

# HEALTH LAW

## Update

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

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### **Proposed Changes to OPPS and ASC Payment Systems for CY 2010: A Sigh of Relief on Supervision and a Potpourri of Payment Changes**

**July 31, 2009**

On July 20, 2009, the Centers for Medicare & Medicaid Services ("CMS") published in the Federal Register proposed updates for calendar year (CY) 2010 to the Outpatient Prospective Payment System ("OPPS") and the ambulatory surgery center ("ASC") payment system (the "Proposed Rule"). These changes include a projected 2.1% increase in reimbursement by Medicare for hospital outpatient services and a projected 0.6% increase for ASC services. In addition, the Proposed Rule contains coverage of 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 Proposed Rule.

#### **Physician Supervision Requirements**

CMS is proposing to revise several policies related to physician supervision of hospital outpatient services. Last year, as part of the 2009 OPSS rule, CMS included some "clarifications" related to physician supervision. These clarifications imposed direct supervision requirements that were more stringent than what many understood to be the previous standards, and, according to some, constituted a policy change rather than a clarification.

In response to a number of questions and concerns about the 2009 rule, CMS is now proposing to permit mid-level practitioners (and not just physicians) to provide direct supervision in certain circumstances. Specifically, CMS proposes that physician assistants, nurse practitioners, certified nurse specialists, and certified nurse-midwives may directly supervise all hospital outpatient *therapeutic* services (except pulmonary or cardiac rehabilitation) that they are able to personally perform within their scope of practice under state law.<sup>1</sup> However, *diagnostic* services would still require supervision by a physician and not a mid-level practitioner.<sup>2</sup>

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<sup>1</sup> 74 Fed. Reg. 35365.

<sup>2</sup> *Id.* at 35369.

*Direct supervision* would be defined, for hospital outpatient *therapeutic* services, to mean that the practitioner is present *in the hospital* or on-campus provider-based department of the hospital, and *immediately available* to furnish assistance and direction *throughout the performance of the procedure*.<sup>3</sup> The 2010 Proposed Rule includes a detailed definition of "in the hospital" and also includes commentary on the meaning of "immediately available" and "throughout the performance."<sup>4</sup> The practitioner would *not* have to be present in the room when the procedure is performed. For therapeutic services provided in an off-campus provider-based department, the practitioner would need to be "in the department" rather than just "in the hospital."<sup>5</sup>

The definition of direct supervision for *diagnostic* services is very similar to that for therapeutic services, but, as mentioned above, supervision would have to be by a physician, and not a mid-level practitioner. Note that CMS is also proposing to require 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 MPFS physician supervision requirements for individual tests.

CMS's proposed supervision changes would apply for calendar year 2010, but would not be retroactive, and CMS noted that "we have not instructed contractors to delay initiation of enforcement actions or to discontinue pursuing pending enforcement actions regarding the physician supervision of hospital outpatient services" during 2009.<sup>6</sup>

### **Proposed OPSS Coverage and Payment Changes**

In addition to the physician supervision changes discussed above, CMS has proposed a number of coverage and payment changes in the OPSS. Also significant is what CMS has *not* done. For example, at least for next year, CMS is not proposing to "bundle" any additional services into "composite" APC payments. In addition, CMS is not yet ready to expand the principles of the IPPS Hospital-Acquired Condition (HAC) provision to the OPSS just yet<sup>7</sup> or to required national reporting guideline for the visit levels at hospital emergency rooms and outpatient clinics. These highlights and others are summarized below:

#### *CMS is Not Proposing Any New Composite APCs*

CMS developed composite APCs (as opposed to per-service APCs) starting in CY 2008 by making a single payment for multiple independent services that are typically performed together during a single clinical encounter.<sup>8</sup> Although CMS is not adding any new composite APCs for

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<sup>3</sup> *Id.* at 35369.

<sup>4</sup> See *id.* at 35365 – 69

<sup>5</sup> *Id.* at 35369.

<sup>6</sup> *Id.* at 35365.

<sup>7</sup> Note that HACs are different from "never events". CMS does not pay for "never events", which are egregious events such as surgery on the wrong body part, while CMS does pay, albeit at a lower rate, for HACs. CMS has addressed "never events" through a recently issued National Coverage Determination.

<sup>8</sup> *Id.* at 35278. There are currently composite APCs under OPSS for limited sets of services including, extended assessment and management services (i.e., observation and monitoring services), low dose rate prostate

CY 2010, CMS will continue to monitor the effects of composite APCs on utilization and payment.<sup>9</sup> CMS has said that the composite APC payment model "enables hospitals to manage their resources" and enhances "incentives for hospitals to provide only necessary, high quality care ... as efficiently as possible."<sup>10</sup>

By way of example, CMS has already implemented a composite APC payment for multiple imaging procedures performed on the same date in the following five categories: (1) ultrasound, (2) computed tomography, (3) computed tomography angiography, (4) magnetic resonance imaging, and (5) magnetic resonance angiography. CMS has refused to modify the composite APC for multiple imaging procedures because it believes that hospitals achieve cost savings for imaging sessions that are performed on the same date, but at different times, by not reusing certain hospital resources. However, CMS has accepted the APC Panel's<sup>11</sup> recommendations to examine different options for payment of multiple imaging procedures.<sup>12</sup>

#### *Hospital-Acquired Conditions – Not Expanded to OPSS 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 HACs, and in the case of a HAC, Medicare will provide payment only as though the secondary diagnosis were not present.<sup>13</sup> In the CY 2009 Proposed Rule, CMS considered whether the policy of not paying more for preventable HACs for services paid under the IPSS could also be applied to payment for outpatient services under the OPSS (to be called "HOP-HACs"). At that time, CMS did not make any changes to the policy but did invite comments on the issue, which highlighted some of the difficulties of applying the principle to the outpatient setting. The conditions considered for HOP-HACs included medication errors, conditions related to complications of hospital outpatient surgery, and infections related to HOPD care. Many commenters expressed concern over how to set the boundaries of an "episode of care" for HACs in the outpatient setting; for example, how would we define what is "during" or "as a result of" care provided in a single outpatient hospital encounter? Many also noted that patients receiving outpatient care often visit other departments of the hospital for services during a "single" outpatient encounter.<sup>14</sup>

Recognizing the operational challenges in implementing a HOP-HAC payment policy to the OPSS, CMS is proposing not to expand the principles of the IPSS HAC provision to the OPSS just yet. CMS will continue to evaluate this issue and welcomes additional comments.

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brachytherapy, cardiac electrophysiologic evaluation and ablation services, mental health services, and multiple imaging services. *Id.*

<sup>9</sup> *Id.* at 35278 - 35279.

<sup>10</sup> *Id.* at 35278.

<sup>11</sup> The Advisory Panel on Ambulatory Payment Classification Groups advises CMS about the clinical integrity of the APC groups and their associated weights.

<sup>12</sup> 74 Fed. Reg. 35283 – 35284.

<sup>13</sup> 74 Fed. Reg. 35405.

<sup>14</sup> 74 Fed. Reg. 35406-7.

### *New Payment for Pulmonary and Cardiac Rehabilitation*

CMS proposes to begin providing payment for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services effective January 1, 2010. This addition would implement provisions of the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA").<sup>15</sup>

### *New Payment for Kidney Disease Education Services*

Another new reimbursable service mandated by MIPPA is Kidney Disease Education (KDE). CMS proposes providing payment for KDE as of January 1, 2010 for Medicare beneficiaries with stage IV chronic kidney disease. This payment is available only for *rural* providers of KDE.<sup>16</sup>

### *Previously "Inpatient Only" Procedures*

CMS has previously identified a list of procedures that are typically provided only in an inpatient setting and that will not be reimbursed by Medicare under the OPSS. This list is known as the "inpatient list." In the 2010 OPSS Proposed Rule, CMS proposes to remove three specific codes from this list, i.e., 21256 (a reconstructive surgery code), 27179 (an osteoplasty code), and 51060 (a bladder surgery code), making them eligible for reimbursement in an outpatient setting.<sup>17</sup>

### *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 APC payment amount; and (b) the APC payment rate plus a fixed-dollar threshold of \$1,800.<sup>18</sup> Effective for CY 2010, CMS is proposing to increase the fixed-dollar threshold to \$2,225.

### *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.<sup>19</sup> Under the 2010 OPSS Proposed Rule, if a hospital receives a partial credit of at least 50% of the cost of certain devices, CMS proposes to reduce the APC payment rate by an amount that is 50% of the cost of a device.<sup>20</sup>

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<sup>15</sup> *Id.* at 35360.

<sup>16</sup> *Id.* at 35358-59. In addition, KDE payments to hospitals would be made under the Medicare Physician Fee Schedule ("MPFS") and not the OPSS. *Id.*

<sup>17</sup> *Id.* at 35357.

<sup>18</sup> *Id.* at 35295.

<sup>19</sup> 74 Fed. Reg. 35267 and 35307.

<sup>20</sup> 74 Fed. Reg. 35267. 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

*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 has been made as a hospital outpatient service under Medicare Part B.<sup>21</sup> The proposed transitional pass-through payment amount for CY 2010 is the Average Sales Price ("ASP") of the drug or biological plus 6%.<sup>22</sup>

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 radiopharmaceutical or non-implantable biological, as applicable, is less than or equal to the applicable OPSS drug packaging threshold. If the estimated per-day cost of a drug, therapeutic radiopharmaceutical or non-implantable biological is more than the applicable OPSS drug packaging threshold, then the drug, therapeutic radiopharmaceutical or biological, as applicable, would be paid separately at the ASP rate plus 4%.<sup>23</sup> The CY 2010 proposed OPSS drug packaging threshold is \$65, which is \$5 more than the 2009 drug packaging threshold.<sup>24</sup> 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.<sup>25</sup>

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

CMS proposes to treat implantable biologicals that are surgically inserted or implanted during a procedure like devices for purposes of calculating the pass-through payment during a transitional period while CMS is collecting claims data.<sup>26</sup> Thus, if finalized, pass-through implantable biologicals would be paid like devices at the hospital's charge adjusted to cost<sup>27</sup> and would no

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inserted or implanted and remain in the patient's body after the procedure is performed, and (3) the cost of the device must be significant --- the cost must constitute at least 40% of the total cost of the APC in which the device is packaged. Thus, the APC payment rate would not be reduced for devices the costs of which are not "significant." 74 Fed. Reg. 35307.

<sup>21</sup> 74 Fed. Reg. 35308. CMS is proposing 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. 74 Fed. Reg. 35315.

<sup>22</sup> 74 Fed. Reg. 35310. If ASP data is not available for a radiopharmaceutical, CMS proposes to pay the wholesale acquisition cost 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. 74 Fed. Reg. 35310.

<sup>23</sup> 74 Fed. Reg. 35309.

<sup>24</sup> 74 Fed. Reg. 35319.

<sup>25</sup> 74 Fed. Reg. 35309. Diagnostic radiopharmaceuticals (not therapeutic radiopharmaceuticals) and contrast agents are "policy packaged" and are not separately payable after the transitional pass-through period expires. *Id.* at 35309 and 35323.

<sup>26</sup> 74 Fed. Reg. 35313.

<sup>27</sup> 74 Fed. Reg. 35314.

longer receive pass-through payment at ASP plus 6%.<sup>28</sup> CMS justified the proposed change to treat implantable biologicals like devices because they sometimes have identical clinical uses and they are similarly regulated by the Food and Drug Administration.<sup>29</sup>

CMS has also proposed for the first time to include 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 non-pass through implantable biologicals are not separately reimbursed, but instead are packaged into the cost of the procedures in which they are implanted, like devices.<sup>30</sup>

### *Brachytherapy Sources*

Through CY 2009, payment for brachytherapy sources is mandated at charges adjusted to cost. Under the Proposed Rule, CMS would implement the general OPPS prospective payment methodology for brachytherapy sources. CMS would pay for brachytherapy sources based on median unit costs, as calculated based on claims data according to the standard OPPS ratesetting methodology.<sup>31</sup> CMS believes this change is appropriate because it produces more consistent and equitable payment amounts by eliminating extremely high and low payments that result from hospital charges adjusted to cost. This new methodology is also meant to incentivize hospitals to more efficiently provide brachytherapy services to Medicare beneficiaries. CMS also proposes to pay for separately payable brachytherapy sources at prospective payment rates based on their source-specific median costs.

### *Hospital Clinic and Emergency Department Visits – No National Reporting Guidelines Yet*

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 the 2008 OPPS proposed rule, CMS invited public comment as to whether there is a pressing need to develop national guidelines for reporting, or whether it is more practical for hospitals to develop their own internal hospital guidelines as instructed by CMS. Based on public comments, CMS is proposing to continue allowing hospitals to create their own internal guidelines for reporting the appropriate visit levels, rather than to implement national visit guidelines. CMS believes that hospitals are generally billing in an accurate and consistent manner based on their own guidelines.

### **Ambulatory Surgery Center Proposed Changes**

Two years ago, CMS significantly restructured payment for services provided in ambulatory surgery centers ("ASCs"). Under the new payment system, which became effective January 1, 2008, ASC reimbursement rates are based on the OPPS rate for the same procedures performed

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<sup>28</sup> 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. 35313 – 35314.

<sup>29</sup> 74 Fed. Reg. 35313.

<sup>30</sup> 74 Fed. Reg. 35313.

<sup>31</sup> 74 Fed. Reg. 35342.

in a hospital outpatient setting – but at a reduced rate to take into account lower overhead costs at ASCs and other factors. The new system is being phased in gradually over a four-year period, and CY 2010 will be the third year of this transition.<sup>32</sup> ASC reimbursement was initially set at 65% of the rate paid under the OPSS 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.* CMS proposes increasing ASC reimbursement rates by 0.6% as an inflation adjustment. By statute, ASC payment rates did *not* receive an inflation adjustment for either CY 2008 or 2009, but for CY 2010 rates would increase by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U), which is estimated to be 0.6%. By contrast, OPSS rates would have an inflation adjustment using a different mechanism (the "market basket" metric) resulting in a 2.1% inflation adjustment.<sup>33</sup>
- *New Covered Procedures.* CMS proposes adding 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 twenty-six 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.<sup>34</sup>
- *Office Based Procedures.* CMS proposes to designate six procedures from the ASC list as being "office based," meaning that they are performed more than fifty percent of the time in physicians' offices.<sup>35</sup> 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 rate for such procedure.

CMS also noted recommendations that have been made by the Medicare Payment Advisory Commission ("MedPAC") that ASCs should be required to submit *cost data* and *quality data* to CMS. In response, CMS noted that with respect to *quality data*, the agency is not proposing to require ASC quality data reporting for 2010, but CMS's "clear intention is to implement ASC quality reporting in the future."<sup>36</sup> With respect to *cost data*, CMS expressed concern that requiring cost reports would be administratively burdensome for ASCs, and noted that ASC

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<sup>32</sup> *Id* at 35385. CY 2010 rates will be a blended rate based 25% on the 2007 rates, and 75% on the "fully implemented" new rates.

<sup>33</sup> The 2010 proposed "conversion factor" for ASCs is \$41.625. The 2010 proposed conversion factor for the OPSS is \$67.439. *Id* at 35291 and 35394.

<sup>34</sup> *Id* at 35379.

<sup>35</sup> *Id* at 35380.

<sup>36</sup> *Id* at 35391.

payment is based on OPPS rates, which already take into account hospital outpatient costs. However, in light of MedPAC's recommendation, CMS is soliciting public comment on the feasibility of ASCs submitting cost information.<sup>37</sup>

### **Hospital Outpatient Quality Reporting**

In the Proposed Rule, CMS strengthens 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 to adult patients in all hospital outpatient settings. As a backdrop to the CY 2010 payment determination, CMS has required HOP QDRP reporting using seven emergency department and perioperative measures that require the hospital to submit chart-abstracted data as well as four imaging measures based on Medicare claims data.

For the CY 2011 payment determination, CMS is proposing to continue requiring hospitals to report the existing 11 HOP QDRP measures. Although CMS considered adding chart-abstracted measures, it proposes not to add any new measures for the CY 2011 payment determinations so as not to increase the reporting burden on hospitals. CMS is also seeking public comments on quality measures for consideration in future years. The additional quality measures that CMS is considering address cancer, emergency department throughput, diabetes, immunization, and imaging efficiency.<sup>38</sup>

Hospitals that fail to report data required for the quality measures designated by CMS incur a 2.0 percent reduction in the annual payment update increase, as required by law. For CY 2010, CMS proposes to continue its established policy of applying the reduction to hospitals that fail to meet the requirements of the HOP QDRP.<sup>39</sup>

CMS is also proposing several changes to the requirements for hospitals' participation in the HOP QDRP. Under the Proposed Rule, CMS would no longer require a hospital to maintain a QualityNet administrator, since this requirement has created a technical burden preventing some hospitals from participating. CMS would also change the deadline for submitting the participation form for hospitals with Medicare acceptance dates<sup>40</sup> on or after January 1, 2010, to 180 days from the Medicare acceptance date. Additionally, CMS is proposing changes to the data collection and submission requirements so as to reduce the burden on hospitals. For example, with respect to some quality measures, hospitals will not be required to submit data for all eligible cases, but only for sampled cases for those measures where a hospital has a sufficiently large number of cases. In addition, hospitals that treat a small number of patients but

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<sup>37</sup> *Id.* at 35391.

<sup>38</sup> *Id.* at 35397.

<sup>39</sup> *Id.* at 35399. 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 OPSS for comprehensive services or procedures that are truly new and significant enough to warrant having their own code.

<sup>40</sup> 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.

otherwise meet the submission requirements for a particular quality measure will not be required to submit patient level data for the entire measure in a quarter.<sup>41</sup>

Under the Proposed Rule, CMS invites public comment on a process that would allow it 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, as well as evidence of the impact of the extraordinary circumstances.

Additionally, CMS is proposing to implement a data validation program to verify the accuracy of reporting measures using chart-abstracted data. Under the program, CMS would select a random sample of 7,300 cases and request patient records relating to those cases to determine how accurately the results were reported. CMS will begin validating hospital submitted data for CY 2011 payment update, but, in order to allow hospitals to gain experience with the medical documentation requests, the results will not affect the hospital's payment until CY 2012.<sup>42</sup>

CMS also states its intention to develop quality methods of submitting data using EHRs to improve efficiency and reduce administrative burdens. CMS indicates that it is actively seeking alternatives to manual chart abstraction for reporting while collaborating with health IT organizations to develop interoperability among data collection systems.

### **Conclusion**

CMS will accept comments on the proposed ASC and OPPI proposed changes until August 31, 2009, and intends to respond to comments in a final rule to be issued by November 1, 2009. If you have any questions on this Health Law Update, please contact any of the attorneys in our Healthcare Practice Group listed below.

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<sup>41</sup> *Id.* at 35400-2.

<sup>42</sup> *Id.* at 35403-4.

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