to help avoid."

The amended bill specifically prohibits the Secretary from establishing a formulary by excluding "any specific covered outpatient drug or class of drugs or the specific use of any covered outpatient drug with respect to a specific indication" from coverage. Exceptions include drugs subject to a proposed order by the FDA to withdraw marketing approval, agents that do not fit the definition for covered home IV therapy drugs, and drugs that the Secretary concludes are not safe or effective.

'Without the specific compendia, it would be possible for the Secretary to fall back on FDA labeling as a method for identifying drugs for payment'

The committee statement also says that "conferees expect that the Secretary will complete a review of the safety and effectiveness of home IV cancer chemotherapy drugs as soon as possible."

Other provisions in the amended bill of importance to cancer care providers include:

• **Screening Mammography.** Screening mammography costs will be covered; however, the bill limits reimbursement to $50 in 1990, and the payment level will be adjusted thereafter according to the percentage increase in the MEI for each subsequent year. The bill also limits eligibility for mammography payment. Women less than 35 years of age are not eligible. Women between 35 and 40 years of age are limited to one screening procedure; high-risk women between 39 and 50 years of age will be reimbursed for one mammography per year; women who are not at high risk are limited to one screening test every two years. In the case of women over 49 years of age, but under 65, 11 months must separate mammography screens, and 23 months must separate tests for women who are more than 64 years of age. The HHS Secretary will be establishing limits for screening mammographies delivered in the hospital outpatient setting when there are separate claims for professional and technical components.

• **Hospice Care.** The conference agreement includes the House provision (to provide for an extension period beyond the current 210-day limit if the beneficiary is recertified as terminally ill) with an amendment to further extend the favorable presumption under the waiver of liability provision for hospice care through October 1990. Effective data is for hospice care furnished on or after January 1, 1989.

NCI BUDGET IN SENATE

It appeared, at the time that *Oncology Issues* went to press, that the monies provided to the National Cancer Institute would be close to the President's request of $1.593 billion—a consolidated figure that included both general appropriations for NCI and an additional $125 million for AIDS funding. The House bill deferred funding for what it considered to be non-authorized programs, including cancer control, research training, and construction line items and allotted NCI $1.364 billion for general appropriations. It also did not consolidate AIDS funding, as the President requested, but separately allocated $125 million as AIDS money.

Unless the Senate is more generous, there will most likely be significant cuts in funding among competing NCI programs. However, until the conference report is released, it is hard to predict what actual line budgets will be. (As of June 30, it was hoped that the budget would clear the Senate floor before the July 4th recess.)

NCI SPONSORS CHEMOTHERAPY REIMBURSEMENT MEETING

In mid-June, the National Cancer Institute (NCI) sponsored a one-day meeting on third-party reimbursement for medical therapy involving investigational agents. The intent of the meeting, which was moderated by Robert Wittes, M.D., associate director for cancer therapy evaluation at the NCI, was to share experiences and information about current reimbursement trends in two areas: patient care costs for clinical trials; and reimbursement for off-

label uses of FDA-approved drugs.

Common experiences included denials for expensive investigational treatments, such as Interleukin and 5-FU, and increasing denials for the patient care costs associated with clinical trials—a trend that is making it "increasingly difficult to accrue patients," said Charles Coltman, M.D., Southwest Oncology Group, San Antonio, TX.

"The biggest [reimbursement] problem we have experienced is with transplants," said Sara Perkel of Johns Hopkins. Hopkins, she said, is handling such patients on a "case-by-case basis, talking with both insurers and, with somewhat more success, employers." However, such negotiations are costly in terms of time and payment delays.

Jerome Yates, M.D., Roswell Park, contended that "with increased competition, we will see HMOs and other providers determining access to clinical trials." If there is to continue to be reimbursement support for investigational trials, "we need information on the medical costs of patients on trial vs. those who are not on trial to deal with insurers on a national basis," Yates said.

The AMA, according to William McGivney, M.D., is experiencing a greater demand for information on investigational/accepted medical treatments than its two-year old information system has the capacity to meet. The service provides subscribing companies and organizations with specific evaluations and the AMA's position on utilization of new technologies. To date, McGivney notes, the vast majority of information requests are being initiated by major third-party payors and HMOs.

Lee Mortenson of ACCC noted that insurers are "shifting the line on what is experimental therapy and what isn't." The Blues, he said, have stated that "coverage for the FDA's new treatment IND category, as well as NCI Group C drugs is precluded by its policy language in 95 percent of their contracts."

Providers "need to make an effort to play fair with insurers," Charles Moertel, M.D., Mayo Clinic, pointed out. "We inform insurers regarding what's appropriate treatment and what isn't. They aren't anti-cancer treatment," he said, "but pro cost-effective care." I hope, he said, "that we would foster and encourage cooperation. There is a great deal at stake."

Some of the suggestions that meeting participants made included:

• **New kinds of insurance policies.** Grace Monaco, J.D., Candlelighters, contended that "any reimbursement strategy must be built on the practical realities of insurance contracts." She said that some insurers she has talked to are willing to offer a type of "clinical research" benefit. Such an insurance supplement would place a "dollar limit on benefits, but would routinely include treatment with IND and Group C drugs." However, a clinical research benefit "can't be open-ended," she observed, suggesting that eligible trials should be listed in a central clearinghouse of some type, such as NCI's PDQ. Other attendees noted that the patient care costs of clinical trials were previously covered in standard contracts.

Insurers are 'shifting the line on what is experimental therapy and what isn't'

• **Institutional licensure vs. individual investigators.** O. Ross McIntyre, M.D., Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, Hanover, NH, suggested that "institutions, not investigators, should be licensed to conduct clinical research." Core costs could be funded via a "peer-reviewed, CRC-type mechanism," he suggested. On the regulatory side, he said the institutions should be audited, but allowed to test new drugs, devices, and medical procedures without any restrictive regulations. Several attendees suggested that this would be unpractical except for phase I studies.

• **Making reimbursement a national health policy.** John Yarbro, M.D., Ph.D., University of Missouri, contended that there are "two simple messages we must get across." First, unlabeled drug uses are "not investigational" and, second, "all NCI/FDA approved clinical trials represent an appropriate standard of care."

Abbey Meyers of the National Organization for Rare Disorders (NORD), urged participants to draft a "consensus statement" that can be brought to the attention of Congress, the presidential candidates, and other important policymakers that endorses adequate reimbursement for investigational research. However, she stressed that the statement should not be limited to the field of cancer.

An attempt was made to develop a "consensus statement" about reimbursement for clinical trials, but there was vociferous disagreement about whether a cost limit should be included. The suggested statement was that "All nationally-approved clinical trials with therapeutic intent should be covered without regard to cost or efficiency criteria."

However, Moertel of the Mayo Clinic advocated a language change to "All 'patient care costs associated with' nationally-approved trials...," claiming that an open-ended statement that neglected the issue of cost would meet with little support or success. Other participants strongly disagreed, stating that clinical trials, especially phase I and II trials, are often expensive, but the costs do eventually decline.

All in all, the participants agreed that it was necessary for all involved parties to present an "united front," if reimbursement for investigational trials and off-label indications was to be improved.

ORPHAN DRUG AMENDMENT PASSED

Rep. Henry Waxman (D-CA), Chairman of the Committee on Energy & Commerce's Health and Environment Subcommittee, was unsuccessful in gaining Congressional support for a revision that would limit orphan drug manufacturers' profits. Waxman's proposed ceiling on orphan drug profits was discarded during the reauthorization process, and does not appear in the Orphan Drug Amendment (H.R. 3459) that was signed into law on April 18.

Abbey Meyers of the National Organization for Rare Disorders (NORD), says that there was "tremendous opposition" to Waxman's proposed cap because of the increasingly high cost of developing new orphan drugs. Moreover, Meyers says that Congress' concern that drug manufacturers were taking advantage of the exclusive manufacturing rights that accompany orphan drug sponsorship through inflated drug prices was attributable to only three of the more than 200 orphan drugs currently available. But, she points out, a ceiling on profits would have negatively affected the development and availability of all orphan drug agents.

The two drugs in particular, which sparked the debate were azidothymidine (AZT), used in the treatment of AIDS patients, which Meyers says costs approximately $14,000 per year per patient, and human growth hormone, which runs from

CHANGING MEDICARE RADIOLOGY PAYMENT METHODOLOGIES: THE IMPACT IS HARD TO PREDICT

If you are trying to determine how the Health Care Financing Administration's (HCFA's) recent and proposed payment changes for hospital outpatient and physician radiation therapy services may impact your program, the news is not good. That's because there isn't much information to share. Here is the status on three current/upcoming regulatory changes by HCFA:

HCFA Transmittal 1200

To date, we have not been able to identify any Medicare intermediaries that are actually enforcing the change to a weekly management fee for radiation oncologists' services.

Blended Payments for Outpatient Services

According to a representative of the Healthcare Financial Management Association (HFMA), there have been forecasts that the change to a blended payment based on physician office costs for hospital outpatient radiology services could reduce hospital payments by 25 to 30 percent. However, it is hard to evaluate the accuracy of those forecasts, because many HCFA intermediaries have not yet established the necessary fee schedules for the proposed change, even though it is due to go into effect on October 1 of this year.

Because the rates will be established on a local and regional basis, and each Medicare intermediary must formulate a fee schedule for its area, HFMA suggests that concerned hospitals press their intermediaries for the schedules. In some cases, they may already be completed.

This change in payment methodology is expected to increase hospitals' administrative burden, because new cost accounting procedures may be needed and HCFA may require new coding or billing procedures for affected services. The change is also likely to prompt reorganizations of outpatient radiology services, such as joint ventures with radiologists, that will enable hospitals to transfer outpatient services to a separate entity.

Relative Value-Based Physician Payments

On January 1, 1989, an entirely new methodology for Medicare payments for radiologists' professional services will be introduced, based on a relative value scale. In devising the new fee schedules, HCFA has been directed to reduce Medicare payments for radiology services by 3 percent. HCFA also has been directed to take into account geographic variations in the cost of providing services. As is the case with blended payments, this new methodology will link hospital outpatient radiology reimbursement levels to physicians' fees for the same services

$20,000 to $30,000 per year per patient.

Despite the fact that Waxman's proposal was not adopted, Meyers warns that if there are future attempts by drug manufacturers to manipulate orphan drug prices with a view to increasing profits, the practice is not likely to escape Congressional action. As a result, NORD is urging individual manufacturers to monitor their pricing structures for orphan drugs.

Important provisions that were included in the final amendment include Congressional budget appropriations of up to $10 million for fiscal year 1988, $12 million for 1989, and $14 million for 1990.

The amendment also requests recommendations from the Department of Health & Human Services on whether tax credits are needed to encourage the development of medical devices or medical foods for rare diseases. Currently, only drugs, biologics and antibiotics are eligible for such tax credits. The credits would apply only to the clinical research phase of development.

HCFA STUDIES OUTPATIENT CHEMO PAYMENT LEVELS

The Health Care Financing Administration (HCFA) is actively studying the "reasonableness" of current Medicare payment levels for outpatient chemotherapy treatment, in preparation for the recommendation it must make by April of next year.

A provision in last year's budget reconciliation bill allotted $70,000 to HCFA to study outpatient chemotherapy treatment costs and to make recommendations to Congress regarding the appropriateness of current funding levels. The American Society of Clinical Oncology (ASCO) and the American Society of Hematologists (ASH) have been working with HCFA to "ensure that good data is obtained," says Gary Ratkin, M.D., chairman of ASCO's clinical practice committee.

Ratkin says that the interest of Congress "must be maintained" if HCFA's recommendation is to translate into significant increases for outpatient chemotherapy services.

NRC RECONSIDERS QUALITY ASSURANCE RULE CHANGES

The Nuclear Regulatory Commission (NRC) is reexamining the proposed quality assurance requirements it issued in October 1987, governing the administration of radioactive materials in hospitals and clinics. According to Norman McElroy, section chief of the Medical and Academic Section of the NRC, the agency's decision to "reconsider the direction of the project was in response, at least in part, to strong concerns expressed by the medical community on the potential impact of the initiative," during the public comment period.

As a result, an options paper submitted to the NRC Commissioner in early June of this year presents three possible approaches: 1) proceed with the current proposed rule changes, despite the amount of negative comment; 2) switch to a performance-based program; or 3) formulate a new set of rules with the assistance of representatives of various concerned associations. A decision from the NRC Commissioner is expected by the end of July.

The decision to amend the Agency's current medical use regulations was prompted by reports of 27 radiotherapy misadministrations and 14 diagnostic isotope administration errors from November 1980 to July 1984. During the public comment period, the American College of Radiology (ACR) noted that 41 misadministrations during a time period when "millions of deliberate medical exposures of patients" were conducted "represents a remarkably good record."

If the NRC decides to scrap the current

(Continued on page 11)

NOMINATIONS FOR ACCC OFFICERS AND TRUSTEES

The ACCC Nominating Committee is soliciting nominations for the following 1989-90 board positions:

- ❑ President-Elect
- ❑ Secretary
- ❑ Four Trustee Seats

The term of President-Elect is one year. The Secretary and Trustee positions are two-year terms. While nominees are not required to be the voting representative from their institution, they must represent an ACCC Delegate Institution.

Letters of nomination should be sent to the ACCC Executive Office, citing the nominees' names and their respective Delegate Institution, along with a copy of their curriculum vitae. **Nominations must be received no later than December 1, 1988.**

Further information about the nomination process may be obtained from Lee E. Mortenson, Executive Director, ACCC Executive Office at 301/984-9496.

proposed rules and formulate new basic quality assurance regulations with the help of concerned associations, Simeon T. Cantril, M.D., chairman of the radiation department at Children's Hospital of San Francisco, and a member of the ACCC board, will act as the ACCC's technical advisor to the NRC during the revision process.

WEICKER CRITICIZES NEGLECT OF HEALTH ISSUES IN CAMPAIGNS

Health is not an issue in this year's presidential race and, if "its not a topic now, it won't become one during the next four years," warned Sen. Lowell P. Weicker, Jr. (R-CT), at a recent meeting of the National Coalition for Cancer Research (NCCR). Weicker, ranking minority member of the Appropriations Subcommittee that funds NIH research programs and a senior member of the Senate Labor and Human Resources Committee, told participants of NCCR's annual Capitol Hill Day that it is up to cancer providers and others who are knowledgeable and concerned about the disease to "elect those who believe science and health are important to the future of this nation and to defeat those who don't."

The presidential and congressional elections make the present the "ideal time to focus on health issues," Weicker said. Those issues need to be raised now if "you want people who are receptive to your needs elected."

Weicker also contended that senior congressmen, rather than cancer care providers and researchers are "carrying the ball on the basis of our seniority," in bringing health care issues to the attention of Congress. We would like to be "part of a majority," he said, but that will require the raising of the "consciousness of the nation with regard to health care"—a challenge that Weicker does not believe the cancer care community is adequately addressing. ■

COPING WITH BREAST CANCER

This practical guide to coping with the emotional impact of breast cancer was written by a psychologist whose breast cancer was successfully treated. "Invisible Scars: A Guide to Coping With the Emotional Impact of Breast Cancer," by Mimi Greenberg, Ph.D., addresses such concerns as the patient-physician relationship, adjusting to the diagnosis and psychologically preparing for treatment, and weighing the emotional pros and cons of available surgical treatment options.

The book is available through the publishing firm of Walker and Company, 720 Fifth Ave., New York, NY 10019 at a cost of $17.95. For more information about the book, call Mallory Tarcher of Dougherty and Associates: 213/273-8177.

LETTERS TO THE EDITOR...

Exerting marketing pressures on insurers

I read with great interest in the Spring 1988 issue of the *Journal of Cancer Program Management* Lee Mortenson's thoughts concerned the rating of insurance companies according to their cancer therapy reimbursement policies.

I think this is a wonderful idea. I have always believed that marketing pressures would be the most effective mechanism for persuading insurance companies to aact in their own interest by supporting cancer research.—*F. J. McKay, executive vice-president, Fox Chase Cancer Center, Philadelphia.*

Taking a lead in reimbursement reform

I found the Winter 1988 issue of the *Journal* extremely interesting. It contained a great deal of food for thought. As a medical oncologist, I have long felt the need for a mechanism to recognize standard practice in the use of oncologics. This recognition should obviously be based on clear cut guidelines. For example, support for an indication might rest upon an article in a peer reviewed journal in which a certain mimimum number of patients have been treated. A certifying group should be fairly liberal in rules and regulations for certifications, which should be designed to encourage patients to take advantage of clinical trials. In other words, the group may, in fact, promulgate the notion that if there is a clinical trial available, the drugs should not be certified when given off protocol.

In any event, as a member of the ACCC, I would certainly like to see our organization take the lead in this sort of effort. This is something that might be done jointly with the ASCO, and I am sure meetings, publication costs, etc. could be borne by drug company contributions. All of this would definitely put pressure on third parties to recognize the realities of oncologic practice and, if done properly, could also limit practice that is not standard.—*Donald J. Higby, M.D., chief of hematology/oncology, Baystate Medical Center, Springfield, MA.* ■