ISSUES

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CMS Releases Proposed Changes to the Hospital OPPS

As Fall 2003 begins, we find ourselves at the crossroads of congressional and agency action regarding Medicare reimbursement. In late June, the House and Senate both passed landmark legislation making historic changes in the Medicare program. Included in both Medicare packages were hardly noticed provisions tinkering with the hospital outpatient payment system (OPPS) to improve the plight of hospital cancer programs (see article about the Medicare debate on page 7).

Do members of Congress intend these provisions to become law, or is the legislation meant to pressure the Centers for Medicare and Medicaid Services (CMS) to do the "right thing" on its own? The answer remains unknown.

What we do know is that on Aug. 6, 2003, CMS made its first move by publishing a proposed rule outlining what payment rates might look like for 2004, giving the public 60 days to comment before final regulations are published in November and implemented Jan. 1, 2004.

Many of the proposals in the rule are likely to have a negative effect on cancer centers generally, although overall, CMS projects that the impact of all changes proposed for 2004 will increase hospital outpatient spending an average of 3.8 percent.

Payment rates for some drugs went up and some went down, but in increments so small that there was no wholesale reversal of the last two years of cuts. Here are a few examples:

- Docetaxel, 7 percent increase
- Rituximab, 5.5 percent increase
- Gemcitabine HCl, 16.5 percent increase
- Cisplatin, 12 percent decrease
- Leuprolide acetate implant, 30 percent decrease.

One reason that appropriate payment rates remain a severe problem is that CMS did not turn enough multiple procedure claims into single claims when it determined payment rates. Because typical cancer claims are almost always multiple procedure claims, oncology reimbursement has suffered in this methodology oversight by CMS. Early analysis of the proposed rule indicates that CMS proposes more ways in which to turn multiples into "singletons." For example, the new rule proposes separating procedures on a typical 30-day cancer claim by date of service, which should prove helpful.

The second problem resulting in this year's inadequate payments has to do with the concept of charge compression. CMS uses a formula to convert reported hospital charges into purported hospital costs. However, the formula does not take into account that many, if not most, hospitals across the country do not set hospital charges uniformly. An aspirin, for example, might be reimbursed at 300 percent above true costs while an expensive sole-source cancer drug may be reimbursed at 50 to 60 percent of AWP. Unlike the multiple claims issue, CMS was silent in its proposed rule on charge compression. While CMS has been made aware of this issue, the agency chose to ignore it.

■ **Pass-through drugs.** CMS states that the duration of transitional pass-through payments for drugs and biologicals must be no less than two years nor any longer than three years. That means brand new drugs will be paid at 95 percent of AWP for up to three years.

Of concern to cancer care providers, the pass-through status will expire on Dec. 31, 2003, for the following drugs and biologicals:

- J9010 alemtuzumab
- J9017 arsenic trioxide
- J9219 leuprolide acetate implant
- C9201 dermagraft
- J0587 botulinum toxin.

These drugs are scheduled for payment status K as single-source drugs (71 percent AWP).

■ **C-codes.** CMS offered no proposal for public comment on how to improve on the current C-code issuance and payment policy. By contrast, in recognition of the long delays in getting a C-code, the House bill provides for new drugs to be paid at 95 percent of AWP until CMS assigns them a C-code.

■ **Generic drugs.** CMS found six drugs that it proposes to be separately paid under the 2004 OPPS. These drugs had generic alternatives approved during the time between October 2001 and December 2002 and include: daunorubicin, bleomycin, pamidronate, paclitaxel, ifosfomide, and idarubicin. Payment rates for all the drugs except idarubicin will be based on 43 percent of AWP. So, for example, the payment amount for paclitaxel was reduced to 43 percent of AWP, or $68.81.

■ **Orphan drugs.** After reviewing comments on the final rule, CMS has identified seven additional drugs that meet its criteria for orphan drug status. These drugs will be paid at reasonable cost and include:

- J2355 injection, oprelvekin, 5 mg
- J3240 injection, thyrotropin alpha, 0.9 mg
- J7513 daclizumab parenteral, 25 mg
- J9015 aldesleukin, per vial
- J9160 denileukin diftitox, 300 mcg
- J9216 interferon, gamma 1-b, 3 million units

- Q2019 injection, basiliximab, 20 mg.

■ **Revised payment methodology for drug administration.** Despite many public comments asking CMS to remove bundling of cheaper drugs and administration costs into one payment, CMS proposes to continue the practice in 2004. Still, the agency does propose some modifications in its methodology for how drugs will be classified as meeting or exceeding the $150/encounter threshold.

CMS would like to ensure that when a hospital administers a separately paid drug, it would receive payment for the drug and the drug administration, but not for any drugs bundled into the administration. CMS considered several coding and payment options and provides an extensive analysis of the claims data in the proposed rule. CMS would create two new sets of HCPCS codes to describe administration of packaged and separately payable drugs. Each of the eight codes would have its own APC payment.

Although payment would not depend on accurate reporting of HCPCS codes for drugs, CMS would require hospitals to use HCPCS codes for both bundled and separately payable drugs to ensure that the agency had reliable data upon which to base future relative weights for these services. CMS would create six lists of drugs in order to facilitate proper payment in the future.

Hospitals would report the appropriate code for the type of drug administered and the route(s) of administration. In this option, hospitals could bill for administration of both chemotherapy agents and administration of non-chemotherapy agents (or non-drug infusions). CMS would permit a maximum of one chemotherapy and one non-chemotherapy administration per day. Scrapping the current administration codes and starting over with many more codes has the potential to create a coding nightmare for hospitals.

■ **Radiopharmaceuticals and nuclear medicine.** CMS proposes to eliminate the six existing APCs for nuclear medicine procedures (0286, 0290, 0291, 0292, 0294, 0666) and create 20 new APCs for nuclear medicine procedures (APC 0389 through APC 0408). Radiopharmaceuticals were removed from new therapies and assigned to these APCs for nuclear medicine. Cancer program administrators must be sure to capture these codes for work provided in the cancer center. CMS stated that it will continue to develop payment that ties procedure with diagnosis or organ/system by its codes.

■ **Radiation oncology.** Most of the normal codes used in planning and simulation were given a 4 to 7 percent increase. Many radiation oncology services and products, however, had cost decreases of 10 percent or more, translating into significant payment decreases (Table 1). For example, services of daily treatment codes 77412-77416 were reduced by 30 percent, and level II and III radiation therapy were reduced by about 33 percent each. By contrast, permanent prostate seed implants received an 8-10 percent increase, and stereotactic radiosurgery did not change dramatically.

Table 1. Proposed Radiation Payment Changes

Service/ Product	Percentage Reduction
Services of daily treatment	30%
IMRT daily treatment	28%
IMRT planning	63%
Brachytherapy conventional, nonprostate	93%
Interstitial nonprostate	81%
HDR	35%
Ethyol	8%

Medicare Debate Rages On

On June 27, both the House and the Senate narrowly passed the most drastic changes made to Medicare since the program's inception in 1965. While both versions of the bill earmark $400 billion over the next ten years to add a prescription drug benefit and make structural changes to the Medicare program, the two bills are quite different. Both versions of the bill contain provisions to improve hospital outpatient payment rates, but the news is not so good for the physician office setting.

Hospitals. Both bills propose reimbursement rates higher than current payments, which on average are about 60 percent of AWP.

The House bill would reimburse generic drugs at 46 percent of AWP and new drugs not yet assigned C-codes at 95 percent of AWP for the next three years. Single-source drugs would be reimbursed at 83 percent of AWP for 2004, 77 percent of AWP for 2005, and 71 percent of AWP for 2006. Multiple-source drugs would be reimbursed at 81.5 percent of AWP for 2004, 75 percent of AWP for 2005, and 68 percent of AWP for 2006.

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For the next three years, the Senate bill calls for reimbursement of single-source drugs at 94 percent of AWP, multiple-source drugs at 91 percent of AWP, and generic drugs at 71 percent of AWP.

Physician Offices. Under the House bill, payment for Part B drugs would be based on average sales price plus 12 percent or a new competitive bidding structure. The Senate's Medicare bill would lower reimbursement from 95 percent of AWP to 85 percent of AWP and directs CMS to determine actual market prices.

Key members of Congress have been appointed to a "conference committee" to work out the final details of the Medicare legislation. ACCC asks its members and others involved in providing cancer care to contact these Congressional members and ask that adequate resources be given to cancer programs so that the nation's cancer patients can

continue to receive quality care. ACCC's web site (*www.accc-cancer.org*) provides contact information for each of these Congressional members.

Medicare Conference Committee Members

Bill Frist (R-Tenn.), Charles Grassley (R-Iowa), Orin Hatch (R-Utah), Don Nickles (R-Okla.), John Breaux (D-La.), Jon Kyl (R-Ariz.), Nancy Johnson (R-Conn.), Thomas Daschle (D-S.Dak.), Max Baucus (D-Mont.), John Rockefeller (D-W. Va.), Tom Delay (R-Tex.), Bill Thomas (R-Calif.), Billy Tauzin (R-La.), Michael Bilirakis (R-Fla.), Charles Rangel (D-N.Y.), John Dingell (D-Mich.), and Marion Berry (D-Ark.).

CMS Proposes Revisions to Physician Fee Schedule

On Aug. 8, 2003, CMS released its proposed 2004 rule for payment policies under the Physician Fee Schedule. Medicare payments to physicians would be reduced an average 4.2 percent in 2004, and much more for some specialties. ACCC is analyzing the proposed rule and will issue its comments shortly. Read the entire proposed rule at CMS's web site: *www.cms.hhs.gov/regulations/pfs/2004.*

CMS is planning to propose four options for changing how it determines payments for Medicare Part B covered drugs and biologics. CMS may also seek to increase reimbursements for administrative costs related to furnishing covered drugs and biologics, while simultaneously reducing Medicare costs for covered drugs. The draft proposal is most compatible with AWP reform provisions included in the Senate's Medicare prescription drug bill.

Following the receipt of public comments, CMS will select the reform model it will implement. This decision will be announced in the form of a final rule scheduled to be issued in November in combination with the proposed Physician Fee Schedule regulation. CMS has stated that it believes that the proposed rule on AWP would cut Medicare funding "at least $4.1 billion and possibly as much as $27.6 billion" over the next 10 years, depending on which reform option it may choose to implement.

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The cut could be reversed by Congress, however, as both the Senate and House versions of Medicare prescription drug legislation (H.R. 1) seek to provide an increase in physician payments for 2004 and 2005. The reduction has been predicted by CMS for some time. The agency said negative physician updates under the physician fee schedule were likely to continue through 2007.

Hospital Inpatient Payment Rates under Medicare to Increase

On August 1, CMS issued a final rule for fiscal year 2004 that includes a 3.4 percent increase in payment rates beginning October 1, 2003, to hospitals for inpatient services provided to Medicare beneficiaries. This rule is only the second time since the inpatient prospective payment system (IPPS) went into effect in 1983 that hospitals have received the full hospital market basket increase—the measure of inflation in goods and services used by acute care hospitals.

Overall, Medicare is expected to pay approximately $98 billion to about 4,087 acute care hospitals in FY 2004, an increase of $4.1 billion over FY 2003. Of the total payments, approximately $1.8 billion is due to payment rate and other policy changes, and the remaining $2.3 billion is due to anticipated increases in inpatient services and increases in the case mix, said CMS.

Nearly all classes of hospitals will receive an increase in total payments in 2004. When outlier overpayments in FY 2003 are disregarded, urban hospitals are expected to receive a 2.8 percent increase in payments for inpatient services, while rural hospital payments should increase 5.4 percent.

Under the IPPS, Medicare bases the payment rate for a beneficiary's stay on the diagnosis-related group (DRG), which reflects the patient's diagnosis and the procedure performed. CMS has defined over 500 DRGs.

Medicare law requires CMS to update the IPPS annually to reflect changes in the hospital market basket, to revise the weights assigned to individual DRGs (and, therefore the payment for those services), and to establish payment rates for any new procedures and technologies.

The final rule also establishes an outlier threshold for FY 2004 of $31,000, down from $50,645 in the proposed rule. The decrease was made possible by recent revisions to the Medicare outlier regulations, designed to curb abuses of the outlier payment system.

Other payment provisions in the final rule include lowering the high-cost threshold for add-on payments for new technologies that offer a significant clinical improvement over existing technologies, but are sufficiently costly that beneficiary access to the technology might be jeopardized absent the additional payments. The lower threshold would apply to applications for new technology add-on payments for FY 2005.

The final rule also includes a provision approving an additional new

technology for add-on payments for FY 2004.

The final rule becomes effective for hospital discharges on or after October 1, 2003.

CMS Issues Final Rule on High Dose IL-2

In its final rule published on Aug. 1, 2003, regarding the IPPS, CMS made a change that will positively impact treatment options for patients with metastatic kidney cancer and metastatic melanoma. CMS created a new ICD-9-CM procedure code for high dose IL-2 therapy, and proposed to modify DRG 492 by adding new procedure code 00.15 to the logic. CMS also modified the title of DRG 492 to "Chemotherapy with Acute Leukemia or With Use of High Dose Chemotherapy Agent," and stated that patients receiving high dose IL-2 therapy are clinically similar to other cases currently assigned to DRG 492. The change is effective Oct. 1, 2003.

Medicare Payment Cuts Felt Across the Country

ACCC is finding that its worst predictions about Medicare's 2003 OPPS rule are coming true. The rule, which reduced payment rates at hospitals for most cancer drugs and biologicals and their corresponding administration payments, has had grave implications for patient care.

Cancer programs are finding it extremely difficult, if not impossible, to continue to provide therapies for which they are so dramatically under-reimbursed. To date, some programs have already closed their doors, while others have discontinued using the newest drugs without a payment code. Here's a snapshot of what is happening at hospitals across the country.

★ Wisconsin A large tertiary care hospital has been monitoring reimbursement for chemotherapy for some time. Although it had seen a 5 to 6 percent margin on chemotherapy as a whole (not just Medicare) in the past, for January and February 2003, it has experienced a minus 8 percent margin—a loss of $245,000 in these two months alone. The hospital has started discussions about sending patients to the physician office setting for chemotherapy.

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★ Colorado One hospital reported an estimated loss of $431,000 for its oncology clinic in fiscal year 2003 due to the lower Medicare payment rates. Another Colorado hospital notes that it has been in discussions with physicians, pharmacy leadership, and nursing managers to review drug cost and reimbursement information to determine if patients should be sent to a physician office for chemotherapy because of the reimbursement differential between hospitals and practices.

★ Pennsylvania A large university hospital is starting to cut many supportive care services such as psychological, educational, pain management, and complementary medicine services. The hospital is conducting a re-evaluation to determine if it should continue operating hospital outpatient oncology clinics (which is its preference) or to convert the clinics to physician practice locations. The hospital is also seriously considering joining the exempt cancer center group because it does not believe it can maintain outpatient oncology operations under the current Medicare payment system.

★ Hawaii A hospital has for years maintained an outpatient chemotherapy clinic. In May this hospital terminated all chemotherapy services due to poor reimbursement and an inability to continue sustaining financial losses. Patients must now commute outside the area to receive treatment at other hospital facilities. Even worse, none of these other hospitals are eager to accept the added patient volume and financial liability. The alternative is for patients to receive chemotherapy in their physician's private office.

★ Florida A hospital with a 70 percent Medicare mix expects to lose $700,000 this year because of the reimbursement cuts. The hospital no longer allows its doctors to order or administer new drugs that do not have a C-code, or it requires patients to pay cash or come up with a payment plan upfront for the drugs. Administration is developing a plan to remove the chemotherapy infusions from the hospital setting.

Also in Florida, one hospital-based oncology center has started using blood transfusions rather than Procrit® or Aranesp® to treat cancer-related anemia, in order to save costs. Another hospital-based oncology center in the state does not prescribe the drug Neulasta™. A very ill older patient at this center was hospitalized twice for neutropenic fever, which may have been prevented with the use of Neulasta. Supportive care drugs have had zero reimbursement since January 2003.

★ Washington Because of the poor reimbursement, a hospital is not able to initiate treatment with Zevalin™, the radioactive anti-lymphoma antibody.

★ Montana One of the only large hospitals in the state has stopped giving drugs without a C-code and is looking into moving chemotherapy infusions out of the hospital. The hospital estimates a loss of $400,000 to $500,000 this year based on the mix of drugs it gave in the first half of last year.

★ Oklahoma A hospital with almost 50 percent Medicare patients has been monitoring reimbursement for the last several months. Using volume and procedures data from 2002, it projects losses of almost 20 percent under the 2003 reimbursement rates.

Hospital-Based Versus Freestanding

Which Model is Best for You?

by Lynn M. Jones, M.H.A., and Linda B. Gledhill, M.H.A.

Every cancer center must make the decision about whether it should be a hospital-based or freestanding facility. And, because advantages and disadvantages are found in both models, the decision is not always an easy one.

The Hospital-Based Model

Medicare mandates basic criteria that must be met in order for a cancer center to qualify as a hospital-based facility. First, the governance of the cancer center must be the same as for the other hospital departments. Financial integration of revenue and expenses and the medical records system used by the cancer center must also be similar to other hospital departments. Finally, unless the facility was grandfathered in prior to October 2002, the facility must be located within 35 miles of the main campus *or* the hospital and cancer center must provide services to 75 percent of the same market.

Those cancer centers that meet these criteria can realize a number of advantages from adopting a hospital-based model. For example, hospital-based cancer centers can bill for new consultations, new patient visits, established patient visits, interdisciplinary conferences, and critical care (see Table 1). They can also bill for services provided by nurses, social workers, and nutritionists. So, for example, services provided by a clinical nurse must be based on resource consumption to qualify for reimbursement under "technical" charges. These charges vary between $43.96 to $76.30. Other benefits include: 1) higher technical revenues, 2) better leverage when contracting with private payers, and 3) 501(c)3 status, which allows the cancer center to conduct fundraising efforts.

Before switching to a hospital-based model, a cancer center must also understand the disadvantages associated with this model. Generally, the costs associated with a hospital-based cancer program are higher than the cost of running a freestanding center. These costs reflect the hospital's larger facility size, which supports multi-specialties, inpatient services, and overall system costs, as well as the cost of operating a facility 24-hours-a-day, seven days a week.

Because their overhead costs are paid by and to the hospitals, physicians working at a hospital (and using place of service code 22) are reimbursed at a lower level for their professional services than those employed at freestanding centers.

Reimbursement for drugs also tends to be lower when compared to freestanding centers. Historically, Medicare reimbursement for hospitals has been approximately 70 percent of AWP, while reimbursement for freestanding cancer centers has been 95 percent of AWP. Before you base your decision on this factor alone, keep in mind that the final OPPS rule changes annually. (See page 6.)

While the 2003 rule drastically cut drug payments to the hospital setting, proposed legislation looks to increase these drug payments for 2004. Table 2 compares the 2003 payment with an *estimate* of the 2004 payment. A hospital-based cancer program should conduct a similar financial evaluation for *all* the drugs it uses to measure the impact that the 2004 drug payment rates will have on the program's bottom line. Such an evaluation will dramatically affect the decision to convert from a hospital-based to freestanding status.

Table 1: Professional Fees for Radiation and Medical Oncology

Code	Description	Hospital-based		Freestanding	
		Professional	Technical	Professional	Technical
99245	New Patient Consult	Yes $190.90	Yes	Yes $234.27	No
99205	New Patient Visit	Yes $138.34	Yes	Yes $170.29	No
99215	Established Patient	Yes $91.84	Yes	Yes $118.46	No

Both hospital-based and freestanding cancer centers are reimbursed an additional amount for administering the drug to the patient. In 2003, however, many low cost and supportive drugs were bundled in with their associated administration payments (Q0081 to Q0085), which had a negative financial impact for the hospital setting.

Finally, the Stark rules, which bar physicians from making referrals to entities in which the physician has a financial relationship, also affect physicians contracted by hospitals. Within a hospital-based arrangement, the relationship between the hospital and the physicians practicing in the facility must be clearly defined and in compliance with the Stark rules and other regulations that prevent kickbacks and inappropriate solicitation.

Freestanding Cancer Centers

Compared to hospital-based centers, freestanding cancer centers usually have lower costs and can benefit from a variety of ownership models. Today, freestanding cancer centers are reimbursed more for drugs than their hospital-based counterparts. Unlike in the hospital setting, however, pending legislation seems to point to a downward trend in drug reimbursement for freestanding centers. Table 3 compares 2003 drug payments with an *estimate* of 2004 payments. A freestanding cancer program that develops a similar spreadsheet for all its drugs will be able to evaluate the effect that the 2004 drug payments will have on its bottom line.

Physicians employed at a freestanding clinic are reimbursed at a higher rate for their professional services. This amount reflects the inclusion of overhead costs and the fact that Medicare does not permit a freestanding facility to charge both professional and technical fees (see Table 1).

As with the hospital-based model, the freestanding model also has its disadvantages. Medicare pays freestanding centers less money for administration services and technical services—for both radiation and medical oncology. Physicians are also subject to stricter "incident to" regulations, which require the prescribing physician to be in the suite when patients are receiving treatment.

Table 2: Drug Reimbursement Comparison of Three Cancer Drugs in a Hospital-based Cancer Center*

HCPS	Drug	2003 Payment†	2004 Payment‡	Difference
J9045	Carboplatin, 50 mg	$77.82	$134.66	$56.84
J9265	Paclitaxel, 30 mg	$120.77	$148.54	$27.77
J1626	Granisetron, 100 mcg	Bundled	$16.79	$16.79
Totals		**$198.59**	**$299.99**	**$101.40**

*Based on legislation proposed for 2004. These numbers may change significantly, depending on the final legislation passed.
†Calculations based on 2003 reimbursement rates.
‡Calculations based on 86 percent of AWP.

Table 3: Drug Reimbursement Comparison of Three Cancer Drugs in a Freestanding Cancer Center*

HCPS	Drug	2003 Payment†	2004 Payment‡	Difference
J9045	Carboplatin, 50 mg	$148.75	$129.96	($18.79)
J9265	Paclitaxel, 30 mg	$164.08	$143.35	($20.73)
J9310	Rituxmab, 100 mg	$475.00	$415.00	($60.00)
Totals		**$787.83**	**$688.31**	**($99.52)**

*Based on legislation proposed for 2004. These numbers may change significantly, depending on the final legislation passed.
†Calculations based on 95 percent of AWP.
‡Calculations based on 83 percent of AWP.

Many factors influence a cancer center's decision to be a hospital-based model or a freestanding center. Whether you are opening a new center or seeking a new designation, you must understand the full financial and programmatic ramifications to you and your organization. Most important, the decision must take into consideration the complex and constantly changing reimbursement regulations. Cancer programs should not rush to change models based on annual administrative rule changes until they have carefully analyzed the long-term consequences to the organization.

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