Hot Topics in Regulatory Reimbursement

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Hot Topics in Regulatory Reimbursement

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Comprehensive Care for Joint Replacement (CCJR) - Bundled Payments

- In July, CMS issued a proposed rule detailing the Comprehensive Care for Joint Replacement ("CCJR") Model.
- Program would require most IPPS hospitals in selected geographic areas throughout the country to accept retrospective bundled payments for episodes of care for hip and knee replacements for Medicare fee-for-service beneficiaries beginning on January 1, 2016 through December 31, 2020.
- Comment period ended September 8, 2015. Final Rule has yet to be issued, so may not take effect on January 1st.

CCJR - Bundled Payments

- Payment
  - During performance years, CMS continues paying hospitals and other providers according to the usual Medicare fee-for-service payment systems.
  - After performance year, Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would be combined to calculate an actual episode payment (AEP).
    - Actual episode payment: Sum of related Medicare claims payments for items and services furnished to a beneficiary during a CCJR episode.
  - The actual episode payment would then be reconciled against an established CCJR target price, with consideration of additional payment adjustments based on quality performance and post-episode spending.

CCJR - Bundled Payments

- Episode of Care
  - Episodes of care would begin with admission to an acute care hospital for a hip or knee replacement procedure assigned to MS-DRG 469 or 470 upon beneficiary discharge and paid under the IPPS.
  - Episode ends 90 days after the date of discharge from the acute care hospital.

CCJR - Bundled Payments

- Financial Risk
  - CMS proposes to hold participant hospitals financially responsible for CCJR episodes of care.
    - Only hospital participants would be directly subject to the requirements of the CCJR program.
    - Participant hospitals would be responsible for ensuring that other providers and suppliers collaborating with the hospital are in compliance with the terms and conditions of the program.
      - Gainsharing Payments/Alignment Payments

CCJR - Proposed Geographic Areas (MSAs)

- Akron, OH
- Toledo, OH
- Cincinnati, OH-KY-IN
- Evansville, IN-KY
- Indianapolis- Carmel-Anderson, IN
- South Bend-Mishawaka, IN

- Complete list of participating MSAs:
https://data.cms.gov/dataset/Comprehensive-Care-for-Joint-Replacement-Model-Met/qek8-9bd4

CCJR - Bundled Payments

Reimbursement requirement waivers

- Waiver of the direct physician/qualified practitioner supervision requirement for certain post-discharge home visits.
- Waiver of certain geographic site requirements, including the originating site requirements, for telehealth.
- Waiver of the SNF 3-day rule (for performance years 2 through 5 only), but only if the beneficiary is admitted to a SNF that is rated 3 stars or better.
- Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.

Changes to Two Midnight Rule

- On July 2, 2015, CMS published its CY 2016 Hospital OPPS and ASC Proposed Rule in which it proposes to create a new exception under the 2-Midnight Rule. These remain proposed rules subject to finalization in November.
- The proposed rules would alter the current rule to the following:
  - Less than one Midnight: Presumptively not an inpatient admission. Inpatient admission only in exceptionally rare instances.
  - Overnight and One Midnight: Case-by-case as supported by medical record. More deference to MD judgment.
  - Two Midnights or More: Continued presumption of inpatient admission.

Changes to Two Midnight Rule

- Rare and Unusual Exceptions Policy
  - CMS identified three factors that, among others, would be relevant to deciding whether Part A payment is appropriate:
    - The severity of the signs and symptoms exhibited by the patient;
    - The medical predictability of something adverse happening to the patient; and
    - The need for diagnostic studies that appropriately are outpatient services.
  - Stays under 24 hours would "rarely qualify for an exception" to the two-midnight benchmark.

Changes to Two Midnight Rule

- New Medical Review Strategy
  - No later than October 1, 2015, CMS will have Quality Improvement Organizations (QIOs) perform "probe and educate" audits of short inpatient stays under the 2-Midnight Rule.
    - Instead of the Medicare Administrative Contractors or Recovery Audit Contractors.
    - CMS believes QIOs have significant history of collaborating with hospitals focusing on educating doctors and hospitals.
  - RACs will be permitted to conduct patient status reviews but only for those providers with high denial rates referred to the RACs by the QIOs and subject to new time limits.

Changes to Two Midnight Rule

- New Medical Review Strategy Cont'd
  - CMS will change the RAC "look-back period" for patient status reviews to six months from the date of service where a hospital submits the claim within three months of the date of service.
  - CMS will limit additional documentation requests imposed by RACs.
  - CMS will require RACs to complete complex reviews within 30 days or forfeit their contingency fee even if an error is identified.
  - CMS will require RACs to wait 30 days before sending a claim to the MAC for adjustment thereby giving the affected provider an opportunity to submit a discussion period request before the MAC makes any payment adjustments.

Changes to Two Midnight Rule

- 0.2% offset to IPPS rates not effected
  - This offset automatically retained in FFY 2016 Rule.
  - Hall Render Appeals will likely add 2016 to existing appeals for participating hospitals.

Impact of Changes on 2 Midnight Rule Appeal

- The case argues the 0.2% reduction to the standardized amount that was implemented in FFY 2014.
- CMS thought the 2 Midnight policy was going to cost the program more money to implement.
- The 0.2% reduction continues in FFY 2015 and will occur again in FFY 2016.

Litigation re. Payment Impact of 2 Midnight Rule Appeal

- AHA has appeal filed for FFY 2014
  - Other firms filed similar appeals with large numbers of hospitals, and these appeals are waiting in the wings.
  - AHA's lead case had oral arguments before the federal district court in DC August 3rd.
    - Judge seemed sympathetic to APA argument.
    - Less so to substantive argument.
  - The judge asked for post-hearing briefs to be filed after the hearing.
  - Case received a decision on September 22, 2015.

Litigation re. Payment Impact of 2 Midnight Rule Appeal

- *Shands Jacksonville Med. Ctr. v. Burwell*, D.D.C. (Sept. 21, 2015)
  - Providers technically secured a victory, but the judge afforded no immediate remedy for the victory.
  - Judge issued subsequent orders remanding to the Secretary for further proceedings with respect to the 0.2 percent reduction "to the . . . standardized amount, the hospital-specific rates, and the Puerto Rico specific standardized amount" used to calculate Medicare inpatient payments for fiscal year 2014.
    - CMS has to publish a notice in the Federal Register by December 1, 2015 and allow for a comment period, with a final notice to be published by March 18, 2016.
    - If CMS deems a notice of proposed rulemaking is needed, then such notice must be published in the Federal Register by December 16, 2015. Then, the final rule must be published no later than April 18, 2016.

Litigation re. Payment Impact of 2 Midnight Rule Appeal

- Other firms have filed appeals for FFY 2014 and FFY 2015.
- Those cases are on hold pending the final outcome of the AHA case.
- Additional appeals are expected to address the 0.2% payment reduction that is still present in FFY 2016 IPPS standardized amount because the *Shands* case will not be resolved before the mid-February deadline to file appeals from the Federal Register.
- Preferable to file these appeals from the Federal Register rather than from the settled cost report.

Changes to Medicare Physician Opt-out Rule

- CMS proposed changes to the Medicare opt-out and private contracting regulations for the Physician Fee Schedule for CY 2016.
- Proposed regulations would automatically renew physicians and practitioners that file Medicare opt-out affidavits every two years, for providers who opt-out on or after June 16, 2015.
- Physicians wanting to cancel their opt-out status would be required to submit a written request to their Medicare Administrative Contractor no later than 30 days before the end of the previous two-year opt-out period in order to terminate status for any subsequent two-year period.

NOTICE Act: Medicare Observation Status Notification Requirements

- Signed by President in August.
- Hospitals must comply within 12 months.
- Must inform patients hospitalized more than 24 hours they are in observation status.
  - Within 36 hours after beginning observation services, informed, both orally and in writing.
  - Written notice must explain that the patient is not an inpatient, the reasons, and the implications for cost-sharing in the hospital and for subsequent eligibility for coverage in a skilled nursing facility.
  - The patient or representative must sign the notice.

FFY 2016 IPPS Final Rule Updates

- 0.9% net payment increase for hospitals that timely submit quality data and are meaningful EHR users.
  - The original 1.7% increase was reduced by the 0.8% documentation and coding recoupment adjustment.
- Hospitals that are not submitting quality data and are not meaningful EHR users will experience a 0.9% payment reduction over last year.
- Hospitals that are not meaningful EHR users will not experience a payment increase over FFY 2015.

FFY 2016 IPPS Final Rule Updates

- Another $1.3 billion in DSH cuts (PPACA mandates).
- This is an approximately 1% payment reduction from FFY 2015.
- For FY 2016, hospitals will still receive the initial 25% payment. However, CMS has finalized their proposal to provide approximately 47.76% (63.69% of the remaining 75%) of the estimated Medicare DSH payments prior to the ACA as additional payment to hospitals for their relative share of the total amount of uncompensated care.

FFY 2016 IPPS Final Rule Updates

- Hospital Acquired Conditions
  - Still a 1% payment reduction to hospitals in the lowest quartile.
  - Score based on 2 Domains.
    - No changes to the Domains for FFY 2016.
    - Domain weights for FFY 2016: Domain 1 = 25% of the score; Domain 2 = 75%.
    - Next year, Domain 1 drops to 15%, and Domain 2 increases to 85%.
  - NEW: Extraordinary Circumstance Exception.
    - Hospitals can request an exemption from HAC.
    - Generally expected that the extraordinary circumstance is a natural disaster or similar calamity.
    - Exception must be requested within 90 days of triggering event.
    - CMS does not anticipate granting many exceptions.

ICD-10 Transition

- Took effect on October 1st
- Claims will be rejected with dates of service after October 1st if ICD-10 codes are not used.
- “Family of Codes”: the base condition in a 3 character code.
  - Rarely, will the 3 character code be used by itself for billing .
  - H25 is an age-related cataract. You can add up to 4 characters behind it to describe which eye, what type of cataract and its severity.
  - If you select the wrong code in the H25 family, the claim will not be denied simply for making the wrong choice.

340B Omnibus Guidance

- Health Resources and Services Administration (HRSA) published new guidance August 28, 2015 (Comments due October 27, 2015).
- Created in 1992, requires manufacturers to make outpatient drugs available at a substantial discount to “covered entities”.
- Eligibility – minimum DSH percentage of 11.75% and 8% for RRCs and SCHs.
- Proposed definition of a patient of a covered entity creates more restrictive standards.
- Requires quarterly reviews and annual independent audits of contract pharmacy locations.
- Relative to HRSA audits of covered entities – creates notice and hearing process for responding to adverse findings, instances of noncompliance, and loss of eligibility.

340B Omnibus Guidance

- Determination of DSH Percentage.
  - Originally based on DSH percentage in as-filed cost report.
  - Then, HRSA said a hospital could use an amended cost report to attain 340B eligibility.
  - **HOWEVER,** the original position has been re-proposed: the DSH percentage is based on the as-filed cost report.

340B Omnibus Guidance

- Eligible Patients → more restrictive standards.
  - An individual who receives follow-up care at a private practice (non-Covered Entity) location is not eligible to receive 340B Drugs.
    - This differs from current 340B Program guidance.
  - An individual must receive health care services from a provider who is either employed by or is "an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider."
    - Previously, HRSA required that the provider be employed by, contracted with or have "other arrangements" with the Covered Entity such that responsibility for the care provided remained with the Covered Entity.

340B Omnibus Guidance

- Miscellaneous Proposals
  - Record retention is proposed to be 5 years (previously there was no standard).
  - The Contract Pharmacy model was essentially left untouched, but the proposed changes to the definition of Eligible patients might functionally alter this model some (because the Eligible Patient must receive services from a provider that is employed by the covered entity or is an independent contractor of a covered entity).

ACA 60-Day Payback Rule

- Fraud Enforcement and Recovery Act of 2009 and ACA 2010 give government new tools.
  - Obligates providers to timely report and return Medicare and Medicaid overpayments
  - Failure to do so means potential civil monetary penalties and FCA liability
- ACA requires providers to report and return Medicare and Medicaid overpayments within 60 days after the date on which the overpayment was identified.
- CMS and OIG have issued proposed rules regarding the 60-day rule, dating back to 2012, but not finalized.
- Leaves many questions unanswered:
  - What does “identification” mean under the 60-day rule and how long can the identification period last?
  - What type of written notification will suffice?
  - Are these requirements retroactive?

Judicial Comments re. 60 Day Rule

- *U.S. ex rel. Kane v. Continuum Health Partners, (*S.D.N.Y., Aug. 3, 2015)
  - No prior Court has interpreted the meaning of when an overpayment is “identified” under this statute.
  - Background:
    - Hospital billed traditional Medicaid as a secondary payer based on incorrect remittance advices from Healthfirst. When Healthfirst fixed the codes in December 2010, it notified the system, and a month later, the New York State Comptroller also notified the System.
    - Feb. 2011: the Relator identified the 900 claims that were overpaid to management, totaling approximately $1M. Four days later, he was fired.
    - Apr. 2011: In the next 60 days, the System repays 5 claims identified by the State Comptroller. Relator files qui tam suit.
    - March 2013: Repayment process ends.
    - June 2014: DOJ files complaint.
    - Sept. 2014: System files Motion to Dismiss.
    - Aug. 2015: Judge denies System’s Motion.

Judicial Comments re. 60 Day Rule

- *U.S. ex rel. Kane*
- Congress suggested that FCA applies when there is an established duty to refund overpayments “even if the precise amount due has yet to be determined”.
- Found that System “tasked [Relator] with investigating the scope of the issue, but when he presented them with a list of potentially affected claims, he was fired, and the Government alleges that [System] did nothing further with his analysis. Although they repaid certain claims that were specifically brought to their attention by the Comptroller, they neglected to repay more than three hundred claims until they received the Government's CID in June 2012”.
- In this situation, FCA exposure exists since Continuum recklessly failed to uncover, or remained deliberately ignorant of, overpayments.

Judicial Comments re. 60 Day Rule

- *U.S. ex rel. Kane*
- Court recognized this imposes a very demanding standard of compliance, especially in light of the penalties and damages available under the FCA.
- Court therefore attempts to distinguish the situation from one in which a provider is diligently investigating potential overpayments.
- “Prosecutorial discretion would counsel against the institution of enforcement actions aimed at well-intentioned healthcare providers working with reasonable haste to address erroneous overpayments. Such actions would be inconsistent with the spirit of the law and would be unlikely to succeed”.
- In other words, if no record of reckless disregard or deliberate ignorance, no FCA action for a reverse false claim.

OIG Fraud Alert – Physician Compensation Arrangements

- June 9, 2015 fraud alert issued regarding potential for medical directorships to violate the anti-kickback statute.
- Compensation arrangements must reflect fair market value for bona fide services that physicians actually provide.
- Looking at both sides (physicians and hospitals) of these arrangements for potential civil and criminal liability.
- Supporting documentation, time studies and job descriptions, should reconcile to contract terms.
- Automated time study systems can be mutually beneficial to all parties in ensuring regulatory compliance and mitigating risk.

DOJ Prosecution of Individuals

- The Department of Justice announced last week a new emphasis to prosecute individual employees of corporations just like the corporations themselves.
  - Always could do this but DOJ is signaling a more aggressive approach.
  - Directed right at CEOs and other senior officers.
- Corporations will not receive credit for cooperation during settlement negotiations for DOJ investigations unless they identify key employees and turn over incriminating evidence.
- http://www.justice.gov/dag/file/769036/download

House Bill Targets New Off-Campus Hospital Departments

- Applicable items and services furnished in off-campus outpatient departments on and after January 1, 2017 will be excluded from coverage as outpatient services.
  - new definition of covered outpatient department services
- Exception for current off-campus hospital departments that are billing for covered Outpatient services on the date of enactment, **November 2**
- no grandfather protection to off-campus sites that are under development.

Cost Report Appeals Litigation Update (LIP Jurisdiction)

- Key update: The PRRB has jurisdiction over the low income payment (LIP) adjustment for inpatient rehabilitation units.
  - At issue is the scope of a statutory bar to review.
    - Applicable to IRF rates, but what of LIP adjustments?
  - *Mercy*: PRRB decided it has jurisdiction; the CMS Administrator reversed the PRRB decision.
  - *Sutter Auburn:* The PRRB again decided it had jurisdiction over LIP, despite the fact the Administrator reversed *Mercy.*
  - *Mercy* is now pending in federal court, and we anticipate *Sutter Auburn* will also go into federal court.

Cost Report Appeals Litigation Update (BNA-2)

- Key update: Settlement for hospitals not involved in BNA-1.
  - About 400 additional Hall Render hospitals settled at the end of last year and received payments earlier this year.
  - A record setting win for hospitals.

Cost Report Appeals Litigation Update (DSH-Allina)

- Hospitals seemed to get a big win at Court of Appeals with *Allina* Decision last year on Medicare Advantage Days.
  - CMS did not comply with APA notice and comment requirements in promulgating rule.
  - Proposed one rule, finalized the opposite.
- But CMS stalling final resolution of case with small door left open by court.
- The *Allina* reopening notices issued by many MACs with cost report settlements are not being followed by MACs.
- Continue perfecting appeal rights for this and other DSH issues.

Cost Report Appeals Litigation Update (Wage Index-Pension)

- Challenges CMS changes to recognizing pension costs for wage index purposes.
- Two major appeals by Hall Render and Hopper Lundy.
- Lack of APA compliance major issue again.
- Both pending in D.C. District Court.
  - Hall Render had oral arguments in May.
  - Both pending court decision.

Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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