Highlights: 2006 HOPD Final Rule

As of Jan. 1, the Centers for Medicare & Medicaid Services (CMS) began paying for most Part B drugs and biologicals administered in hospital outpatient departments (HOPDs) at 106 percent of the manufacturer's average sales price (ASP). According to CMS, payment set at 106 percent of ASP will cover *both* the average acquisition cost and associated overhead cost for drugs furnished in hospital outpatient departments. This final decision marked a substantial change from CMS' initial proposal to pay an additional 2 percent of ASP for drugs and biologicals for 2006 and 2007 to cover pharmacy service and handling costs for drugs, biologicals, and radiopharmaceuticals delivered in the hospital outpatient department.

In its final rule, released Nov. 2, 2005, CMS also made changes to drug administration services, including:

- The adoption of 20 of 33 new CPT codes and the creation of 6 "temporary" HCPCS codes for drug administration services, which describe the highest volume services. Hospitals are now required to use a combination of CPT and C-codes when billing for administration services. (See page 12.)
- Changes to 2006 drug administration reimbursement rates. While some rates dropped by as much as 8 percent between 2005 and 2006, others increased from 3 percent to as much as 19 percent. A table comparing 2005 and 2006 drug administration payments is available at: *www.accc-cancer.org /MEDIA/media_CMS_hopdrule2006final.asp.*
- A $75 temporary add-on payment for hospitals to cover the additional pre-administration-related services required to locate and acquire adequate IVIG (intravenous immune globulin) product and prepare for an IVIG infusion. CMS based this add-on payment on four factors: market instability, access concerns, the growing demand for IVIG, and the move to the ASP payment methodology.

Particularly noteworthy is that CMS did *not* reduce HOPPS payments for some second and subsequent imaging procedures performed within the "identified families" by 50 percent, as it suggested in the proposed rule.

Finally, instead of adopting the national set of coding guidelines developed by the AHA/AHIMA expert panel, CMS engaged a contractor to assist with testing the validity and reliability of a slightly modified draft of the guidelines recommended by the expert panel.

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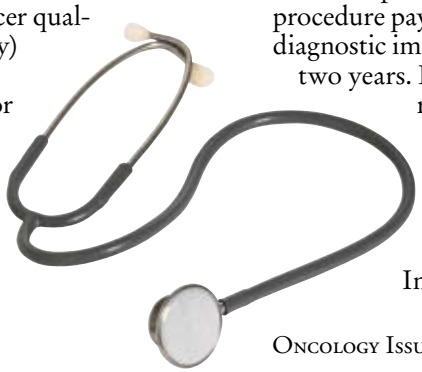
2006 Physician Fee Schedule

Starting Jan. 1, 2006, Medicare payments to oncologists were reduced by approximately 3 percent. This reduction was based on three factors: changes in the conversion factor; changes in relative value units (RVUs), and revisions to the cancer quality demonstration project. Overall, CMS estimates that these changes will be offset by growth in the total volume of services provided, producing no change in total Medicare revenues for oncologists.

In the final rule CMS also extended the cancer quality (chemotherapy) demonstration project with major revisions. Starting Jan. 1, this "revised" demo project *only applies* to oncologists and hematologists who provide level 2-5 evaluation and management (E&M) services to beneficiaries whose primary cancer diagnosis falls into one of 13 major diagnostic categories. To qualify for the additional $23 payment, physicians must provide a level 2-5 E&M service and submit a G-code from each of three categories: primary focus of visit, practice guideline adherence, and current disease site. See page 14 for more information about this "revised" demo project.

The 2006 Physician Fee Schedule made several other changes:

- CMS now pays a $24 supplying fee for oral anticancer and oral antiemetic drugs for the *first* prescription supplied in a 30-day period and $16 for each subsequent prescription in that period. (Initially, CMS proposed to pay $8 for subsequent prescriptions.)
- CMS is phasing-in the multiple procedure payment reduction for diagnostic imaging services over two years. In 2006, payments are reduced by 25 percent for second and subsequent procedures when performed on contiguous body parts in the same session. In 2007, the reduction



PHOTOGRAPH/COMSTOCK

increases to 50 percent. Pending further study, CMS excluded transvaginal ultrasound and ultrasound of the breast from this payment reduction.

- Physicians now receive a $69 temporary add-on payment to cover the additional pre-administration-related services required to locate and acquire adequate IVIG (intravenous immune globulin) product and prepare for an IVIG infusion. As noted in the 2006 HOPD Rule, CMS based this temporary add-on payment on market instability, access concerns, and the growing demand for IVIG.

New! CMS Program Assists Physicians in Reporting Quality Care

CMS' *Physician Voluntary Reporting Program (PVRP)* is collecting and analyzing data on the quality of care provided to Medicare beneficiaries. The data are collected via a set of G-codes established for 36 evidence-based, quality-performance measures that physicians began voluntarily reporting as of Jan. 1, 2006. These 36 Healthcare Common Procedure Coding System (HCPCS) codes complement the claims data doctors submit, so the new data can now be used to measure the quality of services provided in the physician practice setting.

CMS plans to provide feedback to the physicians who submit the data by the summer of 2006. According to the agency, the goal of the program is to assist physicians in improving their data accuracy, reporting rate, and clinical care. The codes are for voluntary reporting purposes only, and physicians should not charge for them. The submission of the codes is intended to serve as an interim step until the electronic submission of data through electronic health records replaces the process.

Four of Nine NCI-CMS Colorectal Cancer Trials Activated

One year ago, CMS issued a National Coverage Determination (NCD) covering the off-label use of certain anticancer drugs in identified clinical trials of colorectal cancer and other cancer types. The NCD requires CMS to cover oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), and bevacizumab (Avastin™) for treatment of colorectal cancer. Coverage is provided for clinical care associated with study participation for Medicare patients enrolled in nine NCI-sponsored Cooperative Group clinical trials.

As of December 20, four of the nine clinical trials identified by the NCD (No. CAG-00179N) have been activated. Log onto ACCC's website at: *www.accc-cancer.org/PUBPOL/pubpol_coverage.asp*, and click on "CMS-NCI Pilot Project Trials" for a complete list of the nine clinical trials.

The first trial to begin accruing patients, E5202, is being led by the Eastern Cooperative Oncology Group (ECOG). E5202 is a randomized Phase III study comparing 5-FU, leucovorin, and oxaliplatin to 5-FU, leucovorin, oxaliplatin, and bevacizumab in patients with Stage II colon cancer at high risk for recurrence based on molecular markers.

For the E5202 clinical trial, research sponsors, Genentech, Inc., and Sanofi-Synthelabo, Inc., are providing the bevacizumab and oxaliplatin, respectively, free of charge. Medicare will cover most study-related costs. Costs *not* covered by Medicare include:

- Data collection not used in the direct

New J-Codes from CMS

Starting Jan. 1, 2006, CMS requires the use of a number of new J-codes for both physician offices and hospital outpatient departments, including:

- Oxaliplatin, injection (Eloxatin®) cannot be billed under HCPCS code C9205. Instead, the new code J9263 per 0.5 mg should be used. (Note quantity change from previous C9205 per 5 mg to J9263 per 0.5 mg). The new J-code was changed for hospitals; physician offices have already been using it.
- Darbepoetin alfa, injection (Aranesp®, for non-ESRD use, 1 microgram) cannot be billed under HCPCS code J0880 and Q0137. Instead, the new code J0881 should be used.
- Epoetin alfa, injection (Procrit®, for non-ESRD use, 1,000 units) cannot be billed under HCPCS code Q0136. Instead, the new code J0885 should be used.
- Azacitidine (Vidaza®, injectable suspension, 1 mg) cannot be billed under its former temporary J-code (J9999) or its former HCPCS code (C9128). Instead, the new code J9025 should be used.

Spotlight on HealthWell Foundation®

HealthWell Foundation® is a non-profit, charitable organization that provides financial assistance to eligible patients to cover certain out-of-pocket healthcare costs, including coinsurance, copayments, and deductibles; health insurance premiums; and the Medicare "dough-nut hole" coverage gap. HealthWell Foundation offers assistance in several disease areas, including:

- Chemotherapy induced anemia
- Chemotherapy induced neutropenia
- Multiple myeloma
- Myelodysplastic syndromes.

The Foundation application process is simple. Applications can be obtained online at *www.healthwellfoundation.org* or by calling 800.675.8416. The application has two parts: a three-page form for the patient to complete, and a one-page form for the physician. HealthWell Foundation processes completed applications within three to five business days. Patients are enrolled for one year and may reapply after that time. HealthWell Foundation agents are available to answer questions Monday through Friday from 9:30 am to 5 pm EST.

clinical management of the patient
- The costs of the research test on tissue to determine randomization or observation
- The costs of all other research tests on tissue and blood conducted as part of the study
- Patient coinsurance and deductibles.

Data collection and research test costs will be covered by other study funds. Patients should check with their health plan(s) about patient coinsurance and deductibles costs related to the clinical trial.

A list of the institutions and sites open to patient participation for E5202 and the other eight clinical trials is available on NCI's website at: *http://www.cancer.gov/search/psrv.aspx?cid=62587&protocolsearchid=2003704.* NCI will update this web page, adding the other studies as they are finalized and receive IRB approvals.

The NCD applies *only* to "ordinary" Medicare, as well as Medicare plans provided through are health maintenance organizations (HMOs) and preferred provider organizations (PPOs). Some states have passed laws requiring that Blue Cross/Blue Shield plans, HMOs, PPOs, and other insurance companies pay, at least in part, for cancer clinical trials. A list of states that have passed such laws is available on NCI's website at: *www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs.*

If no law exists, some private insurers "follow the lead" of Medicare when making decisions about paying for clinical trials. Calling or emailing the appropriate insurers and telling them about Medicare's decision to cover patients enrolled in E5202 may impact the insurer's coverage decision.

For more information about Medicare's coverage decision for E5202, go to *www.cms.hhs.gov/MedlearnMattersArticles/downloads/mm3742.pdf.* Your billing office may also wish to look at: *www.cms.hhs.gov/transmittals/downloads/R38NCD.pdf.*

Alert! E-Prescribing Physicians Caring for Part D Drug Beneficiaries Must Follow Final Rule

The final rule for the electronic prescribing, or e-prescribing, of drugs was published in the *Federal Register* on Nov. 7, 2005. E-prescribing will be optional for physicians and pharmacies, but CMS is requiring providers who electronically prescribe Part D-covered drugs for beneficiaries to follow the specific standards set forth in the final rule. The final rule supersedes any state law or regulation that contradicts it. The final rule is available online at: *www.access.gpo.gov/su_docs/fedreg/a051107c.html.*

CAP Update

The Competitive Acquisition Program (CAP) is scheduled to start July 1, 2006, with the physician election process slated to begin on April 3, 2006, according to the interim final rule released by CMS on Nov. 2, 2005.

During CAP's initial three-year contract period, CMS will *exclude* CAP drugs administered to beneficiaries by participating CAP physicians from average sales price (ASP) calculations. This decision was based on vendor and physician arguments that ASP exemption was "necessary" to ensure manufacturer discounts for CAP drugs. CMS will examine the effect of this exclusion at the conclusion of the initial contract period.

CAP was also addressed in the 2006 Final Physician Fee Schedule where CMS took the following actions:
- Made changes to the list of drugs to be supplied under CAP due to changes in HCPCS codes (additions, deletions, code splits, and consolidations)
- Accelerated the inclusion of new drugs in the CAP by improving the method for vendors to petition the agency during their three-year contracts.
- Allowed vendors to request CMS approval to add single-indication orphan drugs to their CAP offering.
- Reimbursed vendors for the unused portion of a CAP drug—provided the drug is shipped in a single-use vial, and both the vendor and physician make "good faith efforts" to minimize drug wastage.
- Indicated that CAP prices would *not* supersede any Medicare carrier's lowest cost alternative (LCA) policy relating to a particular drug.
- Required CAP vendors to have a grievance process to respond to complaints from participating physicians, beneficiaries, and beneficiary caregivers and set a required response rate at two days for any inquiry, or sooner if the inquiry relates to drug quality.
- Defended its decision to allow CAP vendors to cut off additional drug shipments to patients who fail to make co-payments within 45 days, or 60 days if referred to a charity.

PHOTOGRAPH/PICTUREQUEST