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The Impact of the 2009 Physician Fee Schedule and Hospital Outpatient Department Rules on Coverage and Reimbursement: Selected Issues

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Audio Teleconference

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Overview

- Both rules released October 30, 2008
- Provisions generally take effect January 1, 2009
- Agency accepting comments on certain issues under each rule
  - All comments due no later than 5 PM EST on December 29, 2008
    - Topics for which CMS has solicited comments are highlighted and specified in this presentation

2009 Final Physician Fee Schedule Rule (PFS)

- Implements changes to:
  - Physician fee schedule
  - Other Medicare Part B payment policies, including alteration of ASP methodology established by the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA") (Pub. L. 110-173)
- Discusses and implements certain provisions of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") (Pub. L. 110-275)
  - MIPPA enacted July 15, 2008
  - Post-dated PFS Proposed Rule (dated July 7, 2008)

Average Sales Price (ASP)

- Final Rule aligns ASP regulations with ASP statute
  - CMS finalized proposal to amend ASP regulations to implement new, statutorily-mandated methodology for calculating volume-weighted ASPs
    - ASP methodology first established in the Medicare Modernization Act of 2003 ("MMA") § 303, codified at Social Security Act § 1847A
    - MMSEA of 2007 § 112(a) modified the ASP methodology, effective April 1, 2008
  - Calculation of billing codes now done through a two-step formula (instead of the three-step formula used prior to MMSEA's effective date of April 1, 2008)

Average Sales Price (ASP) (cont'd)

- ASP regulation text revised to implement special payment rule for certain inhalation drugs administered through DME
  - Regulatory language now mirrors new ASP statute, as set forth in MMSEA § 112(b)
  - Payment amounts are subject to a "grandfathering" provision of ASP statute
    - Grandfathering provision requires CMS to treat certain single source drugs as multiple source drugs
  - Under the Final Rule, drugs subject to the special payment rule include albuterol and levalbuterol (unit dose and concentrated forms)
    - No additional drugs identified "at this time" as subject to the rule, but CMS left that possibility open

Average Sales Price (ASP) (cont'd)

- Continuation of five percent as threshold percentage for AMP and WAMP comparisons
  - Status quo maintained for evaluating a drug's ASP as compared to its AMP and WAMP
  - Provision finalized as proposed, applies to CY 2009
  - CMS "recently" received reports from OIG comparing ASP to AMP with new volume-weighted methodology, but agency claims it has had insufficient time to analyze the data, so no changes made in Final Rule

Competitive Acquisition Program (CAP)

- CAP postponed for CY 2009
  - Contrary to Proposed Rule
  - Result of contractual issues with successful bidders
  - No physician elections; CAP drugs no longer provided after December 31, 2008
- CMS is seeking feedback from the public
  - Open Door Forum on CAP scheduled for December (hosted by CMS)
  - Written comments due December 29, 2008

Payment for Pre-Administration Services for IVIG

- PFS: Elimination of separate payment for services related to pre-administration of IVIG
  - Finalizes proposed provisions without modification
  - CMS reasoning: IVIG market "appears more stable" now than in 2006, when payment for pre-administration services began
- HOPPS: Separate payment for pre-administration services relating to IVIG now packaged
  - CMS reasoning: Separate payment was designed to pay hospitals for the "additional, unusual, and temporary costs" associated with obtaining IVIG and scheduling infusions during a "temporary period of market instability"
- Effective date for each rule: January 1, 2009
- CMS says it will continue to work with stakeholders on IVIG pricing and beneficiary-access issues

Physician Self-Referral Issues

- Comment period re-opened on proposed new exception to Stark Law
  - Exception would cover non-abusive programs offered in hospital settings that use economic incentives to foster high quality, cost-effective care (*e.g.*, gainsharing and pay-for-performance programs)
- Proposed exception and proposed safeguards not yet finalized
- Reason for delay: insufficient information from and substantial disagreement among commenters
- Another area where CMS is soliciting public comment

Physician Self-Referral Issues (cont'd)

- Specific areas targeted for public comment
  - CMS identified 55 specific areas for additional comments from relevant stakeholders, including:
    - Identify with specificity which conditions should be made applicable to incentive payment programs (and why)
    - Identify which conditions need not or should not be made applicable to incentive payment programs (and why)
    - Indicate why it would not be necessary to impose the same safeguards against program or patient abuse on traditional gainsharing and shared savings programs
  - Comments due by December 29, 2008

Anti-Markup Issues

- Significant changes between proposed and final rules
  - Proposed Rule would have applied anti-markup provisions where the technical component (TC) or professional component (PC) of a diagnostic testing service is either:
    - (i) purchased from an outside supplier; or
    - (ii) performed or supervised by a physician who does not "share a practice" with billing physician or other supplier
  - Final Rule eliminates all references to diagnostic tests purchased from an "outside supplier"
- Only relevant question under the Final Rule is whether the performing / supervising physician and billing physician "share a practice"

Anti-Markup Issues (cont'd)

- When does the performing / supervising physician "share a practice" with the billing physician?
  - Proposed Rule includes two alternative approaches:
    - "Alternative 1": a physician who is employed by or contracts with a *single* physician or physician organization "shares a practice" with that physician or physician organization
    - "Alternative 2": a physician "shares a practice" with the billing physician or other supplier if the TC and PC of non-purchased tests are performed in "the office of the billing physician or other supplier"
  - Final Rule adopts modified versions of Alternatives 1 and 2:
    - Alternative 1: no longer requires that a physician work exclusively for one physician practice to "share a practice"
    - Alternative 2: now includes an added requirement that the performing physician be an owner, employee or independent contractor of the billing physician or other supplier

Anti-Markup Issues (cont'd)

- Revised anti-markup rules effective January 1, 2009
- CMS may engage in future rulemaking regarding:
  - Stark "in-office ancillary services" exception
  - Possible restrictions to reassignment of diagnostic testing services

IDTF Issues
Improving the Quality of Diagnostic Testing Services

- With respect to physician entities, CMS had proposed:
  - Enrollment as an IDTF for each practice location
  - Exclusion from certain IDTF performance standards
  - Limiting enrollment only to performance of certain services
- Deferred due to enactment of MIPPA § 135
    - MIPPA requires HHS Secretary to establish accreditation process for entities furnishing certain diagnostic testing procedures by 2012

IDTF Issues
Mobile Entity Billing Requirements

- Section 410.33(g)(16) finalized as proposed
  - Requires entities furnishing mobile diagnostic services to enroll in Medicare as an IDTF regardless of where the services are furnished
- Section 410.33(g)(17) finalized as proposed
  - Requires all mobile diagnostic services to bill for the services they furnish, *unless*
    - The mobile service is part of a hospital service and furnished under arrangement with that hospital
- "Mobile entity" appears to include an entity that leases equipment and provides techs to physician offices

IDTF Issues
Revocation of Enrollment and Billing Privileges of IDTFs in Medicare and *Timely Filing Requirements*

- Revoked IDTFs must submit all outstanding claims within 60 calendar days of the revocation date
- Similarly, physician, physician organizations, and NPPs must now submit all claims within 60 days of a supplier number revocation

Multiple Procedure Payment Reduction (MPPR) for Diagnostic Testing

- MPPR applies when two or more procedures within certain imaging code families are furnished on the same patient in a single session
- Where MPPR applies, CMS reimburses the TC of the highest priced procedure at 100% and reimburses the TC of each subsequent procedure at 75%
- Ten additional diagnostic imaging procedures are now subjected to the MPPR:

CPT Code	Procedure
70336	MRI, temporomandibular joint(s)
70554	FMRI brain by tech
75557	Cardiac MRI for morph
75559	Cardiac MRI w/ stress img
75561	Cardiac MRI with morph w/dye
75563	Cardiac MRI w/stress img & dye
76776	Us exam k transpl w/doppler
76870	Us exam, scrotum
77058	MRI, one breast
77059	MRI, both breasts

Hospital Acquired Conditions (HAC)
Payment Provisions

- Agency believes preventable HAC payment provisions currently imposed in the hospital inpatient setting could potentially be applied to other settings of care, including:
  - ESRD facilities
  - Hospital outpatient departments
  - Ambulatory surgery centers
  - Skilled nursing facilities
  - Home health agencies
  - Physician practices
- Nothing finalized yet in this area
- Another area for which CMS is soliciting further comments from industry stakeholders

Payment for Renal Services Furnished by ESRD Facilities

- Final Rule Reflects Proposal and § 153(a) MIPPA Changes
  - Composite rate increase 1% CY 2009, but site neutral
  - Hospital rate decreases slightly
- Zero percent update to drug add-on per treatment (based on ASP data)
- Adjust rates per new wage index methodology
  - Utilize the Core Based Statistical Area ("CBSA") wage index for ESRD facility composite rates
    - First announced in CY 2006 Final Rule
    - Four-year transition implemented
      - CY 2009 is fourth and final year of transition

Diabetes Self-Management Training (DSMT)

- As proposed, CMS did not add individual or group DSMT to the list of approved telehealth services for CY 2009
  - Request was made by the American Telemedicine Association (ATA) and Marshfield Clinic to add individual and group DSMT as approved telehealth services
  - CMS finds it lacks sufficient evidence that providing DSMT via telecommunications is an adequate substitute for providing DSMT in person

Physician Enrollment Issues

- Effective date for Medicare billing privileges
  - Later of (i) "date of filing" or (ii) services at new practice
    - Incomplete apps can preserve original filing date
  - Physicians and NPPs can bill retrospectively for services up to 30 days prior to their effective date of billing, if the following requirements are met:
    - Met all program requirements (including state licensure requirements)
    - Services were provided at the enrolled practice location prior to the date of filing
    - Circumstances precluded enrollment in advance of providing services to Medicare beneficiaries

Physician Enrollment Issues (cont'd)

- Internet-based enrollment established
  - Intended to be more efficient than paper-based Provider Enrollment, Chain and Ownership System (PECOS)
  - Option for paper-based enrollment will remain available
  - Implementation in three phases, with Phase I to begin by the end of CY 2008
  - Date of filing will be when Medicare contractor receives
    - (1) an electronic version of the enrollment application; and
    - (2) a signature page containing an original signature that the Medicare contractor processes to approval

Physician Enrollment Issues (cont'd)

- Several other enrollment issues addressed
- Highlights:
  - CMS is considering further rulemaking or administrative action re: revoking a physician's billing privileges when they have Federal tax delinquency that cannot be levied through the Federal Payment Levy Program (FPLP)
  - § 424.516(d) requires physicians, NPPs, and organizations to notify Medicare of changes in ownership, practice location, or any final adverse action within 30 days of the reportable event
    - Under finalized § 424.535, failure to comply renders provider subject to overpayment charges and could lead to revocation
    - Regulations now define "final adverse action" at § 424.502(a)

CMS maintains a web link to provider enrollment FAQs and educational information:
www.cms.hhs.gov/MedicareProviderSupEnroll

Quality Reporting Measures

- Some proposals mooted by MIPPA
  - *E.g.*, MIPPA authorizes a 2% incentive payment by CMS in CY 2009 for satisfactory reporting of data on quality measures
    - Negates CMS' concern in Proposed Rule that it lacked authorization to make incentive payments for satisfaction of new criteria for reporting quality measures
- Claims-based or qualified registry submission of individual measures
  - At least three applicable measures in at least 80% of cases in which the measure is reportable
  - Claims-based permits fewer measures if n/a to the clinician
- "Measures Groups" submissions
  - Six options for claims-based or registry reporting

Quality Reporting Measures (cont'd)

- Technical requirements for registry-based submissions are available on CMS website
- Declined adoption of electronic health record (EHR) reporting
  - CMS will continue testing EHR reporting methods during CY 2009

Quality Reporting Measures (cont'd)

- Of the 175 quality reporting measures proposed for 2009 PQRI, 153 were finalized (many from 2008)
- Of the 9 proposed measure groups, 7 were finalized
  - Three carried forward into 2009:
    - Diabetes Mellitus; Chronic Kidney Disease; Preventive Care
  - Four new measures groups finalized for 2009 PQRI:
    - Coronary Artery Bypass Graft Surgery; Rheumatoid Arthritis; Perioperative Care; Back Pain
  - Two new measures groups not finalized for 2009 PQRI:
    - Coronary Artery Disease; HIV/AIDS

Oxygen Equipment Rental Payments

Regulations amended to achieve MIPPA consistency:

- Eliminate the title-transfer provision
- Maintain cap on rental payments after 36 months of continuous use
- 36th month supplier must continue furnishing equipment and oxygen contents during any period of medical need until the end of the equipment's reasonable useful lifetime
  - arrangements even if a beneficiary relocates outside of the supplier's service area
- Elimination of maintenance and repair payments

MIPPA
Expansion of Coverage for Preventative Services

- MIPPA provides for coverage under Medicare Part B for "additional preventative services" that the Secretary determines meet certain requirements
  - Effective for services furnished on or after Jan. 1, 2009
- PFS Final Rule revises certain CMS regulations and policies relating to preventative services to conform them to the new MIPPA legislation

MIPPA
Expansion of Coverage for Preventative Services (cont'd)

- Regulatory highlight relating to preventative benefits:
  - CMS will evaluate preventative services not otherwise listed under MIPPA and recommended or strongly recommended by the U.S. Preventative Services Task Force ("USPSTF")
    - CMS will determine whether to open an NCD on one or more categories of preventative service
    - CMS invites public requests on the categories of preventative services recommended or strongly recommended by USPSTF that CMS should consider for an NCD
- Another area where CMS is seeking public comments

MIPPA
Expansion of Coverage for Preventative Services (cont'd)

- Regulatory changes made to conform to MIPPA's statutory requirements:
  - CMS amends regulations relating to the initial preventative physical examination (IPPE) benefit and payment rules
    - Several new G codes issued to identify new IPPE services covered under the IPPE benefit, including:
      - G0402 (initial preventive physical examination)
      - G0403, G0404, and G0405 (various types of electrocardiogram)
    - Existing G codes will be active until December 31, 2008 for beneficiaries with IPPE prior to January 1, 2009
  - CMS amends regulations to include outpatient speech-pathology services as "medical and other health services" covered under Medicare
    - Also includes outpatient physical therapy, occupational therapy
    - Regulations include a list of requirements that speech-pathology services must meet in order to receive coverage

MIPPA
E-prescribing

- MIPPA created E-Prescribing Incentive Program
  - Final Rule establishes implementing regulations
  - CMS considers must of statute self-implementing
- Key provisions of E-Prescribing Incentive Program
  - Physicians who successfully implement e-prescribing are eligible to receive incentive payment until 2013
  - Beginning 2012, fee schedule penalty
  - "Successful prescriber" uses PQRI measure
    - Applies to certain CPT codes only
    - Report on 50% of applicable Part B cases
    - Applicable Part B charges must be >10% of total charges

2009 Final Hospital Outpatient Department Rule (HOPD)

- Released October 30, 2008
- Takes effect on January 1, 2009
- Addresses:
  - Hospital outpatient prospective payment system (OPPS)
  - Revised ambulatory surgical center (ASC) payment system
  - ASC conditions for coverage
- Comments being sought for HCSPCS payment classifications and reimbursement of SCODs under 340(B)

HOPD issues discussed in this teleconference

- Payment for pass-through drugs and biologicals
- Payment for packaging of drugs and biologicals
- Payment for nonpass-through drugs and biologicals
- Payment for nonpass-through drugs and biologicals that are not packaged
- Payment for diagnostic and therapeutic radiopharmaceuticals
- Payment for anti-emetics and blood clotting factors
- Payment for medical devices
- ASC conditions for coverage
- Payment of administration fees

Payment for Pass-Through Drugs and Biologicals

- Different from proposed policy, CMS will pay for pass-through drugs and biologicals at ASP + 6%
  - Same as rate paid in the physician office
- If the Part B drug CAP is reinstituted in 2009, CMS will use the CAP rate for pass-through drugs and biologicals if they are included in the Part B drug competitive acquisition program

Packaging of Drugs and Biologicals

- CMS will continue to use 2007 methodology of annually updating the OPPS packaging threshold for drugs and biologicals by the Producer Price Index
- CMS will pay for packaging of drugs and biologicals with a per administration cost of less than or equal to $60
- CMS will pay for items with an estimated per administration cost of greater than $60 separately

Packaging of Drugs and Biologicals (cont'd)

- CMS used updated data to apply special policies to drugs and biologicals with packaging status different in the Final Rule than in the Proposed Rule
  - Drugs and biologicals paid separately in 2008 and that were proposed for separate payment in 2009 with a per day costs less than or equal to $60 (based on the methodology and data used for the Final Rule) will continue to receive separate payment in CY 2009
  - Drugs and biologicals packaged in 2008 and proposed for separate payment in 2009 and have per day costs less than or equal to $60 will remain packaged in CY 2009
  - Drugs and biologicals proposed for packaged payment in 2009 but have costs greater than $60 per day will receive separate payment in CY 2009
    - Some drugs and biologicals CMS proposed to package now have per day costs greater than $60 and will be paid separately in CY 2009

Payment for Nonpass-Through Drugs and Biologicals

- For separately payable drugs and biologicals that are nonpass-through, CMS stated that it will pay for these drugs at ASP + 4% in CY 2009
- Based on hospitals' CY 2007 claims and recent cost report data, CMS calculated hospitals' average costs for drugs and biologicals to be equivalent to ASP + 2%
- CMS is continuing the transition to a claims-based payment rate for separately payable drugs and biologicals
- For CY 2009, CMS will pay for these products at a transitional rate of ASP + 4%, which reflects a blend of the CY 2008 payment rate of ASP + 5% and the rate from claims data of ASP + 2%

Payment for Nonpass-Through Drugs and Biologicals That Are Not Packaged

- CMS is seeking comment on the impact of § 340B hospital claims data on reimbursement for SCODs
  - 340B hospitals have lower drug acquisition costs than non-340B institutions
  - By including 340B hospitals in the aggregate cost calculations, CMS underpays non-340B hospitals for SCODs
  - Commenters have suggested adopting different payment scheme for different institutions
  - CMS seeking comment on 10 particular questions

Payment for Diagnostic and Therapeutic Radiopharmaceuticals

- CMS will continue to pay for therapeutic radiopharmaceuticals at charges adjusted to cost
- CMS will continue to package payment for all diagnostic radiopharmaceuticals that are used to perform a diagnostic nuclear study into the APC payment for the associated nuclear medicine procedures
- CMS will pay for new therapeutic radiopharmaceuticals that are granted pass-through status at charges adjusted to cost
- For diagnostic radiopharmaceuticals granted pass-through status in 2009, CMS will provide separate payment at ASP + 6%
- Today, no radiopharmaceutical products have pass-through status

Payment for Anti-Emetics and Blood Clotting Factors

- As proposed, CMS continues the exemption of oral and injectable forms of 5HT3 anti-emetic products from the drug packaging methodology for CY 2009
  - Payment for these products will be separate
- Under Final Rule, blood clotting factors reimbursed at a rate of ASP+4%, together with a furnishing fee based on the Consumer Price Index for medical care

Payment for Medical Devices

- CMS finalized proposal to continue using standard methodology for calculating median costs for device-dependent APCs
  - Method utilizes claims data that generally represents the full cost of the required device
- Will discontinue pass-through payment for device categories C1821 (interspinous process distraction device (implantable)) and L8690 (auditory osseointegrated device) as of January 1, 2009
  - CMS will package the costs of the devices into the costs of the procedures with which the devices were billed in CY 2007
- Adopted proposal to continue reducing OPPS payment by 100% of the device offset amount when a hospital furnishes a specified device without cost or with a full credit
- Will continue policy of reducing OPPS payment by 50% of the device offset amount when the hospital receives partial credit in the amount of 50% or more of the cost for the device

ASC Conditions for Coverage

- CMS revised the Conditions for Coverage relating to:
  - governing body and management; surgical services; quality assessment and performance improvement; laboratory and radiologic services
- CMS established new Conditions for Coverage relating to:
  - patient rights; infection control; patient admission and assessment; discharge
- CMS revised the anesthetic risk and evaluation measures to require pre-discharge evaluation of patients for proper anesthesia recovery
- CMS did not adopt its proposal to require ASC radiological services to meet Conditions for Coverage for portable X-ray suppliers
  - Instead, the Final Rule requires such providers to continue meeting hospital conditions of participation for radiological services

Payment of Administration Fees

- The Final Rule implements, as proposed, a five-level APC structure for administration services
  - Replaces previous six-level structure
  - Significant impact on certain products

Charge Compression: Comments Sought

- CMS commissioned RTI to study the effects of charge compression on IPPS and OPPS rates
- RTI recommended changes to hospital cost accounting systems and claims reporting
- Other changes include altering the software used to input claims
- RTI also recommended adoption of the revenue code-to-cost center crosswalk
- No changes this year, but CMS is seeking "informed analysis and public comment regarding potential changes to the revenue code-to-cost center crosswalk upon which OPPS cost estimation is based"

Questions?

Thank you for your participation!

For further information, please contact:

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