Issue Brief

Federal Issue: Medicare Payment for Pathology Services in 2014

Legislative Ask:

Congress must make CMS withdraw cuts in the 2014 Medicare Physician Fee Schedule proposed rule that will threaten patients' access to vital pathology services, such as analyzing human tissue in order to diagnose skin, colon, ovarian, breast and prostate cancer as well as leukemia and lymphoma. Independent laboratories in local communities may have to stop providing some or all of these services. These drastic cuts would impact patients, lab quality, and result in layoffs for health care workers.

CAP Position:

CAP opposes this new round of cuts to pathologists and pathology practices.

CMS' proposal to link payment for pathology services to rates paid in the hospital outpatient prospective payment system fails to take into consideration the technical costs associated with specific individual codes and fails to recognize the distinct costs of physician services.

We believe CMS is overstepping its authority in proposing to pay for physician services using hospital-based payments. By law, CMS is required to base physician payments on the resources required to perform the service. Hospital payments are not determined using such a resource based approach.

CAP supports the existing AMA-RUC process for valuing physician service codes. Codes have been and continue to be revalued through the AMA-RUC process, which has shown itself to be accurate and fair, and has been thoroughly vetted over many years.

Status:

On July 8, CMS issued the proposed 2014 Medicare Physician Fee Schedule rule, which included deep cuts to the technical component (TC) and global payment for 39 anatomic pathology services. The payment reductions are the result of CMS proposing to cap payment for these services to lower rates paid under Medicare's Hospital Outpatient Prospective Payment System (OPPS), the fee schedule used by CMS for hospital outpatient services. The proposal drastically cuts payments for many critical anatomic services by over 50% and some codes as much as 75%.

The proposed 2014 cuts focus largely on Medicare TC and global payments. Of the 211 codes impacted, the 39 pathology services account for nearly 70% of the cuts from this proposed policy change. Other impacted specialties include radiology, oncology, vascular surgery, neurology as well as interventional radiology.

The September 6 deadline for submitting comments to CMS has passed, but the campaign to prevent the proposed cuts from taking effect continues. The CAP has organized an active grassroots push, including a targeted fly-in on September 18, district meetings, emails, and phone calls to Members of Congress. Members of Congress are sympathetic to extent of cuts and the message that CMS is overstepping their authority resonates with them.

Top Ten Reductions to Pathology Services Based on Volume and Proposed Change:

The codes listed in the chart below encompass pathology services for cancers such as breast, bladder, esophageal, lung, digestive, colon, prostate, thyroid and leukemia.

88307	Global	Tissue exam by pathologist	-50%
88342	Global	Immunohistochemistry	-27%
88312	Global	Special stains group 1	-46%
88313	Global	Special stains group 2	-45%
88112	Global	Cytopath cell enhance tech	-22%
88185	TC	Flowcytometry/tc add-on	-75%
88309	Global	Tissue exam by pathologist	-30%
88173	Global	Cytopath eval fna report	-25%
88367	Global	Insitu hybridization auto	-60% (TC only: -80%)
88108	Global	Cytopath concentrate tech	-39%

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SIDLEY AUSTIN LLP
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MEMORANDUM

TO: John Scott
Pam Johnson

FROM: Jim Stansel
Barbara Cammarata

RE: The College of American Pathologists—Resource-Based Practice Expense Relative Value Unit Mandate

DATE: September 4, 2013

EXECUTIVE SUMMARY

The Centers for Medicare and Medicaid Services ("CMS") has proposed a cap on non-facility practice expense ("PE") relative value units ("RVUs") under the Physician Fee Schedule ("PFS") for 2014 (the "2014 Proposed Rule"). Under the proposal, the cap is based on payments under the hospital Outpatient Prospective Payment System ("OPPS") or the Ambulatory Surgical Center ("ASC") payment system. In our judgment the proposed cap violates the statutory Medicare requirement that PE RVUs be resource-based for the particular practice setting. Applicable case law also requires that CMS' implementation of the statutory mandate be reasonable. We believe that the cap proposed by CMS relies on faulty assumptions and inapplicable facility resource data, and does not reflect actual resource costs in the non-facility setting contrary to law and regulation and CMS' stated policies and past practices. Finally, to the extent that CMS perceives a data issue with respect to the current non-facility PE RVU methodology, we do not believe it should be addressed using an approach that violates the resource-based requirement.

This memorandum addresses certain laws and regulations in effect as of the date hereof as well as certain legislative and regulatory history that we consider most pertinent to analysis of this Proposed Rule provision. It does not purport to be an exhaustive review of or comparison between the OPPS, ASC and PFS payment systems, or to address the many intricacies of Medicare billing and coding. We assume no obligation to update our findings based on changes in laws, regulations, guidance, facts, or circumstances occurring after the date of this memorandum, or to reflect the occurrence of unanticipated events such as emerging views influenced by political, policy, health reform or other considerations. Any future federal legislation, changes in agency regulations or guidance, or other changes in law, regulation, or guidance could have a material effect on the analysis set forth in this memorandum.

This memorandum is being provided as legal advice solely to The College of American Pathologists and may not be relied upon by or construed as legal advice to any other party without our express, prior written permission. Anyone receiving a copy of this memorandum should consult their own legal counsel with respect to the matters addressed herein.

Key Points:

We believe the Proposed Rule violates the resource-based requirement because:

- The Medicare statute, 42 U.S.C. §1848(c)(2)(C)(ii), requires that PE RVUs be resource-based for particular practice settings.
- CMS established and has applied separate PE RVUs in the facility and non-facility setting since the inception of the resource-based statutory requirement.[1]
- CMS has previously observed that taking facility costs into account in determining the PFS in the non-facility setting would be inconsistent with a resource-based methodology.[2]
- CMS has previously stated that comparisons between the PFS and OPPS payments for services are not appropriate because of the different nature of the cost inputs and has explicitly refused to impose one payment system on the other in other rulemakings.[3]
- OPPS data is *hospital* data and does not reflect the actual resource costs of physicians in their offices or laboratories. It reflects average costs of "buckets" of services rather than resource costs for individual services performed by physicians.
- CMS' assumptions underlying the cap are not supported by the data. For example, direct resource costs alone in the non-facility setting exceed Medicare payment rates for such costs in the facility setting for many pathology codes. *See* Exhibit A.
- CMS' reliance on a 2012 MedPac Report recommendation is misplaced. MedPAC's recommendation regarding similar payment across practice settings,

[1] 42 C.F.R. § 414.22(b)(5)(i).
[2] HHS, HCFA, Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999; Final Rule, 63 Fed. Reg. 58814, 58830 (Nov. 2, 1998) (hereinafter "1999 PFS Final Rule").
[3] *See, e.g.*, HHS, CMS, Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; Interim and Final Rule with Comment Period, 72 Fed. Reg. 66580, 66697-98, 66722, 66726 (Nov. 27, 2007).

by MedPAC's own admission, addressed only Evaluation & Management ("E&M") codes, not the many other services provided by specialty physicians in multiple practice settings.[4]

- CMS' 2014 Proposed Rule is inconsistent with its own stated goals of ensuring that PE RVUs reflect resource-costs for each service in the non-facility setting and that its PE RVU payment policy be understandable, intuitive and based on the best available data.[5]

BACKGROUND

I. The 2014 PFS Proposed Rule

On July 19, 2013, CMS released its 2014 Proposed Rule, which recommends several significant changes to the manner in which pathologists and clinical laboratories will be paid under the Medicare Physician Fee Schedule. Most significantly, CMS proposes to impose a cap based on payment rates under the OPPS and ASC payment systems when developing resource-based PE RVUs in the non-facility setting under the PFS.

In the 2014 Proposed Rule, CMS explains that it typically establishes two distinct PE RVUs for procedures that can be furnished in either a non-facility (*e.g.*, physician's office) or facility setting.[6] The difference in payment, according to CMS, occurs because Medicare makes a separate payment to the facility for its costs of furnishing a service when a service is furnished in a facility that reflects the resources required by the facility to perform the services.[7] CMS therefore generally assumes that when services are furnished in a facility setting the total Medicare payment (made to the facility and the practitioner combined) should exceed the Medicare payment made for the same services when furnished in the non-facility setting where only the practitioner receives payment.[8] In the 2014 Proposed Rule, however, CMS explains that it has apparently learned that, with respect to a relatively small number of services, the total Medicare payment for non-facility services exceeds the total Medicare payment when the services are furnished in a facility.

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[4] Medicare Payment Advisory Commission (MedPAC), Report to the Congress, Medicare Payment Policy, pp. 45-82 (March 2012) (hereinafter "MedPAC Report").

[5] HHS, CMS, Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Final Rule, 71 Fed. Reg. 69624,69630 (Dec. 1, 2006) (hereinafter "2007 PFS Final Rule").

[6] HHS, CMS, Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Proposed Rule, 78 Fed. Reg. 43282, 43296 (July 19, 2013) (hereinafter "2014 PFS Proposed Rule").

[7] *Id.*

[8] CMS asserts that this payment difference generally reflects the greater costs that facilities incur because, *e.g.*, they maintain the capability to furnish services 24 hours per day, seven days per week, they serve higher acuity patients and have additional regulatory requirements to adhere to including EMTALA and Medicare conditions of participation and coverage. *Id.*

CMS believes this payment differential results from use of inaccurate, outdated data, as well as anomalies in the application of the resource-based PE methodology for particular services.[9] In contrast, the OPPS payment rates CMS plans to rely on in imposing the cap are based on data that, according to CMS, is both auditable and updated annually.[10]

Accordingly, CMS proposes to change the PE payment methodology beginning in 2014 to use the current year OPPS or ASC payment rates as "points of comparison" in establishing PE RVUs under the PFS.[11] Specifically, beginning in 2014, CMS will:

> (i) compare the PFS payment rate of a service furnished in the non-facility setting to the total Medicare payment to facilities and practitioners for the same services furnished in a hospital outpatient department or ASC, as applicable,[12] and then
>
> (ii) limit the payment for the non-facility PE RVU for a given code so that the total non-facility PFS payment amount would not exceed the total combined Medicare payment in the facility setting (*i.e.*, OPPS/ASC payment rate + facility PE RVU) for that code.[13]

CMS provides several exceptions to its proposed policy, generally to address circularity issues, low volume services, and other special circumstances.[14]

CMS indicates that its proposed policy is premised on several assumptions:

- Although the direct costs to furnish a service in the non-facility setting are not always lower than in the facility setting, there are significantly greater indirect resource costs that are carried by facilities even in the event that direct costs

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[9] For example, CMS indicates that it currently relies on voluntary submission of data which it claims can be difficult to validate, inadequate data that may in some instances be based on a single paid invoice, and outdated data due to the Agency's limited practical ability to review and update the PE resource costs, although CMS acknowledges that it does engage in simultaneous review of work RVUs, physician time and direct PE inputs for codes, and review of families of codes when appropriate. CMS also notes as an example new medical devices that experience high growth in volume as they diffuse into practice, leading to a decrease in the cost of an expensive item. Such items may be overpaid in terms of resource costs because of outdated price data. *Id.*

[10] *Id.*

[11] *Id.*

[12] For services with no work RVUs, and thus no PFS payment in the facility setting, CMS would compare directly to the OPPS payment rates. *Id.* at 43297.

[13] For consistency and transparency purposes, CMS proposed to use the current year PFS conversion factors and OPPS/ASC rates in the calculation. *Id.*

[14] *See id.* (listing the following exceptions: (i) services without separate OPPS payment rates, (ii) codes subject to the DRA imaging cap, (iii) codes with low volume in the OPPS or ASC, (iv) codes with ASC rates based on PFS payment rates, (v) codes paid in the facility at nonfacility PFS rates, and (vi) codes with PE RVUs developed outside the PE methodology). It is possible that certain pathology codes may qualify for these exceptions, including, for example, the low volume exception, depending on the methodology CMS employs to calculate service volume in the respective settings.

involved in furnishing a service in the office and facility settings are comparable. The non-facility setting is thus the most cost-effective location for services.[15]

- The current basis for estimating resource costs in furnishing PFS services is "significantly encumbered by [CMS'] current inability to obtain accurate information regarding supply and equipment prices as well as procedure time assumptions." CMS' proposal will mitigate the negative impact of this difficulty on the relativity of PFS services and overall Medicare spending.[16]

- MedPAC has recommended that Medicare should seek to pay similar amounts for similar services across payment settings, taking into account differences in the definitions of services and patient severity.[17]

Finally, CMS concludes that its proposed methodology will more appropriately reflect resource costs in the non-facility setting.

II. Applicable Law

Both Medicare statutory and regulatory authority require that the PE RVU be resource-based, taking into account various practice settings.

A. Statutory Authority

Since 1999, the Medicare statute governing physician payment has mandated that PE RVUs be resource-based:

> *(C) Computation of relative value units for components.—For purpose of this section* ***for each physicians' service****—*
>
> *...(ii) Practice expense relative value units.—The Secretary shall determine a number of practice expense relative value units for the service for years before 1999 equal to the product of—*
>
> *(I) the base allowed charges (as defined in subparagraph (D)) for the service, and*
>
> *(II) the practice expense percentage for the service (as determined under paragraph (3)(C)(ii)),*
>
> *and for years beginning with 1999* ***based on the relative practice expense resources involved in furnishing the service****.*[18]

[15] *Id.* at 43297-98.
[16] *Id.* at 43298.
[17] *Id.*
[18] 42 U.S.C. § 1848(c)(2)(C) (emphasis added).

In 1994, Congress enacted this law by amending the Social Security Act to require CMS to revise the PFS by 1998 so that the PE RVUs would reflect the relative amount of applicable resources physicians expend when they provide a particular service or perform a particular procedure, rather than using the prior charge-based system.[19] According to related legislative history, in developing the resource-based methodology, CMS was to consider the staff, equipment, and supplies used in providing medical and surgical services in various settings.[20] This statute remains current law.[21]

In 1997, Congress added instructions for CMS on proper implementation of the resource-based requirement in the Balanced Budget Act of 1997 ("BBA"), called for Government Accountability Office ("GAO") review, and also required that CMS consult with physician organizations with respect to data and methodology, consider the impact of any changes in implementing the statutory requirement, and phase-in the PE methodology revisions over three years.[22] This law was enacted in response to CMS' issuance of a proposed rule in June 1997 seeking to implement the 1994 Social Security Act amendments that Congress, and various stakeholders, believed might contravene the statutory mandate for resource-based payment. The explicit instructions set forth in BBA § 4505(d) were later repealed by the Patient Protection and Affordable Care Act of 2010 ("ACA"), but the ACA did not repeal the statutory mandate in 42 U.S.C. § 1848(c)(2)(C) that PE RVUs be resource-based. [23]

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[19] Social Security Act Amendments of 1994 (Pub. L. 103-432), Sec. 121, enacted on October 31, 1994. Congress acted as the result of issuance of a report by the Physician Payment Review Commission ("PPRC"), a statutorily established commission that provided advice and recommendations to Congress. The Commission report recommended that a methodology be developed to pay for practice expense and malpractice expense relative values that was more consistent with reform goals of resource-based payments, using direct cost data for delivering services and an incentive-neutral formula to allocate indirect costs. *See* Physician Payment Review Commission, "Practice Expenses Under the Medicare Fee Schedule: A Resource-Based Approach," (Number 92-1); *see also* 1999 PFS Final Rule, 63 Fed. Reg. at 58838.

[20] 139 Cong. Rec. S15909, S15935 (1993). Note that no direct legislative history exists for this provision in Pub. L. 103-432, but related commentary in the Congressional Record in November 1993 includes similar language related to Section 121 including an explanation of the change to a resource-based system for PE RVUs. *See also* 1999 PFS Final Rule, 63 Fed. Reg. at 58816.

[21] In addition, in the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act, Congress directed the Secretary of Health and Human Services to establish a process to accept and use to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data normally collected in determining the PE component of physician payment (so-called supplemental PE survey data). Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, § 212, (enacted Nov. 29, 1999); *see also* HHS, HCFA, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001; Final Rule, 65 Fed. Reg. 65376 (Nov. 1, 2000), HHS, CMS, Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule, 66 Fed. Reg. 55246 (Nov. 1, 2001), HHS, CMS, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004; Final Rule, 68 Fed. Reg. 63196 (Nov. 7, 2003).

[22] Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4505 (enacted Aug. 5, 1997) (hereinafter "BBA").

[23] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3134 (enacted March 23, 2010); codified at 42 U.S.C. §§ 1395w-4(c)(2)(K)&(L). The ACA provides some discretionary authority to CMS to adjust misvalued codes, when, for example, practice expenses change substantially, and to validate RVUs. *Id.* We located no

B. Regulatory Authority

Similarly, CMS, in regulations and rulemaking, has also consistently required a resource-based PE methodology since implementation of the Congressional mandate. In particular, CMS established both a facility and non-facility PE RVU to reflect the different settings, which is codified in current regulations.[24] CMS has recognized that actual resource costs differ between the two settings, noting that physicians incur all of the costs in the non-facility setting, while in the facility setting, the physician may incur some (likely lower) *physician* resource costs, while the hospital incurs additional *hospital* resource costs (for which it is separately paid).[25] CMS has stated:

> As the facility and nonfacility costs to the physician can vary by a considerable amount, we believe that **adopting a single average payment for both sites** would consistently underpay in-office procedures, and overpay those performed in a facility and **would thus be inherently inequitable, not-resource-based, and contrary to the intent of the law**.[26]

When revising the PE RVU methodology in 2007 to reflect a "bottom up" approach to the direct costs determination, CMS articulated a goal of ensuring that the PE portion of PFS payments reflect, to the greatest extent possible, *the relative resources required for each of the services on the PFS,* noting this could only be accomplished by using the "best available data" to calculate the PE RVUs.[27] CMS also identified as goals the need to develop a PE methodology that is understandable and intuitive so that specialties could better predict the impacts of changes in the PE data, and to avoid changes in PE RVUs that produce large fluctuations in the payment for given procedures from year-to-year.[28] Finally, in the 2014 Proposed Rule, CMS again articulated a policy of ensuring that the PE RVUs reflect resource costs in the non-facility setting.[29]

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commentary suggesting this authority extends to a payment cap borrowed from another payment system and potentially imposed on all PFS codes, not just those demonstrating substantial changes in practice expenses.

[24] *See* 42 C.F.R. § 414.22(b)(5)(i); 1999 PFS Final Rule, 63 Fed. Reg. at 58830. This approach replaced the previous policy that systematically reduced the PE RVUs by 50% for certain procedures performed in facilities. 1999 PFS Final Rule, 63 Fed. Reg. at 58830. Certain services are assigned only one kind of PE RVU, if, *e.g.*, they are performed in only one practice setting. *Id.*

[25] *Id.* The separate payments by practice setting helps ensure that CMS does not make duplicate payments to practitioners and facilities for the same services. *Id.* at 58831.

[26] *Id.* at 58830 (emphasis added).

[27] 2007 PFS Final Rule, 71 Fed. Reg. at 69630. Under the "bottom up" approach, which remains in place today, CMS adds up the costs of resources (that is, the clinical staff, equipment and supplies) typically required to provide a service and applies more refined practice expense inputs resulting from use of supplemental survey data and input from the Practice Expense Advisory Committee, among other things. *Id.* at 69634. The Practice Expense Advisory Committee provided recommendations for over 7600 HCPCS codes through March 2004. HHS, CMS, Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule; Final Rule, 76 Fed. Reg. 73026,73034 (Nov. 28, 2011).

[28] 2007 PFS Final Rule, 71 Fed. Reg. at 69630.

[29] *See* 2014 PFS Proposed Rule, 78 Fed. Reg. at 43298.

DISCUSSION

Despite its stated intentions, CMS' use of an OPPS/APC cap methodology in the 2014 Proposed Rule in our judgment violates the statutory mandate that PE RVUs in the non-facility setting be resource-based.[30] We believe use of an OPPS/ASC cap is also an unreasonable and unlawful means to address CMS' perceived data validity problem. Accordingly, the proposed OPPS/ASC cap should be removed from the PE RVU payment methodology.

I. OPPS Based Caps Are Not Resource-Based

Applying payment caps based on the OPPS payment schemes violates the Medicare mandate that PE RVUs be resource-based for the particular practice setting, as discussed below.

A. Vastly Different Settings

As a threshold matter, CMS itself has recognized that the PFS and OPPS systems are vastly different practice settings, subject to different resource inputs.[31] The law requires that the PE methodology be based on resources used in particular practice settings.[32] CMS itself has stated that applying a single payment for both sites of service, as the proposed cap would effectively do, is not resource-based and would be contrary to the statute.[33] Moreover, when asked to impose one payment system on the other in the past, CMS has repeatedly refused stating:

> ...comparisons between the MPFS and OPPS payments for services are not appropriate because the MPFS applies a very different methodology for establishing the payment for the physician's office practices expenses associated with a procedure, based on direct cost inputs.[34]
>
> ...Furthermore, the MPFS applies a very different methodology for establishing payment for the physician's office practice expense associated with a procedure, specifically considering the individual costs of the inputs, whereas the OPPS generally pays based on relative payments weights calculated from hospitals' costs as determined from claims data.[35]

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[30] For purposes of brevity and simplicity, and due to the general similarity of the OPPS and ASC payment schemes, this discussion focuses on the OPPS payment scheme.
[31] 1999 PFS Final Rule, 63 Fed. Reg. at 58830.
[32] *See* 139 Cong. Rec. S15909, S15935 (1993); 42 C.F.R. § 414.22(b)(5)(i).
[33] *Id.*
[34] HHS, CMS, Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; Interim and Final Rule, 72 Fed. Reg. 66580, 66697 (Nov. 27, 2007) (hereinafter "2008 OPPS Final Rule").
[35] *See* 2008 OPPS Final Rule, 72 Fed. Reg. at 66697, 66722, 66726.

As such, CMS should not now contravene prior policy and practice and attempt to impose OPPS payment caps as "points of comparison" in the PFS PE payment system.[36]

B. The OPPS Does Not Capture Physician Resources in the Non-Facility Setting

The OPPS is an extraordinarily complicated payment scheme that relies on bundles of services, labor/equipment/supply costs, the law of averages, geometric means, relative payment weights, geographic adjustments, and conversion factors *applicable to hospitals* to determine the appropriate payment for outpatient care.[37] Numerous features of the OPPS make it fundamentally incompatible with, and inapplicable to, a resource-based approach to payment of physicians in the non-facility setting, including, but not limited to, the features discussed below.

Prospective, Not Actual Resource-Based, Payment. First, the OPPS is a *prospective* payment methodology applicable in the complex hospital setting.[38] It is designed to capture the *average cost* of providing care for a broad range of somewhat comparable services by the many parts of a hospital outpatient department, *rather than the actual cost* of individual services provided by a physician in an office or laboratory. Moreover, in some cases "charge compression" may occur, which may have a disproportionate negative effect on specialties like pathology, to the extent such specialties have higher resource costs that are undervalued.[39]

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[36] We also note that in the 2014 Proposed Rule proposing the cap, CMS seeks to rely on a recent MedPAC recommendation that Medicare should seek to pay similar amounts for similar services across payment settings, taking into account differences in the definitions of services and patient severity. 2014 PFS Proposed Rule, 78 Fed. Reg. at 43298. The MedPAC March 2012 Report to Congress, however, focused in considerable detail on the discrete, controversial, and long-standing debate over site of service differentials in the Evaluation and Management ("E&M") code context. MedPAC Report, at pp. 45-82. Payment for E&M services can cost up to 80% more when paid in the OPPS setting than in the non-facility setting as a result of various factors, many related to the extra costs incurred to operate a hospital. *Id.* at 48. This problem has been exacerbated recently because hospitals are purchasing physician practices (in part due to Health Reform and a general change in physician attitudes), housing them in provider-based hospital outpatient departments, and thus increasing the volume of, and Medicare payments for, E&M services in the facility vs. non-facility setting, imposing a significant financial burden on the Medicare program. *Id.* at 72. The MedPAC Report studies this issue in great detail, devoting almost an entire 34 page chapter to the advantages and disadvantages of such an approach with respect to E&M services. Importantly, however, MedPAC also noted that a similar thorough examination of payment differentials in the facility and non-facility settings for other services should be conducted in the future, but did not include any evaluation of other services, such as specialty services, like pathology, in its report. Accordingly, CMS' reliance on this MedPAC report in the 2014 Proposed Rule is overly broad.

[37] These complicated systems are not summarized in full here, *but see, e.g.*, 42 U.S.C. § 1395l(t)(3)(C); 42 C.F.R. §§ 419.31, 419.32.

[38] *See* 42 U.S.C. § 1395l(t).

[39] The OPPS has historically been criticized for "charge compression," that is, applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. This practice may result in aggregation bias, where higher cost services are undervalued and lower cost services are overvalued as the result of applying an estimate of average markup, embodied in a single cost-to-charge ratio, to a range of items of widely varying values in a single cost center. CMS has attempted to address this issue in various ways (*e.g.*, developing high and low cost centers), but it may nevertheless have a biased affect on costs for certain specialties, like pathology. *See* HHS, CMS, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System, and Quality Reporting Programs; Final Rule, 77 Fed. Reg. 68210, 68223 (Nov. 15, 2012).

Likewise, the system as a whole was designed based on certain reductions to outpatient hospital operating and capital-related costs that were put in place under the prior reasonable cost-based system, and thus it does not reflect actual costs of resources.[40] By definition, a prospective payment system is not intended or designed to, and does not purport to, capture or pay separately for, individual resource inputs and thus we do not believe it can serve as a proxy for PE RVUs for each physician service in the non-facility setting, as required by statute.

Buckets of Services and the "2 Times Rule." Second, the OPPS pays on a rate-for-service basis that varies according to the Ambulatory Payment Classification ("APC") to which the service is assigned. APCs generally consist of "buckets" (groups) of several different services identified by multiple HCPCS codes (varying from one to 213 HCPCS codes within an APC). Under applicable law, these "buckets" of services in each APC are generally intended to be comparable both clinically and in terms of resource use.[41] To be comparable in terms of resources, however, and thus included in the same APC, the "2 Times Rule" applies – the highest median cost (or mean cost if the Secretary so elects) for an item or service in the APC group can be up to two times greater than the lowest median cost (or mean cost if the Secretary so elects) for an item or service within the same APC group.[42] In other words, the cost of resources within an APC can vary *substantially*.

This approach does not transfer to the PE RVU determination in the non-facility setting which, in sharp contrast, is based on *individual* Healthcare Common Procedure Coding System ("HCPCS") codes. As both Congress and CMS have stated, the PFS payment should reflect the relative resources required for each of the services on the PFS.[43] If the OPPS cap is applied, a single APC payment rate reflecting an average of resource costs for services within the "bucket" would be assigned to multiple different HCPCS codes under the PE RVU methodology. Given the variability in cost under the "2 Times Rule," this APC payment may *have no relation whatsoever* to the actual resources needed by the physician in the non-facility setting for the particular code.

This result may be exceptionally harsh for specialty services like pathology. A pathology code is not typically assigned its own individual APC under the OPPS, but instead is mixed with various other unique pathology services, of varying resource costs, in the APC "bucket." To the extent a given pathology service, particularly a highly technical one, involves higher cost services that are "averaged out" by lower cost services in the given APC "bucket" it is assigned to, the APC payment will be inadequate to cover the cost of resources for the particular individual pathology services in the non-facility setting.

In the 2014 Proposed Rule, CMS has assumed that the total cost of the OPPS/APC payment, plus the facility PE RVU payment, will always exceed the non-facility PE RVU

[40] *See* 42 C.F.R. §§ 413.124, 413.130.
[41] 42 U.S.C. § 1395l(t)(2)(b).
[42] 42 C.F.R. § 419.31(a).
[43] 42 U.S.C. § 1848(c)(2)(C); 2007 PFS Final Rule, 71 Fed. Reg. at 69630.

payment (primarily because of perceived greater indirect costs incurred by a hospital).[44] However, for certain services, like pathology, which are significantly affected by the APC "averaging" system, this assumption is faulty. In fact, as the data in Exhibit A demonstrates, the direct resource costs alone for various pathology services in the non-facility setting often exceed the Medicare APC payment rate in the facility setting.[45] *See* Exhibit A. Applying the cap would penalize physicians, like pathologists, by not reimbursing them in a manner that covers their resource costs for each particular service in the non-facility setting. In our view, OPPS caps cannot serve as a proxy for actual physician costs in the non-facility setting.

Use of Hospital Data Inputs. Third, the data related to the cost of resources in the OPPS setting is *hospital* data. It differs greatly from, and is not reflective of, the resources used in the physician practice setting in violation of the statutory directive, and CMS' own policies, that CMS "recognize the staff, equipment, and supplies used in the provision of various medical and surgical services *in various settings*."[46]

Under OPPS, CMS relies on claims-based data reported via a hospital cost report that reflects a *hospital's* costs, not those of a physician in an office or laboratory setting. Notably, the impact of this fact will be very pronounced in those instances where there is no PFS payment in the facility setting and thus only hospital resource costs will be included in the cap applied to the non-facility setting. First, the kinds of resources captured in the OPPS setting differ from typical resources in the non-facility setting. Many of these costs are simply not applicable to the resources used in the non-facility setting, nor are some of the costs incurred by physicians in the non-facility setting even captured in OPPS cost reporting.[47] In addition, as CMS itself has

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[44] 2014 PFS Proposed Rule, 78 Fed. Reg. at 43297-98.

[45] For many pathology codes, the APC payment to the hospital is the only Medicare payment made in the outpatient facility setting. That is, there is no payment to the practitioner in the facility setting for Technical Component only services. In addition, for pathology codes, the PE RVU payment made to the physician for the Professional Component typically is similar in both the facility and non-facility setting.

[46] 139 Cong. Rec. S15909 (1993)(emphasis added); 42 C.F.R. § 414.22(b)(5)(i) (describing the two levels of practice expense RVUs that correspond to each code: facility and nonfacility RVUs).

[47] For example, some of the costs that are packaged into the APC payments for the related procedures or services under the OPPS include: (1) Use of an operating suite, procedure room, or treatment room; (2) Use of recovery room; (3) Use of an observation bed; (4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations; (5) Supplies and equipment for administering and monitoring anesthesia or sedation; (6) Intraocular lenses (IOLs); (7) Incidental services such as venipuncture; (8) Capital-related costs; (9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests; (10) Durable medical equipment that is implantable; (11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and (12) Costs incurred to procure donor tissue other than corneal tissue. 42 C.F.R. 419.2. Likewise, hospital labor costs reflect a different labor market and methodology than that in the PFS. Under the OPPS system, costs are standardized by adjusting for variations in hospital labor costs across geographic areas in a budget neutral manner. The labor-related portion of the payment is wage adjusted using each hospital's wage index value. 42 U.S.C. § 1395l(t)(4); 42 C.F.R. § 419.43(c). Under the PFS, CMS generally looks at six cost pools that apply to the office setting: administrative labor, clinical labor, medical supplies, medical equipment, office supplies and other expenses, and includes such things as rent, utilities, accounting and legal fees. *See* HHS, HCFA, Medicare

acknowledged, hospitals in many instances have greater bargaining power and access to discounts, group purchasing organizations and other mechanisms to obtain equipment, supplies and services at better prices than physicians, making some of their facility resource costs lower than that of a physician or laboratory in the non-facility setting.[48] Finally, hospitals also vary greatly in how they report costs and may not report all costs for every code they bill to Medicare, making the data less reliable when applied to the non-facility setting where resource costs are based on actual costs associated with individual HCPCS codes.[49]Accordingly, in our view imposing the cost of resources required by hospitals in the hospital setting on physicians in the non-facility setting is unreasonable and violates the statutory mandate that PE RVUs in the non-facility practice setting reflect actual physician resource use in that setting.

Inconsistent with CMS' Goals. Finally, for all of the reasons discussed above, the OPPS cap is inconsistent with CMS' stated goals of ensuring that the PE portion of PFS payments reflect, to the greatest extent possible, the relative resources required for each of the services on the PFS relying on the best available data. The OPPS does not capture costs for individual services, nor is hospital cost data the best data to use in the non-facility setting. The proposed caps would also result in large fluctuations in payment from year-to-year for pathologists and laboratories, as demonstrated by Exhibit A, in contravention of CMS' stated goals. Finally, we believe it is neither intuitive nor understandable (which are CMS' articulated goals) to impose a payment cap used by one complicated payment scheme that is applicable to all outpatient operations of a hospital on an entirely different payment system that is used in the more specialized physician office and laboratory setting.

Accordingly, it is our view that the OPPS caps are not resource-based in the non-facility setting and, thus, violate the PE RVU methodology statutory mandate.

II. CMS' Implementation of the Statutory Mandate Is Not Reasonable

Under applicable principles of administrative law, CMS must ensure that its interpretation of statutory requirements are reasonable. Under *Chevron* and its progeny "...the agency, must give effect to the unambiguously expressed intent of Congress."[50] Interpretations that contravene a statutory requirement or are otherwise unreasonable violate the *Chevron* standard.

Program; Revisions to Payment Policies Under the Physician Fee Schedule; Proposed Rule, 62 Fed. Reg. 33158, 33160 (Jun. 18, 1997) (hereinafter "1997 PFS Proposed Rule"); 1999 PFS Final Rule, 63 Fed. Reg. at 58817.

[48] 2014 PFS Proposed Rule, 78 Fed. Reg. at 43297 ("Others have suggested that facilities, like hospitals, have greater purchasing power for medical equipment and disposable supplies so that the direct costs for a facility to furnish a service can be lower than costs for a physician practice furnishing the same service").

[49] It is unclear, for example how the June 30, 2012 expiration of the "grandfathered TC" rule will impact the data used here. Hospitals must now bill Medicare directly for the Technical Component of inpatient and outpatient laboratory tests, and likely will report more costs related to these services on their cost reports. Previously, independent laboratories were permitted to bill Medicare directly for these tests on hospital patients. *See* Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96), Sec. 3006 (Feb. 22, 2012).

[50] *See Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984).

A. Previous Caps Unreasonable

Importantly, the last time that CMS proposed a payment methodology that violated the resource-based requirement, Congress quickly reacted, enacting legislation requiring CMS to ensure that the PE methodology was resource-based. In a June 1997 proposed rule initially seeking to implement the resource-based requirement, CMS used various estimates, allocations, adjustments and caps to set PE RVUs.[51] Among other things, CMS attempted to implement a bottom-up approach and impose a cap on the administrative time of several categories of service based on the administrative time assigned to CPT code 99213 (midlevel office visits) as well as a cap on the nonphysician clinical staff time at 1.5 times the physician time, in minutes, for performing the procedure, both of which would not likely reflect actual resources needed for the particular services in all circumstances.[52]

Just two months later, in Section 4505(d) of the BBA, Congress articulated specific instructions to CMS instructing the agency to include all staff, equipment, supplies, and expenses, not solely those that could be linked to specific procedures, in the PE methodology, and requiring the GAO to review CMS' June 1997 proposed rule.[53] Among other things, the GAO's subsequent report, issued in February 1998, questioned the appropriateness of the proposal to cap administrative and clinical labor time estimates, finding that "although these limits seem reasonable to [CMS], they are not supported by any data or analysis."[54] Specifically, GAO concluded that "[CMS] has not examined its assumptions regarding its capping of administrative and clinical labor time estimates to ensure that they are necessary and reasonable."[55] In light of this, GAO recommended that "[w]here [CMS's] adjustments or assumptions substantially alter the rankings and RVUs of specific procedures, [CMS] should collect additional data to assess the validity of its assumptions . . ."[56]

Accordingly, CMS responded by promulgating a revised rule in November 1998 that, among other things, removed the proposed caps and acknowledged the value of "physician-

[51] 1997 PFS Proposed Rule, 62 Fed. Reg. at 33166.
[52] The proposed "bottom up" approach used estimates of actual practice expense data for each procedure as a base, and then built up from these bases to the actual practice expense value. *Id.*
[53] BBA § 4505. Congress acted in part in response to various stakeholders who argued that CMS should discard its current practice expense data and develop payment data that reflected physicians' "actual costs" and that CMS's proposed rule was inconsistent with Generally Accepted Accounting Principles ("GAAP"), as GAAP requires CMS to use actual practice expense data, while stakeholders believed that the data from the expert panels was based on "erroneous assumptions, or were unverified approximations." HHS, HCFA, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 1999; Proposed Rule, 63 Fed. Reg. 30818, 30824 and 30825 (Jun. 5, 1998) (hereinafter "1999 PFS Proposed Rule"); *see also*, GAO Report, at 2 ("Some physician groups argued that HCFA based its proposed revisions on invalid data and that the reallocation of Medicare payments would be too severe.").
[54] GAO, Medicare: HCFA Can Improve Methods for Revising Physician Practice Expense Payments, GAO/HEHS-98-79, at 4, 20-21, 27 (Feb. 1998) (hereinafter the "GAO Report").
[55] *Id.* at 27.
[56] *Id.* at 28.

reported actual practice expense data" in calculating the PE RVU.[57] We believe that CMS should take similar action here.

B. Caps are an Unreasonable and Unlawful Means to Address a Perceived Data Issue

In the 2014 Proposed Rule, CMS rationalizes the proposed use of OPPS/ASC payments caps as a solution to its concern that its existing PE methodology is "significantly encumbered by its current inability to obtain accurate information regarding supply and equipment prices, as well as procedure time assumptions."[58] CMS states that the data it currently relies on in the PE RVU non-facility methodology is incomplete, based upon a small sample, potentially biased or inaccurate, and outdated.[59] CMS is also concerned that there is no practical means for CMS or stakeholders to routinely update the data.[60] In contrast, according to CMS, the OPPS (hospital) data is updated annually and is auditable. CMS thus deems the OPPS data to be a suitable proxy for actual physician resource costs in the 2014 Proposed Rule.

When CMS attempted to exceed its authority under the resource-based system in 1997, Congress statutorily required the GAO to study CMS' approach and provide specific guidance to CMS on proper implementation of the resource-based rule. Under the recommendations of this statutorily-required GAO report and based on the *Chevron* standard, CMS must examine its underlying assumptions and collect additional data (particularly if proposed adjustments or assumptions alter rankings and RVUs of specific procedures, as is the case here for pathology) to ensure that caps and other mechanisms within its resource-based payment methodology are "necessary and reasonable."[61] Here, we believe that many of CMS' assumptions and adjustments with respect to the proposed cap are arguably neither necessary nor reasonable. In addition, to our knowledge, CMS has not collected additional data to confirm their validity.

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[57] Specifically, CMS stated:

> [W]e have decided to propose the "top-down" methodology. We believe the "top-down" methodology is more responsive than the "bottom up" approach to both BBA 1997 requirements and to many of the concerns of the medical community. By using aggregate specialty practice costs as the basis for establishing the practice expense pool, we are recognizing all of a specialty's costs, not just those linked with a specific procedure. By basing the redistributions of the practice expense system on physician-reported actual practice expense data . . . we avoid many of the criticisms leveled at our original proposal.

See 1999 PFS Proposed Rule, 63 Fed. Reg. at 30826. This revised methodology, among other things, eliminated the proposed caps on clinical and administrative staff times. *Id.*

[58] 2014 PFS Proposed Rule, 78 Fed. Reg. at 43298.

[59] *Id.* at 43296.

[60] *Id.*

[61] With respect to caps that CMS sought to implement in the initial proposed rule in June 1997, the GAO concluded: "[CMS] has not, however, conducted tests or studies that validate these changes and thus cannot be assured that they are reasonable and necessary." GAO Report, at 20.

CMS states that the OPPS data is a superior proxy because it is updated annually and is auditable. While CMS may review and update features of the OPPS,[62] CMS fails to recognize that under the existing PE RVU processes of the American Medical Association's ("AMA") Relative Value Scale Update Committee ("RUC") and its subcommittees, the PE direct cost input data is updated on a rolling basis by the RUC and the indirect practice expense costs are updated periodically using a survey process.[63] In addition, CMS indicates that the OPPS data is auditable, perhaps because of the hospital cost reporting system.[64] Cost reports are not applicable in the physician office or laboratory setting, but under the existing RUC PE RVU processes the AMA assembles data that is evidence-based and typically derived from surveys and invoices of physicians actually providing care to patients in the non-facility setting, which is then carefully reviewed by experienced RUC subcommittees several times a year on a code-by-code, batch basis.[65] CMS itself has recognized the value of physician-reported actual practice expense data like this.[66] Thus, the existing process involves data that is subject to significant, detailed updating and review. As such, it is our view that the use of proxy OPPS data is neither necessary nor reasonable here.

Finally, CMS did not test many of its assumptions using actual data. As Exhibit A shows, payments to the hospital for its resource costs in the facility setting do not always exceed even

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[62] 42 U.S.C. § 1395l(t)(2)(C); 42 C.F.R. § 419.31(b), 419.50. OPPS suffers from a time lag because, under applicable law, the Secretary is required to use hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports (usually about two years old) to establish relative payment weights used for the APC payment calculation.

[63] *See* 1999 PFS Proposed Rule, 63 Fed. Reg. at 30828-29. Such indirect costs were initially based on the AMA's Socioeconomic Monitoring System ("SMS") survey, and then updated by the Physician Practice Information Survey ("PPIS") also conducted by the AMA when the SMS data become obsolete. The SMS survey involved telephone conversations with a nationally representative sample of patient care physicians that collected comprehensive data on time and practice expenses between 1981 and 1999. The PPIS survey was conducted in 2007 and 2008 using multiple modes (online, facsimile and telephone) and included almost 7500 physicians and related health care professionals covering 50 specialties, over 3600 of whom provided complete practice cost information. *See* 1999 PFS Proposed Rule, 63 Fed. Reg. at 30828; "Physician Practice Information Survey" *accessible at* http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/the-resource-based-relative-value-scale/physician-practice-information-survey.page (last visited Aug. 23, 2013).

[64] *See, e.g.*, 42 C.F.R. § 419.43.

[65] CMS has stated that review by an appropriate independent entity would be an effective means to audit survey data. 1999 PFS Final Rule, 63 Fed. Reg. at 58821. The AMA is an independent entity that seeks to ensure that the best available data is used in its RUC process. The RUC PE data is based on actual invoices submitted by the average midsize laboratory (viewed by the RUC as more representative than very small laboratories that only run an occasional test, or very large laboratories that run many tests at once). The RUC subcommittees, like the Practice Expense Refinement Committee, meet several times a year and engage in a code-by-code, batch-based review of the clinical labor, medical supplies and equipment typically used in the non-facility and facility settings, as appropriate. A batch-based review is a means to prorate practice expenses and helps ensure that each service is distinct and that no overlap in practice expenses occurs. *See* American Medical Association, AMA/Specialty Society RVS Update Committee, RUC is/RUC is not, *accessible at* http://www.ama-assn.org/resources/doc/rbrvs/ruc-is-ruc-is-not.pdf (last visited Aug. 20, 2013).

[66] 1999 PFS Proposed Rule, 63 Fed. Reg. at 30826 ("By basing the redistributions of the practice expense system on physician-reported actual practice expense data . . . we avoid many of the criticisms leveled at our original proposal").

the direct resource costs for physicians in the non-facility setting. Many stakeholders, including the College of American Pathologists, believe that the current PE methodology, utilizing the RUC, rather than using OPPS data as a proxy, results in collection of the best available data (CMS' own articulated goal) on which to base payment of physicians in the non-facility setting.[67] Finally, we believe CMS' reliance on a MedPAC recommendation regarding similar payment across practice settings is misplaced. MedPAC's recommendation, by its own admission, addressed only E&M codes, not the many other services provided by specialty physicians in multiple practice settings.[68] In our view, CMS' underlying assumptions in the 2014 Proposed Rule are flawed. Accordingly, in our judgment, the proposed OPPS/ASC cap fails to meet the reasonable and necessary standard and is contrary to law.

III. Conclusion

In our view, application of CMS' proposed OPPS/ASC payment cap in the non-facility PE RVU methodology is not resource-based for the practice setting and is unlawful. Many stakeholders believe that the current process used to determine PFS non-facility PE RVUs relies on the best available data in the non-facility setting. To the extent CMS may perceive a data issue with respect to non-facility PE RVUs, we do not believe it should address the problem through the broad application of an unreasonable and unlawful payment cap like that proposed in the 2014 Proposed Rule.

[67] Stakeholders articulate that CMS has benefited from the organized, thorough and accurate work of RUC for many years. The RUC, which consists of 31 members representing multiple medical specialties, is required to comply with applicable law, applies an evidence-based approach, gives CMS a seat at the table during all RUC discussions, and provides its services to CMS free of charge. CMS is also not obligated to accept its recommendations if it disagrees with the RUC. The RUC also recommends both increases and decreases in costs and payments as appropriate. For example, under the ACA's misvalued code initiative, the RUC has reviewed about 1300 misvalued services and recommended reductions or deletions of more than 750 services (saving $2.5 billion for Medicare). *See, e.g.*, "AMA-convened expert panel benefits Medicare," (Aug. 5, 21013) *accessible at* http://www.amednews.com/article/20130805/opinion/130809973/6/ (last visited Aug. 23, 2013).

[68] MedPAC Report, at pp. 45-82; *see also supra* note 36.

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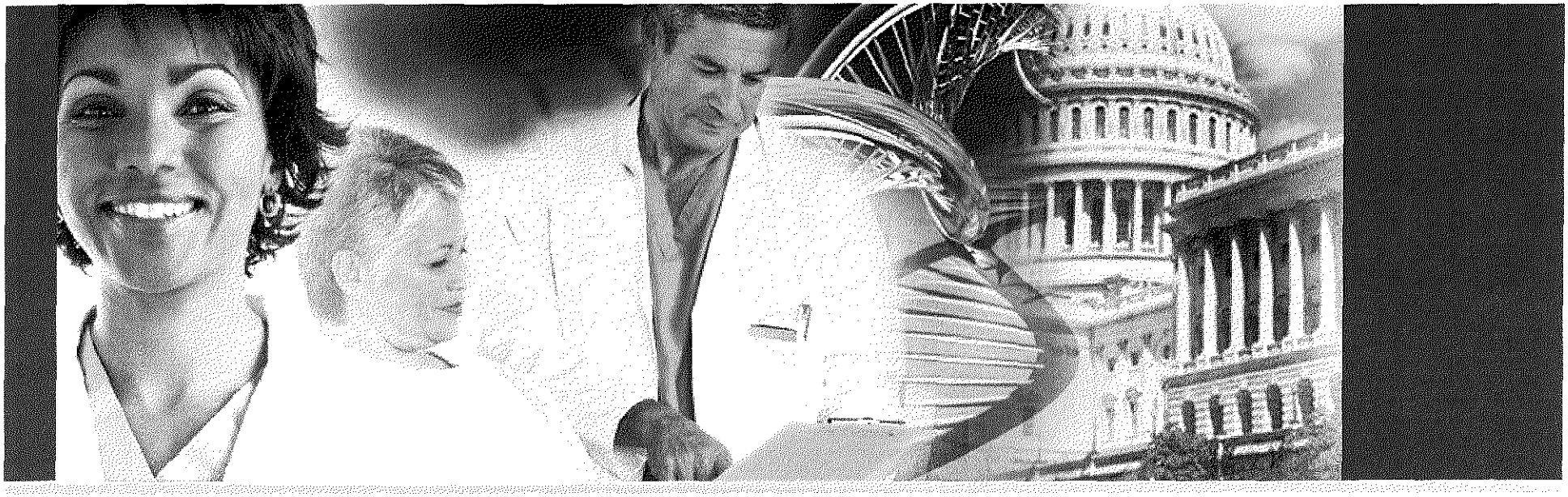
Exhibit A

EXHIBIT A

CMS Total Direct Practice Expense Inputs and 2013 APC Payment Rates - Pathology Examples

CPT Code	Descriptor	2013 NF PE RVUs	2013 NF PE RVU Payment*	APC	NF Direct Inputs Total Cost	2013 APC Payment Rate	Amount of Direct Input Costs that are Greater than the 2013 APC Payment
88104	Cytopath fl nongyn smears	1.39	$47.29	0433	$33.22	$23.43	$9.79
88106	Cytopath fl nongyn filter	1.94	$66.00	0433	$46.57	$23.43	$23.14
88108	Cytopath concentrate tech	1.66	$56.48	0433	$44.52	$23.43	$21.09
88112	Cytopath cell enhance tech	1.50	$51.03	0433	$43.96	$23.43	$20.53
88160	Cytopath smear other source	1.11	$37.77	0342	$26.90	$12.71	$14.19
88161	Cytopath smear other source	1.05	$35.72	0342	$29.17	$12.71	$16.46
88162	Cytopath smear other source	1.67	$56.82	0433	$39.25	$23.43	$15.82
88173	Cytopath eval fna report	2.34	$79.61	0343	$60.87	$38.10	$22.77
88182	Cell marker study	2.15	$73.15	0343	$81.05	$38.10	$42.95
88184	Flowcytometry/ tc 1 marker	2.60	$88.46	0433	$123.59	$23.43	$100.16
88185	Flowcytometry/tc add-on	1.58	$53.76	0342	$78.26	$12.71	$65.55
88304	Tissue exam by pathologist	0.97	$33.00	0433	$26.73	$23.43	$3.30
88307	Tissue exam by pathologist	6.32	$215.03	0344	$153.64	$60.45	$93.19
88309	Tissue exam by pathologist	8.92	$303.49	0661	$215.61	$157.05	$58.56
88312	Special stains group 1	2.08	$70.77	0433	$62.12	$23.43	$38.69
88313	Special stains group 2	1.63	$55.46	0433	$50.40	$23.43	$26.97
88314	Histochemical stains add-on	1.71	$58.18	0433	$51.87	$23.43	$28.44
88319	Enzyme histochemistry	1.76	$59.88	0433	$43.72	$23.43	$20.29
88323	Microslide consultation	1.71	$58.18	0343	$67.85	$38.10	$29.75
88325	Comprehensive review of data	3.56	$121.12	0344	$68.79	$60.45	$8.34
88329	Path consult introp	0.98	$33.34	0342	$15.87	$12.71	$3.16
88331	Path consult intraop 1 bloc	1.12	$38.11	0433	$26.14	$23.43	$2.71
88333	Intraop cyto path consult 1	1.25	$42.53	0433	$30.36	$23.43	$6.93
88334	Intraop cyto path consult 2	0.79	$26.88	0342	$18.31	$12.71	$5.60
88342	Immunohistochemistry	2.14	$72.81	0343	$64.22	$38.10	$26.12
88346	Immunofluorescent study	1.97	$67.03	0343	$65.37	$38.10	$27.27
88347	Immunofluorescent study	1.20	$40.83	0433	$48.87	$23.43	$25.44
88348	Electron microscopy	19.06	$648.48	0661	$584.31	$157.05	$427.26
88349	Scanning electron microscopy	11.64	$396.03	0661	$250.13	$157.05	$93.08
88355	Analysis skeletal muscle	2.93	$99.69	0343	$119.40	$38.10	$81.30
88360	Tumor immunohistochem/manual	2.19	$74.51	0343	$76.57	$38.10	$38.47
88361	Tumor immunohistochem/comput	2.91	$99.01	0343	$103.26	$38.10	$65.16
88362	Nerve teasing preparations	5.92	$201.42	0344	$140.78	$60.45	$80.33
88363	Xm archive tissue molec anal	1.27	$43.21	0342	$32.43	$12.71	$19.72
88365	Insitu hybridization (fish)	3.53	$120.10	0343	$119.83	$38.10	$81.73
88367	Insitu hybridization auto	5.82	$198.01	0343	$240.92	$38.10	$202.82
88368	Insitu hybridization manual	5.00	$170.12	0344	$228.17	$60.45	$167.72

* Calculated using the 2013 PFS conversion factor of $34.023



College of American Pathologists
Meeting with Office of Information and Regulatory Affairs, Office of Management and Budget
2014 Proposed Physician Fee Schedule
October 30, 2013

2014 Proposed Physician Fee Schedule

- CMS proposed to link payment for over 200 services to hospital outpatient ambulatory payment classification (APC) rates
  - Reduces technical component (TC) and global payments of 39 pathology codes billed for non-hospital patients
  - Responsible for 5% overall cut to pathology Medicare payment; 26% cut to laboratories
  - Nearly 70% of the total dollar reduction under this proposal comes from laboratories

Problem with Hospital Outpatient Linkage

- **Physician Fee Schedule pays for specific resources**
- **Hospital APC grouping represents average costs for group of codes**
  - **APC codes grouped based on comparable resource utilization**
  - **Median costs determined for each code**
  - **Codes are not similar if the resource costs of the highest is more than 2 times the cost of the lowest**
  - **Types of costs hospitals incur are different than those incurred in the non-facility setting**
- **Some code costs are higher, some lower than APC rate**
- **Specific resources per code lost under APC**

CMS Proposal Violates Medicare Statute

- **Sidley Austin prepared legal analysis showing that proposal violates statutory requirement that the practice expense relative value units (PE RVUs) under the Physician Fee Schedule be resource-based**

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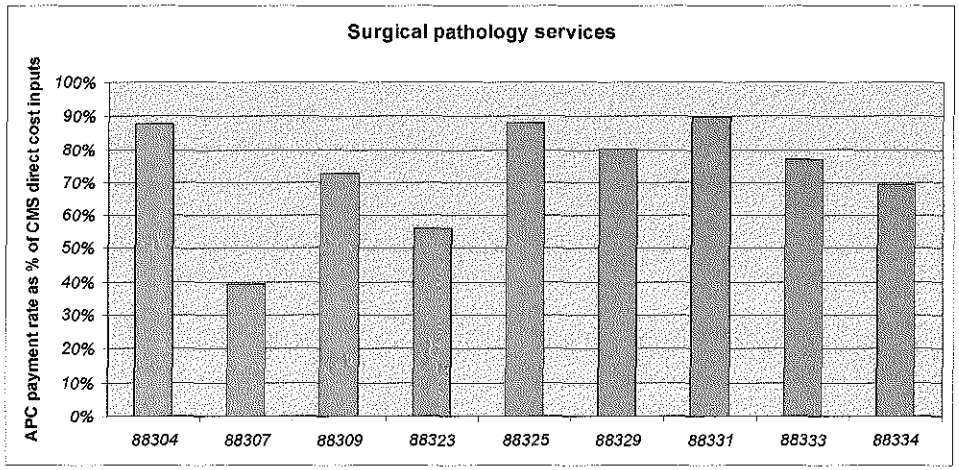
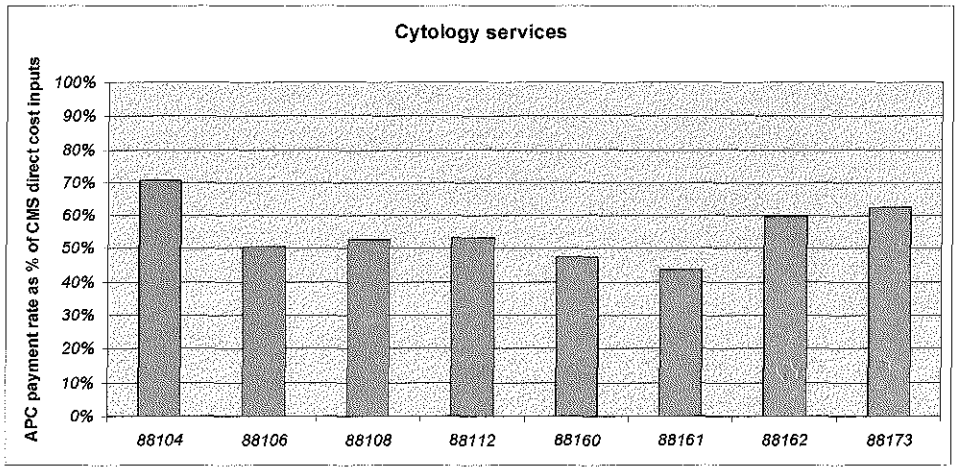
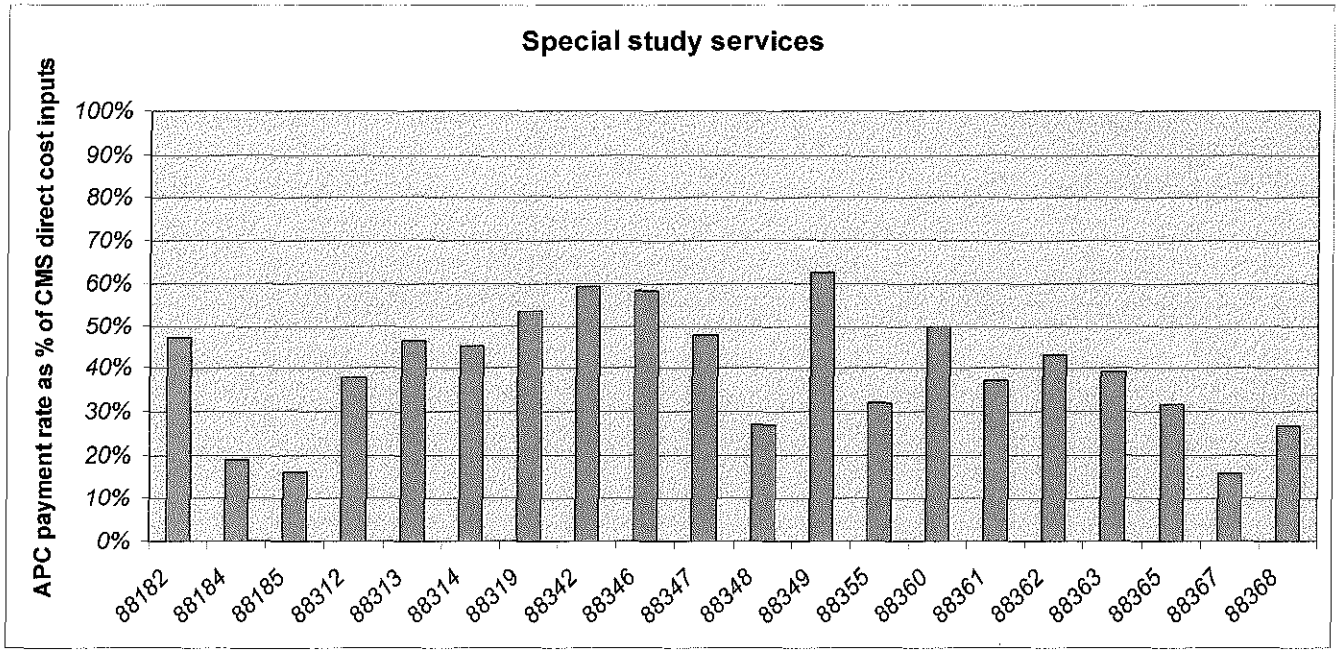
APC Payments as % of CMS Direct Cost Inputs







Example of Payment Inadequacy

- **CPT Code 88367 – insitu hybridization (breast cancer test to determine appropriate therapy)**
  - **Requires $150 kit in CMS' physician fee database**
  - **Rarely performed in hospital outpatient setting**
  - **Hospital APC costs averaged with less costly services**
  - **CMS proposes payment of $40 based on flawed proposal**

CAP's Response

- **Payment linkage to the hospital outpatient rates fails to take into consideration the technical costs associated with specific individual codes**
- **Current law requires physician fee schedule values to be resource-based.**
- **Linking payment to the hospital outpatient grouping system fails to recognize distinct resources**

Many Concerned Stakeholders

August 23, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

The undersigned organizations are writing to express our deep concerns with the reimbursement cuts to pathology services proposed by CMS in the Physician Fee Schedule Proposed Rule for CY 2014. The proposal includes changes that will adversely impact a broad array of diagnostic pathology tests which are critical in the diagnosis and treatment of many

American Medical Association
American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American Association of Oral and Maxillofacial Surgeons
American Clinical Neurophysiology Society
American College of Cardiology
American College of Chest Physicians
American College of Gastroenterology
American College of Mohs Surgery
American College of Physicians
American College of Radiation Oncology
American College of Radiology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Society for Blood and Marrow Transplantation
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Hematology
American Thoracic Society
American Urogynecologic Society
American Urological Association
Association of Freestanding Radiation Oncology Centers
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
Joint Council of Allergy, Asthma, and Immunology

United States Senate
WASHINGTON, DC 20510

October 17, 2013

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Tavenner:

We are writing to express our serious concerns with a proposal in the Centers for Medicare & Medicaid Services (CMS) proposed 2014 Medicare Physician Fee Schedule (PFS) rule to significantly reduce Medicare payments to laboratories for anatomic pathology services. We are concerned that the proposed new rates are not supported by adequate cost data and could lead to unintended consequences, including loss of patient access to critical cancer diagnostic services and increased costs elsewhere in the Medicare program. Furthermore, by law, CMS is required to determine payment for physician services using a resource-based methodology. Proposing to cap payments for anatomic pathology services at the Hospital Outpatient Prospective Payment System (OPPS) levels seems contrary to this statutory mandate.

While we appreciate CMS's efforts to improve payment accuracy and review potentially misvalued service codes, we are concerned that the methodology used to calculate OPPS rates does not necessarily reflect the actual cost of pathology services. In fact, we have heard from our constituents that some of the proposed payment rates will fall well below the cost of providing these diagnostic tests. Implementing cuts that average 26 percent across the board, and exceed 75 percent for some anatomic pathology services, could have a severe impact on the ability of laboratories, particularly independent laboratories in our local communities, to continue to provide these services to Medicare beneficiaries.

As our health care system moves further in the direction of precision medicine, the ability to obtain an accurate diagnosis is critically important. Diagnostic tests that are reimbursed at several hundred dollars under the current PFS are used to determine whether a patient is likely to respond to a course of therapy that may cost tens of thousands of dollars. We are concerned that reduced access to diagnostic services may result in some patients never receiving a treatment that could help them, while others receive expensive treatments that are ineffective for their particular condition, adding unnecessary costs to the Medicare program.

We are also concerned about whether CMS is taking into account the overall cost of treating patients in different settings. While the Proposed Rule focuses on anatomic pathology and other services that are reimbursed at a higher rate under the PFS than under the OPPS, many other services are reimbursed at a significantly higher rate under OPPS. If the proposed PFS cuts result in more patients receiving treatment in a hospital setting where the overall cost of care is higher, savings to the Medicare program will not be achieved.

Thank you for your attention to this matter. We urge you to reconsider this proposal in light of the extensive concerns our constituents have raised in their comments on the Proposed Rule, and we look forward to hearing from you.

Sincerely,

Heidi Heitkamp

Bill Nelson

Congress of the United States
Washington, DC 20515

October 7, 2013

The Honorable Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Washington, DC 20201

Dear Administrator Tavenner:

We write to express our strong opposition to a proposal in the Centers for Medicare & Medicaid Services (CMS) proposed rule updating the Medicare physician fee schedule (PFS) rates and policies for calendar year (CY) 2014. Under the 2014 Medicare Physician Fee Schedule Proposed Rule, Medicare payments to independent laboratories for anatomic pathology services that diagnose a broad range of illness for non-hospital patients would be drastically cut. Without fully accounting for the resources provided and expertise required to perform these vital tests, CMS's proposed rule would diminish beneficiary access to crucial anatomic pathology services. We, therefore, urge CMS to reconsider its proposal to cap payments for anatomic pathology services at the Hospital Outpatient Prospective Payment System (OPPS) levels.

While CMS estimates that the 2014 policy change would cut global payments rates to independent laboratories an average of 26%, CMS is proposing to cut some anatomic pathology services by over 75%. Moreover, in many cases, the new payment rates will actually be below the cost of providing these tests. As a result, the ability of independent laboratories to continue to provide the full range of anatomic pathology services in our communities will be severely limited or curtailed.

Our chief concern is with the methodology used in determining the proposed cuts. The recommendation in the Proposed Rule to compare PFS data to the OPPS data diverges from the requirements set forth by statute and regulation, thereby circumscribing the Relative Value Unit (RVU) framework. Current law requires CMS to use a resource-based methodology to determine payment for physician services on the PFS, not OPPS. The PFS provides granular, code-level data for each anatomic pathology service, while OPPS data contains only lump, aggregate lab cost reporting from hospitals for all anatomic and clinical laboratory services. As such, the actual cost for providing anatomic pathology services are not necessary reflected in the OPPS data set. Unlike other site neutral payment proposals, the structural differences between PFS and OPPS may undercut CMS' ability to make valid comparisons between the two systems.

To better understand the rationale for the proposed rule, we are interested in learning why CMS did not make adjustments within the current methodology it uses for determining the value of physician fee schedule services as well as the statutory basis for using OPPS data to determine payments for clinical lab services paid under the physician fee schedule.

While pathology services account for less than 2% percent of Medicare spending, 70% of clinical decisions are based on the diagnostic and monitoring services provided by labs. Medicare beneficiary access to lab results are critical. Based on anatomic pathology services, physicians are best able to determine the most appropriate and effective medical care for their patients. Pathology services, including biopsies, are critical to the timely and effective treatment of millions of cancer patients. Limiting beneficiary access to the full-range of testing services will serve only to increase misdiagnoses or unnecessary, ineffective treatments without improved health care outcomes or reducing Medicare spending costs.

As CMS moves forward with rulemaking to finalize payment policies for CY 2014, we urge you to reconsider the proposed payment cap for anatomic pathology services at the OPPS levels. We believe the current proposal would have a detrimental impact on Medicare beneficiaries and their physicians who rely on anatomic pathology services to make accurate diagnosis.

Thank you in advance for consideration of our comments. We remain committed to working with you on payment policies that provide fair and accurate reimbursement and maintain Medicare beneficiary access to these vital diagnostic tools and look forward to your timely response to our questions.

Sincerely,

Member of Congress

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