Cancer Drugs and APCs

On Nov. 30, 2001, the Centers for Medicare and Medicaid Services (CMS, formerly known as HCFA) published a final rule announcing the final ambulatory payment classification (APC) groups, relative weights, and payment rates under the hospital outpatient prospective payment system (OPPS) for 2002. A month later, CMS issued a notice acknowledging that the agency had made "several inadvertent technical errors" in the November rule. These errors would require that a new set of weights and rates be published and mean a delay in implementation until April 1, 2002.

However, to implement the new rates on April 1, CMS needed to publish the new rates no later than February 1, so Congress would have the 60-day review time required by statute. CMS has not yet devised a process by which it can receive formal feedback from manufacturers, providers, and other stakeholders about the errors in the November rule. It remains unclear whether such a process will be set up, or whether CMS will attempt to identify and fix these errors through some internal process alone. In either case, there is some speculation that the April 1 implementation date may slip.

Whenever the new 2002 rates do go into effect, they will contain, for the first time, a new payment structure for drugs on the pass-through list. As all cancer drugs are on the pass-through, this new payment structure is of particular interest to the oncology community.

Until now, the Medicare program paid for cancer drugs at 95 percent of average wholesale price (AWP). Whenever the 2002 rates are implemented, the Medicare program will start to differentiate between sole-source, multi-source, and generic cancer drugs and pay for them at different percentages of AWP. These percentages cannot be determined until the new rates are published. Whatever level of payment is set for each category of drugs, the question becomes how—and by whom—will drugs be placed in each of these categories.

While the Medicaid program contains some definitions for these terms, CMS has offered no guidance on whether these definitions will apply to the Medicare program. These terms can have many different definitions, and the line between sole-source and multi-source is especially fuzzy. Will the chemical composition or the indications of a drug differentiate between sole-source and multi-source drugs? If indications are used, will approved indications or off-label uses be the guide?

PHOTOGRAPH BY WASHINGTON DC CONVENTION AND VISITORS ASSOCIATION

Chemotherapy Administration Codes

APC (HCPCS Code)	Final (Nov. 2000) Payment for CY* 2001	Proposed (Aug. 2001) Payment for CY 2002	Final (Nov. 30 2001) Payment for CY 2002	Portion "Fold In" for Device CY 2002	Status Indicator for CY 2002
0120 (CPT Q0081)	$82.33	$119.48	$156.78	$34.10	T—Significant procedure, multiple procedure reduction applies
0116 (CPT Q0083)	$116.06	$49.83	$46.32	N/A	S—Not discounted when multiple
0117 (CPT Q0084)	$91.26	$176.93	$204.13	$29.02	S—Not discounted when multiple
0118 (CPT Q0085)	$143.83	$178.96	$213.80	$27.49	S—Not discounted when multiple
0352 (CPT 90782)	N/A	$22.88	$20.87	N/A	X—Ancillary service, paid under OPPS

*CY = Calendar year

PHOTOGRAPH BY PHOTODISC

Indications—approved and off-label—for oncology drugs are in a constant state of flux as new clinical studies are completed and researchers and oncologists search for the best combination of drugs.

Providers have spent a lot of time over the last year ensuring that overall Medicare reimbursement is sufficient and does not become a factor in deciding whether patients will have access to certain drugs. The issue of drug classification has gone largely unnoticed, but will need to be addressed as the new 2002 APC rates are implemented later this year.

On a related issue, the errors identified by CMS will affect another part of hospital payments. After APC rates and pass-through payment amounts are set, CMS will calculate whether the pass-through payments exceed the statutory cap for such payments. When Congress passed legislation in 2000 creating the pass-through payment structure, it sought to contain costs by limiting all such payments to no more than 2.5 percent of overall outpatient spending. Once that cap is reached, all pass-through payments are cut by a pro-rated amount. The amount of that pro-rata cut will need to be recalculated after the errors in the November rule are identified and corrected.

In other words, the December announcement of a delay and the need for a recalculation mean that all payments are back in play until another rule is issued by CMS. The only constant is the fact that hospitals remain uncertain about what they will be paid for the outpatient Medicare services they provide.

Finally, reimbursement rates for three of the five chemotherapy administration codes (CPT Q0081, CPT Q0084, and CPT Q0085) were increased at the end of 2001. And all radiation treatment delivery and device reimbursements were increased for 2002, particularly series 77761-63 and 77776-8, which went from $205.49 to $1,649.29. CMS indicated that the increases were the result of agency recognition that certain pass-through device costs had not been accounted for in the initial payment rates.

Before we celebrate, however, be aware that these new increases are *not* final—despite their publication in a "final rule." As already mentioned, CMS is doing a wholesale review of the APC payment rates and intends to publish new rates prior to their implementation on April 1, 2002. Only then will hospitals know for sure what their APC payment rates will be for these five chemotherapy administration procedures as well as their other APCs.

Oregonians Angry About Possible Circumvention of Assisted Suicide Law

In 1997 the U.S. Supreme Court ruled that it could not adjudicate the matter of assisted suicide because no mention of it was made in the Constitution. The justices encouraged state experiments, and Chief Justice William Rehnquist said in the record that, "Our holding permits this debate to continue as it should in a democratic society."

The citizens of Oregon led the way by voting their Death With Dignity Act into law, and in the four years since the measure was enacted it has, according to Salem, Oreg., oncologist Peter Rasmussen, "worked smoothly." Although only 70 Oregonians have used the statute to end their lives, Rasmussen told the *Washington Post* in a Jan. 1, 2002, article that many of his patients say they are comforted by knowing the option is available.

Now U.S. Attorney General John Ashcroft has ordered the Drug Enforcement Administration, under the statutory authority of the Controlled Substances Act, to rescind the controlled substance license of any physician who prescribes a federally controlled drug to assist suicide, and to levy other civil and criminal penalties as well. In other words, doctors in Oregon who obey their state law will be breaking a federal regulation. By using an existing statute, Ashcroft can bypass the legislative process that requires that proposed rulings be announced in the *Federal Register*, be subject to a public comment period, and be voted on by the House and Senate.

According to a Nov. 21, 2001 article in the *Health Care Daily Report* published by the Bureau of National Affairs (BNA) in Washington, D.C., after Ashcroft's directive on November 6, Oregon Attorney General Hardy Myers and two interveners immediately went to court to block the order. On November 8, Judge Robert E. Jones of the U.S. District Court for the District of Oregon issued a temporary restraining order blocking the Ashcroft ruling, which was extended for four months after a hearing on November 20. During the delay, Jones is reviewing arguments from all parties.

Jones gave the state of Oregon 60 days to file a motion for summary judgment and the federal government 30 days to respond to it. The state had another 14 days to respond in kind. When all these options have been exercised, Jones was expected to hold a hearing on

the motion and cross motion and issue his decision within 30 days.

The Oregon law allows doctors to prescribe, but not administer, a lethal dose of Nembutal. To receive a prescription, patients must have two physicians certify that these patients are terminally ill with less than six months to live and are mentally competent to make such a decision. If they appear to be depressed, a psychiatrist must examine them. When a prescription is written, the patient must wait another 15 days to have it filled, and patients who are unable to take the medication themselves (i.e., who are unconscious or paralyzed) may not participate.

David H. Regan, M.D., a Portland, Oreg. medical oncologist, says he would not write an assisted suicide prescription, although the issue does not come up in his practice. "We assure our patients that, if things get that bad, we will make sure they have whatever they need to be unaware of pain and suffering," Regan told *Oncology Issues*. "People aren't as afraid of dying as they are of suffering or their family being 'put through hell.' Our hospice comfort measures are very effective and people pass away peacefully, comfortably, and quickly since they are not eating or drinking."

Regan said Oregonians are very angry about the possibility of their law being nullified by a federal agency since they have voted on it twice. The measure was passed with a wider margin in 1997 than it received the first time it appeared as a referendum in 1994.

According to the *Post* article, a survey of more than 2,600 Oregon doctors conducted by Linda Ganzini, a professor of psychiatry at Oregon Health Sciences University, found that only 5 percent of the physicians surveyed had received requests from patients to prescribe lethal medication since the law took effect. In 68 of the 142 cases described in Ganzini's survey, the request for a prescription prompted the doctor to take other measures such as improving pain treatment, referring the patient to a hospice, or administering antidepressants. Morphine has also been prescribed more often since the initiative passed. Almost half of those who received such interventions changed their minds about assisted suicide.

Opponents of the law predicted it would be used disproportionately by poor or socially isolated people, the uninsured, or those without access to good medical care or hospice services. However, three years of data collected by the state health department have proved these projections wrong. The *Post* article reported that Oregonians who used the law to obtain lethal prescriptions were usually highly educated and well insured. Eighty percent were receiving hospice services. Most of the people who used the law had cancer, but some had heart disease, lung problems, or degenerative neurological disorders, such as amyotrophic lateral sclerosis.

"What comes through is [that] this is an unusual group of people," said Ganzini. "They place a high value on control and independence. Compromise is not in their vocabulary… Nobody who knows them is surprised by the request."

Rasmussen has been present at the deaths of his patients who have used the assisted suicide law whenever they would permit it, and said the experience was very different from attending the deaths of his other cancer patients whose family members have usually been awake many nights coping with the patient's symptoms and are exhausted. "All that [trauma] is missing with these planned deaths," Rasmussen said. "Instead, the focus is on the patient and his or her relationships with other people. And that is a beautiful thing."

Are Industry-Funded Clinical Trials Really Fair?

There is no question that important advances in cancer treatment would not have occurred without pharmaceutical company-sponsored research, yet critics maintain that drug companies have too much control over the evaluation of their own drugs. Now people are asking how such tremendous influence may be affecting the validity of clinical trials.

Today, 70 percent of the money for clinical drug trials in the U.S. comes from industry sources rather than from the National Institutes of Health. That's quite a dramatic shift from two decades ago when most trials were supported by the NIH and conducted at academic medical centers. Moreover, in its efforts to expedite trials, industry is turning from academic and community-based cancer programs to a growing for-profit marketplace, whose key players are contract research organizations (CROs).

In the May 18, 2000, *New England Journal of Medicine*, Thomas Bodenheimer, M.D., reported that, in 1991, 80 percent of industry money for clinical trials went to academic medical centers. By 1998 that figure had dropped to 40 percent. Bodenheimer cited evidence suggesting that the commercial sector completes trials more rapidly and more cheaply than academic medical centers.

Bodenheimer also said that, although academic-industry drug trials have been tainted by the profit incentive, they do contain the potential for balance between the commercial interests of industry and the scientific goals of investigators. In contrast, trials conducted in the commercial sector are heavily tipped toward industry interests since for-profit CROs, contracting with industry in a competitive market, will fail if they offend their funding sources.

"Everyone must be aware of potential conflicts of interest," said James L. Wade III, M.D., F.A.C.P., president of Decatur Memorial Hospital, Cancer Care Specialists of Central Illinois. Wade is principal investigator for Decatur's CCOP and a 17-year veteran of clinical research.

"Investigators who are writing the studies that go to NCI for approval really need to fully disclose any relationships they may have, for example, on advisory boards or as consultants to pharmaceutical companies that make the drug the clinical investigators are working on."

Wade maintains that, although they have different goals, both publicly-funded and industry-funded trials are important and critical to the development of new knowledge that will improve the treatment of cancer. NCI-approved trials (either NCI-specific trials or trials conducted through the cooperative group system) are testing a scientific hypothesis to advance care. There are many checks and balances worked into the design of these trials, and the process is slow and labor intensive.

Industry trials are different, according to Wade, who is also director of research at Decatur's Cancer Care Institute. "The intellectual horsepower is within one organization rather than spread out across many different organizations such as different universities. The goals of the trial are much more focused toward new drug development or the broadening of drug use. It may not be proving a hypothesis that is important, but in some instances redoing what has already been done to enhance a drug's FDA profile."

Perhaps too many trials are aimed at approved or expanded application of "me-too" or "copycat" drugs. A good example is Zometa, a new version of an older drug, Aredia. Zometa and Aredia are both biphosphanates that are approved by the FDA for the treatment of hypercalcemia secondary to malignancy. Zometa has the advantage of being administered over 30 minutes rather than over two hours. In randomized trials it appears to be at least as efficacious as Aredia in reducing the complications of skeletal events related to specific cancers such as breast cancer and multiple myeloma. Industry-sponsored clinical trials are now underway to determine if its currently approved FDA indication can be expanded.

The first major new 5HT8 antiemetic was Zofran, which revolutionized cancer therapy. Other drugs that followed, such as Kytril and Anzemet, may be considered me-too drugs.

"In all fairness, you won't have newer models of drugs that may be so much better than the original unless you go through this process," Wade said. None would have come on the market without industry-sponsored trials. He also maintains that market competition of multiple drugs made by different companies for the same therapy has driven down drug prices.

A recent article in the *Journal of the National Cancer Institute* (Vol. 93, No. 21, Nov. 7, 2001) quoted Frank Davidoff, M.D., clinical professor of the University of Connecticut Medical School, Farmington, and editor emeritus of *Annals of Internal Medicine*. Davidoff acknowledged that the pharmaceutical industry makes an easy target and is sometimes unfairly demonized. But he said the pressures of turning a profit can have negative consequences. "…pressures sometimes lead people to do things that serve the commercial agenda of selling drugs more than the academic agenda of finding and reporting scientific truth."

In the same article, Davidoff

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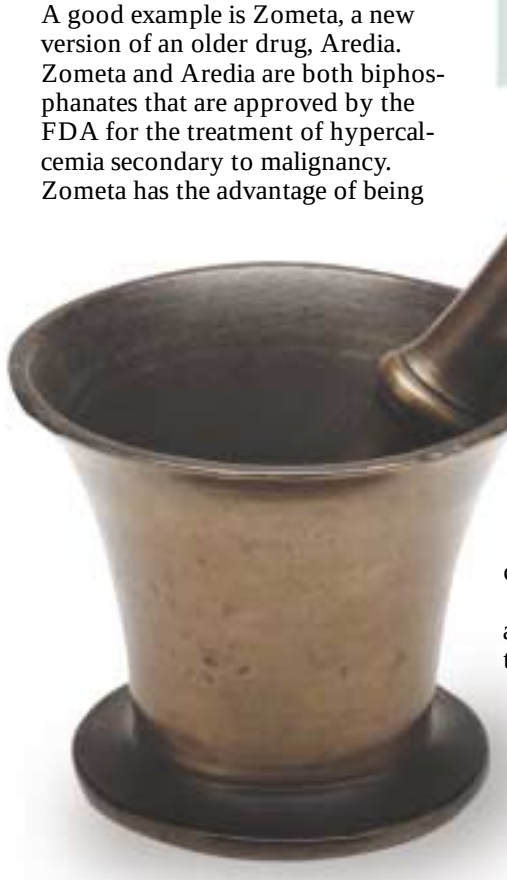

PHOTOGRAPH BY PHOTODISC

Hospital Profitability… Or Not

Fitch, the bond rating service, recently published its 2000 report on the financial ratios of nonprofit hospitals and health care systems. The study, which covered audited data from 178 organizations representing $41.3 billion of debt, focused on financial ratios in the areas of liquidity, profitability, capital structure, and cash flow. Key findings regarding this sector's financial status and outlook were reported in the November 2001 *Healthcare Leadership Review* (Vol. 20, No. 10), published by COR Healthcare Resources.

- Overall there was little change in financial ratios for 2000 vs. 1999.
- Median days cash-on-hand decreased 2.7 days in 2000, or less than 2 percent.
- Days in accounts receivable also declined 0.6 days, primarily due to a more aggressive write-off approach.
- Profitability measures were flat, with downward pressures on revenue from managed care, losses on employed physicians, and increasing expenses.
- Most hospitals showed a slight improvement in debt service covered by EBITDA (earnings before interest, taxes, depreciation, and amortization).

For the future, new operating pressures will likely lead to flat or weaker operating margins. Liquidity will be pressed, with minimal profitability and the need for capital expenditures. Pressure on profitability will come from higher supply and labor costs, particularly in the area of nursing. As more nurses leave the field than enter, hospitals are forced to deal with the resulting shortage by paying for agency nurses.

New Billing Codes for Medical Nutrition Therapy in 2002

by Dorothy Knight, M.P.M.

Look what's new! Effective for dates of service beginning Jan. 1, 2002, a qualifying registered dietitian or nutritional professional can apply for a Medicare provider number and bill a professional charge for medical nutrition therapy.

Q What kinds of professionals meet the Medicare guidelines?

A The requirements are as follows:
- Before Dec. 22, 2000, any dietitian or nutrition professional who is licensed or certified in a state is eligible for provider status.
- After Dec. 22, 2000, an individual applying for provider status must hold a bachelor's or higher degree granted by a regionally accredited college in the U.S. (or an equivalent foreign degree) and have completed the academic requirements of a program in nutrition or dietetics. The applicant must also have completed at least 900 hours of supervised dietetics practice under the direct supervision of a registered dietitian or nutrition professional and be licensed or certified as a dietitian or nutrition professional by the state in which the services will be provided.

Q What codes should be billed for these services?

A The new codes are as follows:
- 97802 Initial assessment and intervention, face-to-face with the patient, each 15 minutes
- 97803 Reassessment and intervention, face-to-face with the patient, each 15 minutes
- 97804 Group (with 2 or more individuals), each 30 minutes.

These codes are covered for patients who have diabetes and renal disease (and not on dialysis). The new Medicare provider category is particularly helpful to cancer centers for patients who meet the diagnosis criteria. Currently, the dietitian or nutrition professional is one of many hospital employees who accumulate service under the clinic visit charge. Provider status allows nutrition services (for certain diagnoses) to be billed separately rather than accumulated toward the clinic visit. Therefore, your institution may have to bill two charges—one technical charge for nursing or social services and another for professional services for nutrition, rather than one technical charge for nursing, social services, and/or nutrition combined.

Q What if you have no one qualified to bill as a nutrition provider?

A Under the outpatient prospective payment system (OOPS), other hospital staff can bill for these services using clinic visit codes. There are a range of HCPCS codes that are used to define the intensity of the visit provided. It is important to note that these codes and descriptions were originally designed for physician billing, and the language of the CPT number does not accurately reflect the resources the facility used to provide visit services.

The Centers for Medicare and Medicaid Services (CMS) is instructing hospitals to develop an internal system to map the services provided, or to combine services to match the different levels of effort represented by each of the HCPCS codes. Each facility will be held accountable for following its own system for assigning different levels for each of the HCPCS codes.

Q What are the compliance guidelines for your internal coding system?

A The compliance guidelines are as follows:
- The services must be furnished, documented, and medically necessary.
- The facility must follow its own internal coding system.
- The facility's system must reasonably relate the intensity of hospital resources to the applicable HCPCS codes (99201-99205, 99211-99215, 99241-99245, 99271-99275).

If your hospital has not yet developed an internal system for billing visits provided by non-physician providers, you will need to address that issue before you can begin to use the visit codes to capture reimbursement.

Q What do you need to get started?

A If you register as a provider, contact your Patient Accounting Department to complete the necessary Medicare HCFA-855 enrollment form. It typically takes 120 days for Medicare to assign the appropriate provider number. This time period may vary from state to state. Also contact your Finance Department to determine the codes to use and make sure that they are on your chargemaster.

If you bill as a non-provider, contact your Finance Department to learn how to code visits for non-physician providers. Meet with the Finance Department to develop new chargemaster codes for your department, if necessary.

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noted that even extremely well-conducted industry trials are sometimes reported with a definite marketing spin and that many industry-sponsored trials are for trivial or me-too drugs.

Bodenheimer concluded in his *New England Journal of Medicine* article that the pharmaceutical industry must appreciate the risks inherent in its partnership with the commercial drug-trial sector, including potential public and physician skepticism about the results of clinical drug trials and a devaluation of the insights provided through close relationships with academic scientists. Perhaps, he noted, drug trials should be funded by industry, but their design, implementation, data analysis, and publication should be controlled entirely by academic medical centers and investigators.

The Jan. 2, 2002, issue of the *Journal of the American Medical Association* (*JAMA*) ran several position papers on the ethical issues of clinical trials. *JAMA* stressed its concern about trials being performed because the results could be of economic benefit to the investigator and went so far as to recommend that informed consent be obtained by someone who is *not* the patient's physician. Many disagree with this position, and the so-called financial windfall attributed to clinical trials enrollment is not supported by the ASCO survey, which measured costs and showed that the average accrual on an industry trial is reimbursed at a rate slightly less than the actual cost of doing the study.

Everyone agrees, however, that whether a trial is NCI- or industry-sponsored, patients must come first.

Margaret A. Riley, M.N., R.N., C.N.A.A., director at Saint Joseph's Hospital of Atlanta, Ga., and a CCOP administrator for 14 years, said it best: "Accruals to industry-sponsored and NIH-sponsored trials can and ought to co-exist because of the need to accomplish both endpoints. However, patients must have a full explanation of all protocol components—for example, author, purpose, and goals—so they can make an informed decision for themselves."

Furthermore, Wade added: "Community-based oncology investigators should select industry-sponsored clinical trials based on several factors, including scientific merit, better access for patients to receive cutting-edge therapy, and improvements in patients' quality of life."

Recruitment of Medical Oncologists Becoming Difficult

Oncology is experiencing significant inflation in pay levels for both new recruits and experienced physicians, according to the January 2002 *Physician Compensation Report* published by the Medical Group Management Association (MGMA) and the Atlantic Information Services.

According to the article, in the year 2000 new medical oncologists coming out of a three-year fellowship (following a three-year internal medicine residency) were getting $140,000 to $150,000 annually to work in popular metro areas. Today those figures are $180,000 to $220,000, with most deals closing near the top of the range.

Despite these salaries, practice managers interviewed for the article report that recruiting is difficult, although "eventually it can be done." Forecasts are that, in 10 years, there will be only about half the oncologists that are needed by the rapidly aging baby-boomer population because the number of fellowship grads is rising slowly.

Medical oncology has by far the highest overhead ratio of any specialty, including primary care, because chemotherapy drugs are so expensive and used in such large quantities. Oncologists tallied $1.7 million in median revenues for single-specialty practices per full-time equivalent physician in MGMA's new *Cost Survey: 2001 Report Based on 2000 Data*, almost twice the figure of any other specialty.

PHOTOGRAPH BY EYEWIRE

Final Stark II Regulations Take Effect

The year 2002 will see the implementation of the final Stark II regulations on physician self-referral. The final rules by the Centers for Medicare and Medicaid Services (CMS) establish government requirements for physician practices that refer patients who need designated health services to entities in which the physician or an immediate family member has a financial interest. The final rules allow physician members of a group practice to be compensated directly for productivity, including for designated health services performed by them. They may not, however, be paid in proportion based on referrals to designated health services.

Direct supervision is no longer required under Stark. Instead, physicians must meet CMS reimbursement rules for the supervision of clinical staff. While the final rules allow physicians to accept non-monetary gifts of more than $50, total gifts over the course of a year cannot equal more than $300.