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Final 2011 Medicare Physician Fee Schedule Update Implements Key Reform Provisions

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The Centers for Medicare & Medicaid Services (CMS) finalized its 2011 Medicare Physician Fee Schedule (MPFS) update (Final 2011 Update), first proposed by CMS on July 13, 2010. The Final 2011 Update finalizes rules implementing key provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act). The Final 2011 Update was published in the November 29, 2010, *Federal Register*, and is effective January 1, 2011. Comments on interim final rules contained in the Final 2011 Update are due January 3, 2011.

The Final 2011 Update affects a range of Medicare Part B payment policies, including policies affecting access to wellness and preventative services, e-prescribing incentives for physicians, outpatient rehabilitation coverage, diagnostic imaging reimbursement, telehealth coverage and the Stark in-office ancillary services exception. This *White Paper* discusses certain of the more notable provisions of the Final 2011 Update.

Physician Payment Update

Acting to avert a 21.3-percent cut in Medicare payments to physicians for 2010 mandated by the statutory sustainable growth rate (SGR) formula that limits the growth of spending under the MPFS, the U.S. Congress increased by 2.2 percent payment for services furnished to Medicare beneficiaries from June 1, 2010, through November 30, 2010. Acting to avert a 23-percent SGR-mandated cut effective December 1, Congress passed the Physician Payment and Therapy Relief Act of 2010, which replaces the cut with a 2.2-percent payment increase for the month of December. A 24.9-percent SGR-mandated cut is scheduled to go into effect January 1, 2011, but Congress deferred until next year a long-term fix to the problem the SGR formula poses for physician payments.

Incentive Payments for Primary Care Services and Rural General Surgery

Incentive Payments for Primary Care Services

The Affordable Care Act provides incentive payments equal to 10 percent of a primary care practitioner's allowed charges for primary care services. The incentive payment is effective for calendar years 2011–2016. The law defines primary care practitioners as physicians who have a primary specialty designation of family medicine, internal medicine, geriatric medicine or pediatric medicine, as well as nurse practitioners, clinical nurse specialists and physician assistants for whom primary care services account for at least 60 percent of the practitioner's allowed charges under Part B for the applicable reference period. In response to comments, CMS decided that, for purposes of the 60-percent calculation, only charges made under the MPFS, excluding charges for hospital inpatient and emergency department visits, will be used. CMS will use a practitioner's specialty designation and claims data from calendar year 2009 for calendar year 2011, because it contains the most recent claims data available. CMS will update the list of primary care practitioners annually using the same two-year lag, except that CMS will use more recent data for practitioners who are new to the Medicare program.

The 10-percent incentive payment will be applied to the primary care practitioner's Medicare allowed charges for primary care services, defined as:

- New and established patient office or other outpatient evaluation and management (E/M) visits
- Initial, subsequent, discharge and other nursing facility E/M services
- New and established patient domiciliary, rest home (*e.g.*, boarding home) or custodial care E/M services
- Domiciliary, rest home (*e.g.*, assisted living facility) or home care plan oversight services
- New and established patient home E/M visits

Although physicians working in a health professional shortage area (HPSA) continue to qualify for an HPSA-based incentive payment, for purposes of the primary care incentive payment the 10 percent will not be applied to the HPSA-based incentive. The payments will be made on a quarterly basis.

HPSA Surgery Incentive Payments

The Affordable Care Act provides a 10-percent incentive payment for major surgical procedures performed in HPSAs by surgeons enrolled in Medicare as general surgeons. The incentive payment is effective for calendar years 2011–2016. A major surgical procedure is defined as a 10-day or 90-day global surgical procedure. The Final 2011 Update implements this incentive payment consistent with the law, providing clarifying guidance on how CMS will, technically, identify surgeries performed in a HPSA. The payments will be made on a quarterly basis.

Wellness and Preventative Services

Removal of Barriers to Preventive Services

The Affordable Care Act revises the definition of "preventive services" under the Social Security Act to include the following: a list of specific preventive services, an initial preventive physical examination (IPPE) and an annual wellness visit (discussed further below). The Final 2011 Update also adds preventive services to benefits covered under Medicare Part B. The Affordable Care Act requires 100 percent Medicare payment for the IPPE and certain preventive services to which the U.S. Preventive Services Task Force has given a grade of A or B, and the provision waives any coinsurance or Part B deductible that would otherwise be applicable to such preventive services or for the annual wellness visit. This provision is specifically designed to remove barriers to affording and obtaining preventive services under Medicare. Such provisions are effective for services provided on and after January 1, 2011. The deductible for the IPPE was the subject of a statutory waiver, effective January 1, 2009. CMS notes all existing Medicare coverage policies for such services, including any limitations based on indication or population, continue to apply.

The Final 2011 Update finalizes the inclusion of certain services *not* subject to the Part B annual deductible: the IPPE; the annual wellness visit; pneumococcal, influenza and hepatitis B vaccines and their administration; screening mammography; screening pap smear and screening pelvic exam; prostate cancer screening tests; colorectal cancer screening tests; outpatient diabetes self-management training (DSMT); bone mass measurement; screening for glaucoma; medical nutrition therapy services; cardiovascular screening blood tests; diabetes screening tests; ultrasound screening for abdominal aortic aneurysm; and additional preventive services identified for coverage through the national coverage determination (NCD) process. To date, two services also have been added as "additional preventive services" by NCDs: HIV screening for at-risk individuals and smoking and tobacco cessation counseling for asymptomatic individuals. With regard to Federally Qualified Health Centers (FQHCs), the Final 2011 Update finalizes application of the new definition of preventive services as described above to the new Medicare FQHC preventive services definition, waiver of coinsurance for the preventive services that are recommended with a grade of A or B by the U.S. Preventive Services Task Force for any indication or population, and the addition of a 20-percent co-pay on all other FQHC services after implementation of the FQHC prospective payment system. The Final 2011 Update also extends the Affordable Care Act's waiver of deductible to services furnished in connection with or in relation to a colorectal cancer screening test that becomes diagnostic or therapeutic.

Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan

The Final 2011 Update implements Section 4103 of the Affordable Care Act, which expanded Medicare coverage under Part B to include an annual wellness visit that provides personalized prevention plan services, effective January 1, 2011. In the proposed 2011 update, CMS defined key terms and the required elements for the first annual wellness visit and subsequent annual wellness visits. The proposed elements for the first annual wellness visit include: establishment of the individual's medical and family history; establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the

individual; measurement of height, weight, body mass index (or waist circumference), blood pressure and other routine measurements deemed appropriate for the particular individual; detection of cognitive impairment; review of individual's potential for depression; review of individual's functional ability and level of safety; establishment of a written screening schedule and a list of risk factors for which primary, secondary and tertiary interventions are under way; and furnishing of personalized health advice and a referral to a health education or preventive counseling service or program if needed. CMS also proposed to add additional elements in the future through the National Coverage Determination process. The proposed elements for subsequent visits are similar, though they exclude screening for depression and assessment of functional ability. CMS did not propose to include the health risk assessment provided for in section 4103 because the guidelines and the model tool for the health risk assessment, both of which are also required by section 4103, are not yet available.

The Final 2011 Update adopts without change CMS' proposed elements of the first and subsequent wellness visits; however, CMS added voluntary advance care planning as a new element to these annual visits. Voluntary advance planning is defined as:

> Verbal or written information regarding the following areas: (1) An individual's ability to prepare an advance directive in the case where an injury or illness causes the individual to be unable to make health care decisions[; and] (2) Whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

Stark-Required Notice to Patients of Alternative Imaging Suppliers

The Affordable Care Act amended the statutory Stark in-office ancillary services exception to require that CMS impose a requirement (under the exception) that a Medicare beneficiary referred for an MRI, CT or PET scan be given, at the time of the referral, a written notice that the patient may receive the services from a supplier other than the referring practice and that informs the patient of alternative suppliers located in the area in which the patient resides. This statutory amendment was effective January 1, 2010, but CMS has adopted a January 1, 2011, effective date for its regulatory amendments to the in-office exception.

The proposed 2011 update required that Medicare beneficiaries referred for MRI, CT or PET scans be given a written notice at the time of referral that the patient may receive the scan from a supplier other than the referring practice and that lists at least 10 alternative imaging suppliers located within a 25-mile radius of the practice site. If there are not 10 alternative imaging suppliers within a 25-mile radius of the practice site, then the list must include all of the alternative imaging suppliers within this area. If there are no alternative imaging suppliers within a 25-mile area, the practice is only required to give the patient a written notice that the patient may receive the referred services from a supplier other than the referring practice. The written notice must include for each supplier on the list the supplier's name, address, telephone number and distance from the referring practice's site.

Based on comments it received, CMS made four material changes to its proposals in the Final 2011 Update. First, CMS reduced to five the number of the alternative suppliers that must be included in the list of alternative suppliers. Notably, the referring physician is not required to list the five imaging suppliers closest to the referring physician's office, and is not required to provide a list at all if there are no alternative suppliers within a 25-mile radius of the referring physician's office location. Second, the list does not have to specify how far away from the referring physician's office location the alternative supplier's facility is located. Third, the referring physician, may, but is not required to, include hospitals on the list of alternative imaging facilities, provided the physician still complies with the five supplier rule. Fourth, the physician is not required to obtain the patient's signature on the notice and document the notice in the patient's medical record. CMS declined to permit verbal notices alone, but recognized that in certain cases of telephonic referrals the written notice may need to follow a verbal notice by email or a letter.

Electronic Prescribing Incentive Program

2011 eRx Incentive Payment

The Final 2011 Update decreases the incentive payment for successful electronic prescribers under Medicare's Electronic Prescribing (eRx) incentive program to 1 percent of the total estimated allowed charges for all covered professional services

furnished during the 2011 calendar year. (The incentive payment was 2 percent in each of 2009 and 2010.) The incentive payment for 2012 will remain at 1 percent, while the payment will further decrease to 0.5 percent in 2013.

To determine whether an individual eligible professional (EP) or group practice is a successful electronic prescriber, EPs and group practices must submit reports to CMS using an eRx measure. Under the eRx measure, individual EPs must report a minimum of 25 Part B professional service patient encounters during the 2011 calendar year, where certain current procedural terminology (CPT®) codes are implicated and where at least one prescription is generated and transmitted electronically through a qualified eRx system. Group practices on the other hand must meet a minimum patient-encounter benchmark that is a sliding scale based on the number of national provider identifier (NPI) numbers linked to the group practice (*e.g.*, 75 reporting patient encounters for a group of 2–10 NPIs). The U.S. Department of Health and Human Services (HHS) plans to post the final eRx measure by December 31, 2010, on the CMS website.

In addition, the EP or group practice's total 2011 MPFS-allowed charges for all covered professional services submitted under the eRx measure, divided by the EP's total allowed charges for all covered professional services, must be 10 percent or more. If the result of this calculation is less than 10 percent, the EP or group practice will not earn an eRx incentive payment.

2012 eRx Penalty

Beginning in 2012, if an EP or group practice is not a successful electronic prescriber for the reporting year, the MPFS amount for covered professional services furnished by such professional during the year will be less than the amount that would otherwise apply by 1 percent for 2012, 1.5 percent for 2013 and 2 percent for 2014. CMS has stated this penalty should not penalize those for whom the adoption and use of e-prescribing may be impractical given the lower volume of prescribing.

Relationship to Medicare and Medicaid EHR Incentive Programs

If an EP chooses to participate in the Medicare electronic health record (EHR) incentive program established under the Health Information Technology for Economic and Clinical Health Act, part of the American Recovery and Reinvestment Act of 2009 (HITECH Act), the EP cannot simultaneously participate in the eRx incentive program in the same program year. However, the EP may simultaneously participate in the eRx incentive program and the Medicaid EHR incentive program established under the HITECH Act. For more information on the Medicare and Medicaid EHR incentive programs, see "Navigating the Government's Final Rules for Earning Incentive Dollars Through 'Meaningful Use' of E-Health Record Technology."

Physician Quality Reporting and Related Payment Incentives

The Physician Quality Reporting System (PQRS, previously known as the Physician Quality Reporting Initiative, or PQRI) is a voluntary program for EPs (physicians and other specified non-physician practitioners) to receive incentive payments for reporting data to CMS on selected quality measures. The Final 2011 Update continues the reporting of PQRS measures via claims-based, registry-based or EHR-based reporting for a 12-month period (for all reporting methods) or a six-month period (for claims-based and registry-based reporting methods).

The Final 2011 Update implements the same method for selection of PQRS measures used in 2009 and 2010—measures were required to have a high impact on health care, facilitate alignment with other federal health care programs, be endorsed by the National Quality Forum, address gaps in the existing PQRS measure set, measure various aspects of clinical quality and be functional. Based on these criteria, CMS retains 171 individual quality measures currently used in the 2010 PQRS and implements 16 new individual quality measures. Finally, the Final 2011 Update makes several changes to the PQRS in response to Affordable Care Act provisions. CMS reduced the incentive payment amount from 2 percent to 1 percent of estimated allowed charges, and will convert the existing Physician and Other Health Care Directory into the Physician Compare website. The Final 2011 Update also implements the Affordable Care Act provision providing for additional incentive payments to EPs that submit PQRS data through a Maintenance of Certification Program operated by the American Board of Medical Specialties.

In order to implement the provision requiring alignment of PQRS measures with the clinical quality measures required for purposes of demonstrating "meaningful use" of a certified EHR under the Medicare and Medicaid EHR incentive programs, CMS adopted many of the core clinical quality measures required to demonstrate meaningful use as PQRS measures. CMS also expanded their existing feedback process to include interim feedback reports, beginning in 2012, in order to comply with the Affordable Care Act's requirement that CMS implement a "timely" feedback program and to make modifications to their existing inquiry process to comply with the act's requirement that CMS implement an informal review process permitting EPs to seek review of a determination that the EP did not meet PQRS submission requirements.

Resource Use Measurement and Reporting Program

CMS first implemented the Physician Resource Use Measurement and Reporting Program on January 1, 2009. Under the program, physicians receive confidential reports measuring the resources involved in furnishing care to Medicare beneficiaries. Phase I of the program involved data analysis activities and sending reports to individual practicing physicians in 12 geographic areas that provided feedback on resource use measures. Phase II will involve reporting on the quality of care furnished to Medicare beneficiaries by physicians or groups of physicians.

Section 3007 of the Affordable Care Act requires the HHS Secretary to phase in a budget-neutral payment modifier to the fee-for service physician fee schedule payment formula beginning January 1, 2015. The modifier will provide for differential payment under the fee schedule to physicians and groups of physicians based on the relative quality and cost of care to their Medicare beneficiaries. The work done in connection with the confidential feedback reports will inform the implementation of the payment modifier and Medicare physicians will receive a confidential feedback report prior to implementation of the payment modifier.

In the proposed 2011 update, CMS sought comment on various aspects of program design, including cost and quality measures, methodologies for compositing measures and feedback report content and delivery. In response to those comments, the Final 2011 Update discontinues use of commercially available proprietary episode grouping software for the Phase II reports, excludes the use of PQRS data in those reports and implements the electronic delivery of the reports.

Payment Reductions for Advanced Imaging Services

The Final 2011 Update includes three provisions that will effectively lower payments for certain diagnostic imaging services. First, as mandated by the Affordable Care Act, effective January 1, 2011, CMS will assign a 75 percent utilization rate assumption to CT and MRI equipment, an increase that has the effect of lowering the practice expense relative value units, and, thus, payment for imaging services utilizing this equipment.

Second, CMS expanded the list of imaging services affected by this change in the utilization rate assumption to include CT angiography and MRI angiography services. This reduction in expenditures for CT and MRI services is not being made on a budget-neutral basis.

Finally, CMS expanded the multiple procedure payment reduction (MPPR) to the technical component of 20 percent more imaging services than under current policy. Currently, as revised by the Affordable Care Act, the MPPR imposes a 50-percent payment reduction (up from 25 percent) on the second and any subsequent CT, MRI or ultrasound service furnished during the same session, on the same or a contiguous body part and involving the same imaging modality. Effective January 1, 2011, CMS will apply the MPPR to multiple CT, MRI and ultrasound services performed in the same session without regard to whether the subsequent images involve the same imaging modality or a contiguous body part.

Additional Telehealth Services

The Final 2011 Update includes the addition of the following services to the list of Medicare telehealth services for calendar year 2011:

- Individual and group kidney disease education services (HCPCS codes G0420 and G0421, respectively)

- Individual and group diabetes self-management training (DSMT) services, with a minimum of one hour of in-person instruction to be furnished in the year following the initial DSMT service to ensure effective injection training (HCPCS codes G0108 and G0109, respectively)

- Group medical nutrition therapy and health and behavior assessment and intervention services (CPT codes 97804, 96153 and 96154, respectively)

- Subsequent hospital care services, with the limitation for the patient's admitting practitioner of one telehealth visit every three days (CPT codes 99231, 99232 and 99233)

- Subsequent nursing facility care services, with the limitation for the patient's admitting practitioner of one telehealth visit every 30 days (CPT codes 99307, 99308, 99309 and 99310)

Regulations regarding payment for telehealth services will be revised to add the above-listed services and the list of telehealth services for which payment will be made at the applicable MPFS payment amount for the service of the practitioner will be reorganized. CMS is continuing to specify that the initial and periodic personal physician visits required to be made to residents of skilled nursing facilities (SNFs) under 42 C.F.R. 483.40(c) may not be furnished as telehealth services.

CMS emphasizes the requirements for certain minimum in-person instruction or interaction, and limits on the number of telehealth visits in a certain span of time, address concerns regarding the centrality of in-person interaction to the effectiveness of the service, and the limitations inherent in the use of telehealth for hospital and SNF inpatients with acute and/or complex medical conditions.

Shortened Period for Submitting Medicare Claims

As mandated by the Affordable Care Act, CMS finalized its proposed rule that, for dates of service on and after January 1, 2011, Medicare fee-for-service claims must be filed no later than one calendar year after the date of service. Under the prior rule, providers and suppliers had up to 27 months to submit a claim, depending on the date of service. For services furnished during the last three months of calendar year 2009 all claims must be filed no later than December 31, 2010. The Final 2011 Update provides for an extension to the one-year filing deadline for failure to meet the deadline due to an error or misrepresentation by an agent of the Medicare program, and late filing caused by a determination of Medicare entitlement for a beneficiary made after the date of service but with an effective date retroactive to or before the date of service to the beneficiary. The time period of the extension varies depending on the circumstances, but is generally six months from the date of the event resulting in a failure to meet the one-year deadline.

Physician Assistants Included as "Physician Extenders" Permitted to Order Post-Hospital Extended Care Services

Medicare Part A pays for post-hospital SNF care furnished by a SNF, or critical access hospital with swing-bed approval, only if there is a level of care certification of the needed skilled services and, as necessary, recertification of continued need by authorized medical personnel. Effective for items and services furnished on or after January 1, 2011, the Affordable Care Act adds physician assistants (PAs) to the list of "physician extenders" (currently, nurse practitioners and clinical nurse specialists are included as physician extenders) who, working in collaboration with a physician, can perform the required initial certification and periodic recertification that an individual needs skilled nursing care or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF or a swing-bed hospital on an inpatient basis. In light of the Affordable Care Act provision adding PAs to the category of physician extenders, CMS proposed to revise the Medicare regulation to add PAs to the list of "physician extenders" permitted to certify coverage for post-hospital SNF care. Existing legal prohibitions that apply to the direct or indirect employment of physician extenders by the facility will continue to apply to PAs ordering post-hospital extended care services, as a result of the inclusion of PAs as physician extenders. CMS received no comments on this proposal and finalized this provision as proposed.

Reasonable Cost Payments for Clinical Diagnostic Tests Furnished to Hospital Patients in Rural Areas Extended for Additional Cost Reporting Periods

The Medicare Modernization Act established a reasonable cost payment for outpatient clinical diagnostic laboratory tests furnished by hospitals with fewer than 50 beds that are located in qualified rural areas for cost-reporting periods beginning during the two-year period beginning on July 1, 2004. This period was subsequently extended twice, most recently to cost-reporting periods beginning July 1, 2004, and ending June 30, 2008. For some hospitals with cost reports that began as late as June 30, 2008, this extension affected services performed as late as June 29, 2009, because this was the date those cost reports would have closed. The Affordable Care Act reinstitutes this reasonable cost payment for clinical diagnostic laboratory tests performed by hospitals with fewer than 50 beds that are located in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011. For some hospitals with cost reports that begin as late as June 30, 2011, this reinstitution of reasonable cost payment could affect services performed as late as June 29, 2012, because this is the date those cost reports will close. CMS received no comments on this proposal and finalized this provision as proposed.

Therapy Services

In the proposed 2011 update, CMS solicited comments on three potential alternatives to outpatient therapy caps, which impose a per beneficiary combined cap on expenses incurred for outpatient physical therapy and speech-language pathology services under Part B and a separate cap on outpatient occupational therapy services under Part B. The alternatives are intended to improve upon existing payment policies by identifying appropriate payments for medically necessary and effective therapy services, and CMS makes clear that the alternatives are not intended as mutually exclusive of one another. The proposed alternatives are based on the June 30, 2009, report from the Short Term Alternatives to Therapy Services (STATS) project, a two-year project funded by the Tax Relief and Health Care Act of 2006, as well as stakeholder input and further communications with the contractor who prepared the STATS report. CMS did not formally propose any of the options; rather, the agency solicited comments to assess the strengths and weaknesses of each approach.

Under the first option, clinicians would be required to submit new function-related nonpayable HCPCS codes to replace the –KX modifier. These codes would be required at episode onset and at periodic intervals, rather than on every claim. These new codes would enable contractors to more readily identify and limit claims for beneficiaries for whom the therapy services show no efficacy. In addition, the data collected through these codes may enable CMS to develop new payment approaches that better identify efficient and effective medically necessary services.

Under the second option, CMS would use existing therapy utilization data to develop annual per-beneficiary medical necessity payment edits (*e.g.* limits to the number of services per session, per episode or per diagnostic group) for exceptions to the therapy caps. These would be set at benchmark payment levels that would affect only a small percentage of beneficiaries each year. Once a beneficiary reaches the payment level, claims would be denied and practitioners would need to appeal in order to obtain payment.

Under the third option, practitioner therapy services currently reported and paid separately for an outpatient therapy session would be bundled into a new Level-II HCPCS code. Payment for the code would be based on patient characteristics and the complexity of the evaluation/assessment and intervention (E&I) services furnished during the session. CMS anticipates 12 new E&I codes and proposes a pilot study to determine whether different practice patterns in physical therapy, occupational therapy and speech-language pathology might justify separate relative value determinations for each E&I code by type of therapy. If so, there may be as many as 36 new Level-II codes (12 for each type of therapy). CMS believes this type of bundling could lead to more accurate payments and, ultimately, fewer beneficiaries subject to the therapy caps each year.

CMS received a number of comments on each of the three options. Comments were generally opposed to the second option and supportive of the first and third options. MedPac supported all three options. As none of the options was actually formally proposed, CMS did not take any steps to finalize a new policy.

Congress has repeatedly adopted exceptions to the therapy caps. The current exceptions are scheduled to expire December 30, 2010.

For more information, please contact your regular McDermott lawyer, or:

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