

HEALTH LAW UPDATE

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Final 2010 Updates for OPPS and ASC Payment Systems

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On November 20, 2009, the Centers for Medicare & Medicaid Services ("CMS") published final calendar year (CY) 2010 updates to the Outpatient Prospective Payment System ("OPPS") and the ambulatory surgery center ("ASC") payment system (the "Final Rule").¹ These changes include a 2.1% increase in reimbursement by Medicare for hospital outpatient services and a 1.2% increase for ASC services. CMS projects total payments of \$32.2 billion for Medicare patients in hospital outpatient departments during CY 2010 and total payments of \$3.4 billion for Medicare patients under the ASC payment system. In addition, the Final Rule covers certain new services and a number of modifications to existing regulatory requirements, including physician supervision requirements and quality reporting requirements. This Health Law Update provides a high level summary of some of the highlights of the Final Rule.

Physician Supervision Requirements

CMS has finalized its proposal to revise several policies related to physician supervision of hospital outpatient services. Under the Final Rule, the following non-physician practitioners ("NPP") may directly supervise all hospital outpatient *therapeutic* services (except pulmonary, cardiac, or intensive cardiac rehabilitation services) that they are able to personally perform in accordance with state law: clinical psychologists; licensed clinical social workers; physician assistants; nurse practitioners; certified nurse specialists; and certified nurse-midwives. *Diagnostic* services, however, still require supervision by a physician and not an NPP. CMS emphasized in the preamble commentary that the supervising physician or NPP must be prepared and able to "step in and perform the service, not just to respond to an emergency."

Under the Final Rule, the definition of *direct supervision* depends on the location where the outpatient therapeutic services are being delivered. For therapeutic services delivered *in a hospital or critical access hospital* (CAH) or in an on-campus outpatient department of the hospital or CAH the physician or NPP must be "present *on the same campus* and *immediately available* to furnish assistance and direction *throughout the performance of the procedure*." For therapeutic services delivered in an off-campus hospital facility, the definition is the same except that the physician or NPP must be in the off-campus hospital facility rather than just on the same campus. The Final Rule further clarifies that *direct supervision* does *not* mean that the physician or NPP must be present in the room when the procedure is performed.

Interestingly, whereas the proposed rule required a physician or non-physician to be present "in the hospital" or in the on-campus provider-based department in order to meet the direct supervision requirement, the Final Rule permits the physician or non-physician practitioner to be

¹ 74 Fed. Reg. 60316 (Nov. 20, 2009).

anywhere on the hospital's campus.² Instead of defining "campus" in the revised regulation, CMS refers in the preamble commentary to the provider-based rules, which define "campus" as "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."³ In the preamble commentary, CMS also recognizes that some hospital campuses are expansive, sometimes spanning several city blocks and commented that "it would be neither appropriate nor 'immediate' for the supervisory physician or [NPP] to be so physically far away on the main campus from where hospital outpatient services are being furnished that he or she could not intervene right away."

CMS also finalized for CY 2010 its proposed requirement that all hospital outpatient diagnostic services furnished directly or under arrangement, whether provided in the hospital, in a provider-based department, or at a nonhospital location, follow the Medicare Physician Fee Schedule (MPFS) physician supervision requirements for individual tests. Note that all of the above supervision requirements for both diagnostic and therapeutic services apply only to hospitals and hospital outpatient services and not to outpatient services provided in freestanding facilities or physician offices.

2010 Final OPPS Coverage and Payment Changes

In addition to the physician supervision changes discussed above, CMS has finalized a number of coverage and payment changes in the OPPS that are summarized below:

Hospital-Acquired Conditions – Not Expanded to OPPS Just Yet

CMS continues to report concerns with the total national costs associated with medical errors and hospital-acquired conditions ("HACs"). Since October 1, 2007, CMS has required hospitals to submit information regarding inpatient HACs, and in the case of a HAC, Medicare will provide payment only as though the secondary diagnosis were not present. In the CY 2009 Proposed Rule, CMS considered whether the policy of not paying more for preventable HACs for services paid under the inpatient prospective payment system could also be applied to payment for preventable HACs for outpatient services under the OPPS (to be called "OPPS-HACs"). The conditions considered for OPSS-HACs included medication errors, conditions related to complications of hospital outpatient surgery, and infections related to hospital outpatient care. CMS continues to recognize the "operational challenges" in implementing a OPSS-HAC payment policy and will continue to consider comments as it evaluates this issue.

New Payment for Pulmonary and Cardiac Rehabilitation

Pursuant to provisions of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), CMS will make payment for pulmonary rehabilitation and intensive cardiac rehabilitation services effective January 1, 2010 for Medicare patients with chronic obstructive pulmonary disease, cardiovascular disease and other related conditions.

New Payment for Kidney Disease Education Services

² The Final Rule defines *in the hospital or CAH* to mean "areas in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital's or CAH's CMS Certification Number." 74 Fed. Reg. 60680.

³ Another subsection of the Medicare regulations defines "Campus" at 42 C.F.R. § 413.65.

Another new reimbursable service mandated by MIPPA is Kidney Disease Education ("KDE"). CMS will make payment to rural providers of KDE as of January 1, 2010 for Medicare beneficiaries with stage IV chronic kidney disease.⁴

Increase to Fixed-Dollar Threshold for Outlier Payments

Outlier payments under OPSS are currently paid on a per-service basis if the cost of furnishing the service or procedure exceeds each of the following thresholds: (a) 1.75 times the ambulatory payment classification (APC) payment amount; and (b) the APC payment rate plus a fixed-dollar threshold of \$1,800. Effective for CY 2010, CMS will increase the fixed-dollar threshold to \$2,175, which is \$50 less than the proposed increase of \$2,225. CMS will also continue to reconcile outlier payments in CY 2010 through cost reporting settlements.

Changes to Device-Dependent APC Payment Methodology

Device-dependent APCs typically include codes that require a device to be implanted or used to perform a procedure and for which the median cost is based on the full cost of the device. Historically, device APCs have excluded from the median cost certain devices that are obtained for free, devices obtained for "token charges" (less than \$1.01), and devices for which the full cost was credited back to the hospital. CMS did not receive any comments to its proposal in the 2010 OPSS Proposed Rule that if a hospital should receive a partial credit of at least 50% of the cost of certain devices, CMS would reduce the APC payment rate by an amount that is 50% of the cost of a device.⁵ Therefore, CMS adopted its proposal without modification.

Pass-Through Payments, Packaged Payments and Separate Payments for Drugs, Radiopharmaceuticals and Non-Implantable Biologicals

Transitional pass-through payments for certain drugs, radiopharmaceuticals and non-implantable biologicals are permitted for two to three years after the first payment for the product (to any hospital) has been made as a hospital outpatient service under Medicare Part B.⁶ The transitional pass-through payment amount for CY 2010 is the Average Sales Price ("ASP") of the drug or biological plus 6%.⁷

After the transitional pass-through period expires, CMS will determine whether the drug, therapeutic radiopharmaceutical or non-implantable biological should be paid as part of the packaged APC payment rate or paid separately outside the APC payment rate. Drugs, therapeutic radiopharmaceuticals and non-implantable biologicals are packaged into the APC payment rate for the associated procedure if the estimated per-day cost of a drug, therapeutic

⁴ 74 Fed. Reg. 60566. KDE payments to hospitals will be made under the Medicare Physician Fee Schedule ("MPFS") and not the OPSS. *Id.*

⁵ 74 Fed. Reg. 60371 and 60465. This payment reduction to the APC payment rate would only apply to certain device APCs that meet the following three requirements: (1) all procedures assigned to the APC must involve implantable devices that would be reported if device insertion procedures were performed, (2) the required devices must be surgically inserted or implanted and remain in the patient's body after the procedures is performed, and (3) the cost of the device must be significant --- the cost must constitute at least 40% of the APC cost. Thus, the APC payment rate would not be reduced for devices the costs of which are not "significant." *Id.* at 60645.

⁶ 74 Fed. Reg. 60462 and 60466. CMS did not finalize its proposal to begin the two to three year transitional pass-through payment period for drugs and non-implantable biologicals on the date of first sale of the drug or non-implantable biological in the United States following approval by the Food and Drug Administration.

⁷ 74 Fed. Reg. 60468 and 60470. If ASP data is not available for a radiopharmaceutical, CMS proposes to pay the wholesale acquisition cost ("WAC") plus 6%. If WAC information is not available, then CMS would pay 95% of the most recent average wholesale price of the drug or biological. *Id.* at 60470, 60480 and 60526 - 60527.

radiopharmaceutical or non-implantable biological, as applicable, is less than or equal to the applicable OPPS drug packaging threshold. If the estimated per-day cost of a drug, therapeutic radiopharmaceutical or non-implantable biological is more than the applicable OPPS drug packaging threshold, then the non-pass through drug, therapeutic radiopharmaceutical or biological, as applicable, would be paid separately at the ASP rate plus 4%. The CY 2010 OPPS drug packaging threshold is \$65, which is \$5 more than the 2009 drug packaging threshold. Certain drugs, however, are not eligible for separate payment and must be packaged if they are not being paid under the transitional pass-through payment.⁸

CMS Proposes to Treat Implantable Biologicals like Devices for Pass-Through and Non-Pass Through Payment Methodology

CMS finalized its proposal to treat implantable biologicals that are surgically inserted or implanted during a procedure using device category pass-through payments (rather than drug and biological pass-through payments) for purposes of calculating the pass-through payment during a transitional period. Thus, pass-through implantable biologicals will be paid like devices at the hospital's charge adjusted to cost for the two to three year pass-through period and will no longer receive pass-through payment at ASP plus 6%.⁹

CMS will also include, for the first time, in the calculation of APC offset amounts for device categories certain non-pass through implantable biologicals that are surgically inserted or implanted during a procedure. CMS reasoned that the costs of implantable biologicals not eligible for pass-through payment (i.e., separate reimbursement) are packaged into the cost of the procedures in which they are implanted, like devices.

Brachytherapy Sources

CMS adopted its proposal to implement the general OPPS prospective payment methodology for brachytherapy sources. Thus, in CY 2010, CMS will pay for brachytherapy sources based on median unit costs, as calculated based on claims data according to the standard OPPS ratesetting methodology. CMS believes this change is appropriate because it produces more consistent, predictable, and equitable payment amounts ... by eliminating some of the extremely high and low payments resulting from payment based on hospitals' charges adjusted to cost." This new methodology is also meant to incentivize hospitals to more efficiently provide brachytherapy sources to Medicare beneficiaries.

Hospital Clinic and Emergency Department Visits – No National Reporting Guidelines

CMS requires hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level. In CY 2010, CMS will continue to allow hospitals to create their own

⁸ 74 Fed. Reg. 60481. Diagnostic radiopharmaceuticals (not therapeutic radiopharmaceuticals) and contrast agents are "policy packaged" regardless of their per-day costs and are not separately payable after the transitional pass-through period expires. CMS asserts that "[p]ackaging costs into a single aggregate payment for a service, encounter, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility." *Id.* at 60481 – 60482 and 60496 – 60499.

⁹ If an implantable biological is being treated as a biological (not a device) for pass-through payments prior to CY 2010, CMS would continue to make payment at ASP plus 6% for the remainder of the transitional pass-through period. 74 Fed. Reg. 60473 – 60476.

internal guidelines for reporting the appropriate visit levels, rather than to implement national visit guidelines.¹⁰

Ambulatory Surgery Center Payment

CY 2010 will be the third year of a four year phase-in toward the new payment system for ASCs that became effective January 1, 2008. Under the new payment system, ASC reimbursement rates are based on a percentage of the OPPS rate for the same procedures performed in a hospital outpatient setting, although there are a few exceptions. ASC reimbursement was initially set at 65% of the rate paid under the OPPS system for the same surgical procedure, but the ratio has decreased since then.

CMS's proposed ASC payment changes for CY 2010 are not as extensive or significant as the CY 2008 changes. Some of the more notable proposed changes include:

- *Inflation Adjustment.* By statute, ASC payment rates did *not* receive an inflation adjustment for either CY 2008 or 2009, but for CY 2010 rates will increase by 1.2%, which is the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U). By contrast, OPPS rates will receive an inflation adjustment of 2.1%, based on a different mechanism, the hospital "market basket" metric.
- *New Covered Procedures.* CMS added 28 procedures to the "ASC list" – *i.e.*, the list of procedures approved for reimbursement when performed at an ASC. Two of these additions to the ASC list are new procedure codes. The other 26 are codes that CMS had previously excluded from the ASC list because they were deemed to pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in an ASC. After conducting a clinical review, CMS reassessed these procedure codes and has determined that they are appropriate for an ASC setting.
- *Office Based Procedures.* CMS designated six new procedures and temporarily designated an additional 16 procedures as "office based," meaning that they are performed more than 50% of the time in physicians' offices. For procedures that are deemed "office based", CMS sets reimbursement at the *lower* of: (i) the amount that would otherwise be received under the ASC payment system, or (ii) the physician office (MPFS) rate for such procedure.
- *Post-Operative Supervision.* In response to a commenter regarding the lack of physician supervision requirements during a patient's post-operative recovery period, CMS has acknowledged that it could be appropriate to consider establishing requirements for physician or NPP supervision in ASCs similar to the requirements for the direct supervision of hospital supervision of hospital outpatient therapeutic services discussed above. As a result, in the Final Rule, CMS requests comments regarding the current supervisory practices in ASCs, particularly during extended post-operative recovery periods, and whether the supervision requirements in ASCs should parallel the hospital outpatient supervision requirements.

Hospital Outpatient Quality Reporting

CMS strengthened its quality measure reporting programs by updating quality measures under the hospital outpatient quality reporting data program ("HOP QDRP"). CMS requires reporting of a designated set of quality measures designed to address the diversity of care services provided

¹⁰ 74 Fed. Reg. 60552. "In the absence of national guidelines, we will continue to regularly reevaluate patterns of hospital outpatient visit reporting at varying levels of disaggregation below the national level to ensure that hospitals continue to bill appropriately and differentially for these services." *Id.*

to adult patients in all hospital outpatient settings. As a backdrop to the CY 2010 payment determination, CMS has required HOP QDRP reporting using 11 HOP QDRP measures ---- seven emergency department and surgical care measures that require the hospital to submit chart-abstracted data and four imaging measures based on Medicare claims data. For the CY 2011 payment determination, CMS will continue to require hospitals to report the existing 11 HOP QDRP measures.

Hospitals that fail to report 2009 data required for the quality measures designated by CMS incur a 2.0% reduction in the annual payment update, for a net increase of .1%. However, this reduction will not apply to payments for separately reimbursable pass-through drugs, biologicals and devices, non-pass-through drugs and non-implantable biologicals, and therapeutic radiopharmaceuticals. For CY 2010, CMS will continue its established policy of applying the reduction to hospitals that fail to meet the requirements of the HOP QDRP.¹¹

CMS did not adopt its proposal to discontinue requiring a hospital to maintain a QualityNet administrator. Instead, hospitals must continue to maintain a QualityNet security administrator to comply with HOP QDRP requirements. CMS finalized its proposal to change the deadline for submitting the participation form for hospitals with Medicare acceptance dates¹² on or after January 1, 2010, to 180 days from the Medicare acceptance date. CMS adopted its proposal to grant extensions or waivers for reporting under the HOP QDRP to hospitals that are unable to submit data due to extraordinary circumstances that are not within their control. To be considered for a waiver or extension, a hospital would need to submit a request to CMS identifying the reason for the request within 45 days of the extraordinary circumstance as well as evidence of the impact of the extraordinary circumstances.

Additionally, CMS is implementing a data validation program to verify the accuracy of reporting measures using chart-abstracted data. Under the program, CMS will randomly select cases to re-abstract the quality measures and compare such data to the quality measures reported by hospitals. Although CMS will evaluate hospital submitted data for CY 2010, the results will not affect the hospital's payment in 2011.

If you have any questions on this Health Law Update, please contact any of the attorneys in our Healthcare Practice Group listed below.

¹¹ 74 Fed. Reg. 60427 – 60428. The reduction will not apply to payments for separately payable pass-through drugs and biologicals, separately payable non pass-through drugs and biologicals, separately payable radiopharmaceuticals, and services assigned to New Technology APCs. New Technology APCs are intended to provide payment under the OPPS for comprehensive services or procedures that are truly new and significant enough to warrant having their own code until CMS is able to gather sufficient claims data to assign an appropriate APC. *Id.* at 60438.

¹² The Medicare acceptance date is the earliest date that a hospital can receive Medicare payment for the services it provides, as identified on the CMS Online System Certification and Reporting ("OSCAR") system. 74 Fed. Reg. 60643.

Bass, Berry & Sims Healthcare Attorneys

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Krista Thornton Cooper
(615) 742-7734
kt Thornton@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Elisa E. Harris
(615) 742-6553
eharris@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

Clevonne M. Jacobs
(615) 742-7769
vjacobs@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Brian D. Roark
(615) 742-7753
broark@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Nesrin Garan Tift
(615) 742-7903
ntift@bassberry.com

Leigh Walton, Co-Chair
(615) 742-6201
lwalton@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

Douglas M. Wolford
(615) 742-7917
dwolford@bassberry.com

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