September 5, 2013

VIA Electronic Submission to http://www.regulations.gov

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1590-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: [CMS-1600-P] Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

Dear Ms. Tavenner:

On behalf of undersigned organizations representing laboratories performing diagnostic laboratory tests and physician pathology services to help inform important therapeutic management decisions for Medicare beneficiaries and manufacturers of devices used in these critical services, we are pleased to submit comments in response to the above-captioned Medicare Physician Fee Schedule (MPFS) Proposed Rule for CY 2014 regarding the proposal to use Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) rates in developing practice expense relative value units (PE RVUs) [78 Fed. Reg. 43296 – 43298]. We believe the proposal is seriously flawed on several independent grounds, and, if implemented, will have significant, negative impact on Medicare beneficiaries.

In brief, our comments are as follows:

- **Hospital Charge-Based Cost Data Do Not Reflect the True Costs to Perform Physician Pathology Tests**
- **RUC-based PE RVUs Are a More Accurate Proxy for True Costs to Provide Physician Pathology Services than Hospital Cost-Report Based Estimates Used for the Outpatient Prospective Payment System (OPPS)**
- **CMS is Required to Use a Resource-Based System to Determine PE RVUs**
- **CMS Should Publish (1) All Data Used to Identify Procedures Subject to the Proposed Cap, (2) The Specific Methodology It Would Intend to Use Should This Proposal Be Finalized**
- **The CMS Proposal is Not Consistent with MedPAC Proposals to Adopt Site-Neutral Payment Policies**

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In section II.A.3.[1] of the Proposed Rule, the Centers for Medicare & Medicaid Services (CMS) proposes to limit the non-facility PE RVUs for certain codes so that the total non-facility Medicare Physician Fee

[1] *See* 78 Fed. Reg. 43,296 – 43,298 (July 19, 2013).

Schedule (MPFS) payment amount would not exceed the total combined amount that Medicare would pay for the same code in a facility setting (i.e., hospital outpatient or ambulatory surgery center setting) (the "OPPS Cap"). Although we appreciate CMS's objective to avoid excessive payments for procedures, as proposed, the policy fails to introduce a rational standard to support the MPFS prices that would result. The policy would override the existing statutory basis for MPFS resource-based price and is inconsistent with existing regulations, to which no change was proposed. In the case of pathology services, the proposal selectively affects the higher-cost services within the various pathology APCs, which is evidence that the averaging effect of APC calculations for diverse services in an APC causes lower payment for higher-cost services within an APC. The policy also treats APC median prices as actual procedure-specific cost values, despite years of CMS statements to the contrary. If implemented, the policy would have a substantial negative impact on payments for physician pathology procedures—resulting in payment rate drops in excess of 80-percent in some cases. CMS cannot assert that reductions in payments at this level would have no impact on access to services or quality of care. For the reasons set forth in our comments below, we strongly urge CMS to reconsider this proposal.

A. Hospital Charge-Based Cost Data Do Not Reflect the True Costs to Perform Physician Pathology Tests

1. Hospital Cost Reports are not Audited with Respect to Individual Line Items

On August 29, 2013, members of the undersigned organizations met with Marc Hartstein, Chris Ritter, Kathy Bryant and other CMS staff to discuss CMS's proposal to use OPPS and ASC rates in developing PE RVUs. During this meeting, CMS asked us why hospital cost-report-based cost estimates are not more robust than RUC-based estimates insofar as the hospital cost-report-based estimates reflect cost reports that are audited by the Part A Medicare Administrative Contractors (MACs) whereas the RUC-based estimates reflect inputs provided by professional societies, which are not verified or audited by third parties.

Although it is true that the Part A MACs audit the Medicare cost reports, these reports do not represent—nor do the MACs audit—the accuracy of the reports in identifying costs for specific items or services reported by HCPCS or CPT codes. The Medicare cost reports comprise worksheets on which hospitals report allowed costs that are allocated across various cost centers. Expenditures that reflect hospital-wide costs for non-revenue producing departments or areas (e.g., housekeeping or laundry) are allocated to revenue producing cost centers (e.g., laboratory) through a step-down process. This indicates the costs incurred by the entire hospital system and, assuming costs are allocated correctly, for individual departments.

The only way in which the cost reports reflect costs for specific items or services identified by HCPCS or CPT codes is through the apportionment of costs on the basis of charges. In other words, if a specific cost center, such as laboratory, has $1 million in costs (both direct and allocated) and $4 million in charges, then the relative amounts of the costs applicable to each item or service billed by the laboratory are reflected through the ratio of the charges for the individual item or service divided by the total charges for the laboratory cost center and then multiplied by the total costs in the cost center.

For example, using the sample figures above, if a procedure has a $100 charge and it is performed 1,000 times, then because it accounts for $100,000 of the $4 million charges, then it would be tallied as accounting for 2.5 percent of both charges and costs; the resulting inferred cost for the 1,000 tests is $25,000. However, this does not mean that the item or service actually costs $25,000 for the 1,000 services furnished. It simply means that as apportioned by charges, the service represents 2.5 percent of the hospitals charges. The item or service may, in fact, represent 2.5 percent of the departmental costs or may represent a substantially higher or lower percentage of the costs.

The Medicare cost reports—as CMS itself has repeatedly confirmed—have never been intended to be accurate representations of the costs of individual items or services. When used to reconcile overall hospital system-wide costs or charges to determine payments under the former reasonable cost system—as the lesser of costs or charges—the cost reports are accurate. As a reflection of the costs of *individual* items or services, however, the cost reports can vary widely from an accurate activity-based cost discovery method.

2. Hospital Laboratory Costs Are Substantially Higher than the OPPS Data Indicate

To help estimate whether hospital laboratory costs for performing physician pathology procedures subject to the proposed OPPS Cap are more consistent with the hospital charge-based costs that support the OPPS payments than the detailed cost data we obtained from surveys of independent laboratories, we conducted a survey of hospital laboratories seeking cost data on procedures subject to the proposed OPPS Cap. We provided hospital laboratories a template workbook to collect data on equipment, supplies, and clinical labor required to perform each test. This involves a line-by-line identification of the supplies, clinical labor, and equipment required to run a typical batch of the test as well as the number of tests run in a typical batch.

More specifically, for supplies, we requested purchase prices and quantities for each reagent, kit, and supply used to perform the test. For equipment, we requested that labs provide the equipment required for the assay, the purchase prices and useful life (e.g., $100k/7 years) as well as an estimate of the minutes the equipment is in use for a typical batch. For clinical labor, we requested non-physician clinical staff required to process the assay and time required to perform each step in the procedure for the typical batch. We then applied an overhead factor to reflect the direct:indirect ratio between the direct factors identified above and indirect factors, such as non-clinical personnel, non-clinical supplies, and facilities.

We were still in the process of receiving hospital laboratory cost data at the time of the comment submission deadline. We will continue to analyze these data, and, if appropriate, share this data with CMS at a later date.

In the next section, we explain why imputed costs in the OPPS data may be considerably lower than the actual procedure-level costs incurred by the hospital and reported in our survey.

3. Systematic Bias in the Hospital Charge-Based Cost Estimates Explain Why the OPPS Data Do Not Accurately Reflect True Costs for Physician Pathology Services

As has been discussed in comments submitted to CMS on OPPS since the initial proposed rulemaking in 1998, and as CMS itself has acknowledged, the Medicare cost-to-charge ratios (CCR), which are used to deflate billed charges for individual procedures into estimated costs, reflect a phenomenon referred to as "charge compression," under which lower cost procedures tend to have higher relative charge mark-ups than higher cost procedures. Therefore, after a CCR is applied, cost estimates for lower cost procedures tend to be higher than true costs; cost estimates for higher cost procedures tend to be lower than true costs.[2] This occurs because the CCRs represent the overall relationship of costs and charges in a cost center. They do not represent the relationship between costs and charges for any specific procedure.

[2] This phenomena results in what is commonly reported as the $25 aspirin or the $100 bag of saline. High charges for low cost items create a low CCR, which when applied to other items whose charge markup may be only 2x or

This issue was evaluated in a report prepared for CMS by the Research Triangle Institute ("RTI"). CMS addressed the issues raised in this report, as well as the recommendations from the report and public comments, in the CY 2009 OPPS/ASC final rule with comment period.[3] RTI found that there was aggregation bias in both the Inpatient Prospective Payment System ("IPPS") and OPPS cost estimation of expensive and inexpensive medical supplies, thus supporting the fact that the OPPS charge-based cost data do not accurately represent the cost for any individual procedure.

Looking specifically at the hospital charge-based cost data for laboratory services, we identified that although there are 12 possible cost centers, per hospital cost report data, most hospitals use only one laboratory cost center "Laboratory". This means that from the lowest cost to highest cost tests, a single CCR applies with the assumption that the mark from cost to charge is equivalent across all of these tests. The CCRs observed from review of the data are 0.3195 (geometric mean) with a range of 0.0687 to 13.165 (based on 2009 cost reports). This contributes to substantial charge compression for services reported under this cost center.

Moreover, the single cost center used by most hospitals includes both inpatient tests as well as outpatient tests and tests paid on the CLFS as well as those paid under OPPS. Insofar as much of the testing is performed on an inpatient basis, costs, charges, and the relationship between those parameters may differ from those performed for outpatients (i.e., CCRs for inpatient tests might differ from those for outpatient tests if distinct CCRs were calculated). In addition, insofar as outpatient tests paid under the CLFS have been paid separately unrelated to costs, charges, and CCRs, hospitals have had little incentive to assure that the charges and CCRs for such tests reflect actual costs. Applying CCRs from the single laboratory cost center used by most hospitals to identify costs for specific, outpatient, physician pathology services would not be expected to reflect true costs to perform such tests.

We also note that only 1,700 IPPS hospitals have a valid laboratory CCR. There are close to 2,200 hospitals with laboratory cost center charges, but no costs (also based on 2009 cost reports) This suggests a significant disconnect between the way costs and charges are allocated for laboratory procedures and calls into substantial question the validity of any "cost" estimates made from these data.

The Moran Company ("Moran") was commissioned by the American Clinical Laboratory Association ("ACLA") to conduct a survey of clinical laboratory companies designed to collect data on the direct and indirect costs they incurred to perform anatomical pathology services. In their analysis, Moran also analyzed the CCRs employed in generating OPPS cost findings; their analysis was limited to 38 CPT codes that describe anatomical pathology services.[4]

In the Moran report, CCRs were calculated based on the costs and charges that CMS used to set the final 2013 payment rates for these services. Of the observed CCRs used in ratesetting, 96-percent were matched to CCRs for revenue codes in the "Laboratory Anatomical" family, while the rest were derived from other laboratory revenue codes.[5] Of note, more than 99-percent of the hospitals reporting furnished CCRs for these revenue codes that are identical across all of the laboratory revenue codes reporting, which implies that, in setting rates, CMS is using CCRs that are aggregated across all of the "Laboratory

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3x, results in latter items latter items having apparent costs below their real cost. See New York Times, August 26, 2013: http://www.nytimes.com/2013/8/27/health/exploring-salines-secret-costs.html

[3] *See* 73 Fed. Reg. 68,519 through 68,527.

[4] Moran limited their analysis to anatomical pathology services described by the following CPT codes: 88104, 88106, 88108, 88112, 88120, 88160, 88161, 88162, 88173, 88182, 88184, 88185, 88304, 88307, 88309, 88312, 88313, 88314, 88319, 88323, 88325, 88329, 88331, 88333, 88334, 88342, 88346, 88347, 88348, 88349, 88355, 88360, 88361, 88362, 88363, 88365, 88367, and 88368.

[5] The CCRs used by CMS were derived from 1,763,757 claims lines containing any one of the 38 codes for anatomical pathology services as submitted by 2,885 hospitals.

Anatomical" departments rather than specific to the type of anatomical pathology service that was reported. This introduces an additional bias, since it is highly unlikely that diverse lab services would, in actuality, have identical CCRs had cost centers and their direct and indirect costs been reported on the available and more granular levels.

Consistent with these observations, Moran found that using these higher level CCRs resulted in many codes being grouped together under the same CCR. In this case, higher volume, lower cost codes likely had a downward impact on the CCR, subjecting such codes to a lower CCR than if a more granular revenue center had been used and the codes had not been grouped with other high volume, lower cost codes.

Moran also found that the CCRs CMS had available in applying its methodology contain a large number of very low CCR values. In their analysis, the reported CCRs had values lower than 0.100 in 20.3-percent of the cases; another 40.5-percent had CCR values between 0.100 and 0.200, while CCRs for other ancillary departments typically range from 0.250 – 0.350. Moran concluded that the low CCRs for anatomical pathology services imply that hospitals are applying large charge markups to these services. Moran also noted that the way in which hospitals allocate costs to particular costs centers could impact the CCRs. For example, capital costs may not be fully captured in the associated cost center and may instead be spread over all costs centers as part of overhead costs. Expensive lab equipment, which is used in anatomical pathology services, could fall into this category, which would result in the CCRs associated with laboratory departments to be artificially low.

Insofar as CMS is proposing only to reduce payments where OPPS payments for an APC are lower than MPFS payments for a particular service, its analysis is biased against higher cost procedures where OPPS charge-based costs are systematically lower than true costs. This proposal will result in arbitrarily lower payments for higher cost procedures rather than improving the accuracy of the resource-based relative value payment system. Although we oppose finalization of the proposed policy, should CMS decide to move forward with this policy, we urge the Agency first to analyze carefully the CCRs that apply in the laboratory setting to evaluate how the single laboratory CCR applicable to most hospitals predicts physician pathology services offered in the outpatient setting. Only after such analysis is completed and vetted publicly and only if CMS determines that such data accurately reflect costs, should CMS consider whether adjusting non-facility PE RVUs based on OPPS data is reasonable.

4. CMS Should Never Apply an OPPS Cap Where there is Great Variability in the Relationship Between PE RVUs and Hospital Charge Based Costs for Individual Procedures Found in One APC Group

In Table 1 below, we map the PE RVUs for physician pathology services to the APCs to which those codes are assigned under OPPS to observe the variability in the range of inputs among individual procedures.[6]

[6] We mapped the 2013 Final Rule PE RVUs to the 2014 APCs because the 2014 Proposed Rule PE RVUs for these procedures reflect the impact of the OPPS Cap.

Table 1: PE RVUs Mapped to APCs for Physician Pathology Services

2014 APC	Analysis of Pathology APCs by 2013 PE RVUs for Included Pathology Services			
	N (# CPT Codes)	RVU Range	RVU Multiple (Hi/Lo)	Statistics
Level I Pathology (0342)	**n=16**	**0.33 – 2.12**	**6.4**	mean = 1.29; stdev = 0.57
Level II Pathology (0433)	**n=13**	**0.06 – 4.96**	**82.7**	mean = 1.56; stdev = 1.33
Level III Pathology (0343)	**n=16**	**0.2 – 16.99**	**85**	mean = 4.86; stdev = 5.71
Level IV Pathology (0344)	**n=6**	**1.54 – 6.23**	**4**	mean = 3.41; stdev = 1.91
Level V Pathology (0661)	**n=4**	**6.86 – 19.69**	**2.9**	mean = 12.22; stdev = 5.42

These data show that there is a very wide variability in the known RBRVS input costs for the procedures subject to the OPPS Cap when these are mapped to the APCs which would cap the rates for these procedures. This suggests that it is inappropriate to base non-facility payments to rates derived from APCs because the procedures are not sufficiently homogeneous economically in the non-hospital setting to be grouped as they are in the hospital setting. If this range of variability were observed in the hospital setting, it would result in a violation of the 2-times rule.

Clearly, based on this variability, it is not reasonable to assume that the higher-cost services placed within a particular pathology APC and paid based on a much lower, geometric mean cost for the APC, are necessarily mispriced. Yet, this is the fundamental basis of CMS's proposed policy. CMS should not move forward with a proposal to implement the OPPS Cap before it has considered the appropriateness of determining rates for these non-facility procedures by reference to assignments to clearly and substantially non-homogeneous groups.

Moran further explored the distribution of anatomic pathology cost findings used by CMS to set the OPPS rates. For each of the 38 anatomic pathology codes that are affected by the OPPS cap, Moran calculated cost findings for the single claims and examined the distribution of costs findings for these services around the mean value used by CMS to set rates. Moran found the range of variation to be substantial. The standard deviations around the means were also relatively sizable, and actually exceeded the mean value for 16 out of 37 codes.[7] This means, by definition, that the data is not normally distributed. Weighting toward more or less frequently used services creates additional and potential large distortions in the relationship between the APC price and the real-world cost per service. The exceptional degree of variation should give CMS pause when considering use of this information to set payment rates

[7] The data for CPT code 88355 was blinded to prevent disclosure of data for cells containing fewer than eleven observations.

for services outside of the OPPS setting. These data are not reflective of the actual costs to perform a particular procedure, and as such, are not comparable to the costs to perform these same procedures outside of the OPPS setting.

B. RUC-based PE RVUs Are a More Accurate Proxy for True Costs to Perform Physician Pathology Services than Hospital Cost-Report Based Estimates Used for the Outpatient Prospective Payment System (OPPS)

Based upon analyses we have conducted as well as our understanding of the Relative Value Update Committee (RUC) process and of the Medicare charge and cost data used to identify "costs" for procedures in the hospital setting, we believe the RUC-based data provide reasonably accurate estimates of the direct input costs for most physician pathology procedures and should continue to form the basis for ratesetting under the MPFS in the non-facility setting.

CMS's new proposal requires the assumption that OPPS charge-based data, after conversion to single APC rates for diverse group of services, represent better estimates of procedure costs than RUC-based data. CMS's rationale for this new assumption is that the RUC data are unverified and that the OPPS data reflect hospital cost reports. However, CMS knows well that OPPS charge-based cost data were neither designed nor intended to be accurate estimates of procedure costs at the code level. The hospital charge-based cost data used for OPPS rate-setting allow CMS to estimate costs for purposes of grouping a number of procedures (multiple distinct codes) into appropriate clinically and economically homogeneous Ambulatory Payment Classification groups (APCs). These data do not identify actual costs for specific procedures.

1. Commissioned Cost Analyses

To support discussions with payers when new laboratory services are developed, Abbott Molecular regularly conducts detailed cost analyses for laboratory tests they develop, including some of those now proposed to be subject to the OPPS Cap. In 2009 and 2010, Abbott Molecular commissioned Boston Healthcare Associates, Inc. ("BHA") to survey laboratory users of their fluorescence in situ hybridization assays that are described by CPT codes 88120, 88121, and 88368, and to conduct detailed micro-costing analyses to determine the true cost to perform these assays.

While CMS proposes to cap RBRVS payments based on APC-level data, in the tables below we use procedure-level hospital reported data for these three specific physician pathology services.

Below are data for physician pathology services based on in situ hybridization technology:

Table 2: Cost Analysis for Code 88368 "Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual"

	Commissioned Cost Analysis	MPFS Direct Practice Expense Inputs Database	2014 Proposed OPPS – Geometric Mean Cost[8]	2014 Proposed OPPS – Median Cost[9]
Labor	$92.48	$21.65		
Supplies	$430.56	$199.46		
Equipment	$14.64	$7.06		
Total Direct Cost	$537.68	$228.17		
Indirect Cost[10]	$476.81	$202.34		
TOTAL	**$1,014.49[11]**	**$430.51**	**$305.82**	**$278.64**

[8] 2013 Geometric Mean Cost = $58.27

[9] 2013 Median Cost = $62.48

[10] We used 53:47 direct:indirect factors as these are what we calculated for 88368 per the "CY 2012 Utilization Data Crosswalk to CY 2014" that was published with the CY 2014 MPFS Proposed Rule (CMS-1600-P)

[11] These costs reflect a 90-percent efficiency factor; 10-percent of the specimens do not hybridize. One hundred-percent efficiency would result in a total cost of $863.13 (labor - $86.10; supplies - $357.87; equipment - $13.49; total direct costs - $457.46; indirect cost - $405.67)

Table 3: Cost Analysis for Code 88120 "Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual"

	Commissioned Cost Analysis	MPFS Direct Practice Expense Inputs Database	2014 Proposed OPPS – Geometric Mean Cost[12]	2014 Proposed OPPS – Median Cost[13]
Labor	$46.30	$38.79		
Supplies	$430.99	$571.12		
Equipment	$11.63	$15.99		
Total Direct Cost	$488.92	$625.90		
Indirect Cost[14]	$733.38	$938.84		
TOTAL	**$1,222.30[15]**	**$1,564.74**	**$148.64**	**$142.43**

[12] 2013 Geometric Mean Cost = $117.25
[13] 2013 Median Cost = $114.89
[14] We used 40:60 direct:indirect factors as these are what we calculated for 88120 per the "CY 2012 Utilization Data Crosswalk to CY 2014" that was published with the CY 2014 MPFS Proposed Rule (CMS-1600-P)
[15] These costs reflect an 85-percent efficiency factor

Table 4: Cost Analysis for Code 88121 "Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology"

	Commissioned Cost Analysis	MPFS Direct Practice Expense Inputs Database	2014 Proposed OPPS – Geometric Mean Cost[16]	2014 Proposed OPPS – Median Cost[17]
Labor	$26.93	$18.88		
Supplies	$334.32	$415.17		
Equipment	$17.91	$27.49		
Total Direct Cost	$379.16	$461.54		
Indirect Cost[18]	$645.60	$937.07		
TOTAL	**$1,024.76**[7]	**$1,398.61**	**$170.65**	**$184.98**

These examples represent a sample of physician pathology codes. Because we have not had time to collect detailed cost data on a broad range of tests during the short window of the comment period, these are illustrative examples showing that the costs required to perform these tests are substantially higher than those one would estimate from the hospital charge-based cost data. In other sections of this letter, we explain why well-known cost-to charge biases explain the excessively low hospital values.

2. Findings from The Moran Company's Analyses

As stated above, the Moran Company ("Moran") was commissioned by the American Clinical Laboratory Association ("ACLA") to conduct a survey of clinical laboratory companies designed to collect data on the direct and indirect costs they incurred to perform 38 anatomical pathology services.[19] Companies were asked to provide cost information on both the direct and indirect costs they incurred to provide each of these 38 services. Moran received responses from ten companies and a total of 154 discrete code/company responses. Moran calculated the mean and median costs to perform these services based on the survey responses and compared these data to the mean and median costs used by CMS to set the 2013 OPPS rates for these same services. For most codes, the mean costs observed in the survey responses were substantially higher than those used by CMS to set the 2013 OPPS rates.

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[16] 2013 Geometric Mean Cost = $188.86

[17] 2013 Median Cost = $236.18

[18] We used 37:63 direct:indirect factors as these are what we calculated for 88121 per the "CY 2012 Utilization Data Crosswalk to CY 2014" that was published with the CY 2014 MPFS Proposed Rule (CMS-1600-P)

[19] The Moran Company. The Effects of CMS's Proposed Cross-Site Payment Caps on Reimbursement for Anatomical Pathology Services. July 2013.

Of note, there were a few cases where the OPPS mean costs are higher than the survey data mean costs. Moran believes that in these instances, survey respondents may have provided a per marker or per unit cost, while the OPPS data represents line level cost, which may include multiple markers. Moran concluded that this further demonstrates that the data in the OPPS cannot be easily compared to costs outside of the OPPS system.

C. CMS is Required to Use a Resource-Based System to Determine PE RVUs

CMS is required under Section 1848(c)(2)(C)(ii) of the Social Security Act to develop a methodology for a resource-based system, resulting in the creation of PE RVUs for each physician service. The statute states that "[t]he methodology utilized shall recognize staff, equipment, and supplies used in the provision of various medical and surgical services in various settings"[20]. Further, the section directs that PE RVUs "shall be determined based entirely on such relative practice expense resources".

In the non-facility setting, practice expense resources refer to those resources (e.g., staff, equipment and supplies) that are required to provide the service in the non-facility setting. Charge-based hospital cost data do not reflect practice expense resources for procedures performed in the non-facility setting, not simply because of various economies of scale in purchasing, but because of the many flaws and biases in service-level calculation that we have discussed. The law requires CMS to establish PE RVUs based upon practice expense resources regardless of whether or not these are higher than "costs" identified from charges for the services furnished in hospital outpatient departments. As a result, Congress issued a statutory directive to adjust PE RVUs for imaging procedures when these exceed OPPS-based amounts, overriding the plain text of 1848(c)(2)(C)(ii). There is no such statutory exception or authorization for other services.

CMS's proposal can also be distinguished in other ways from the statutory cap between APC and RBRVS pricing. In the imaging setting, CMS has adopted substantial packaging policies that frequently result in the OPPS payments exceeding the more granular MPFS rates such that the OPPS caps are not triggered – only 16-percent of imaging codes subject to the cap are actually capped. Based upon analysis of the physician pathology codes, however, it appears that the proposed OPPS cap would apply frequently to these codes – 46-percent of physician pathology codes subject to the cap would be capped under this proposal.

Finally, we note that when the OPPS was developed, it was expressly stated by CMS that it was not intended to reflect 100-percent of hospital costs, but rather an approximately 15-percent discount from costs (to be neutral with adjustments that were in place to operating and capital costs under the prior reasonable cost-based payment system).[21] Therefore, CMS would need to inflate any payments based upon reference to OPPS rates by at least 15-percent to adjust for the discrepancy between OPPS rates and costs built in to the OPPS payment system.

D. CMS Should Publish (1) All Data Used to Identify Procedures Subject to the Proposed Cap, (2) The Specific Methodology It Would Intend to Use Should This Proposal Be Finalized

CMS is proposing to apply the OPPS cap when:

[20] *See* Pub. L. 103-432
[21] *See* 65 Fed. Reg. 18,434

Pre-Adjustment CY 2014 Non-facility RVUs*CY 2013 Conversion Factor
>
CY 2013 OPPS/ASC Payment+Pre-Adjustment CY2014 Facility RVUs*CY2013 CF

CMS is also "proposing to exclude any service for which 5 percent or less of the total number of services are furnished in the OPPS setting relative to the total number of MPFS/OPPS allowed services.[22]

CMS has not published the specific methodology nor the data showing (1) how it identified procedures where the non-facility payments exceed the facility payments nor (2) how it identified which of those procedures were performed more than 5-percent of the time in the OPPS setting.

To evaluate the 5-percent threshold that CMS is proposing, we attempted to replicate CMS' calculations by comparing the OPPS volumes of physician pathology services (determined from total frequency claims in the CY2014 OPPS Proposed Rule) with the combination of the OPPS volumes and the global and technical volumes for the same services performed in the non-facility setting (determined from the utilization data posted with the CY2014 Proposed Rule).[23] In doing so, we identified that code 88120 should have been exempted from the policy but appears to have been subjected to the policy under the rates published in the Proposed Rule. In response to this inquiry, CMS noted that there was "an error in the calculation of the applicability of the new OPD/ASC cap. This error only affects 88120, which should not have been included on the list" of impacted codes. Although we understand from informal responses received from inquiries made to CMS about this code that it was not intended to be subjected to the proposal, it emphasizes the need for stakeholders to have access to the underlying analysis supporting CMS's potential implementation of this proposal so stakeholders can evaluate whether rates are being determined accurately under the proposal.[24]

It is also unclear whether CMS intends in the Final Rule to continue to base its calculations using CY2014 Pre-Adjustment RVUs (non-facility and facility) and CY2013 OPPS/ASC Payments or to base its calculations on CY2014 values for both the MPFS and OPPS inputs. Given the importance of this issue to fair ratesetting, it is critically important that CMS explain its methodology and make available the data so that stakeholders can replicate CMS's determinations.

E. The CMS Proposal is Not Consistent with MedPAC Proposals to Adopt Site-Neutral Payment Policies

We are aware of recommendations by the Medicare Payment Advisory Commission (MedPAC) that CMS adopt site-neutral payment policies where procedures are performed substantially (more than 50-percent of the time) in an office/non-facility setting at an allowed rate that is lower than the allowed rate in a facility setting.[25] The concern has been that the higher payment in a facility setting would incentivize a

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[22] *See* 78 Fed. Reg. 43,297.

[23] 2014 OPPS NPRM Cost Statistics File, available at: http://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1601-P-Cost-Statistics.zip

[24] Correspondence between Nicole Sweeney, Senior Associate at Boston Healthcare Associates, Inc. and Chava Sheffield, PhD, OTR/L, Division of Practitioner Services, Hospital and Ambulatory Policy Group, on July 16, 2013, confirmed that 88120 was subjected to the proposed policy in error.

[25] Zabinski D and Winter A. Addressing Medicare Payment Differences Across Settings. November 2, 2012. *Available at:* http://medpac.gov/transcripts/crosssectorpricing_Nov12.pdf; Addressing Medicare Payment Differences Across Settings. March 7, 2013. *Available at:*

shift in services from the lower cost non-facility setting to the higher cost facility setting. MedPAC required a substantial volume of procedures to occur in the less-expensive non-facility setting to confirm the procedure can safely be performed in that setting, so shifts in utilization toward the facility setting would be attributed to financial incentives and not clinical requirements.

Although it may be reasonable to explore policy changes when more than 50-percent of the utilization of a procedure occurs in a less costly setting, that dynamic does not pertain to the present policy proposal. Under the OPPS Cap proposal, we have services that have higher rates in the non-facility setting—not the hospital setting. CMS is proposing to apply the facility rate even when the utilization in that setting is very low—just 5-percent. This is entirely different from the scenario about which MedPAC has made its recommendations.

If payments are grossly inadequate in a particular setting, it would be unlikely that the setting would support more than 50-percent of the utilization of the service. However, one cannot make the same assumption with procedures that are only rarely performed in a particular setting. OPPS payments may be inadequate for specific physician pathology services, but because hospitals offer a very broad range of services (including less-expensive laboratory services with higher markups) they may still offer certain physician pathology services because the hospital is made whole considering their overall OPPS payments. Under the CMS proposal, however, laboratories will not be able to balance OPPS rates that fall well below true costs with other OPPS rates that are above costs because the OPPS Cap works only one way—OPPS rates apply only if lower. Laboratories' share of the procedures subject to the OPPS Cap will be substantial because for most of the physician pathology procedures subject to the OPPS Cap, utilization is substantially higher in the non-facility setting than in the hospital setting.

F. Recommendations

1) *We recommend that CMS not move forward with this proposal.*

2) *If CMS believes certain physician pathology services may be misvalued because of substantial differences between payments allowed under the PE RVUs in the non-institutional setting versus payments allowed in the hospital setting, then the Agency should identify these as potentially misvalued codes and follow established processes to consider the appropriate valuation.*

3) *We welcome the opportunity to discuss with CMS approaches to identifying verifiable cost data from laboratories, including surveys of laboratory costs, with third party audits.*

* * * *

Finally, as we have explained, neither independent laboratories nor hospital laboratories can perform the physician pathology services targeted for substantial reductions under the OPPS Cap at the payment rates identified in the Proposed Rule. If CMS were to finalize the rule as proposed, we anticipate that many laboratories—especially specialty laboratories which often have the greatest expertise in performing these complex and critically important procedures—would discontinue offering these services. They simply cannot be expected to perform these services while incurring substantial losses. Although hospitals may continue to perform a low volume of these tests because the losses are minimized by the low volumes, hospital laboratories will not be able to absorb the extra volume if independent laboratories cease to perform the large proportion of these services that they currently perform. Hospital laboratories generally

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http://medpac.gov/transcripts/addressing%20payment%20differences%20across%20settings_March%2013_public.pdf

are not set up to perform large volumes of these tests nor are they financially able to perform large volumes incurring substantial losses.

The undersigned appreciate the opportunity to provide comments on the CY2014 MPFS Proposed Rule. If you have any questions about these comments, please contact Paul Radensky at 202.756.8794 or via email at pradensky@mwe.com.

Sincerely,

Abbott

BD

Beckman Coulter, Inc. & Leica Biosystems, p/a Leica Microsystems Inc., companies of the Danaher Corporation

Clarient Inc., a GE Healthcare Company

Genoptix Medical Laboratory, a Novartis Company

Roche Diagnostics Corporation