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On October 30, 2008, the Centers for Medicare & Medicaid Services ("CMS") released the final Medicare physician fee schedule and related rules for 2009. The notice will be published in the Federal Register on November 19, 2008. This memorandum is a summary of the provisions in the notice that are likely to be of greatest interest to oncologists.

PAYMENTS FOR SERVICES

Overall Payment Changes

As required by the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), the 2009 update for the conversion factor will be an increase of 1.1%. If MIPPA had not been enacted, the conversion factor for 2009 would have been reduced by 15.1%. In the absence of additional legislation, the estimated update for 2010 is a reduction of about 21%, followed by further reductions of about 5% annually for several years.

The conversion factor in 2009 will be $36.0666, compared to the 2008 conversion factor of $38.0870. Although, as noted above, the update factor is a positive 1.1%, the 2009 conversion factor will be adjusted downward by 6.41% in a budget neutrality adjustment to account for relative value increases that were made as a result of the 5-year review of physician work relative values that was implemented in 2007 and 2008. In 2008, CMS implemented the budget neutrality requirement by reducing the physician work relative values for all codes by 11.94%. MIPPA, however, requires CMS to impose budget neutrality through the conversion factor, rather than through the work values. Therefore, CMS has converted the 11.94% reduction of work values to a 6.41% reduction in the conversion factor.

Because of this change, codes with significant physician work values will benefit. For example, CMS says that the payment for a level 3 office visit for an established patient (CPT 99213) will increase from an average of $59.80 in 2008 to $61.31 in 2009 (a 3% increase). CMS estimates that the net effect on the hematology/oncology specialty from this and less important changes is that Medicare payments will fall 1%.

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

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peritoneocentesis), 96450 (chemotherapy administration requiring spinal puncture), and 96542 (subarachnoid or intraventricular chemotherapy injection via subcutaneous reservoir). CMS accepted the RUC's recommendations.

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

CPT Code	Current Non-Facility	New Non-Facility	Current Facility	New Facility
96440	5.55	15.97	0.98	1.09
96445	5.41	4.73	0.96	0.80
96450	4.99	3.21	0.83	0.66
96542	3.55	2.44	0.32	0.37

Reconfiguration of Payment Localities

Payments under the physician fee schedule are adjusted in each payment locality based on the applicable geographic adjustment factor. CMS is undertaking a broad review of payment localities and posted a study of alternative locality options on its website on August 21, 2008. It is making no changes at this time.

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.* CMS had proposed to review, every two years and with the assistance of specialty societies, the prices of high-cost supplies that are used in calculating practice expense relative values. CMS did not finalize this process but instead stated that it planned to research the possibility of using a contractor to obtain accurate pricing information for supplies.
- *Review of procedures that are performed together.* CMS had proposed to review non-surgical CPT codes that are commonly reported together 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. In the final notice, CMS stated only that it would continue to work to identify additional services that should be subject to bundling or a multiple procedure payment reduction.
- *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.

- ° <u>The Harvard-valued codes.</u> 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.
- ° <u>Practice expense relative values.</u> 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. According to the notice, the RUC takes the position that increases to the practice expense relative values for certain codes are not attributable to the direct inputs under the revised practice expense methodology but are the result of CMS's accepting supplemental survey data for certain specialties.

Stereotactic Radiosurgery Codes

The CPT Editorial Panel significantly revised the stereotactic radiosurgery codes for cranial and spinal lesions to replace CPT 61793. CMS disagrees with the relative values recommended by the RUC for a number of the new codes. Nevertheless, CMS accepted the recommended values on an interim basis and urged the RUC to reconsider them.

Gamma Knife Payment (Stereotactic radiosurgery, multi-source Cobalt 60 based)

The proposed payment under the physician fee schedule for CPT 77371 was $1260 compared to $7608 in the hospital outpatient department. In response to comments, CMS decided to have the office-based payment determined by the Medicare contractors in 2009 pending review by the RUC.

Moderate (Conscious) Sedation Codes (99143-99150)

In 2006, the CPT Editorial Panel adopted moderate sedation codes. At that time, CMS rejected the work values recommended by the RUC, however, and instead designated them as contractor-priced. In September 2008, a RUC workgroup again recommended to CMS that it accept the previous recommendations. CMS stated that it will continue to review them.

Telehealth Inpatient Hospital Consultations

CMS has decided to issue a series of codes and pay for follow-up inpatient telehealth consultations (G0406-G0408). CMS adopted these G-codes because the CPT deleted its codes for follow-up inpatient consultations (and therefore required use of the subsequent hospital care codes in follow-up situations). Under the new codes, a telehealth follow-up consultation cannot be provided by the physician of record or the attending physician and is distinct from the follow-up care provided by such a physician.

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 stated in its proposal that there is a wide range of physician involvement in the certification and recertification process and that it would prefer to see active

physician involvement, including direct contact with the patient. In the final notice, CMS did not take any action but stated that it would continue to study the matter.

PAYMENTS FOR DRUGS

Intravenous Immune Globulin (IVIG)

CMS has discontinued the special payment for IVIG pre-administration services for 2009. The notice states that there was a modest increase in IVIG use in physician offices in 2007 compared to 2006, in contrast to a shift from offices to hospital outpatient departments from 2005 to 2006. In addition, overall IVIG use has increased, and the supply of IVIG has been above or near its 12-month moving average. Based on these factors, CMS concluded that the reasons for adopting the IVIG-related payment no longer exist.

Changes in the Calculation of Average Sales Price

CMS is updating its 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 a particular drug exceeds ASP by more than a specified threshold percentage. For 2009, CMS maintained that threshold percentage at 5%, which is the current amount.

Competitive Acquisition Program

CMS had proposed several mostly minor refinements to the Competitive Acquisition Program ("CAP") for drugs. Because the CAP has been suspended, CMS did not finalize its proposals.

COVERAGE ISSUES

Coverage of Additional Preventive Services

MIPPA authorizes CMS to extend coverage under Medicare Part B to additional preventive services through the national coverage determination process. Newly covered services would have to meet certain criteria, including that they be recommended with a grade of A or B by the U.S. Preventive Services Task Force (http://www.ahrq.gov/clinic/prevenix.htm) According to CMS, there are about 15 to 20 services with a grade of A or B that may be appropriate for the Medicare population. The cancer-related recommendations that have a grade of A or B and may be relevant to the Medicare population are the following, some of which are already covered by Medicare:

- screening mammography, with or without clinical breast examination, every 1-2 years for women aged 40 and older

- screening for cervical cancer in women who have been sexually active and have a cervix
- screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years
- screening all adults for tobacco use and providing tobacco cessation interventions for those who use tobacco products.

CMS states that it is reviewing the recommendations to determine which should be the subject of a national coverage determination proceeding, and it invites public comment.

QUALITY-RELATED AND OTHER SIMILAR PROGRAMS

Physician Quality Reporting Initiative (PQRI)

The recent MIPPA legislation provided for a 2% bonus payment in 2009 for participation in the PQRI. The 2009 PQRI will include several new quality measures related to cancer treatment that have been adopted by the AQA Alliance:

- Oncology: Medical and Radiation – Plan of Care for Pain
- Oncology: Medical and Radiation – Pain Quantified
- Oncology: Radiation Dose Limits to Normal Tissues
- Oncology: Recording of Clinical Stage for Lung Cancer and Esophageal Cancer

Pursuant to a requirement in MIPPA, in 2010 CMS will publicly list on its Internet site (www.medicare.gov) the names of the physicians who satisfactorily participated in the 2009 PQRI and earned a bonus payment. CMS said that it is its goal to eventually make performance information public as well.

Electronic Prescribing Incentive Program

MIPPA enacted a program to encourage electronic prescribing. For 2009, a "successful electronic prescriber" will receive a 2% bonus payment. The amount of the bonus payment declines in future years, and beginning in 2012 there is a penalty in the form of reduced payments for physicians who are not "successful electronic prescribers."

For 2009, CMS will use what was PQRI Measure #125 to determine who is a "successful electronic prescriber." This measure requires a report on the Medicare claim in connection with office visits and similar encounters. For each such encounter, the physician will report one of three G-codes indicating that (a) all prescriptions were billed electronically, (b) no prescriptions were generated during the visit, or (c) some or all prescriptions were written or phoned in because of patient request, legal requirements, pharmacy inability to receive an e-prescription, or the fact that the prescription was for a controlled substance. To qualify for the bonus, the physician must have an operational electronic prescribing system that meets certain functionality criteria and must submit a G-code for at least 50% of the applicable encounters. In addition, the allowed charges for the visits and other encounters for which G-codes can be submitted must be at least 10% of the physician's total allowed charges.

Physician Resource Use Feedback Program

MIPPA requires CMS to implement a physician feedback program by January 1, 2009, to provide confidential reports to physicians, based on Medicare claims data, that measure the resources used by a particular physician in furnishing care to Medicare patients compared to a larger group of physicians. CMS plans to implement this program in phases, with the first phase consisting of a pilot program it is currently operating in Boston and Baltimore, possibly supplemented by additional locations.

The resource utilization reports in the Baltimore project compare a physician's resource use on a per patient (per capita) basis, while the Boston reports use both a per capita and per episode basis of comparison. Information provided to physicians is broken down by service category (e.g., imaging services, inpatient admissions). CMS is seeking comment on various aspects of this program, including identification of high cost or high volume priority conditions that could be the subject of the reports (treatment of prostate cancer is one of such conditions in the Boston and Baltimore programs), the medical specialties to be involved (medical oncology was one of the specialties covered in Boston and Baltimore), and the larger physician group to which an individual physician's resource use should be compared.

Non-Payment for Preventable Conditions

Medicare recently adopted a policy of not paying hospitals for preventable conditions acquired during a hospital stay and in the proposal stated that the same principle could be applied in other settings, including physician practices. CMS did not propose any specific changes. In the final notice, CMS states that it looks forward to working with stakeholders to apply "value based purchasing" initiatives in all settings and that it intends to host a public listening session in late 2008 to discuss expanding the policy on preventable conditions in both the hospital inpatient and outpatient settings.

OTHER RULE CHANGES

Standards for Providing Diagnostic Services in Physician Offices

Medicare rules establish standards for independent diagnostic testing facilities ("IDTFs"). In the proposal, CMS stated its concern that entities furnishing diagnostic services are enrolling as physician practices to avoid the standards for IDTFs, and CMS therefore proposed 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.

In the final notice, CMS is deferring action on its proposal to apply IDTF standards to physician offices due to the enactment of section 135 of MIPPA. MIPPA requires CMS to establish an accreditation process for entities furnishing advanced diagnostic services, including MRI, CT, and PET, and certain other diagnostic procedures by January 1, 2012.

Billing for Services Furnished Prior to Medicare Enrollment

Currently, physicians and nonphysician practitioners ("NPPs") 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.)

Under the final rule, which is effective January 1, 2009, retroactive billing is limited to services furnished on or after the date on which the enrollment application was filed or, if later, the date that the physician or NPP first started furnishing services at a new practice location. Billing for 30 days prior to that date is permitted in certain circumstances – when the enrolling physician met all program requirements including state licensure requirements, the services were furnished at the enrolled practice location, and circumstances prevented enrollment in advance of providing services to Medicare beneficiaries. In addition, services furnished up to 90 days before the application was submitted would be permitted if there was Presidentially declared disaster.

The notice states CMS's view that its new enrollment system will speed enrollment. CMS states that the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) will be operational for individual physicians and NPPs by January 2009 and will be operational for entities (other than DMEPOS suppliers) by June 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. Physicians and NPPs who submit claims through billing agents, clearinghouses, academic medical institutions, and other entities will be required to submit a paper application to enroll or make a change in their enrollment information.

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.

CMS has now modified the rules, effective January 1, 2009. As finalized, the anti-markup rule can be avoided only if both the ordering and performing physicians "share a practice," and there are two ways in which they can be considered to share a practice. Under the first approach, the anti-markup rule will not apply if the physician performing the professional component or supervising the technical component performs at least 75% of his or her professional services for the billing physician. The 75% test can be satisfied either by looking at the previous 12 months (including the month in which the service is provided) or by estimating services in the future 12 months (including the month in which the service is provided). If the 75% test is met, the two physicians are said to share a practice, and the anti-markup rule will not apply.

If the arrangement does not meet the 75% test, a particular service will still be exempt from the anti-markup rule if the physician who provides the professional component, or supervises the technical component, is an owner, employee, or independent contractor of the billing physician and provides or supervises the service in a building in which the ordering physician provides the

full range of services that the ordering physician generally provides. The definition of "same building" is the existing definition in the Stark Law regulations, which includes one or more structures with the same street address as assigned by the Postal Service, but does not include mobile vehicles.

If the anti-markup rule applies, the Medicare payment to the billing physician or supplier may not exceed the performing physician's net charge to the billing physician (and cannot exceed the actual charge or fee schedule amount). If the furnishing physician is not paid a fixed fee, then only the salary and benefits paid to the physician (and not overhead) may be considered in determining the net charge.

Hospital-Sponsored 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 incentive payment and shared savings programs designed to improve quality of care or lower costs.

CMS proposed a new exception under the Stark Law that would permit certain hospital-sponsored incentive payment and shared savings arrangements between physicians and hospitals. The proposed regulations included a long list of criteria that a program would need to satisfy to qualify for the exception. CMS decided not to finalize its proposal, however, but instead reopened the comment period. CMS asked for comment on a number of specific issues, including:

- Whether there should be different rules for "incentive payment programs" (such as pay for performance) as opposed to "shared savings programs" (such as gainsharing), as most commenters recommended, and, if so, how those terms should be defined.
- Whether there is less risk of patient abuse in the case of incentive payment programs, as some comments contended.
- Whether CMS is authorized to issue an exception for shared savings programs in light of the statutory restriction that permits exceptions only if there is no risk of program or patient abuse.

In addition, CMS is seeking additional comment on the various criteria that it proposed for an exception.

Retention of Referral Documentation

CMS revised its regulations to require physicians and NPPs to maintain written ordering and referral documentation for seven years from the date of service.

Computer-Generated Fax Prescriptions

Use of electronic prescriptions for drugs covered by Medicare Part D is voluntary but any electronic prescribing must conform to CMS standards. Originally, CMS exempted computer-generated fax prescriptions from the standards so that physicians using this method would not revert to paper prescriptions. Last year, CMS reduced the exemption so that it would apply only in the case of temporary or transient network failures effective January 1, 2009.

In this notice, CMS has reinstated the original exemption for computer-generated fax prescriptions. The exemption will remain in effect until January 1, 2012, when the disincentives for e-prescribing enacted in MIPPA go into effect. Beginning in 2012, computer-generated faxes could be used for Part D prescriptions only in the event of temporary or transient network failures.