Medicare Physician Fee Schedule for 2008

On November 1, 2007, the Centers for Medicare & Medicaid Services (CMS) issued a notice on the Medicare physician fee schedule for 2008. It will be published in the Federal Register on November 27, 2007. The following is a summary of the provisions of greatest interest to oncologists.

Conversion Factor Update

Because of the sustainable growth rate methodology, the conversion factor will decline by 10.1% in 2008 unless Congress acts to substitute a different update factor. For 2008, the conversion factor will be $34.0682, compared to the 2007 conversion factor of $37.8975.

Changes in Relative Value Units

CMS has made various changes in the relative value units for physician work, notably increasing the values for anesthesiology services. A budget neutrality requirement means that increased payments for some services are offset by decreased payments for other services. In addition, 2008 is the second year of the transition to the new method for calculating practice expense relative value units.

CMS estimates that the changes in the physician work relative value units will cause a 1% reduction in Medicare payments to physicians in the hematology/oncology specialties (which CMS calculates together). The effect of the change in the practice expense relative value units rounds to 0%, for a net total effect in 2008 of minus 1% in Medicare payments under the physician fee schedule to hematology/oncology.

Drug Compendia

The Medicare statute confers coverage on off-label uses of drugs used in cancer chemotherapy regimens if those uses are listed as accepted in specified compendia. In the notice, CMS has adopted an annual process to consider whether additional drug compendia should be recognized or existing compendia should be deleted from the recognized group.

Under the new process, CMS will be open to receiving requests for changes in the list of recognized compendia for a 30-day period beginning each January 15. The requests will be posted by March 15 for a 30-day public comment period. CMS will make a decision within 90 days after the close of the comment period.

The Medicare Evidence Development and Coverage Advisory Committee had adopted a list of desirable characteristics of compendia. CMS stated that it will use these characteristics as a "framework and guidance" in the review process. Although CMS did not explain the weight that would be given to each of the various factors, it stated that the characteristics referencing a "publicly transparent process for evaluating therapies" and a "process for public identification and notification of potential conflicts of interest of the compendia's parent and sibling organizations, reviewers, and committee members" are of high priority.

The notice did not discuss whether the new compendium DRUGPOINTS is considered a successor publication to U.S. PHARMACOPOEIA – DRUG INFORMATION and therefore entitled to authoritative status. However, in conversation with ASCO, CMS Coverage and Analysis staff have said that Medicare contractors may consider DRUGPOINTS listings in making off-label coverage determinations.

IVIG

CMS finalized its proposal to continue the extra payment for "preadministration services" related to intravenous immune globulin. The relative value units for this service in 2008 will be the same as in 2007. A decision whether to continue the extra payment in 2009 will be made later.

ASP Calculation – Bundling

CMS had proposed a specific methodology to determine the average sales prices (ASPs) of products sold in "bundled" arrangements, i.e., when the price of one product is determined based on the purchase of another product, the satisfaction of a performance requirement, or a similar factor. CMS decided not to finalize its proposal at this time. Manufacturers can continue to use reasonable assumptions in reporting the prices for products sold in bundled arrangements.

WAMP/AMP Threshold

If the ASP for a drug exceeds the widely available market price (WAMP) or average manufacturer price (AMP) of the drug by more than a specified threshold percentage, CMS is authorized to substitute a payment method based on WAMP or AMP for the normal payment amount of ASP+6%. CMS finalized its proposal to maintain that threshold percentage at 5% in 2008, the same as it was in 2007.

Competitive Acquisition Program

Physicians can elect to receive Medicare Part B drugs from a vendor under the competitive acquisition program (CAP), rather than purchasing the drugs and billing for them. CMS has made a number of changes in the CAP, as follows:

The law was changed, effective April 1, 2007, to allow the CAP vendor to bill Medicare after it had shipped a drug to a physician but before it had confirmation that the drug had been administered to the patient. The law requires post-payment reviews to determine that the drugs paid for by Medicare were ultimately administered to Medicare patients. CMS states that the post-payment review will consist of (1) matching claims from the contractor to claims submitted by physicians bearing the appropriate CAP prescription number, and (2) statistical sampling to determine whether the drugs were medically necessary. Physicians may be asked for medical records as part of this process.

- The CAP vendor cannot legally bill the beneficiary for coinsurance until the drug has been administered. CMS suggests ways in which the vendor can determine when the drug is administered: (1) a voluntary agreement with a physician under which the

physician agrees to provide such information to the vendor, or (2) the vendor may call the physician's office to verify administration. The CAP vendor may bill the beneficiary after receiving payments from Medicare and any supplemental insurer.

- CMS will allow a physician who has elected the CAP to revoke that decision based on "exigent circumstances." A physician can invoke the "exigent circumstances" factor and terminate CAP participation in the first 60 days (e.g., by March 1, 2008, for an election that begins January 1, 2008). In addition, a physician may terminate CAP participation at any time during the year if a circumstance not previously known to the practice becomes a burden. "Exigent circumstances" are not defined and will be evaluated on a case-by-case basis. CMS cites examples of burdens that might arise after the initial 60 days as including a change in practice personnel, patient population, computer systems, or vendor behavior that makes it harder to participate in the program.
- CMS had solicited comments on its current prohibition against transporting CAP drugs from the site at which they are received to another site for administration. CMS stated that it expected to make a specific proposal next year and that the proposal would permit transport of CAP drugs subject to voluntary agreements between the approved CAP vendor and the participating CAP physician that complied with all applicable state and federal laws and regulations and product liability requirements.
- CMS said that it did not receive any comments showing how use of the CAP prescription number could be eliminated from the claim submitted by the physician to Medicare but that it is still interested in receiving comments on this issue.
- CMS stated that if a standard-of-care drug used in the control group of a clinical trial is on the CAP drug list, the participating physician may order the drug from the CAP vendor. If it is not on the CAP drug list, the physician may buy and bill for it in the normal manner. This is useful confirmation that Medicare covers standard-of-care drugs used as active controls in clinical trials. CMS asked for any information that CAP participation prevents participation in clinical trials and said that it would address the issue if it receives such comments.
- CMS has increased the time limit by which CAP physicians must file claims. Physicians participating in the CAP must file claims within 30 days after the drug is administered, rather than 14 days. Since the CAP vendor is now paid prior to confirmation that the drug has been administered, CMS agreed that the period for filing claims can be extended.

Physician Quality Reporting Initiative

The Physician Quality Reporting Initiative (PQRI) in 2007 offers physicians a bonus payment if they report specified quality measures. CMS states that it plans to make the results of the 2007 PQRI public and that the publicly information would not identify specific physicians or practices.

CMS decided to use the $1.35 billion authorized by Congress for 2008 to fund a PQRI bonus payment in 2008, similar to the bonus payment that applies in 2007. The amount paid to each

physician cannot be calculated until all of the data are submitted in 2008, but CMS estimates that the bonus in 2008 will again be about 1.5% of total fee schedule payments, as it is in 2007.

Under the statute, the quality measures used in the PQRI must be endorsed or adopted by a consensus organization and developed through a consensus-based process. CMS concluded that only the National Quality Forum (NQF) meets all of the applicable requirements, although standards adopted by the AQA Alliance, which functions more quickly than the NQF, are acceptable pending consideration of those standards by the NQF.

CMS proposed 148 quality measures for use in 2008. The final measures are included in the notice, and detailed measure specifications will be issued separately before the end of the year. The following oncology-related measures from the 2007 PQRI are being carried over to 2008:

- Myelodysplastic syndrome (MDS) and acute leukemias: baseline cytogenetic testing performed on bone marrow
- MDS: treatment with bisphosphonates
- Chronic lymphocytic leukemia: baseline flow cytometry
- Hormonal therapy for stage IC-III ER/PR positive breast cancer
- Chemotherapy for stage III colon cancer patients
- Plan for chemotherapy documented before chemotherapy administered
- Radiation therapy recommended for invasive breast cancer patients who have undergone breast conserving surgery

CMS noted that the detailed specifications for the measures may be different in 2008 than they were in 2007.

The following oncology-related measures were proposed by the American Medical Association – Physicians Consortium for Performance Improvement and were endorsed by the NQF or adopted by the AQA Alliance. They will be new PQRI measures for 2008:

- Breast cancer patients who have a pT and pN category and histologic grade for their cancer
- Colorectal cancer patients who have a pT and pN category and histologic grade for their cancer
- Appropriate initial evaluation of patients with prostate cancer
- Inappropriate use of bone scan for staging low-risk prostate cancer patients
- Review of treatment options in patients with clinically localized prostate cancer
- Adjuvant hormonal therapy for high-risk prostate cancer patients
- Three-dimensional radiotherapy for patients with prostate cancer

The law requires CMS to adopt structural measures, and CMS adopted the following two measures:

- HIT – Adoption/use of e-prescribing
- HIT – Adoption/use of health information technology (electronic health records)

CMS adopted the following oncology-related measures from the AQA Starter Set:

- Screening mammography
- Colorectal cancer screening
- Inquiry regarding tobacco use
- Advising smokers to quit

CMS considered whether data on quality measures could be submitted through a registry or other means but concluded that for 2008 the only feasible approach was claims-based submission, as was used in 2007. CMS plans, however, to test in 2008 submissions based on registries and electronic health registries.

The two types of registry-based submissions that will be tested are (1) a system in which the registry provides quality codes, diagnosis codes, and limited beneficiary information to CMS, which will calculate the physician's performance rate, and (2) a system in which the registry itself calculates the physician's performance rate, subject to a validation process. In 2008, registries can volunteer to participate in this testing, but physicians will still have to submit the quality codes as part of claims to qualify for the PQRI bonus.

CMS also stated that it will partner with several electronic health records (EHR) vendors and groups to develop and test EHR clinical quality data submission. As in the case of the registries, physicians would have to submit information through the normal claims process to qualify for the PQRI bonus.

Reporting of Hemoglobin/Hematocrit Levels

Effective January 1, 2008, the law requires each Medicare Part B claim for a drug to treat chemotherapy-related anemia to include information on the patient's hemoglobin or hematocrit level. The requirement is to report the "most recent" hemoglobin or hematocrit level, and CMS is not specifying when that level must have been determined. CMS clarified that the requirement is not limited to use of erythropoiesis stimulating agents, but also applies in the event that some other drug is administered to treat chemotherapy-related anemia. CMS will issue further details on the reporting through contractor instructions.

CMS stated that it will use this information "to help determine the prevalence and severity of anemia associated with cancer therapy, the clinical and hematologic responses to the institution of anti-anemia therapy, and the outcomes associated with various doses of anti-anemia therapy."

Physician Self-Referral (Stark Law) Issues

CMS had proposed a number of changes to its regulations implementing the Stark Law, which governs physician referrals to entities with which the physician has a financial relationship. CMS did not finalize the proposals at this time.

Anti-Markup Provision

CMS adopted a new rule that applies when a physician bills for a purchased diagnostic test or bills for a diagnostic test for which the professional or technical component was performed at a site other than the physician's office. If the test was purchased, the Medicare payment to the physician (including coinsurance and deductible) cannot exceed the net charge that the physician paid for it. If either the technical component or the professional component was furnished outside the physician's office, then this anti-markup provision applies to that component.

Computer-Generated Fax Prescriptions

CMS has authority to regulate the standards for electronic prescriptions for patients enrolled in Medicare Part D. These standards do not require electronic prescriptions but govern any electronic prescribing that is voluntarily undertaken. Under the current rules, the standards do not apply to prescriptions transmitted by computer-generated faxes.

CMS has now terminated the exemption for computed-generated faxes effective January 1, 2009. After that date, prescribers will be required to use true electronic prescription software or revert to use of paper prescriptions. Computer-generated faxes can continue to be used as a temporary fall-back transmission method, however, in the case of a network failure or similar temporary communication problem.