Sidley Austin's Analysis of Key Provisions of the CY 2012 Medicare Physician Fee Schedule Final Rule

Key Provisions

Code-Specific Issue Related to G0365

- In response to comments urging CMS to reconsider using the standard PE methodology to update RVUs for code G0365, CMS re-examined the disparity in the payment rate between the CY 2011 PE RVUs and those that appeared in the proposed rule. CMS discovered that an inadvertent data entry error in the proposed direct PE database had led to the development and display of an erroneous PE RVU. (p. 74)

- The corrected direct PE database and the development of PE RVUs for G0365 are more similar to the current PE RVUs.

Identification and Review of Potentially Misvalued Services

- In response to comments regarding the possible inadequacies of the proposal to review evaluation and management codes, CMS is not finalizing its proposal to review 91 such codes. (p. 121)

- CMS is finalizing its proposal to review a select list of high PFS expenditure procedural codes representing services furnished by an array of specialties. (p. 122)

- Adjustment of these high expenditure procedural codes could affect a variety of specialists, including oncologists (code 96413, chemotherapy infusion), orthopedic surgeons (code 27447, total knee arthroplasty; code 27130, total hip arthroplasty), pathologists (code 88342, immunohistochemistry; code 88112, cytopatholgoy), radiologists (code 70450, head CT; code 70553, brain MRI; code 72148, lumbar spine MRI), and cardiologists (code 93000, complete electrocardiogram; code 93015, stress test). (p. 123-24)

- CMS also published a list of specific codes that may be potentially misvalued, which were brought to its attention by public stakeholders. Those codes include abdominal and pelvic CT (p. 97), various types of tissue pathology (p. 99), and in situ hybridization (p. 100). (p. 128-35)

- CMS is also asking the AMA to review and provide recommendations on potential inconsistencies with the prices related to ultrasound equipment as found in the practice expense database. (p. 136)

Expansion of the Multiple Procedure Payment Reduction Policy

- CMS has a policy to reduce payment for the second and subsequent nuclear medicine diagnostic and surgical procedures provided to a single patient by the same physician on the same day, a policy referred to as the Multiple Procedure Payment Reduction ("MPPR") policy.

- CMS will extend the MPRR to the Professional Component ("PC") of Advanced Imaging Services, including MRI, CT, and ultrasound procedures. CMS will apply a 25% payment reduction that already applies to the Technical Component ("TC") of these imaging services to the PC as well. (p. 157)

- Under the Final Rule, full payment would be given for the TC and PC of the highest paid procedure, and payment would be reduced by 25% for the PC and TC for each additional procedure provided by the same physician to the patient in the same session. (p. 158)

- In future years, CMS will aggressively work to identify additional codes that are inappropriately valued, and accordingly, should be subject to the MPPR. (p. 169)
  - In particular, CMS will consider applying the MPRR to the TC of all imaging services, including x-ray, fluoroscopy, echocardiography, and nuclear medicine procedures, in addition to MRI, CT and ultrasound procedures. Diagnostic and screening mammography services will be excluded, and add-on codes may be excluded. (p. 169)
  - CMS will also consider applying the MPPR to the PC of all imaging services. (p. 169)
  - Finally, CMS will consider applying the MPPR to the TC of all diagnostic tests, including, for example, cardiology and radiology diagnostics. (p. 170)

Allowed Expenditures for Physicians' Services and the SGR

- Because CMS is required to issue a final rule that reflects current law, the Final Rule across-the-board cuts to Medicare physician payment rates by about 27.2%, which will take effect January 1, 2012, unless Congress intervenes to change the underlying law. (p. 625-640)

- Provider interest groups are actively lobbying for a Congressional act to repeal the SGR formula. According to a trade press article quoting key Congressional staff, legislation to cancel the physician payment cuts would cost between $20 billion and $25 billion for just one year.

Annual Wellness Visit and Personalized Prevent Plan under Medicare Part B

- The Patient Protection and Affordable Care Act established an annual wellness visit for Medicare Part B patients, which is designed to provide personalized prevention plan services, as defined in the statute. Part of that prevention plan is a Health Risk Assessment ("HRA"), which is "an evaluation tool designed to provide a systematic approach to obtaining accurate information about the

patient's health status, injury risks, modifiable risk factors, and urgent health needs."

- Definition of HRA: CMS has decided to finalize its definition of HRA, as established in the proposed rule, except to correct a typo and alter the definition in relation to behavioral risks. In particular, the agency chose not to expand the HRA to encourage increased data collection for the assessment of risks of diabetes and other common conditions faced by seniors. (p. 766)

- Definitions of First Annual Wellness Visit and Subsequent Annual Wellness Visit: CMS has decided to finalize these definitions as written in the proposed rule, except that it modified the definition of the term "subsequent annual wellness visit providing personalized prevention plan services" to recognize that patients may only need to update their HRA after a first annual wellness visit. (p. 766)

- Payment for AWV Services: Responding to provider criticism about increased responsibility without corresponding increases in compensation, CMS agreed to increase the PE RVU from the current level 4 Evaluation and Management service to include greater clinical labor time. On the basis that the CDC estimates that an HRA should take no more than 20 minutes to complete, and because not all patients will need assistance completing their HRA, CMS has decided to increase the clinical labor time for the initial AWV by 10 minutes, or one-half of the estimated HRA completion time. For subsequent AWVs, when an HRA is likely only to be updated, CMS has agreed to increase the clinical labor time by 5 minutes. (p. 769-770)

Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

- CMS is updating its list of CPT/HCPCS codes, which will be effective January 1, 2012, that it considers to be designated health services ("DHS"); physicians are prohibited from referring a Medicare beneficiary for certain DHS to an entity with which the physician or a member of the physician's immediate family has a financial relationship unless an exception applies. (p. 1120)
  - The updated list of services which fit into these codes are considered DHS and, thus, would be subject to the self-referral prohibition.
  - CMS adds that codes listed reflect the entire scope of DHS for the following categories of services:
    - Clinical laboratory services.
    - Physical therapy, occupational therapy, and outpatient speech-language pathology services.
    - Radiology and certain other imaging services.
    - Radiation therapy services and supplies. (p. 1121)

Physician Incentive Programs (PQRI, ePrescribing, EHR)

- The Final Rule also updated various physician incentive programs, including the Physician Quality Reporting Initiative ("PQRI"), the Electronic Prescribing Incentive Program ("ePrescribing Program"), and the Electronic Health Records Incentive Program ("EHR Program").

- Physician Quality Reporting Initiative
  - The PQRI provides an incentive payment to eligible professionals who comply with the program's data reporting requirements related to quality measures for services furnished to Medicare beneficiaries. Eligible professionals may participate in the PQRI either as individuals or as part of a group practice. (p. 771-772)
  - For 2012, CMS proposed to retain all 14 of the measures groups under the 2011 PQRI and also proposed to add 10 new measures groups, including Cardiovascular Prevention and Radiology. The agency finalized all proposed measures groups (with changes for some of them), except for Epilepsy and Radiology. (p. 915-919)
  - Several commenters suggested additional measures groups, such as Cardiac Imaging. CMS is not finalizing these because there was no opportunity for public comment, but it will consider them for future program years. (p. 923)
  - CMS proposed to retain all individual measures used in the 2011 PQRI for claims and registry reporting. CMS also proposed 26 new individual measures for inclusion in the 2012 PQRI, two of which are endorsed by the National Quality Forum ("NQF"): (1) Anticoagulation for Acute Pulmonary Embolus Patients; and (2) Pregnancy Test for Female Abdominal Pain Patients. (p. 880-887, 891)
  - In response to comments urging CMS to include only NQF-endorsed measures, CMS in the Final Rule reiterates its "exception authority" under the statute to include measures not endorsed by NQF. (p. 861, 864-865)
  - CMS included 14 of the 44 EHR Incentive Program measures under the 2011 PQRI EHR-reporting mechanism. For the 2012 PQRI, CMS received several comments supporting its proposal to make all 44 of these clinical quality measures available for EHR-based reporting. The agency is finalizing that proposal. (p. 909-911)
  - For group practice reporting in 2012, CMS is finalizing its proposal to retire the following 3 measures: (1) Diabetes Mellitus: Hemoglobin A1c Testing; (2) Diabetes Mellitus: Lipid Profile; and (3) Hypertension ("HTN"): Blood Pressure Measurement. (p. 937-943)
  - CMS finalized its proposal to eliminate the 6-month reporting period for claims and for individual measures reported via registry under the PQRI, but to retain the 6-month reporting period for reporting measures groups via registry. (p. 784-787)
  - CMS finalized its proposal to adopt a 2012 PQRI set of "core measures" aimed at promoting cardiovascular care. Due to operational limitations, however, CMS is not finalizing its proposed requirement that physicians practicing in certain specialties (internal medicine, family practice, general

practice, and cardiology) report at least one of these newly adopted core measures. While eligible professionals in these specialties may still report on these measures under the PQRI, they are not required to meet the reporting criterion that was proposed.
  - Some commenters urged CMS to create additional core measure sets related to other disease modules, such as diabetes, for future years. (p. 877-878)
  - CMS finalized its proposal to change the regulatory definition of a "group practice" by consolidating what was previously two group reporting options into a single option, which now defines a "group practice" as 25 or more individual eligible professionals. (p. 776-777)

- ePrescribing Program. Under this program, which CMS first implemented in 2009, "successful electronic prescribers" may earn an incentive payment equal to a percentage of their total estimated Medicare Part B PFS charges for all covered professional services furnished during the reporting period. The Final Rule sets forth the program requirements for the remainder of the program, which runs through 2014.
  - For 2012, the incentive payment will be 1% of the eligible professional's total estimated Medicare Part B PFS allowed charges, the same as in 2011. (p. 975)
  - Starting in 2012, the program will also impose penalties on eligible professionals who are not "successful electronic prescribers". The penalties will be applied as a "payment adjustment" in the following calendar year. (p. 975-976)
  - For the 2013 and 2014 payment adjustments, CMS finalized its proposal to retain the same four "significant hardship exemption" categories previously finalized for the 2012 payment adjustments. (p. 1036-1045)

- Electronic Health Record ("EHR") Program. Under the EHR program, eligible professionals, hospitals, and critical access hospitals participating in Medicare and Medicaid can earn incentive payments if they successfully adopt, implement, upgrade, or demonstrate meaningful use of certified EHR technology. In prior rulemakings, CMS has specified the initial criteria in order to qualify for an incentive payment, including the initial clinical quality measures ("CQMs") for which eligible providers must submit information to the Secretary.
  - CMS finalized its proposal that, for the 2012 payment year, eligible providers may continue to report CQM results by attestation. This modifies a prior requirement that CQM reporting must be done electronically. CMS also finalized its proposal to establish a pilot mechanism through which eligible providers in the EHR Incentive Program may report CQM information electronically using certified EHR technology. (p. 1071-1072)
  - Specifically, CMS is creating a Physician Quality Reporting System-Medicare EHR Incentive Pilot, under which eligible professionals can meet the CQM requirements of the EHR Incentive Program and the PQRI through a single electronically submitted report. CMS is encouraging but not requiring participation in this pilot for payment year 2012. (p. 1072-1076)

Bundling of Payments: 3-Day Payment Window

- The three-day payment window policy requires that certain services (otherwise billable under Part B) provided to a Medicare patient in the three days preceding a hospital inpatient stay be included in the hospital's bundled diagnosis related group ("DRG") payment. (p. 654)
- Consistent with the Preservation of Access Act's expansion, the Final Rule clarifies that the three-day payment window policy also applies to nondiagnostic services that are clinically related to an inpatient admission when preadmission services are furnished in a wholly owned or wholly operated entity (p. 678), noting further that whether an outpatient service is "clinically related" requires case-by-case assessment of the specific clinical circumstances surrounding a patient's inpatient admission. (p. 664)
- Under the Final Rule, facility practice expense RVUs apply to services furnished to patients in places of service including, but not limited to, a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated "entity" (as opposed to the proposed "physician practice") providing preadmission services. (p. 660, 1221). CMS clarified that "entities" do not include provider-based entities, rural health clinics, or Federally qualified health centers. (p. 662).
- Although the new HCPCS code modifier will be available Jan. 1, 2012, CMS delayed implementation of the new HCPCS code modifier until July 1, 2012, out of concern that hospitals may not have the infrastructure in place to comply with the new requirement by Jan. 1, 2012. (p. 679).
- CMS finalized its proposal to clarify that services subject to a global surgery package payment are subject to the three-day payment window policy when the outpatient diagnostic or nondiagnostic preadmission services are provided within three days of the actual inpatient surgery. If the date of the surgical procedure falls outside of the three-day window, the policy would not apply. In other words, it is the date of surgery, not the date of hospital admission that would matter in instances involving a global surgery package. Post-operative services will remain bundled under this policy. (p. 673-674)

Productivity Adjustment for the ASCs, Ambulances, Clinical Labs, and DMEPOS

- CMS finalized its proposal to revise the proxy series used to adjust update factors under the following payment systems: (1) the ambulatory surgical center payment system; (2) the ambulance fee schedule; (3) the clinical laboratory fee schedule; (4) and the DMEPOS fee schedule.
- PPACA requires that the productivity adjustment equals the ten-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP), calculated using a series of proxy variables. Instead of relying on an earlier-used series (man-hours in private nonfarm establishments), CMS will now forecast MFP using hours of all persons in private nonfarm establishments, adjusted for labor composition effects. This series provides a more suitable proxy because it accounts for changes in skill-mix of the workforce over time. (p. 721-723)

Clinical Laboratory Fee Schedule: Signature on Requisition

- CMS finalized its proposal to retract the policy that was finalized in the CY 2011 PFS Final Rule with Comment Period, which required a physician's or qualified nonphysician practitioner's signature on a requisition for clinical diagnostic laboratory tests paid under the Clinical Lab Fee Schedule. In this CY 2012 Final Rule, CMS has reinstated its prior policy that such signature is not required. (p. 737)

Section 105: Extension of Payment for Technical Component of Certain Physician Pathology Services

- CMS finalized its proposal that an independent laboratory may not bill a Medicare contractor for the technical component of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital for services furnished after December 31, 2011. This policy was originally adopted for CY 2001, but implementation has been delayed by legislative action.

Therapy Services-Outpatient Therapy Caps for CY 2012

- CMS noted that its authority to provide for exceptions to the caps on expenses incurred for outpatient physical therapy, speech-language pathology and occupational therapy services under Medicare Part B expires on December 31, 2011 unless Congress acts to extend it. If the exceptions process expires, the caps will apply, except for services furnished and billed by outpatient hospital departments. The therapy cap amount for CY 2012 is $1,880. (p. 680).

Medicare Telehealth Services for the Physician Fee Schedule

- CMS agreed to add only one new service to the list of approved Medicare Telehealth Services, denying several other proposals. Moreover, the agency modified the standard under which it considers services for inclusion in Medicare Telehealth Services.
  - New Services: CMS has decided to include smoking cessation services as a Medicare Telehealth Service. (p. 222)
  - Denied Services: CMS has decided not to include the following services as Medicare Telehealth Services: (p. 223-33)
    - Critical Care Services: Existing evidence does not meet the CMS criteria for Medicare Telehealth Services.
    - Domiciliary or Rest Home Evaluation and Management Services: Domiciliary or rest homes are not permitted under current statute to serve as an originating site for Medicare Telehealth Services.
    - Genetic Counseling Services: Genetic counselors who would provide these services cannot bill Medicare directly for their professional services and are not on the list of practitioners who can furnish telehealth services.
    - Online Evaluation and Management Services: CMS does not believe it is appropriate to make payment for services furnished via telehealth when those services would not otherwise be covered under Medicare.

- Data Collection Services: CMS does not believe it is appropriate to make separate payment for services furnished via telehealth when Medicare would not otherwise make separate payment for these services. Under current Medicare rules, payment for data collection services are bundled with other evaluation and management services.
- Audiology Services: CMS does not have authority to pay audiologists for services furnished via telehealth, because the statute only provides authority for payment for telehealth services that are provided by a physician or practitioner as defined under the statute.

- New Standard for Consideration of Telehealth Services: CMS announced that it will finalize its plan to review Category 2 proposed services (i.e., services that are not similar to current telehealth services) under the clinical benefit standard. That standard would evaluate whether the service is accurately described by the corresponding code when delivered via Medicare Telehealth Services and whether use of a telecommunications system to deliver the service demonstrates a clinical benefit to the patient. (p. 248)

Technical Corrections

- CMS proposed two technical corrections to the Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements Regulations. CMS did not receive any public comments on these proposals.
  - The finalized revision to the definition of deemed entity now reads: Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under §410.145(b) to furnish training. (p. 1125)
  - The finalized revision to the condition of coverage regarding training orders now reads: Training orders. Following an evaluation of the beneficiary's need for the training, the training is ordered by the physician (or qualified non-physician practitioner) (as defined in §410.32(a)(2)) treating the beneficiary's diabetes. (p. 1126)