Summary of the Proposed Rule for the 2009 Medicare Physician Fee Schedule

On June 30, 2008, the Centers for Medicare & Medicaid Services (“CMS”) released a notice proposing changes in the Medicare physician fee schedule and related rules for 2009. The notice will be published in the Federal Register on July 7, 2008. This memorandum is a summary of the provisions in the notice that are likely to be of greatest interest to oncologists.

Conversion Factor Update

Under the sustainable growth rate formula, the conversion factor would have declined by 10.1 percent in 2008, but Congress enacted legislation increasing the conversion factor by 0.5 percent. Because the effect of that legislation expired on June 30, 2008, the conversion factor for the second half of 2008 will be 10.6 percent lower than the conversion factor in the first half of 2008 unless Congress intervenes again. CMS has also estimated that the conversion factor will decline another 5.4 percent in 2009 under current law.

RUC Practice Expense Recommendations

The American Medical Association’s Relative Value Update Committee (“RUC”) recommended revising the practice expense relative values for a number of codes including 96440 (chemotherapy administration requiring thoracentesis), 96445 (chemotherapy administration requiring peritoneocentesis), 96450 (chemotherapy administration requiring spinal puncture), and 96542 (subarachnoid or intraventricular chemotherapy injection via subcutaneous reservoir). CMS is proposing to accept the RUC’s recommendations.

The following chart compares the current and proposed practice expense relative values for these codes after the on-going transition is fully implemented:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Current Non-Facility</th>
<th>Proposed Non-Facility</th>
<th>Current Facility</th>
<th>Proposed Facility</th>
</tr>
</thead>
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<tr>
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<td>3.55</td>
<td>2.51</td>
<td>0.32</td>
<td>0.34</td>
</tr>
</tbody>
</table>
Reconfiguration of Payment Localities

Payments under the physician fee schedule are adjusted in each payment locality based on the applicable geographic adjustment factor. Last year, CMS proposed several options to revise the payment localities for California, but after further consideration, CMS has decided to make no changes.

CMS has, however, undertaken a broader review of payment localities. The notice includes a discussion of several possible approaches, but CMS emphasizes that it would not change payment localities without further extensive opportunity for public comment. The possible approaches outlined in the notice are the following:

- **Designate localities based on metropolitan statistical areas (MSAs).** Under this approach, each MSA would be a payment locality, and all the area in a state outside of MSAs would be a locality.

- **Remove high-cost counties from existing localities.** Under this approach, counties with costs that exceed the average costs in an existing locality by more than 5 percent would be removed from the locality and designated as a new locality.

- **Separate MSAs from statewide localities.** Under this approach, CMS would start with the presumption of a single statewide locality. Individual MSAs would then be removed from the statewide locality and designated as a locality if costs in the MSA exceeded statewide average costs by more than 5 percent.

- **Group counties into locality tiers.** Under this approach, the counties in each state would be grouped into locality tiers based on their costs. Tiers would be established for counties with similar costs even if they are not geographically contiguous.

CMS will be posting on its website an interim report on these locality reconfiguration approaches.
Potentially Misvalued Services Under the Physician Fee Schedule

CMS is concerned that that there are a significant number of services that are misvalued under the physician fee schedule, and the notice sets forth several approaches that CMS plans to take to address the issue:

- **Review of the estimated prices of high-cost supplies.** Every two years, CMS plans to review the prices of high-cost supplies (greater than $150) that are used in calculating practice expense relative values. Specialty societies or other organizations would need to document the price of the supply during the review process. The notice identifies 65 high-cost supplies, none of which appear to be used significantly by medical oncologists.

- **Review of procedures that are performed together.** CMS plans to review non-surgical CPT codes that are commonly reported together (for example, 60-70 percent of the time) to assess whether the services should be bundled or whether some of the services should be subject to a reduced payment amount when furnished in combination with other services. CMS analogizes this potential payment reduction to reductions that currently apply in the case of multiple surgical and imaging procedures.

- **Establish priorities for RUC review.** CMS has identified certain classes of services that it would like the RUC to give priority attention to. These are:
  - The fastest growing procedure codes. The notice identifies the 100 fastest growing codes meeting certain criteria. The identified codes include certain CT imaging and radiation therapy codes but no drug administration codes.
  - The Harvard-valued codes. There are about 2900 CPT codes that were valued in the initial work by Harvard that led to establishment of the physician fee schedule and have not been subsequently reviewed by the RUC.
  - Practice expense relative values. CMS has asked the RUC to focus on high-volume codes for which the practice expense payment is significantly increasing as a result of CMS’s adoption in 2007 of a revised methodology for determining practice expense relative values.

Intravenous Immune Globulin (IVIG)

Medicare currently makes an additional payment when IVIG is administered. The payment is ostensibly for pre-administration services incurred in locating sources of
IVIG. CMS is proposing to discontinue the special payment for IVIG, since it believes that the market conditions for IVIG have improved.

Changes in the Calculation of Average Sales Price

CMS is updating the regulations to reflect statutory changes in the calculation of average sales price (“ASP”) of drugs that went into effect April 1, 2008. The changes affect calculation of the weighted average ASP for multiple source drugs and the payment for certain inhalation drugs.

Alternative to ASP-Based Payment Methodology

Under the Medicare statute, CMS may substitute a different payment methodology for ASP+6% if the average manufacturer price or the widely available market price for the drug exceeds ASP by more than a specified threshold percentage. CMS is proposing to maintain that threshold percentage at 5%, which is the current amount.

Competitive Acquisition Program

CMS is proposing several mostly minor refinements to the Competitive Acquisition Program (“CAP”) for drugs. One change would modify the current prohibition against transporting CAP drugs from one practice location to another practice location. Under the proposal, such transportation would be permitted if the CAP vendor and the physician voluntarily agree to it. Any such agreements must comply with legal requirements and must include requirements that drugs are not subjected to conditions that will jeopardize their integrity, stability, and/or sterility while being transported.

Non-Payment for Preventable Conditions

Medicare recently adopted a policy of not paying hospitals for preventable conditions acquired during a hospital stay. CMS states in the notice that the same principle could be applied in other settings, including physician practices. In addition, CMS notes that, when the patient is treated in a different setting than the setting in which the preventable condition was acquired, the entity that caused the condition might be required to pay for the treatment in the second setting. CMS is not proposing any changes at this time but is soliciting comment on the issue.

Standards for Providing Diagnostic Services in Physician Offices

Medicare rules (42 C.F.R. § 410.33) establish standards for independent diagnostic testing facilities (“IDTFs”). In the notice, CMS states its concern that entities furnishing diagnostic services are enrolling as physician practices to avoid the standards for IDTFs,
and CMS is therefore proposing to require physicians who furnish diagnostic services to enroll in Medicare as an IDTF and comply with most of the IDTF standards by September 30, 2009.

The requirements that would apply include: (1) licensing or certification of nonphysician personnel who furnish diagnostic tests, or if there is no state licensing, accreditation by a national credentialing body; (2) maintaining specified records concerning diagnostic testing equipment and notifying Medicare of any changes; (3) disclosure to the government of any person having a financial interest in the practice within 30 days of a change; (4) testing and calibrating equipment in compliance with the manufacturer’s recommendations; (5) allowing CMS inspections; and (6) a prohibition against leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization or sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

CMS is seeking comment on whether the requirements should be limited to certain types of diagnostic procedures. It asks whether the rules should be limited to (a) practices that furnish diagnostic services that use costly testing and equipment, (b) practices that furnish imaging services, or (c) practices that furnish advanced imaging services, such as CT.

**Billing for Services Furnished Prior to Medicare Enrollment**

Currently, physicians and nonphysician practitioners can bill for services furnished to Medicare patients prior to the date that the Medicare program officially accepted their enrollment. (This policy contrasts with the Medicare policy for some other types of entities, such as hospitals, which cannot bill for services furnished prior to their enrollment.)

CMS states that it is concerned about its current policy, since physicians may not have been in compliance with Medicare requirements prior to their enrollment. CMS cites compliance with the rules on advance beneficiary notices as an example. CMS is proposing two alternative approaches to deal with this issue.

Under the first approach, physicians and nonphysician practitioners (“NPPs”) could not bill for services furnished to Medicare patients prior to the date on which the Medicare contractor approved their enrollment. Under the second approach, physicians and NPPs who are enrolled in Medicare could retroactively bill for services after the date on which they submitted the enrollment application to Medicare. If they established or changed practice location after submitting the application, they could bill retroactively only to the date on which the practice location was established or changed.
The notice states CMS’s view that its new enrollment system will speed enrollment. The Internet-based Provider Enrollment, Chain and Ownership System (PECOS) will be available in most states in early 2009 and in California, Missouri, and New York by September 30, 2009. CMS expects that PECOS enrollment applications will be processed in 30 to 45 calendar days, compared to 60 to 90 days under the current system.

**Anti-Markup Rule**

Last year CMS adopted new rules prohibiting physicians from charging Medicare more than the cost of diagnostic services that were either (a) purchased or (b) furnished by an employee or contractor at a site different from the office of the billing physician. Subsequently, CMS delayed implementation of part of the rule. As the rule went into effect on January 1, 2008, it applied only to purchased tests and to anatomic pathology diagnostic tests furnished in a different building than the location of the billing physician.

In the notice, CMS is now proposing two alternative approaches to deal with the issue of possible overutilization of services resulting from certain arrangements. Under the first approach, the anti-markup provision would apply to services performed or supervised by a physician who does not “share a practice” with the billing physician. A physician who is employed by or contracts with a single practice would be considered to share the practice, and therefore diagnostic tests furnished or supervised by that physician would not be subject to the anti-markup rule. A physician who is employed by or contracts with more than one practice, however, would not be considered to share any of the practices, and the anti-markup rule would apply. CMS asks for comment on how to allow a physician to furnish occasional diagnostic services to other practices, such as in a locum tenens arrangement.

Alternatively, CMS is proposing to continue the current site-related approach. The current rules would be modified, however, to clarify what is the same office location. In general, the anti-markup rule would not apply if the diagnostic service is furnished in the same building as substantially the full range of services furnished by the practice. If the practice has different specialties in different buildings, the anti-markup rule would not apply if the diagnostic service is furnished in the same building in which the ordering physician furnishes substantially the full range of patient care services that the ordering physician provides generally. In the case of the technical component of a diagnostic service, both the technician and the supervising physician would have to be located in the office space of the billing physician. CMS is asking for comments on campus-type and other similar arrangements.
Incentive Payment and Shared Savings Programs

The Stark Law generally prohibits physicians from referring patients for “designated health services” to an entity with which the physician has a financial relationship unless one of the exceptions is satisfied. The federal anti-kickback law prohibits remuneration intended to influence referrals. These laws have been seen as obstacles to creation of financial arrangements in which physicians and hospitals share the savings generated by programs to improve quality of care or lower costs (sometimes called “gainsharing”).

CMS is proposing a new exception under the Stark Law that would permit certain incentive and shared savings arrangements between physicians and hospitals. The proposed regulations include a long list of criteria that a program would need to satisfy to qualify for the exception. Some of the proposed criteria are as follows:

- The program must be intended (a) to improve quality of hospital care through changes in physician clinical or administrative practices or (b) to generate actual cost savings for the hospital from the reduction of waste or changes in physician clinical or administrative practices, without an adverse affect on or diminution in the quality of hospital patient care services.

- The program must include patient care quality or cost savings measures (or both) supported by objective, independent medical evidence indicating that the measures would not adversely affect patient care.

- Cost savings measures would need to use an objective methodology, be verifiable, be supported by credible medical evidence indicating that the measures would not adversely affect patient care, be individually tracked, and reasonably relate to the services provided.

- The program must undergo independent medical review of its impact on the quality of care.

- Participation in the program would be limited to those physicians who are members of the hospital’s medical staff at the commencement of the program to protect against abusive programs that serve as inducements to attract physicians from competing hospitals.

- Physicians participating in the program must do so in pools of five or more physicians. The aggregate incentive payment must be shared by physicians in the pool on a per capita basis.
Physicians participating in a program must have access to items or supplies that they deem medically necessary for an individual patient’s care, including all FDA-approved drugs.

CMS is considering various restrictions on the amount and structure of the incentive. As an example, CMS states that if the goal of the program was to reduce utilization of a particular procedure from 80 percent (the hospital’s rate) to 20 percent (the national rate), and after one year the rate had been reduced to 60 percent, physician incentive payments during the second year would need to be based on reductions from the 60 percent level.

Patients must be notified about the program and told which physicians are participating.

Programs must last one to three years.

Physician Quality Reporting Initiative (PQRI)

In 2007 and 2008, the PQRI offers physicians a 1.5 percent bonus for reporting certain quality-related information. Based on preliminary data, CMS estimates that about 100,000 professionals – about 16 percent of the eligible universe – participated in the 2007 PQRI.

The notice includes proposed revisions in the quality measures that would be used in the 2009 PQRI. Currently, however, there is no legislation authorizing a payment in 2009 for participation in the PQRI.

The quality measures used in the 2008 PQRI would largely be retained for 2009. Two oncology-related measures from 2008 will not be used in 2009 because the National Quality Forum declined to endorse them: Measure #74, Radiation Therapy Recommended for Invasive Breast Cancer Patients who have Undergone Breast Conserving Surgery and Measure #103, Review of Treatment Options in Patients with Localized Prostate Cancer.

CMS is proposing to adopt a number of new cancer-related quality measures that have been adopted by the AQA Alliance:

- Melanoma: Follow-Up Aspects of Care
- Melanoma: Continuity of Care – Recall System
- Melanoma: Coordination of Care
- Cancer Care: Medical and Radiation – Plan of Care for Pain
- Cancer Care: Pain Intensity Quantified
CMS is also proposing methods of reporting quality measures through registries and electronic health records systems.

**Physician Certification for Home Health Services**

Medicare requires that a physician certify a patient’s plan of care for home health services and recertify it every 60 days. CMS states in the notice that it has become aware that there is a wide range of physician involvement in the certification and recertification process. CMS would prefer to see active physician involvement, including direct contact with the patient.

CMS states that it is exploring options to address this concern. One option would be to reduce the payment amount for certification and recertification to reflect the level of physician involvement that CMS believes is actually taking place. Another option would be to impose rules requiring a specific level of physician involvement, including, for example, a requirement for direct contact with the patient.