Biotechnology Industry Organization

September 6, 2013

BY ELECTRONIC DELIVERY

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals [CMS-1601-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding payment policies under the calendar year (CY) 2014 hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 19, 2013 (the "Proposed Rule").[1] BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

BIO represents an industry that is committed to improving health care through the discovery of new therapies. We recognize that appropriate reimbursement based on an accurate payment methodology is critical to ensuring that beneficiaries are able to access necessary care. An accurate payment methodology also fosters continued investment in innovation. Accordingly, BIO strongly supports CMS's proposal to continue reimbursing separately payable drugs and biologicals at average sales price (ASP) plus six percent in CY 2014. BIO believes it provides the predictable, appropriate payment rates necessary to ensure that beneficiaries will continue to have access to critical therapies in the hospital outpatient setting. Until CMS develops a methodology to more accurately and predictably estimate acquisition and overhead costs involved in furnishing these therapies – a goal BIO looks forward to helping the agency pursue, CMS should continue to reimburse these drugs and biologicals at the statutory default of ASP plus six percent. BIO urges CMS to finalize

[1] 78 Fed. Reg. 43534 (July 19, 2013).

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this proposal. We are concerned, however, that the agency's proposal to expand packaging for drugs, biologicals, and radiopharmaceuticals based on their purported function and cost and to package payment for many drug administration services will counteract this and other improvements in payment that CMS has achieved in recent years. As discussed in depth below, we ask that the agency reconsider those proposals.

With the goal of ensuring patient access to necessary treatments and therapies, we recommend that CMS:

- Finalize its proposal to continue paying ASP plus six percent for separately payable drugs and biologicals administered in the OPPS;
- Not consider finalizing any proposed packaging policies until it resolves the inconsistencies in its CY 2014 OPPS rate-setting methodology and data calculations;
- Continue separate payment at ASP plus six percent for Food and Drug Administration (FDA) approved drugs and biologicals regardless of their function in diagnostic or surgical procedures and restore separate payment for contrast agents and for diagnostic radiopharmaceuticals following the expiration of transitional pass-through payment;
- Continue to make separate payment for all add-on codes, including the codes for drug administration services;
- Continue to pay separately for all ancillary services currently assigned a status indicator of "X";
- Make separate payment for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes in the OPPS just as the agency does for these therapies when they are administered in a physician office setting or, alternatively, not increase the packaging threshold for these therapies. If any drugs remain packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636;
- Continue to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer and reimburse these therapies at ASP plus six percent;
- Reimburse blood clotting factors at ASP plus six percent plus an updated furnishing fee;
- Continue using the existing device-dependent ambulatory payment classifications (APCs) and ensure accurate payment for hospital-administered drugs;
- Finalize its proposal to continue to adjust OPPS payments to certain cancer hospitals in CY 2014;
- Consider implantable biologicals approved under biological license applications (BLAs) for pass-through status as drugs or biologicals, or, if CMS does not implement this recommendation, revise its regulations to clarify that a biological will be evaluated as a device for pass-through status only if it is solely surgically implanted according to its FDA-approved indication; and

- Analyze the trend of hospital acquisition of physician practices and resulting provision of physician services in an outpatient setting using the proposed methods of studying this trend.

These comments are discussed in detail below.

I. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status – CMS should finalize its proposal to continue paying ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.

For CY 2013, after several years of revising its methodology for estimating acquisition and pharmacy service costs, CMS adopted the "statutory default" to reimburse separately payable drugs and biologicals at ASP plus six percent. The Social Security Act (SSA) requires Medicare to reimburse specified covered outpatient drugs (SCODS) at the "average acquisition cost for the drug for the year," as determined by the Secretary using survey data.[2] If acquisition costs are unavailable, the statute requires that payment be set at the average price for the drug established under section 1842(o), 1847A, or 1847B (e.g. ASP plus six percent or the rates determined under the Competitive Acquisition Program).[3]

BIO supports this approach because it is consistent with the statute and Congressional intent to reimburse hospitals for these therapies based on either an accurate methodology to determine average acquisition cost for each drug or the rates established under section 1842(o), 1847A, and 1847B of the SSA. Although CMS's adjustments for pharmacy overhead costs helped to produce more appropriate rates than would be achieved using the estimates of acquisition cost alone, CMS's reallocation methodology generated rates that varied from year to year. In contrast, the statutory default approach yields greater predictability in payment for drugs and biologicals under the OPPS. Furthermore, using the statutory default reimbursement method sets Medicare payment for drugs and biologicals at the same rate in the hospital and physician office settings, thereby encouraging patients to seek care in the most appropriate setting rather than selecting a setting based on reimbursement incentives. BIO appreciates CMS's recognition of the importance of providing predicable reimbursement within the OPPS and urges CMS to finalize this proposal for CY 2014.

In CY 2013 OPPS final rule, CMS indicated its intent to continue developing a methodology that more "accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately."[4] BIO supports this goal, and we look forward to working with the agency to develop an improved methodology, as appropriate payment is essential to ensuring patient access to drugs and biologicals in the most clinically appropriate setting and to avoid inappropriate, financially driven shifts in the site of care. Until such a methodology has been developed,

[2] SSA § 1833(t)(14)(A)(iii)(I).
[3] *Id.* § 1833(t)(14)(A)(iii)(II).
[4] 77 Fed. Reg. 68210, 68389 (Nov. 15, 2012).

we strongly support CMS's proposal to continue reimbursing drugs and biologicals at ASP plus six percent.

II. Proposed Changes to Packaged Items and Services

CMS proposes several changes to packaged items and services to achieve its "overarching goal… to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item."[5] CMS proposes to package certain items and services that it deems are "integral, ancillary, supportive, dependent, or adjunctive to the provision of care" of a primary service with the cost of that primary service.[6] These items and services include drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; drugs and biologicals that function as supplies or devices when used in a surgical procedure; clinical diagnostic laboratory tests; procedures described by add-on codes; ancillary services (status indicator "X"); diagnostic tests on the bypass list; and device removal procedures.

Although BIO supports CMS's goal to incentivize the efficient provision of care, we are concerned that these proposed policies will fail to satisfy a critical goal of the OPPS: that "overall payment is adequate to ensure access to appropriate care."[7] BIO is concerned that these policies do not adequately account for the importance of physician-patient decision-making, based on assessments of the clinical appropriateness of each aspect of a therapy regimen for an individual patient. BIO also is concerned that these payment policies will limit patient access to effective therapies, a concern heighted by the fact that CMS has not prospectively assessed the direct and indirect impact such policies may have on patients, and neither has it proposed mechanisms to retrospectively assess the ramifications of these proposed policy changes on patients. BIO believes that, in general, expanded packaging establishes a perilous precedent for the future. Our comments below first address significant issues with CMS' rate-setting methodology for CY 2014 that BIO believes prevent stakeholders from being able to provide informed feedback on the impact of the Proposed Rule's provisions. BIO goes on to address our concerns about the policy implications and potential effect on patient access of specific proposed changes to packaged services, which would exist even in the absence of such data concerns.

A. Issues in the CY 2014 Proposed OPPS Rate-Setting Process – CMS should not consider finalizing any proposed packaging policies until it resolves the inconsistencies in its rate-setting methodology and data calculations.

In previous years, BIO has often included in our comments independent analyses of the impact of specific proposed provisions. These analyses are based on utilizing CMS claims data to replicate its rate-setting calculations. However, for CY 2014, this effort has not been effective. A series of independent analyses, included in Appendix A, reveal numerous issues with the CY 2014 OPPS rate-setting methodology that call into question the accuracy and

[5] 78 Fed. Reg. at 43569.
[6] *Id*. at 43570.
[7] *Id.* at 43568.

completeness of CMS' published analysis. For example, while individual data elements contributing to the calculation of the geometric mean cost for APC 0634—the proposed APC for evaluation and management—could initially be replicated, efforts to employ CMS methodology to derive the mean cost did not yield a match to CMS' stated value. On the night of August 28, 2013—less than six days before the end of the comment period, CMS released files which address this issue and some—but not all—of the other issues raised by the analyses in Appendix A. BIO continued to hold serious questions about the reproducibility of the agency's rate setting methodology in the data that CMS released, and based on the limited time available to analyze these issues, only a preliminary analysis of the revised files had been possible. On September 5—just one day before the end of the comment period—CMS released another correction for the proposed rule, as well as a limited extension for the comment period. Unfortunately, the time allowed for the comment period extension does not allow BIO to conduct a full analysis and provide a detailed response for the changes in the data files of the proposed rule. BIO's subsequent comments in this letter therefore reflect that fact.

The lack of reproducibility of CMS rate-setting methodology prevents a detailed and predictive analysis of the impact of these policies both from CMS and external stakeholders. Because the OPPS relies on interdependent calculations, the rate-setting process can be highly sensitive to changes in individual data elements. This creates the potential for significant distortions across the spectrum of OPPS reimbursement rates. To ensure that the impact of proposed polices is well understood by both CMS and external stakeholders, BIO urges CMS not to consider finalizing any of the proposed packaging policies until such a time as replicable methodologies and data are made publically available, likely not before the CY 2015 OPPS update. Without these methodologies and data, BIO and other members of the public cannot comment meaningfully on CMS's proposals.

B. <u>Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Surgical Procedure</u> – CMS should continue separate payment for FDA-approved drugs and biologicals regardless of their function in diagnostic or surgical procedures. CMS also should restore separate payment for contrast agents and for diagnostic radiopharmaceuticals following the expiration of transitional pass-through payment.

CMS proposes to continue packaging payment for all diagnostic radiopharmaceuticals and contrast agents and to expand its list of "policy-packaged" drugs to include drugs and biologicals that function as supplies when used in a diagnostic or a surgical procedure. These proposals affect several drugs and biologicals that meet the statutory definition of a SCOD and thus are subject to specific statutory payment provisions, as well as drugs and biological that CMS has treated as SCODs under its longstanding policy of applying a uniform payment methodology to these therapies. BIO believes these proposals are inconsistent with the statute and Congressional intent and will harm beneficiary access to appropriate drugs, biologicals, and radiopharmaceuticals. As a result, BIO urges CMS not to implement them.

BIO firmly has rejected the packaging of diagnostic radiopharmaceuticals and contrast agents on the basis that CMS's rationale ignores the plain language of the statute as well as Congressional intent. On the same grounds, we disagree with the packaging of certain drugs and biologicals when used in a diagnostic or surgical procedure. The statute defines a SCOD as a "covered outpatient drug…for which a separate ambulatory payment classification group (APC) has been established" and that is a radiopharmaceutical or a drug or biological for which pass-through payments were made on or before December 31, 2002.[8] The statute does not distinguish between drugs and biologicals that serve a therapeutic modality and those used with other services. CMS does not have the authority to reclassify a drug or biological as a supply simply to avoid payment for these drugs and biologicals as SCODs.

Congress did not intend for CMS to circumvent the statutory payment provisions for SCODs by packaging entire classes of therapies. In certain cases, Congress allows CMS to package drugs and biologicals, but this authority is based on the cost, not the function, of the therapy. To package these drugs and biologicals based on function would render the statute's explicit payment instructions meaningless. We urge CMS to make separate payment at ASP plus six percent for all drugs and biologicals, regardless of their function, as CMS does for other SCODs and drugs and biologicals treated as SCODs. We also ask that CMS restore separate payment for contrast agents and for diagnostic radiopharmaceuticals following the expiration of transitional pass-through payment.

CMS proposes to package all skin substitute products based on their function. BIO believes this is impermissible by the plain language of the statute. Where products meet the definition of a SCOD, the SSA requires that payment be made either at the average acquisition cost for the drug or biological or under the statutory default. In the 2013 Final OPPS rule, CMS adopted the statutory default for SCODs and has proposed continuing this policy in CY 2014. BIO also is concerned about packaging skin substitutes because packaging provides incentives to use the least expensive therapy – not necessarily the most appropriate one for the patient. The proposal encourages an economic decision instead a clinical one by limiting access to skin substitutes that have received FDA premarket approval (PMA) with Level 1 evidence showing improved healing rates versus those with limited data and conventional treatment. PMA-approved therapies have been held to a higher evidentiary standard versus products with 510(k) clearance or human cells, tissues, or cellular or tissue-based product status. This policy removes the physician-patient decision-making process encouraging the use of lower cost wound dressings versus utilizing skin substitutes that have proven healing rates over conventional treatment. Using less expensive therapies that are not clinically optimal for the individual patient may lead to greater healthcare costs and lower quality patient outcomes over the long run.

The Proposed Rule additionally identifies stress agents in its discussion of therapies CMS believes appropriate for packaging: BIO strongly disagrees. Stress agents can be used to induce requisite cardiac stress prior to myocardial perfusion imaging (MPI), but the three stress agents that CMS identifies represent different procedural needs and levels of patient

[8] SSA § 1833(t)(14)(B).

satisfaction, among other distinctions. Exercise also is identified as an alternative to stress agents prior to MPI, but is only appropriate for patients who are able to undergo prolonged physical activity. Despite these differences between stress agents and between the use of stress agents or exercise, CMS proposes to package all MPI services at a single reimbursement rate. BIO urges CMS to reverse this proposal as it will only exacerbate our concerns about incentivizing decisions based on cost rather than clinical appropriateness. The differential cost of using different stress agents or using exercise is paired with significant differences in clinical appropriateness of one mechanism over the other for individual patients. Moreover, neither exercise nor stress agents are used at a one-to-one ratio with MPI, failing to meet CMS' threshold of "integral to" this diagnostic service. In fact because MPI employs each mechanism with substantial frequency, BIO is concerned about the accurate reporting of the use of stress agents if MPI services are bundled. For example, in cases where the use of stress agents are not specifically reported, CMS could assume exercise was used and would not necessarily make further inquiries. This would result in under-reported use of stress agents in MPI and could dramatically impact future rates for the MPI bundle, further skewing incentives away from the clinically appropriate use of stress agents. BIO urges CMS not to package stress agents on the basis that doing so would obscure important distinctions between different stress agents and between the use of stress agents or exercise, adversely impacting patient care.

If CMS does not make separate payment for these drugs, biologicals, and radiopharmaceuticals, the agency must ensure that payment remains sufficient to protect access to appropriate care. We are concerned about CMS's methodology for determining payment for packaged drugs, biologicals, and radiopharmaceuticals due to our experience with packaged diagnostic radiopharmaceuticals. CMS's methodology for determining payment for packaged diagnostic radiopharmaceuticals generates rates that do not reasonably and accurately reflect the true resource costs to hospitals offering diagnostic radiopharmaceuticals. Numerous radiopharmaceuticals with widely varying costs are packaged into a single nuclear medicine APC. In some cases, the payment for the procedure does not adequately cover the costs of the appropriate radiopharmaceutical and performance of the procedure. Paying separately for all drugs, biologicals, and radiopharmaceuticals following the expiration of transitional pass-through payment is consistent with the statute and Congressional intent and is the best way to ensure beneficiary access to appropriate care.

C. <u>Procedures Described by Add-On Codes</u> – CMS should continue to make separate payment for all add-on codes, including the codes for drug administration services.

For CY 2014, CMS proposes to unconditionally package all procedures described by add-on codes in the OPPS, including the codes for sequential, additional, and concurrent drug administration services. Many complex drug and biological regimens involve multiple administration services and additional hours of infusions. Further, the duration of infusion for a drug or biological is dictated by its labeling, with length of infusion times chosen to assure patient safety. Therefore, it is impossible to conclude that infusion times above a certain threshold are "incremental".

CMS's coding guidance instructs hospitals to report "only one initial service per encounter, for each vascular site, no matter how many types of infusion services are provided."[9] All additional hours and additional services through the same vascular access site are reported via the sequential, concurrent, or additional hour add-on codes. Under the Proposed Rule, payment for all of the additional drug administration services and additional hours of infusion services would be packaged, along with all drugs below the packaging threshold and all policy-packaged drugs.

We are deeply concerned that the proposed payment rates for primary services and their associated add-on codes would not be sufficient to cover hospitals' costs for these services and drugs. CMS's proposal "to unconditionally package all procedures described by add-on codes in the OPPS"[10] will adversely impact adequate reimbursement for the provision of complex therapeutic regiments, such as chemotherapy infusion. The surgical service add-on "incremental" procedure example included in the proposed rule is not relevant in the case of add-on codes that describe the administration of drugs and biological. Unlike surgical procedures where treatment patterns might be fairly standard, choice of pharmaceuticals in practices such as oncology have significant variability based on clinical decision-making. The length of time such therapies are used varies considerably among patients, and BIO is concerned that a single reimbursement for these packaged procedures fails to capture adequately these differences. Inadequate reimbursement for these therapies will impede patient access to them.

Further, as a result of eliminating payment for add-on codes in the outpatient setting, CMS will be unable to compare the cost of providing these same services in the physician offices. We discuss elsewhere CMS's efforts to collect data on off-campus provider-based departments to compare with the same services in physicians' offices. Not having access to similar data across the two settings will make it harder to make such comparison.

In addition, BIO objects to the bundling of add-on codes because it affects payment for electromyography (EMG) and electrical muscle stimulation guidance (e-stim) and will disincentive the performance of these procedures when medically necessary. CMS should not package items or procedures unless they are performed in a one-to-one ratio with the primary procedure (or at least nearly so). By definition of an "add-on procedure," a primary procedure is performed 100% of the time that the add-on procedure is performed. The converse is not necessarily true, however; an add-on procedure is not performed 100% of the time that the primary procedure is performed. When the procedures are essentially always paired, it is reasonable to package them together. However, when they are not paired in all cases, then setting the payment rate as a packaged payment provides a significant disincentive to perform the add-on procedure, when necessary, because there will be no additional payment.

[9] Medicare Claims Processing Manual, Ch. 4, § 230.2.C.
[10] 78 Fed. Reg. at 43573.

We urge CMS to continue to pay for each component of a therapy separately to ensure adequate and appropriate reimbursement. This is the best way to ensure procedures are individualized to patient needs.

D. Ancillary Services – CMS should continue to make separate payments for all ancillary services currently assigned a status indicator of "X".

As part of its approach to making "the OPPS be more of a prospective payment system through expanding packaging,"[11] CMS proposes to conditionally package all ancillary services assigned a status indicator "X" when they are performed with another service; they will continue to be paid separately when performed alone. BIO urges CMS not to finalize this policy as it could disrupt the efficient provision of care and limit access to these services when it is appropriate for them to be performed in conjunction with another service. BIO disagrees with CMS' characterization of these tests as "minor", as many are critical to the diagnosis and treatment of life-threatening diseases such as cancer (e.g., blood tests, tissue exams by pathologists, surgical pathology procedures). If finalized, the proposal to conditionally package these services may incentivize inefficient care if patients are asked to make additional visits instead of receiving all necessary services during the same visit. Moreover, decreased reimbursement for these services—especially in the context of other statutory cuts and the impact of sequestration—could decrease their appropriate use, limit patient access, and impact patients' ability to make well-informed decisions with their physicians about treatment options. To avoid these consequences, BIO urges CMS to continue to pay for ancillary services separately in CY 2014.

III. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals – CMS should make separate payment for all drugs and biologicals with HCPCS codes or, alternatively, should not increase the packaging threshold for these therapies. If any drugs and biologicals remain packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636.

CMS has rapidly increased the packaging threshold over the past 4 years. In 2010, the threshold was set at $65, and CMS increased it to $70 in 2011, $75 in 2012, and $80 in 2013. For CY 2014, CMS proposes to increase the threshold to $90, a 40% increase from the threshold set in 2010.

BIO believes this rapid increase is inconsistent with Congressional intent. When Congress enacted the definition of a SCOD, it also established a packaging threshold of $50 for drugs and biological in 2005 and 2006.[12] Congress codified the $50 threshold for these years because it objected to the $150 packaging threshold that was in effect in 2003 and wanted to lower the threshold. The absence of a statutory requirement regarding a packaging threshold after 2006 should not be interpreted as support for widespread packaging.

[11] Id. at 43574.
[12] SSA §1833(t)(16)(B).

BIO asserts that CMS should make separate payment for all drugs and biologicals with HCPCS codes in the OPPS just as the agency does for these therapies when they are administered in a physician office. If this recommendation is not implemented, at minimum, the packaging threshold should not be increased above the current level. To the extent that drugs and biologicals continue to be packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636.

We recognize and appreciate that CMS has encouraged hospitals "to change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, when specific HCPCS codes are available for those drugs and biologicals."[13] A more firm instruction from CMS is necessary, however. Requiring hospitals to bill for drugs and biologicals using HCPCS codes and revenue code 636 will provide CMS with better data for future rate-setting if CMS does not continue to reimburse all separately payable drugs and biologicals at ASP plus six percent after CY 2014. In addition, under the Affordable Care Act, CMS is now required to measure drug utilization to calculate the pharmaceutical tax, and our recommended instructions to hospitals would help CMS to satisfy this new requirement.

CMS should continue to require procedure-to-radiolabeled product edits for nuclear medicine claims in order to ensure that the claims data provide complete information about use of radiopharmaceuticals. CMS proposes to discontinue these edits but anticipates that hospitals will continue to report the codes. BIO is concerned that once the edits are removed, hospitals may not report the packaged radiopharmaceuticals, and CMS would not be able to collect complete cost data for these services. We request that CMS continue to apply these edits to ensure that it collects the cost data needed to establish appropriate payment rates.

IV. Proposed Payment Policy for Therapeutic Radiopharmaceuticals – CMS should continue to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer and reimburse these therapies at ASP plus six percent.

CMS proposes to continue its established policy of paying "for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals."[14] BIO urges CMS to finalize its proposal to reimburse non-pass through separately payable therapeutic radiopharmaceuticals at ASP plus six percent when ASP information is available. BIO agrees that using ASP data is the most appropriate way to pay for therapeutic radiopharmaceuticals.

V. Proposed Payment for Blood Clotting Factors – CMS should reimburse blood clotting factors at ASP plus six percent plus an updated furnishing fee.

[13] 77 Fed. Reg. 68210, 68389 (Nov. 15, 2012).
[14] 78 Fed. Reg. at 43609.

For CY 2014, CMS is proposing to pay for blood clotting factors at ASP plus six percent, "consistent with [its] proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue [the agency's] policy for payment of the furnishing fee using an updated amount."[15] BIO asks CMS to finalize its proposal to pay for blood clotting factors at ASP plus six percent plus an updated furnishing fee – consistent with reimbursement in physician offices and in the hospital inpatient setting – for CY 2014, consistent with our support for ASP plus six percent reimbursement for separately payable drugs, biologicals, and radiopharmaceuticals without pass through status.

VI. Proposed Establishment of Comprehensive APCs – CMS should continue to use the existing device-dependent APCs and ensure accurate payment for hospital-administered drugs.

CMS proposes "to create 29 comprehensive APCs to replace 29 existing device-dependent APCs" and "to make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service."[16] The comprehensive APCs would include items and services that are not typically reported as outpatient procedure costs, such as room and board, as well as hospital-administered drugs. In fact, "all medications provided by the hospital for delivery during a comprehensive service pursuant to a physician order, regardless of the route of administration, would be considered to be adjunctive supplies and therefore packaged as part of the comprehensive APC."[17]

BIO is concerned that this proposal is not premised on data-driven evidence: CMS is not proposing to conduct a demonstration project and has not otherwise offered findings from studies that model the impact of such a policy shift. Moreover, there were challenges with the data release that accompanied the issuing of the Proposed Rule that make it difficult for external organizations to analyze the potential consequences of this proposal. This lack of evidence exacerbates BIO's concern that including all hospital-administered drugs, regardless of the route of administration, in these comprehensive APCs will not accurately account for the frequency and duration of their use based on individual patient requirements. Use of drugs and biologicals may vary significantly from patient to patient, unlike other items and services that CMS proposes to package into the comprehensive APCs. As a result, the payment rate for a comprehensive APC might not provide adequate reimbursement for the specific drugs and biological an individual beneficiary needs, and hospitals would be discouraged from providing appropriate therapies. In addition, CMS has not prospectively assessed the direct and indirect impact such policies may have on patients, and neither has it proposed mechanisms to retrospectively assess the ramifications of these proposed policy changes on patients. As a result of this lack of evidence and the potential for adverse consequences for patient access, we urge CMS to continue using the existing device-dependent APCs rather than adopt the proposed 29 comprehensive APCs.

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[15] *Id.*
[16] *Id.* at 43558.
[17] *Id.* at 43560.

VII. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act – CMS should finalize its proposal to continue to adjust OPPS payments for certain cancer hospitals in CY 2014.

CMS proposes "to continue [its] policy to provide additional payments to cancer hospitals so that each cancer hospital's final PCR (payment-to-cost) ratio is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule."[18] CMS first implemented this adjustment for CY 2012, pursuant to section 3138 of the Affordable Care Act. Using the most current data available, CMS proposes to use a target PCR of 0.90 to determine the CY 2014 cancer hospital payment adjustment that would be paid at cost report settlement. BIO believes that CMS should finalize this proposal to adjust payment for certain cancer hospitals paid under the OPPS to result in a proposed target PCR equal to 0.90 for each cancer hospital. Cancer hospitals incur substantially higher costs than other hospitals paid under the OPPS. This adjustment helps to ensure that Medicare payments to these hospitals are adequate to cover the costs of care they provide.

VIII. Proposed Pass-Through Payments for Implantable Biologicals – Biologicals approved under BLAs should be eligible for pass-through drug status.

CMS proposes to continue its policy of treating implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) as devices for the purposes of the pass-through evaluation process and payment methodology.[19] Under this policy, CMS evaluates new implantable biologicals under the device pass-through evaluation process and packages payment for all nonpass-through implantable biologicals.

BIO continues to oppose this policy. Some implantable biologicals meet the SSA's definition of "biological"[20] even though they are approved by the FDA as devices. CMS believes these implantable biologicals "function as implantable devices," and therefore should be subject to the same reimbursement policies as devices.[21] CMS also has noted that biological and non-biological implantable devices share payment methodologies during their non-pass-through periods, have "overlapping and sometimes identical clinical uses," and "similar regulation by the FDA as devices."[22] CMS believes that "the most consistent pass-through payment policy for these different types of items that are surgically inserted

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[18] *Id.* at 43582.
[19] *Id.* at 43595.
[20] SSA § 1861(t)(1) ("The term 'drugs' and the term 'biologicals', except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.").
[21] 74 Fed. Reg. 60316, 60496 (Nov. 20, 2009).
[22] *Id.* at 60473.

or implanted and that may sometimes substitute for one another is to evaluate all such devices, both biological and nonbiological, only under the device pass-through process."[23] To implement this policy, CMS revised the pass-through regulations at 42 CFR §§ 419.64 to exclude implantable biologicals from consideration for drug and biological pass-through payment beginning on January 1, 2010.[24]

BIO urges CMS to allow biologicals approved by the FDA under a BLA to be eligible for pass-through payment as drugs, regardless of whether they are implanted. When Congress implemented the current payment system for SCODs that previously had pass-through status, it intended for biologicals approved under BLAs to be reimbursed under the specific statutory provisions for drugs.[25] Therefore, Congress clearly intended for these BLA-approved therapies to be reimbursed as pass-through drugs as well. Thus, our position is consistent with both with Congressional intent to reimburse biologicals approved under BLAs under the methodologies for drugs and biologicals and with CMS's goal of treating products approved as devices similarly.

If CMS continues to evaluate implantable biologicals for pass-through status as devices, CMS should clarify that it will apply the device pass-through criteria only to biologicals if they are solely surgically implanted according to their FDA-approved indications. In the final rule for 2012, CMS explained that it "mean[s] to exclude from consideration for drug and biological pass-through status any biological that has an indication such that it may function as a surgically implanted or inserted biological, even if there are also other indications in which the biological is not surgically implanted or inserted."[26] This interpretation of the regulation is inconsistent with CMS's prior description of its policy, its application of the policy to date, and the agency's billing instructions to hospitals for biological products that do not always function as devices.

In the final rules for 2010 and 2011, CMS describes the current approach as applying to "implantable biologicals that are *always* surgically inserted or implanted (through a surgical incision or a natural orifice)."[27] CMS also refers to its instructions to hospitals to not bill separately for biologicals that *sometimes* can be used as implantable devices when used as such.[28] Under these instructions, hospitals can bill separately for these biologicals when they are not used as implantable devices. In addition, the products that CMS has treated as implantable biologicals for determination of separate payment upon expiration of pass-through status have been products that are solely surgically implanted according to their FDA-approved indications.[29] To ensure that the regulatory text is consistent with CMS's policy and practices, we recommend that CMS revise the regulation to refer to "a biological that is not always surgically implanted or inserted into the body."

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[23] *Id.*
[24] *Id.* at 60474.
[25] Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, H. Rep. No. 108-391, at 679.
[26] 76 Fed. Reg. at 74280.
[27] 74 Fed. Reg. at 60532; 75 Fed. Reg. 71800, 71975 (Nov. 24, 2010) (emphasis added).
[28] 75 Fed. Reg. at 71928; 76 Fed. Reg. at 74310 (emphasis added).
[29] 74 Fed. Reg. at 60472, 60496; 75 Fed. Reg. at 71928; 76 Fed. Reg. at 74310.

IX. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments – BIO supports the goal of analyzing the trend of hospital acquisition of physician practices and resulting provision of physician services in an outpatient setting and supports the proposed methods of studying this trend.

In the Proposed Rule, CMS notes the increased trend toward hospital acquisition of physician practices and integration of those practices as a department of the hospital, with a resulting increase in furnishing of physicians' services in a hospital outpatient setting. CMS requests recommendations on how it can study the frequency, type, and payment for services furnished in off-campus provider-based departments of hospitals.

BIO applauds CMS's recognition of this growing trend and the significant impact it has on patients both in terms of where and from whom they receive their care, as well as the impact on patients' out-of-pocket costs. It is especially important to understand the effect of these changes on the quality and cost of care for patients receiving physician-administered drugs for chronic diseases and serious illnesses such as cancer. In the BIO supports the methods CMS has considered to study this trend as each has the potential to yield detailed data. BIO also recommends that CMS gather and analyze information on the types of hospitals that are driving this trend to determine if common characteristics exist that would help to explain those hospitals' rationales and incentives.

X. Conclusion

BIO thanks CMS for this opportunity to comment on the CY 2014 OPPS Proposed Rule. We again urge CMS to finalize its proposal to continue reimbursing separately payable drugs and biologicals at ASP plus six percent. We also urge CMS to continue making separate payments for drugs, biologicals, and radiopharmaceuticals, and drug administration services in the circumstances that we have described above. BIO looks forward to continuing to work with the agency to ensure that hospitals are reimbursed appropriately for the costs of acquiring, preparing, and administering drug and biological therapies so that beneficiaries will have appropriate access to them.

Please contact me at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel L. Todd
Managing Director, Reimbursement and Health Policy

APPENDIX

Issues in the reproducibility of OPPS payment policies in the FY 2014 rule

By Christopher Hogan, Ph.D., Direct Research, LLC

This paper summarizes difficulties I had replicating the OPPS 2014 proposed rule APC-level geometric mean costs. It focuses on issues that first arose in the 2014 rule. Throughout, I reference the OPPS 2014 proposed rule and associated data files as originally posted by CMS. The corrected files, posted by CMS on 8/28/2013, are referenced only where noted.

I place the problems in six categories. In some cases, I can show where CMS clearly appears to have made an error. In others, I can only show that my calculated rates differ from the CMS rates or that CMS may or may not have shown significant relevant information.

Theses areas are:

1) Some inputs to the rate-setting (the bypass list, the rates use to find highest-cost codes on claims) reflect prior-year rules. Making them consistent with proposed rules would create large changes in some APC rates.
2) The description of the comprehensive APCs required clarification. APC 0085 cost is much too high due to duplication of composite APC 8000 claims.
3) The visit APC costs appear wrong and are inconsistent between APC and CPT cost file.
4) Radiosurgery excluded certain obsolete codes.
5) Other miscellaneous surprises (e.g., missing wage index data).
6) Residual unexplained discrepancies between published and calculated rates.

A separate document describes why modeling the OPPS rates is so difficult.

1 Updating the inputs to the rate-setting process to reflect the new rules

CMS uses 2013 and earlier rules for some inputs to the rate calibration. When CMS says it selects the highest-paid service on a claim, it always means highest-paid based on *last year's rates*. (This is typically left unsaid, and is only stated in passing for Q2 services.) And, while CMS provides rules for inclusion of services on the bypass list, CMS typically (though not always) keeps services on the bypass list that it identified in prior year rules, without testing whether they continue to meet the criteria.

In years when changes in the rules are small, feeding obsolete (prior year) information into the rate-setting process is an understandable shortcut. As CMS makes the first pass through the data, it does not yet have the proposed-rule payment rates. Using current-year data would require passing through the data at least twice. In a typical year, the use of the obsolete data has only minimal impact on the rates. It scarcely matters that the way the payment rates are calibrated is not the way the claims will actually be paid.[1]

However, this year when packaging rules and payment rates shift dramatically, the CMS methods may show only part of the full transition to the new rates. The way services are *sorted to generate* the 2014 rates differs from the way they are *sorted to be paid under* the 2014 rates. For the bypass list, analysis by Dr. Susan White shows that the majority of codes on the list no longer meet CMS' criteria, largely as a consequence of the enhanced packaging rules. CMS can either ignore the inconsistency or review the bypass list in light of the change in packaging. If the latter, a revised bypass list will change the set of claims counted as "single-procedure" claims, resulting in changes in the APC rates.

The upshot is that applying the new rules consistently – using the 2014 prices to determine highest-paying codes, and using 2014 packaging to determine the bypass list -- will generate materially different rates than those shown in the proposed rule.

Table 1 shows high-volume APCs that will undergo the largest gains and losses if the rate calibration were made completely consistent. This table was derived by using 2014 prices to find highest-paying codes on claims, and constructing the bypass list using CMS's criteria along with the 2014 packaging rules.[2] The first two columns of numbers are CMS published data. The third column shows that we can replicate the CMS geometric means reasonably well. The fourth column shows what will happen (in 2015, say), when CMS uses 2014 prices as input to the rate calibration, and makes the bypass list consistent with the new packaging rules.

Whether or not CMS erred in failing to note this is debatable. Most of the change is due to making the bypass list consistent with CMS's criteria and new packaging rules. The original intent of the bypass list was to find codes that seldom involved significant packaged costs. But with the proposed packaging policy, most of those codes now include such costs. CMS could just ignore that inconsistency. But if it does not, the rates will eventually change as shown.

[1] When CMS actually pays the claims, it will use the current-year (i.e., 2014) rates to determine which APC is paid, for both the comprehensive APCs and for the conditionally-packaged services.

[2] Thanks to Dr. Susan White for supplying the revised bypass list.

OPPS 2014 Proposed Rule, Effect of Using Prior-Year Data as Inputs to Rate Calibration												
Services with at least 5000 single procedures, largest gains and losses if prices and bypass list were made consistent with 2014 proposed rule.												
		CMS as published				**Calculated from file**						
APC	**group title**	**Single Frequency**	**Geo metric mean**			**Use 2013 prices to sort codes, use historical bypass list**		**Use 2014 prices to sort codes, make bypass consistent with packaging rules**		**% change**		
Largest losses, 2015 versus 2014												
0368	Level II Pulmonary Tests	107,935	$	145		$	147	$	93	-37%		
0635	Type A Emergency Visits	6,760,593	$	215		$	252	$	196	-22%		
0274	Myelography	9,565	$	616		$	609	$	506	-17%		
0099	Electrocardiograms/Cardiography	1,302,504	$	74		$	78	$	66	-16%		
0433	Level II Pathology	658,726	$	59		$	60	$	54	-10%		
0189	Level III Female Reproductive Proc	8,866	$	216		$	218	$	197	-10%		
Largest gains, 2015 versus 2014												
0059	Level I Strapping	33,054	$	59		$	60	$	66	11%		
0332	Computed Tomography w/o Contrast	3,612,764	$	116		$	117	$	132	13%		
0191	Level I Female Reproductive Proc	28,772	$	11		$	11	$	12	13%		
0344	Level IV Pathology	38,951	$	280		$	295	$	336	14%		
0367	Level I Pulmonary Test	23,202	$	170		$	175	$	211	21%		
0432	Level II Health and Behavior Svcs	21,989	$	46		$	46	$	60	31%		
0260	Level I Plain Film Except Teeth	9,468,810	$	62		$	63	$	85	37%		

2 Comprehensive APCs

The majority of my time spent modeling the OPPS rates this year was spent on the new comprehensive APCs. In theory, these should have been simple. With few exceptions, add up the costs on the claim, and then summarize by APC. In practice, I ran into several issues, and never did successfully model all of the comprehensive APCs.

2.1 Ambiguous language in the Rule, logically inconsistent method chosen by CMS

Most of the difficulty arose from one simple question: When two or more comprehensive-APC codes appear on a claim, which one is paid? The proposed rule (78 Fed Reg 43560) says this: "Any claims that contained more than one of these procedures were identified but were included in calculating the cost of the procedure that had the greatest cost when traditional HCPCS level accounting was applied."

Because the rates change so radically between 2013 and 2014, I originally assumed CMS meant a two-step process. Calculate average cost, under the 2014 rules, for the claims with just one procedure (traditional HCPCS level accounting). Then assign multi-procedure claims using the 2014-rules cost of the single-procedure claims. That would come as close as possible to an internally-consistent process (where the ordering used to calibrate the claims matches the one used to pay the claims).

In fact, based on conversations with Dan Duvall at CMS, claims were assigned based on highest 2013 payment on any line, with full accounting for units of service billed. The description in the text "that had the greatest cost when traditional HCPCS level accounting was applied" actually meant APC (not HCPCS), and payment (not cost). Traditional apparently meant 2013. This is inconsistent with the way these claims will be paid both due to use of prior-year rates, and due to inclusion of units in the calculation (CMS will only pay for one unit of a code).

The 'units' clause particularly shuffles discharges among claims where multiple device leads can be implanted with a device. This is illogical in the sense that there is a difference between the claims as calibrated and the claims as paid, i.e., some claims that contribute to the cost of one APC will actually be paid under a different APC.[3] This makes a difference of a few hundred dollars in the rates of a few comprehensive APCs.

2.2 Incorrect geometric mean cost for APC 0085

I spent considerable time puzzling out what CMS did with APC 0085 and composite APC 8000. In 2012 (file-year) CPT coding, APC 8000 requires codes in APC 0085. Summing the claim counts on the cost files, CMS clearly duplicated some claims, because the total grossly exceeds the APC 0085 claims on the file.

The answer is that the APC 0085 cost is grossly too high. It includes all of the expensive composite 8000 claims, and it should not. In 2014 CPT, those composites will (largely or entirely) be coded with new CPT codes that automatically place them into 8000. Excluding the APC 8000 composite claims, the geometric mean cost of 0085 falls from the listed value of $11,633 to $4,943. Unsurprisingly, that's just modestly higher than last year's value of $4,035.

2.3 Illogical data in the APC and CPT cost files, Addendum A and Addendum B file

For many of the new comprehensive APCs, CMS shows more single procedures than total procedures on the cost statistics file. That should be impossible. Mostly that is due to too low a total count on the cost file, but for three procedures CMS literally shows more comprehensive claims than there are claims on the file (APCs 0108, 0293, and 0318).

Another complication in calculation of comprehensive APC rates is the conflicting information on the payment status for HCPCS codes assigned to comprehensive APCs (status indicator J1). You can't use the payment status on Addendum B to flag the J1 codes. You have to take the

[3] While this may not immediately strike the reader as odd, consider the comment it would raise if under the IPPS, CMS randomly shuffled claims among MS-DRGs, purely as a side-effect of the rate calibration process. That's analogous to what the OPPS does for the composite APCs.

payment status for the APC, then flag all codes in that APC. For example, for APC 0085, to get CMS's 0085 claims count, one must ignore the status on Addendum B and treat all the codes as J1 codes. (Possibly, this related to the 0085 error discussed above – that CMS intended to treat those codes differently but did not.)

I don't know the extent to which CMS has or has not corrected this on the 8/28/2013 files.

3 Visit APCs

CMS's APC-level cost file values for the visit APCs do not match the (correctly-calculated) sum of the CPT-level data. My estimated match the CPT-level data. If you roll up the CPTs in APCs 634, 635, and 636, you end up with about the right singles count, but with a geometric mean that is 11%, 17%, 8% over the geometric mean showing on the APC file.

This error appears to have been corrected in the revised files that CMS related on 8/28/2013.

4 SRS/SBRT, omission of obsolete codes

For Stereotactic Radio Surgery (SRS) and Stereotactic Body Radio Therapy (SBRT), CMS, inconsistent with past and current practice, did not use the data for predecessor codes (G0173, G0251, G0339,and G0340) that are deleted in this rule to calculate the payment rate for the replacement codes (77371, 77372, and 77373). There were a few other codes that this applies to but the SRS/SBRT codes were the only ones with significant claim volume. This appears to be an error.

This error appears to have been corrected in the files released on August 28th.

5 Other new issues with the 2014 OPPS proposed rule

5.1 Missing wage index data

This year, for the first time ever, about 0.5% of claims have no wage index. This is for about 40 hospitals. Because this has never occurred before, I only found it by accident. It's not clear what CMS did with them. In all prior years, analysts either had to put the wage index on each claim (earlier years) or CMS put the wage index on each claim (later years). Either way, it has never been missing before.

5.2 Ambiguity of use of procedure-to-device edits

CMS says they propose to abandon the procedure-to-device edits, but the cost file is still "after screens". Not that it matters much in this file, as the claims wouldn't have been paid without satisfying the edits. But it would be nice to know what CMS actually did.

5.3 Inconsistencies between CMS CPT and APC cost files

In theory, the APC cost file is supposed to be a summary of the CPT cost file, ignoring certain not-elsewhere-classified and miscellaneous services codes. It is not. The table on the next page shows all the APCs where there was a discrepancy of greater than 1% in either the count or the geometric mean or both.

Inconsistencies between CMS published CPT and APC cost files, 2014 proposed rule					
Unlisted services omitted using CMS published 2013 list					
Note: Some of these probably were corrected in the 8/28/2013 corrected files.					
	APC cost file		**Summary of CPT cost file (excluding unspecified, miscellaneous, N.E.C. codes)**		**Discrepancy**
APC	**single frequency APC**	**geometric mean APC**	**single frequency cpt**	**geometric mean cpt**	**single frequency error**	**geometric mean error**
0635	6,760,593	$ 215	6,773,576	$ 252	0%	17%
0634	20,396,735	$ 89	20,433,216	$ 99	0%	11%
0061	2,357	$ 8,906	2,140	$ 7,985	-9%	-10%
0318	708	$ 27,226	644	$ 26,981	-9%	-1%
0636	175,374	$ 86	175,375	$ 92	0%	8%
0108	20,110	$ 31,911	18,583	$ 32,251	-8%	1%
0432	21,989	$ 46	21,989	$ 49	0%	7%
0040	9,605	$ 5,539	9,109	$ 5,303	-5%	-4%
0137	14,665	$ 1,628	14,665	$ 1,711	0%	5%
0207	609,426	$ 687	609,426	$ 668	0%	-3%
0106	2,741	$ 5,932	2,669	$ 5,818	-3%	-2%
0241	1,630	$ 2,001	1,630	$ 2,049	0%	2%
0075	5,094	$ 2,378	5,094	$ 2,338	0%	-2%
0382	30,176	$ 202	30,176	$ 199	0%	-2%
0039	20,271	$ 21,370	19,962	$ 21,426	-2%	0%
0315	1,615	$ 23,447	1,591	$ 23,392	-1%	0%
0279	51,881	$ 2,700	51,881	$ 2,662	0%	-1%
0648	3,540	$ 7,140	3,491	$ 7,131	-1%	0%
0074	15,530	$ 1,547	15,530	$ 1,568	0%	1%
0293	152	$ 8,604	150	$ 8,624	-1%	0%
0319	4,669	$ 17,333	4,613	$ 17,326	-1%	0%
0030	6,876	$ 4,126	6,876	$ 4,083	0%	-1%
0083	229,696	$ 4,587	227,391	$ 4,592	-1%	0%
0229	81,318	$ 10,576	80,598	$ 10,570	-1%	0%
0227	4,574	$ 15,528	4,538	$ 15,527	-1%	0%
0425	3,815	$ 10,191	3,785	$ 10,174	-1%	0%
0206	45,810	$ 364	45,810	$ 367	0%	1%
0082	12,304	$ 10,446	12,208	$ 10,449	-1%	0%
0259	2,072	$ 30,240	2,056	$ 30,226	-1%	0%
0104	19,557	$ 8,888	19,415	$ 8,881	-1%	0%
0253	9,771	$ 1,292	9,771	$ 1,301	0%	1%
0202	24,378	$ 4,842	24,222	$ 4,843	-1%	0%

Inconsistencies between CMS published CPT and APC cost files, 2014 proposed rule								
Unlisted services omitted using CMS published 2013 list								
Note: Some of these probably were corrected in the 8/28/2013 corrected files.								
	APC cost file			**Summary of CPT cost file (excluding unspecified, miscellaneous, N.E.C. codes)**			**Discrepancy**	
APC	**single frequency APC**		**geometric mean APC**	**single frequency cpt**		**geometric mean cpt**	**single frequency error**	**geometric mean error**
0091	9,183	$	2,956	9,183	$	2,974	0%	1%
0252	4,853	$	568	4,853	$	571	0%	1%
0237	1,058	$	1,556	1,058	$	1,565	0%	1%
0674	1,914	$	8,030	1,903	$	8,040	-1%	0%
0231	6,227	$	263	6,227	$	261	0%	-1%
0656	73,880	$	10,526	73,469	$	10,517	-1%	0%
0131	88,950	$	3,803	88,950	$	3,783	0%	-1%
0051	8,091	$	3,880	8,091	$	3,860	0%	-1%

5.4 Bypass list

As noted earlier, the bypass list is now grossly inconsistent with CMS's criteria, and the new packaging rules. The bypass list has repercussions throughout the APCs, because it plays a role in determining what claims are counted as "single procedure" claims.

6 Residual unexplained discrepancies and summary of discrepancies.

The table below shows where my estimated APC geometric means differ from the published values by more than 5 percent. I have divided these discrepancies into those newly arising in the 2014 proposed rule, versus discrepancies that existed to some degree in prior rules (and so reflect unknown but long-standing differences between what CMS does and my calculation).

2014 Proposed Rule, APCs With Discrepancy Between CMS Published and Calculated Values								
All APCs where published and calculated mean cost disagreed by 5% or more.								
For single-procedure claims and geometric mean cost								
			CMS published		**Calculated**		**Memo: CMS CPT and APC cost files disagree?**	
APC	**group title**		**Count**	**Mean**	**Count**	**Mean**	**Count**	**Mean**
New issues with 2014 rule								
0040	Level I Neuro. Electrodes	J1	9,605	$ 5,539	9,044	$ 5,269	Yes	Yes
0061	Level II Neuro. Electrodes	J1	2,357	$ 8,906	2,257	$ 8,491	Yes	Yes
0099	Electrocardiograms	S	1,302,504	$ 74	1,238,246	$ 78		
0106	Pacemaker	J1	2,741	$ 5,932	2,530	$ 5,262	Yes	Yes

0137	Level VI Skin Repair	T	14,665	$ 1,628	14,677	$ 1,717		Yes
0634	Hospital Clinic Visits	V	20,396,735	$ 89	20,410,510	$ 100		Yes
New issue or exacerbation of pre-existing discrepancy								
0633	Level 3 Examinations	V	3,925	$ 359	21,400	$ 768		
0635	Type A Emergency Visits	V	6,760,593	$ 215	6,640,083	$ 252		Yes
0636	Type B Emergency Visits	V	175,374	$ 86	171,615	$ 93		Yes
Exacerbation of pre-existing discrepancy								
0344	Level IV Pathology	S	38,951	$ 280	39,071	$ 295		
0345	Level I Transfusion	S	277,709	$ 85	253,331	$ 92		
0346	Level II Transfusion	S	15,020	$ 144	9,514	$ 221		
0370	Multiple Allergy Tests	S	1,392	$ 822	1,057	$ 556		
0381	Single Allergy Tests	S	295	$ 118	198	$ 77		

Why is it so hard to model the OPPS rates?

By Christopher Hogan, Ph.D., Direct Research, LLC

This paper summarizes difficulties that we have in replicating the OPPS rules historically. It is impossible to fully understand the difficulties in reproducing the payment policies in the FY 2014 proposed rule without an understanding of the ambiguous and haphazard nature of replicating the OPPS rule in past years. The difficulties in replicating the policies this year compared with past years were compounded by the number of and ambitious nature of the new payment policies proposed this year.

Modeling CMS' OPPS rates is a complex task. By way of illustration, the computer program that CMS uses to *price* outpatient claims runs 960 single-spaced 8.5x11 pages.[1] And pricing the claims (attaching the correct payment rates to the services) is substantially simpler than determining those OPPS rates in the first place.

This task is *inherently* complex, for several reasons. First, over time, CMS has developed a large body of ad-hoc rules governing the determination of the rates. A partial list of rules includes:

- What claims constitute "single procedure" claims, and the various steps allowed for breaking up larger claims into fragments to be counted as single procedure claims.
- What procedures can be ignored for that process (the bypass list).
- Which combinations of codes count as if they were a single procedure (composite APCs).
- Which combinations of codes *sometimes* count as if they were a single procedure (imaging composites).
- What costs are packaged.
- What services are sometimes packaged, depending on circumstances.
- Special rules and edits applying to specific services (allergy tests, hyperbaric oxygen, and others).
- Statistical trims for cost, cost-to-charge ratio edits, crosswalks from revenue center codes to cost report lines, device-to-procedure edits, edits for partial-credit devices … and so on.

Each of these ad-hoc rules has the potential to interact strongly with the others in unpredictable ways. For example, in the 2014 rule, CMS packaged ancillary services (payment status X). This decision greatly *reduced* the number of single-procedure claims in several unrelated APCs. Why? Where the status X code was formerly on the bypass list, this created packaged costs on claims that formerly had none. In turn, that blocked creation of single-procedure claims where multiple payable codes occurred on a claim without packaged costs. This unanticipated drop in single-procedure claims was due to the interaction of bypass list, the single-procedure claim algorithm, and packaging policy.

Second, each of the underlying claims contains a mix of unrelated services, creating additional unpredictable interactions. For example, imaging, tests, and surgery will typically be found on the same claim. Changes in the treatment of one type of code (e.g., ancillary tests) can

[1] http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PCPricer/Outpatient-PPS-Pricer-Code.html

profoundly affect the set of single-procedure claims used to estimate costs for a completely unrelated code (e.g., surgical services that happen to involve that test routinely.)

These interactions – among the rules and among services on the same claim -- mean that modest changes in implementation of one rule may have large and unexpected effects on seemingly unrelated APCs. Looking at that the other way around, interactions among rules and the spillovers across claims often make it impossible to determine why a particular modeled APC rate differs from the published CMS value.

The result is a system that is ludicrously difficult to "debug". When modeled and published APC rates differ, it is often impossible to determine why the discrepancies occur. Discrepancy between modeled APC rates and the rates published by CMS may result from a) a mistake directly related to that APC, b) a mistake on some completely unrelated APC, or c) a seemingly trivial difference of opinion on the exact meaning of some portion of some rule, that one would not even call a mistake. And the mistakes can be either by CMS, by the modeler, or both.

Modeling each year's OPPS then becomes an iterative guessing game. That is, guess what the error might be, then test that guess -- over and over. And because the rules interact with each other, and the services are commingled on claims, the only way to test each guess is to modify the underlying programming *and re-run the rate-setting model in its entirety*.

This is labor-intensive and consumes substantial calendar time. In a good year, this process proceeds until there is a reasonably good fit between modeled and published APC rates. In a bad year, the work proceeds until the available time runs out. The 2014 proposed rule was a particularly bad year.

CMS complicates this already difficult process in two ways.

- First, written descriptions of the rate-setting process are typically unclear and sometimes contradictory.
- Second, CMS often makes small and large technical mistakes, both in its published cost and rate files, and in its underlying programming.

1. Written descriptions of the rate-setting process are typically unclear and sometimes contradictory

There is a fundamental and long-standing problem with the documentation of the programming logic for the payment system. The description of how CMS goes about generating the single-procedure claims, in the proposed rule text and in the claims accounting document are supposed to be describing the same process, but they are different in terms of the order in which steps occur in the processing. Doing steps in a different order can have very different results on payment rates. Further, the logic often refers to CMS assigned properties of HCPCS codes to determine the logic branch that that that claim should take, for example the status indicator of a code or whether it appears on the bypass list. I will call these look-up tables. The status indicators and the codes on the by-pass list change from year to year and the documentation does not describe which year of the look-up tables is to be used, the year the claim was paid, the

current year, or the new proposed status. When there are numerous changes in the policies, the year chosen can also have a significant effect on the results. In past years through trial and error I have been able to determine which was used. The look-up tables used have often been from past years and thus not internally consistent with the policies proposed in the rule in question.

Another longstanding issue involves the payment status indicator, while CMS assigns ONE payment status, you need three or four to show what the actual payment status of a code is, for purposes of rate calibration. You often have to hunt out what the actual payment status is, in any one situation. For some codes, CMS lists different payment statuses on different supporting files, e.g. Addendum B and Addendum M, which further complicates the situation.

A particularly problematic example is: 75635 Ct angio abdominal arteries. This year, I noticed in the rule a discussion about forming the imaging composites (Q3) except when the code is a conditionally packaged (Q2) code, in which case, we conditionally package first, and then form the imaging composite. How can a code be both Q2 and Q3? Well, that's the code. You have to start it in the processing as Q2, do the conditional packaging, then if it survives, flip it to Q3, and carry on with forming the imaging composites. The only way to tell that is to take Addendum M, map on the Addendum B status, and see that for that one code, it's Q3 on M and Q2 on B.

In fact, there are all kinds of cases where you have to change the payment status of a code mid-way through processing in order to get the cost numbers that CMS publishes. In my processing, I count four separate, distinct payment statuses, depending on the situation. I believe I now process those as CMS does, but CMS does not adequately document the process and I could only replicate the published cost numbers by trial and error.

An example of the complexity of the programming logic follows. You have a bunch of status Q3 imaging HCPCS on a claim. You resolve those and determine which ones are and are not part of an imaging composite. You then need to resolve the Q1s on the claim. In order to do that (I think) you must flip the Q2s to their ultimate payment status (typically S), and if Q1s appear on the same claim, they are then packaged. So a Q1 code, on same claim and date as a Q3 code, will get packaged, one way or the other. But, nominally, Q1s only package under STV codes. You have to flip the Q3 to S to get that right. (But for imaging composites, do that for only one code in the composite.)

The programming logic is extraordinarily complicated. It started out complicated at the beginning of the payment system and has only gotten more layers of complication added to it.

2. **Small and large technical mistakes, both in its published cost and rate files, and in its underlying programming**

Each year has brought its own errors that are not documented in the rule text or claims accounting and can only be surmised by the trial and error process of trying to replicate CMS's published cost numbers. Below is a sample of transient problems from past years:

- When CMS first put the "MJMC" indicator on the claims file to show the payment status of each code and claim, it turned out that these were the obsolete payment status from the year in which the claim was paid and not status for the proposed rule year. They now reflect service and claim status under the proposed rule, not as they existed in the claims payment year.

- There have been services grossly mispriced and over-paid, due to errors in the crosswalk between cost report line and claims revenue center. One service was paid about 80% too much for a year before we brought that to CMS's attention.

Sometimes the inconsistencies or mistakes resolve themselves in the next rule cycle and sometimes they persist over time. CMS never publically documents them.

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Data analysis informing sound policy

Policy Issues Introduced in the 2014 OPPS Proposed Rule
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It is impossible to fully understand the difficulties in reproducing the payment policies in the FY 2014 proposed rule without an understanding of the ambiguous and haphazard nature of replicating the OPPS rule in past years. The difficulties in replicating the policies this year compared with past years were compounded by the number of and ambitious nature of the new payment policies proposed this year.

Even if the exact programming logic was well documented including all look-up tables, the tremendous complexity of the logic of the processing is far beyond other payment systems that CMS administers, such as the Inpatient Prospective Payment System (IPPS). This undoubtedly due to the impossible task set out for this payment system from the start. From the beginning of the OPPS, the payment policy has tried to be somewhere between a fee-schedule paying for each service and a bundled payment system that packages items together so as to create incentives for efficiency. This year's policies are an attempt to move the system further toward the bundled payment without an appreciation of the tangled thicket that the current rate-setting programming logic is or the preliminary research that is required to design a bundled payment program properly.

Even when a classification system is well researched translating that to bundled payment can have its own "intended and unintended sequelae." It is worthwhile remembering that the IPPS system originally implemented in 1983 was based on a classification system designed as a hospital management tool that took years of research to develop. The developer of the DRG classification system, John D. Thompson warned that "probably the most important observation about DRGs is that the payment system has demonstrated that hospitals and clinicians will alter their patterns in response to economic incentives far more subtle than stock options or performance bonuses. Any consideration of future replacements for DRGs should remember this lesson." [1]

An example of the potential unintended sequelae is the packaging of clinical lab services and ancillary services. The clinical lab fee schedule (current payment rates) has much lower rates than the "costs" that appear on the claims file. The effect of packaging the clinical lab services is to inflate the costs for the services where these costs appear relative to what would be paid if they were to continue to be paid separately under the fee schedule payment rates. All other things being equal this raises overall Medicare costs.

[1] Thompson, JD. DRG prepayment: its purpose and performance. *Bull N Y Acad Med*. 1988 Jan-Feb;64(1):28-51. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1630001/

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Data analysis informing sound policy

Also in the short term, if they conditionally package clinical labs (and the same logic applies for other ancillary services), providers will respond by performing these services on a different day whenever possible so that they can get the additional reimbursement. The net result is that CMS will pay for some portion of the ancillary in the APC for the procedure and pay again when the ancillary services are performed on a different day. This has the additional unintended consequence of inconveniencing the patient. The likely and predictable net effect is to raise costs to Medicare and lower quality. If the claims payment system were able to handle a payment window (include days around a procedure in the package), then the problem may be mitigated, though not eliminated. Such a claims payment processing change would take time to implement and likely could not be ready for 2014. The issue of the 'cost' of the clinical labs on the claims compared to the fee schedule would still remain.

The timeframe of a proposed rule comment period is not sufficient to respond to such broad and significant policy proposals. The claims file that is needed by outside analysts to replicate the CMS methodology and assist clients in responding to the rule is at best released the same day as the rule is released (assuming that the requester has been pre-cleared for receipt with a data use agreement). At best, that leaves only 60 days to program all the new policies and through trial and error figure out the logic that is not documented and conduct all the client specific analysis. The timeframe is even shorter when there are delays in shipping the file due to lost orders or other administrative delays that can occur with the privacy office or the vendor that fulfills data orders. Due to the extraordinary complexity of the payment logic and the historically undocumented idiosyncrasies, multiple data runs each lasting 12 hours or more are needed during the process of attempting to replicate the CMS logic. As a result only three consultants have been able to come close to replicating CMS's rates and are the only sources of in-depth analysis of CMS policies for every interested party that wants to comment meaningfully on the rule. For rules with significant policy changes, the resulting workload is untenable.

If the intent is to move the OPPS payment system to a true bundled payment system and eliminate the fee schedule aspect of payment, then the arguments laid out here call for a more thoughtful and deliberate process. First, solid research into what would be clinically appropriate bundles needs to be done, including possibly length of time around a service which would be bundled and investigating the impact of patient specific characteristics on resource use. Then the research, with accompanying data files, needs to be publicly available for comments. Second, a plan for how to transition a classification system to a payment system with its accompanying predictable behavior changing incentives should be described and proposed payments calculated. This also should be available for public inspection, with all necessary data files, with a comment period that is appropriate to the complexity of the plan. This would most likely be longer than 60 days. Then a new payment system could be responsibly rolled out. There will still be unforeseen and unintended consequences, but such a process will minimize sequelae.

Issues in the CY2014 Proposed Outpatient Prospective Payment System (OPPS) Rate-setting Process

Updated on: September 6, 2013

In The Moran Company's review of the Centers for Medicare & Medicaid Services' (CMS) Proposed Outpatient Prospective Payment System (OPPS) Rule for Calendar Year (CY) 2014 and our attempts to replicate the agency's rate-setting methodology, we found numerous issues and inconsistencies which call into question the accuracy and completeness of the CMS published analysis. At a minimum, we believe that additional information, clarifications, and potentially corrections are necessary in order to more appropriately document CMS' methodology and allow the public to understand the CMS analysis.

In the evening of August 28, less than six business days before the end of the OPPS comment period, CMS released new data files that correct some of the issues we had identified. Then, on September 5, one day before the comment period ended, CMS released a correction notice that provided a brief description of the issues addressed in the August 28 data files, and extended the comment period for issues relating to the new data to September 16. This document is an updated version of our previous report dated August 22. In this update, we provide an accounting of the issues that CMS has corrected, and the data concerns still outstanding. We note that given the late release date of the new files, we have only been able to perform preliminary analyses of the updated files. The complexity of the OPPS requires significant time to run the replication and alternatives. The release of the files so close to the end of the comment period has limited the analyses possible prior to the end of the comment period—even with the comment period extension due to the length of time required for running simulations. In addition, changes can have unintended consequences which there is not time to explore and understand.

Introduction

In order to help our clients evaluate proposed policies in the OPPS proposed rule each year, The Moran Company attempts to match the OPPS published rates by replicating the OPPS rate-setting methodology. We use those results as a baseline, against which we compare the effects of the proposed policies.

The payment weights and then payment amounts are based on historical OPPS claims that have been split apart to represent a major procedure and accompanying costs (a combination used in rate-setting is known generally as a "single bill" or "single." Although there are several types of "singles," we will use the term to refer to any part of a claim used in rate-setting). These singles are then combined into different Ambulatory Payment Classification (APCs) groups by HCPCS code. The geometric mean cost of an APC is compared against a reference APC to assign a weight and then a payment amount.

This system is complex, and subject to sensitivity in both what is determined to be a single and the cost characteristics of each single.

Historically, we have been able to match the CMS published statistics with a great deal of accuracy. We generally start by comparing our counts of the number of singles used in rate setting and the geometric mean cost (median cost in previous years). We do this at the HCPCS and APC levels. For example, with the CY 2013 Final Rule, for the count of singles, we had more than 66% of the HCPCS codes within 0.5% of the CMS published figures and over 90% of the HCPCS codes within 5% of these counts. When comparing geometric means on a case weighted basis, we had over 80% within 0.5% of the CMS published figures, and over 99% within 5.0%. Our APC results were similar.

In contrast, even after multiple and significant attempts to incorporate the CMS policy proposals for CY2014, our comparisons with the agency's figures are further apart than previous years—even after incorporating the most recent updated files.. There is enough of a discrepancy that we engaged in significant efforts to identify elements that could lead to differences between our analyses and the agency's.

Based on our research using the data, comparisons and examinations of the published statistics in the rule, we have found several issues which call into question the accuracy of some of the estimates CMS published with the rule.

This brief report lays out some of the major issues that we have identified to date. These range from issues of numbers that CMS reported that appear to conflict with the data released and other calculations, to internal inconsistencies between tables and appendices that CMS has released, to theoretical issues. These issues, both individual and jointly, could have dramatically affected the CMS released results and the potential expected impact of proposed policies.

The issues to be discussed are:

- Calculation of the geometric mean cost for APC 0634;
- Inconsistent status indicators in CMS published appendices; and
- Treatment of E&M codes and the bypass list.

Update: As detailed below, CMS has corrected the issue related to the geometric mean cost for APC 0634, and partially corrected the inconsistent status indicators of the published appendices. The treatment of E&M codes on the bypass list is not addressed. In addition, our replication is still not comparable to what we have achieved in previous years and we have concerns that other issues in the data and documentation remain.

It should be noted that each issue raised here can have interactions with the other issues. These issues may make it problematic for the public to understand the analyses CMS used to support the policies of the proposed rule, thereby making it difficult for the public to comment on the proposals in an informed way. Finally, we would note that these issues affect other proposals, such as packaging, not directly discussed in this document.

We do not believe that this is an exhaustive list of issues, but merely those we have been able to identify in the relatively short time available during the comment period to date. We have

learned that other analysts attempting to replicate CMS' rate-setting methodology have run into some of the same problems we have, and have discovered other potential issues with the CMS data and documentation. In this document, we have focused on the issues that will have the most effect on the ability of stakeholders to analyze and comment on CMS' proposals. We recognize that there may be other issues present or questions that could also have a material impact on the results of various analyses.

Calculation of the geometric mean cost for APC 0634

Please note that this analysis was conducted prior to the updated results released by CMS at the end of August. We are continuing to include this analysis because it highlights the complexity of the system, and the challenges that CMS left to researchers attempting to understand the CMS proposals for CY2104.

While we were able to come close to matching CMS' published geometric mean costs for most APCs, we were more than 10% off in our calculation of the geometric mean cost for one particular APC—APC 0634, which is the new proposed APC for Evaluation & Management (E&M).[1] This is a major concern because CMS has proposed to make APC 0634 the base APC in calculating the weights of all other APCs. The general formula for an APC's weight is: geometric mean cost for the APC divided by geometric mean cost for APC 0634. Thus, any problems with the geometric mean cost for APC 0634 leads to improperly calculated weights for all other APCs.

A table showing the CMS calculation and ours is immediately below. The CMS numbers are from the APC cost statistics file, released as a part of the rule.

APC Level Comparison

		Moran Computed			CMS Reported			Ratio: (Moran/CMS) -1		
APC Code	SI	Single Count	Median Cost	Geomean cost	Single Count	Median Cost	Geomean cost	Single Count	Median Cost	Geomean cost
0634	V	20,408,966	$ 95.85	$ 99.69	20,396,735	$ 86.07	$ 89.20	0.06%	11.36%	11.76%

As can be seen in the table, we found very similar numbers of singles as CMS. Generally, when we are far off on geometric mean costs, we are also relatively far off on counts of singles. However, that is not the case here. We also observed that the comparison of our results to CMS' was much more similar at the HCPCS level than at the APC level, and the single largest point of difference at the APC level was APC 0634.

To examine why our findings differed so dramatically from the agency's, we approached this by performing a:

1) Close examination of our data results compared to CMS'; and
2) Close examination of the consistency of the results that CMS reported.

[1] For comparison in our replication, we have only 11 APCs where we are 10+% away on geometric mean, and we have more than 50% of the APCs within 0.5% of the CMS published figures.

Data results compared to CMS

In order to troubleshoot our calculation for APC 0634, we looked at the values CMS reports for the component HCPCS codes. We match closely CMS' values for the underlying HCPCS codes. We are generally within 0.5% for the count of singles, and generally within 1% on the median and geometric mean for the HCPCS codes. We match on the component parts for APC 0634, but do not match on the aggregation, which suggests that CMS' APC calculation may be incorrect. The CMS numbers we used as a point of comparison that appear in the table below are from the HCPCS cost statistics file released as a part of the rule.

HCPCS Level Comparison

			Moran Computed			CMS Reported			Ratio: (Moran/CMS) -1		
HCPCS Codes	SI	APC	Single Count	Median Cost	Geomean cost	Single Count	Median Cost	Geomean cost	Single Count	Median Cost	Geomean cost
99201	V	0634	160,390	$ 74.33	$ 84.62	162,472	$ 73.24	$ 83.40	-1.28%	1.49%	1.46%
99202	V	0634	159,837	$ 101.26	$ 104.60	160,204	$ 100.78	$ 103.57	-0.23%	0.47%	0.99%
99203	V	0634	267,824	$ 132.17	$ 136.98	267,189	$ 131.26	$ 136.42	0.24%	0.70%	0.41%
99204	V	0634	202,916	$ 174.96	$ 171.51	203,004	$ 173.51	$ 170.65	-0.04%	0.84%	0.50%
99205	V	0634	94,737	$ 211.69	$ 214.54	94,640	$ 211.69	$ 213.49	0.10%	0.00%	0.49%
99211	V	0634	4,494,680	$ 76.67	$ 81.38	4,514,357	$ 76.42	$ 80.58	-0.44%	0.33%	0.99%
99212	V	0634	4,440,942	$ 88.06	$ 90.99	4,438,154	$ 88.06	$ 90.76	0.06%	0.00%	0.25%
99213	V	0634	5,851,135	$ 94.44	$ 97.72	5,843,094	$ 94.24	$ 97.61	0.14%	0.21%	0.11%
99214	V	0634	4,065,873	$ 119.56	$ 121.40	4,078,881	$ 119.57	$ 121.27	-0.32%	-0.01%	0.11%
99215	V	0634	670,632	$ 174.62	$ 176.99	671,221	$ 173.28	$ 176.07	-0.09%	0.77%	0.52%

Thus, from a data analysis perspective, we found inconsistencies. We also note that the sum of singles from the HCPCS cost statistics file for APC 0634 does not match the number of singles reported in the APC cost statistics file.

CMS internal comparison

We then explored the issue from a purely theoretical perspective, using only the data that CMS published. We attempted to roll-up the geometric mean costs of the HCPCS codes that make up APC 0634 to calculate the APC's geometric mean cost. In theory, we should be able to compute the geometric mean cost for an APC by taking a weighted average of the geometric mean cost for all of the component codes.

To calculate the weighted average geometric mean, we took the natural log of the geometric mean values for the HCPCS codes and computed a weighted average of the logged values. Finally, we took the exponential to convert back to the overall geometric mean cost. Using this method, and using CMS' own reported data, we calculated a weighted geometric mean cost value of $99.31, which is 11.3% higher than what is published in the APC table of the rule (but only 0.65% lower than our calculated geometric mean cost for the APC of $99.69).

We also examined the proposed rule—both the preamble text and accompanying files—to see if there were any steps or changes that were different for this year compared to previous years. We were not able to find any differences in methodology documented in the rule.

Summary: This potential error has major implications for the entire OPPS rule-making process. The error also makes it difficult to assess if CMS appropriately measured the impact of the proposed E&M coding changes, in addition to every other proposal in the rule.

Update: The new files released by CMS on August 28 provide updated weights for APC 0634. With the updated files, CMS is now reporting a result within $0.40 of our result. However, this update also forced a recalculation of all of the other weights and payment amounts. In a correction notice that CMS issued on September 5th, CMS gave an explanation of how this error occurred.

Inconsistent status indicators in CMS published appendices

Please note: This analysis was conducted prior to the update at the end of August. Based on a preliminary review, we believe that CMS corrected the inconsistencies with the codes with the J1 status indicators, however, some of the others are still present.

In order to determine the appropriate payment weights for particular procedures, CMS pulls lines from the claims to create single claims. The creation of these singles depends on the categorization of HCPCS procedure codes listed on each line. The HCPCS codes (and certain revenue centers) are categorized using a "status indicator" that CMS assigns to each HCPCS code. CMS reports the status indicator for HCPCS codes in two files accompanying the rule: Addendum B and the Cost Statistics file.

We have found multiple instances where the status indicator for a code is inconsistent across the different files that CMS has released. We are unable to determine which status indicator CMS used in its rate-setting (or whether different status indicators were used for different parts of the methodology). An error in the status indicator assignment will affect the creation of singles and geometric mean costs across multiple procedure codes.

The following table provides details on inconsistencies we were not able to reconcile.

		From Addendum B			From Cost Statistics File		
HCPCS	Short Description	SI	APC	Payment Rate	SI	APC	Payment Rate
22526	Idet single level	E			T	0050	2598.32
27216	Treat pelvic ring fracture	E			T	0050	2598.32
33233	Removal of pm generator	Q2	0088	3294.15	J1	0106O	5873.24
75635	Ct angio abdominal arteries	Q2	0662	283.78	Q3	0662	283.78
75962	Repair arterial blockage	N			J1	0083O	4541.84
75966	Repair arterial blockage	N			J1	0083O	4541.84
93619	Electrophysiology evaluation	Q3	0085	11517.62	J1	0085O	11517.62
93620	Electrophysiology evaluation	Q3	0085	11517.62	J1	0085O	11517.62
93650	Ablate heart dysrhythm focus	Q3	0085	11517.62	J1	0085O	11517.62
96110	Developmental screen	E			S	0373	116.42

In particular, we note HCPCS code 33233 for "Removal of PM generator." Depending on the data source, this code is assigned to two distinctly different APCs, complete with different

payment rates. This should not be possible given CMS' described methodology. This leads us to believe that either CMS made a mistake or has not fully documented its methodology.

The inconsistency in the assignments of the other codes will have an effect primarily on the codes and APCs listed, but will also have secondary effects on all other statistics in the system. Also, the J1 codes are a new proposed code for Comprehensive APCs—a significant change proposed for the first time in the current rule.

Summary: The problems found with consistency of Status Indicators could affect weights and payment amounts throughout the entire system. In addition, the inconsistency on a select group of HCPCS codes with J1 status indicators poses problems for those seeking to appropriately comment on the CMS Comprehensive APC proposal.

Update: The newly released files correct the status indicator inconsistencies for some, but not all codes. The J1status indicators appear to be corrected. In the correction notice of September 5th, CMS describes adjusting these status indicators, but not how the errors occurred. In addition, inconsistencies remain.

Evaluation & Management Codes and the Bypass list

Please note: This issue does not appear to be addressed at all from the CMS updated files, and so is still an unresolved issue.

In the proposed rule, CMS proposed collapsing 10 different E&M HCPCS codes into a single new HCPCS code, and assigning the codes to a new APC. Table 29 in the rule illustrated this proposal, with HCPCS code ranges 99201-99205 and 99211-99215 assigned to a single new HCPCS (placeholder of "GXXXC") code and APC 0634.

To be analytically consistent, all of these codes should be treated the same way for determination of single bills. However, Addendum N of the rule lists which codes are considered "bypass" codes. Bypass codes are treated in a certain way for identification of singles, and are believed to include only minor amounts of packaging.

However, as can be seen from Addendum N, only 8 of the 10 codes proposed for APC 0634 are on the bypass list. 99211 and 99215 are not included on the bypass list.

Our understanding of the current methodology based on our review of the current and previous years' rules have no circumstances where it is possible to have a non-imaging code only be considered a "bypass" code some of the time.

This inconsistency then raises issues as to the appropriate calculation of the new E&M APC, and all associated weights. It is not possible to tell if:

1) Addendum N is wrong, and all codes in this range should be on the bypass list;
2) Addendum N is wrong, and none of the codes should be on the bypass list;
3) There is a new policy that has not been sufficiently documented; or

4) There was a mistake in CMS calculations.

Since this is the "reference APC" which all weights are assigned off of, this inconsistency is problematic.

Summary: This inconsistency raises questions as to the creation of APC 0634, which leads to issues both in other weights, and also for the ability to appropriately comment on the E&M proposals in particular.

Update: The newly released files do not address the inconsistencies in the bypass list. This issue is also not addressed in the correction notice update of September 5th.

RE: Reproducibility of the 2014 NPRM OPPS Rule

Date: August 28, 2013

From: Susan E. White, Ph.D., CHDA
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Health Policy Analytics, LLC models the OPPS proposed rule for a number of clients based on information released by CMS. We have been doing this for the past decade using CMS' OPPS claims accounting document, titled, "CMS-1601-P-2014-OPPS-Claims-Accounting-narrative,"and the text released by CMS in its annual proposed rule(s). For the OPPS proposed rules released from 2004 to 2013, we were able replicate CMS' calculation of geometric mean costs (and, previously, median costs) at both the HCPCS and APC level, along with counts of the single/pseudo-single claims within 0.5% or less of CMS' published figures. Unfortunately, this year, for the first time ever, we were unable to replicate the 2014 OPPS proposed rule. We believe this inability stems from a number of significant data-related issues that we discovered during six weeks of analyses conducted since we received the claims data file from CMS. These issues are described below.

1. Inconsistency in the status indicator codes assigned to HCPCS/CPT codes
   In order to properly identify single and pseudo-single procedure claims to calculate the geometric mean cost of each HCPCS and APC group, the status for each HCPCS code must be identified. We have always relied on the information CMS releases in Addendum B to identify the status indicators for every HCPCS/CPT code, including status indicator changes. This year, we observed that the status indicators for certain HCPCS/CPT codes did not match between Addendum B and CMS' cost statistics file released in support of the CY 2014 OPPS Proposed Rule. For example, CPT codes 75962, 75966, 93619, 93620 and 93650 are assigned to status indicator J1 in the CPT Cost Statistics file, but to status indicator N or Q3 in Addendum B. Since CMS is newly proposing status indicator J1 to designate comprehensive APCs, this mismatch in status indicators hampers efforts to simulate the proposed rule.

2. Identification of Q1 codes that receive packaging when multiple occur

   It is not clear what logic CMS used to determine which CPT codes assigned to status indicator Q1 receive packaged costs when more than one code occurs on the claim. In the Claims Accounting Narrative, CMS states that the highest-weighted HCPCS/CPT code assigned status indicator Q1 would be retained for rate-setting, while the lower-weighted codes would be packaged. We followed this process, but were unable to replicate the rule. It does not appear that this is the logic CMS actually used to make this assignment. We tried to discover how CMS treated multiple HCPCS/CPT codes that are assigned status indicator Q1 when they are present on the same claim; specifically, we created and implemented other algorithms that we believe CMS might have used. After multiple 12-hour data runs, however, we still have not been able to determine the actual logic CMS used.

3. Incorrect Bypass Code List

The codes that CMS proposes for the CY 2014 bypass list appear to be incorrect. We suspect that CMS did not update the bypass code list to include the packaging of HCPCS/CPT codes it proposes to assign to status indicator Q1 along with all of the other newly unconditionally packaged codes included in Addendum P. For instance, some evaluation and management (E/M) CPT codes continue to be present on the bypass list, despite the fact that our analysis shows that the natural single-procedure claims have more packaging costs associated with them than CMS' bypass criteria allow. For example, 20-30% of the natural singles for CPT codes 99201-99205 and 99212, 99213, and 99215 have packaged costs associated with them, which violates CMS' own criteria for inclusion on the bypass list. We were able to analyze 171 of the 179 codes on the bypass list and found that more than 5% of the natural singles for 109 of the 171 codes (63.7%) included packaged costs after the Q1 codes were conditionally packaged. Therefore, none of these codes should be on CMS' bypass list according to its own criteria.

4. APC Visit 0634 Geometric Mean

We had limited success in identifying single-procedure claims and calculating the geometric mean cost for clinic visits CPT codes 99201-99215. Unfortunately, we were not able to reproduce the geometric mean cost for APC 0634. Our simulation, built up from single-procedure claims used to successfully replicate the HCPCS code-level geometric mean costs, results in a value of $98 for APC 0634. This is 10% higher than dollar amount reported by CMS for the rate-setting process.

The issues identified above are a subset of the multiple problems we encountered during our many attempts to replicate the CY 2014 OPPS Proposed Rule. This rule includes more sweeping changes than have been proposed in the past, and it is understandable that some of the rate-setting steps CMS utilized may have been inadvertently un-documented in the claims accounting narrative, the rule text, and the addenda files. If the process itself was flawed (rather than just being undocumented), however, it presents an even larger problem.

Due to the issues described above, we have been unable to provide many clients with the data analyses they require to form thoughtful, data-driven arguments to support their comments on CMS' CY 2014 OPPS Proposed Rule. In the time available and with the information released, it was virtually impossible for us to carve out certain portions of the rule for analysis due to the massive changes proposed for packaging. The status of any one HCPCS/CPT code, the order of operations used to determine the singles and pseudo-singles, and the presence of codes on the bypass list all interact to cause erroneous conclusions from any partial analysis.