Health Policy Update

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Recent Health Policy Highlights

- Fraud Enforcement and Recovery Act
- American Recovery and Reinvestment Act
- Patient Protection and Affordable Care Act (and Reconciliation Act)
  - Fraud and Abuse
  - Reimbursement
  - Coverage
- State Activity – Legislative, Judicial and Regulatory
  - Pennsylvania, New Jersey, Washington, Maryland

Capitol Hill

- What to expect from the 112th Congress
  - Health care reform debate
  - Fraud and abuse enforcement

Capitol Hill

- Representatives Waxman, Levin and Stark directed the GAO to conduct a study on the impact of physician self-referral of advanced diagnostic imaging and radiation oncology services (April 16, 2010 letter to GAO)
- Study to address the extent of physician self-referral arrangements for advanced imaging and radiation oncology services provided to Medicare beneficiaries and the effect of such arrangements, specifically:
  - Prevalence, patterns and trends in physician self-referral for advanced imaging and radiation oncology services
  - Medicare spending on these physician self-referred services
  - The extent to which self-referral may have led to increases in the provision of, and Medicare spending for, advanced imaging and radiation oncology services

Medicare Payment Advisory Commission (MedPAC)

- March 2010 Report to the Congress
- June 2010 Report to the Congress
- September 2010 Public Meeting
  - Shared savings program for ACOs
  - Addressing the growth of ancillary services in physicians' offices
- October 2010 Public Meeting
  - SGR System
- November 2010 Public Meeting

Medicare Payment Advisory Commission (MedPAC)

- Three shared savings models for ACOs discussed by MedPAC
  - Bonus-only
  - Bonus-Penalty
  - Medicare Advantage ACO
- MedPAC staff notes stronger incentives to constrain spending in bonus-penalty model
  - Accept risk of penalty to share in the first dollar of potential savings
  - Bonus-only model has a threshold before ACO members share in bonus
- All bonuses contingent on quality scores
  - MedPAC staff recommends a small set of quality measures

Medicare Payment Advisory Commission (MedPAC)

- Options advanced by MedPAC staff with respect to in-office ancillary services: radiation therapy; PT, OT and SLP; diagnostic imaging; and laboratory tests
  - Exclude services from in-office ancillary services (IOAS) exception
  - Exclude services unless the group practice is "clinically integrated"
  - Bundle payment to include the ancillary services
- Options advanced with respect only to diagnostic imaging and/or laboratory tests
  - Reduce payment rates for diagnostic and laboratory tests furnished by self-referring physicians
  - Require prior authorization for advanced imaging

Medicare Payment Advisory Commission (MedPAC)

- Proposals for longer-term SGR modifications identified by MedPAC staff
  - Make adjustments by type of service
    - Growth rate and target rate for each service category would be calculated and applied separately
  - Adjust the cumulative aspect of the SGR formula
  - Create an allowance corridor around the spending target line
  - Exempt certain physicians from the SGR target
    - Multi-specialty group practices
    - Hospital medical staff
    - Outliers
  - Broader expenditure target
    - Encompass all FFS payments in expenditure target
- MedPAC staff indicates that discussion will continue with respect to SGR modification recommendations

Government Accountability Office (GAO)

- Charged with conducting a review of the impact of physician self-referral on advanced imaging and radiation therapy services
- Beginning stages of study design
- Meeting with industry stakeholders
- Report expected to take 12-18 months

U.S. Department of Health and Human Services

- Office of Delivery System Reform
  - Oversees HHS efforts on ACOs, bundled payment, etc.
  - Peter Lee, Director (formerly of Pacific Business Group on Health)
- Office of Consumer Information and Insurance
  - Implements all private insurance reforms
  - Jay Angoff, Director (former Missouri Insurance Commissioner)
  - Joel Ario, Director of the Office of Insurance Exchanges within OCCIO (former Pennsylvania Insurance Commissioner)

U.S. Department of Health and Human Services

- Office of Inspector General
  - 2011 Work Plan
    - Coding of and payment for E&M services
    - Payments for Part B Imaging Services
    - Excessive payments for diagnostic tests
    - Trends in laboratory utilization
    - Compliance with assignment rules
    - Medicare incentive payments for electronic health records
- Enhanced fraud and abuse enforcement
  - Settlement with United Shockwave Services, United Prostate Centers, and United Urology Centers (United)
    - Physician-owned company
    - 5-year Corporate Integrity Agreement
  - $2M Civil Monetary Penalty settlement with West Valley Imaging
    - Radiology practice failed to obtain physician orders, billed for tests not supported by medical record
    - One of the largest settlements ever negotiated under OIG's CMP authority
    - 5-year Corporate Integrity Agreement

Centers for Medicare & Medicaid Services

- Center for Medicare and Medicaid Innovation (CMMI)
  - Tests innovative payment and delivery system models
  - Goal of reducing program expenditures while preserving or enhancing quality of care
  - Richard Gilfillan, MD, Director (formerly of Geisinger Health Plan and Geisinger Health System)
- Pilot Programs on Physician Payment
  - $10B to fund pilot programs between 2011 and 2019
  - Intended to slow Medicare spending
  - CMS is looking for “rapid-cycle innovation”
  - May be expanded nationally without additional Congressional approval

Centers for Medicare & Medicaid Services

- In-office Ancillary Services Exception
- NEW notification requirements under PPACA
  - CY 2011 Physician Fee Schedule contains the regulatory implementation
  - Key provisions in proposed rule
    - Applies only to MRI, CT and PET
    - CMS did not propose to extend the notification requirement to any other radiology services or other DHS (including radiation therapy or pathology)
    - Physician groups need not identify hospital competitors in the notice to beneficiaries
    - Applies to MRI, CT and PET services furnished on or after January 1, 2011

Centers for Medicare & Medicaid Services

- Need not include any available <u>providers</u> of services (e.g., hospitals)
- Must include at least 10 (or as many that exist if less than 10) other suppliers
  - Within a 25-mile radius of the "physician's office location *at the time of the referral*"
  - Not tied to the location of the patient's residence (as stated in PPACA) or necessarily to the location at which the DHS will be furnished
- Group practice/physician may choose which suppliers to include
- Must include, for each listed supplier:
  - Name
  - Address
  - Phone number
  - Distance from the physician's office location at the time of the referral
- No notice required if there are no alternative suppliers within a 25-mile radius of the physician's office location
- Physician must maintain a record of the patient's signature on the disclosure notification in the patient's medical record

Centers for Medicare & Medicaid Services

- Physician-owned Hospitals
- CY 2011 Physician Fee Schedule
  - Establishes a new section in the Stark regulations
  - Hospitals must meet the requirements of new 42 C.F.R. § 411.362 no later than September 23, 2011
- Applies to a ‘‘physician owner or investor’’
  - Physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital

Centers for Medicare & Medicaid Services

- Hospital must have physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act in effect on that date
- Hospital will be limited to the number of operating rooms, procedure rooms, and beds for which the hospital is licensed on March 23, 2010
  - If the hospital did not have a provider agreement in effect as of that date, but does have an agreement in effect on December 31, 2010, the limitation applies to the number of ***rooms*** and ***beds*** as of the effective date of such provider agreement
  - Applies to ***operating rooms*** and ***procedure rooms*** regardless of whether a State licenses these rooms
    - Procedure rooms include rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed
    - Does not include emergency departments
    - CMS did not propose to expand the definition of “procedure room” to include space where other types of services are furnished, but questioned whether CT or PET should be included
  - Exception to Rooms and Bed Limitation
    - Regulations regarding implementation of process for obtaining an exception to the limitation will be in a separate rulemaking

Centers for Medicare & Medicaid Services

- Physician owners and investors must make certain patient disclosures regarding their ownership/investment
  - All treating and referring physicians must make the disclosure
  - Must disclose on any public Web site for the hospital and in any public advertising that it is owned or invested in by physicians
  - Must be met no later than September 23, 2011
- Referrals are prohibited if made by physician owners and investors after facility expansion and prior to the Secretary's granting of an exception to the capacity restriction

Centers for Medicare & Medicaid Services

- Safety Requirements
  - Hospital must disclose to patient if it does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient
    - Must obtain signed acknowledgement from the patient
  - Hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address
- Per PPACA, the hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010

Centers for Medicare & Medicaid Services

- September 23, 2010 proposed rule regarding Program Integrity/Enrollment Standards: conditions on initial and continued enrollment
  - Enhanced provider screening under Medicare, Medicaid and CHIP
  - Temporary moratoria on enrollment of Medicare providers and suppliers, and Medicaid and CHIP providers
  - Suspension of Medicare and Medicaid payments pending investigation of credible allegations of fraud
  - Termination of provider participation in all states' Medicaid programs following a termination of provider participation in Medicare or one state's Medicaid program
- Providers and suppliers are classified into three tiers based on the level of risk for fraud, waste and abuse associated with their respective provider or supplier types
- Apply to newly enrolling providers and suppliers beginning on March 23, 2011
  - Providers and suppliers that are currently enrolled would be subject to the new requirements through the revalidation process
- Important because billing privileges may be revoked for a period of not less than one and not more than three years

Centers for Medicare & Medicaid Services

- Physician Self-referral Disclosure Protocol (SRDP)
  - Under PPACA, CMS now has the authority to accept a reduced overpayment (*i.e.*, less than 100%)
  - CMS is clear to point out that it is under no obligation to accept the disclosing party's calculation of its financial liability or to compromise the overpayment at all
  - There are no limits on the reduction that CMS may make
    - Theoretically, CMS could reduce the overpayment to $0
  - Parties have no guarantee of acceptance into the SRDP

Centers for Medicare & Medicaid Services

- Substantive requirements for the submission include a thorough description of the parties, the type of financial relationship, the time periods that the arrangement was out of compliance, the DHS at issue, and an explanation of the roles of the individuals involved in the matter
- Disclosing party must perform an analysis of the application of the Stark law to the conduct at issue, including which elements of an exception were met and not met
- Disclosing party must perform a complete financial analysis, identifying the 100% overpayment amount
  - CMS uses the term “look back” period, which appears to mean period of noncompliance, NOT the reopening period
- Describe compliance efforts prior to and since the discovery of the Stark violation

Centers for Medicare & Medicaid Services

- Caution!
  - CMS demands access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced
    - This statement is unclear: does CMS suggest that parties cannot assert privilege or that it will demand access to all information that is not privileged (i.e., “without the assertion of privileges”)
  - CMS is clear that referrals to law enforcement may be made based on information contained in the disclosure
  - CMS may use the information contained in the disclosure to make a referral to OIG and DOJ for resolution of FCA liability, CMP liability, or other issues

Centers for Medicare & Medicaid Services

- Medicare Evidence Development & Coverage Advisory Committee
  - November 17, 2010: On-label and Off-label Use of Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer
    - CMS called the meeting to consider the currently available evidence regarding the clinical benefits and harms of on-label and off-label use of autologous cellular immunotherapy treatment of metastatic prostate cancer
  - April 21, 2010: Radiation Therapy for Localized Prostate Cancer
    - CMS called the meeting to consider the evidence on the impact of radiotherapy for the treatment of localized prostate cancer on health outcomes
- MEDCAC's role is to judge the strength of the available evidence and make coverage recommendations to CMS based on that evidence

State-level Health Policy

- Physician self-referral
  - Pennsylvania
    - New self-referral statute to apply beyond workers compensation
  - New Jersey
    - Moratorium on new radiation therapy centers under IOAS exception
  - New York
    - Incorporates Federal Stark Law exception
  - Maryland
    - Imaging services
    - CRNA arrangements
  - Washington
    - In-office PT
- Out-of-network legislation
  - New Jersey

Resources

- www.healthcare.gov
- www.hhs.gov
  - www.oig.hhs.gov
  - www.hhs.gov/occio
- www.cms.hhs.gov
  - www.cms.hhs.gov/PhysicianSelfReferral
  - www.cms.hhs.gov/Center/healthreform

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