August 29, 2013

American Clinical Laboratory Association

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

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, and Other Revisions to Part B for CY 2014, Proposed Rule (CMS-1600-P)

Dear Ms. Tavenner,

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") proposed rule on revisions to the Physician Fee Schedule, Clinical Laboratory Fee Schedule, and Part B payment for calendar year ("CY") 2014.[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are developed openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

ACLA's comments focus on two aspects of the proposed rule: using Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgery Center ("ASC") rates in limiting practice expense relative value units ("PE RVUs") for codes with higher total Medicare payments in the office setting than in a hospital or ASC, and CMS's proposals regarding adjusting payment for laboratory test codes on the Clinical Laboratory Fee Schedule ("CLFS") based on technological changes.

ACLA strongly urges CMS to withdraw its proposal to limit the non-facility PE RVUs for individual codes so that the total non-facility Physician Fee Schedule ("PFS") payment amount would not exceed the total combined amount Medicare would pay for the same codes in the facility setting. Among the individual codes for which CMS seeks to limit payment in this way are 38 anatomic pathology codes. This proposed policy is built upon the faulty assumption that facility cost reports yield more accurate data about the actual cost of providing a service and that the cost to perform a service in a physician's office always must be lower. The OPPS and PFS systems are hardly comparable, being derived through entirely different methodologies and for different purposes, and individual codes on the PFS cannot and should not be compared to Ambulatory Payment Classification ("APC") rates in the facility context. Not only does this proposal lack a sound policy basis, but it would discourage innovation and continued offering of

[1] 78 Fed. Reg. 43282 (July 19, 2013) ("Proposed Rule").

certain assays by slashing reimbursement for tests that are vital to the treatment of Medicare beneficiaries with cancer and other serious diseases.

With respect to CMS's proposed review of technological changes that may affect the cost of performing some laboratory tests, ACLA urges CMS to proceed with great caution in this effort, in order to ensure that it does not impose unreasonable cuts to laboratory reimbursement, since laboratories already are struggling to absorb the cumulative and disproportionate impacts of numerous recent cuts, including the effects of sequestration. While we take issue with the premise that payment amounts for test codes on the CLFS have remained unchanged for years, we do agree that technological changes can affect the cost of performing laboratory tests, both increasing the costs and decreasing the costs. In reviewing these technological changes, it is essential that all parties – CMS, laboratories, and other interested members of the public – be involved in the development and refinement of the review process. It is vital that this process be carried out transparently, consistently, and with opportunity for meaningful involvement by the industry. In particular, all parties should have the same understanding of the scope of a review and the meaning of the terms included in the definition of "technological changes." Since this project is an enormous undertaking, CMS should start with a pilot project in which it reviews a limited number of test codes. It also should spread its review over a greater number of years than currently proposed, balance its review of high-volume and low-volume codes, and cap and phase in fee adjustments.

I. Using OPPS and ASC Rates in Developing PE RVUs for Codes with Higher Total Medicare Payments in the Office than in the Hospital or ASC

CMS proposes that when the amount paid under the PFS for a service is higher than what is paid for that same service under the OPPS, the Agency would adjust the PE RVUs under the PFS so that the amounts paid are equal.[2] We urge CMS to withdraw its proposal because there is not a legally or conceptually sound basis for establishing such a payment policy.

ACLA and all other laboratory organizations with which we work have significant concerns with CMS's proposal to limit payment under the PFS for certain codes to that which would be paid in the facility setting. First, CMS provides no rationale for this change other than the fact that some hospital rates may be lower than some PFS rates. However, the PFS and OPPS are two entirely different payment methodologies, and it is inappropriate to make a direct comparison of a CPT code payment under the PFS with an APC payment under the OPPS. Second, the rates change constantly relative to each other. CMS uses 2013 OPPS rates for the comparison, but if it used 2014 rates instead, it would find the very same services reimbursed at *lower* rates under the PFS. Third, CMS's suggestion that the hospital payment system provides a more accurate basis for determining appropriate payment is wrong and is belied by the Agency's proposal to reduce higher PFS rates but not increase lower PFS rates, as well as the Agency's own past statements.

[2] *Id*. at 43296.

A. Summary of CMS's Proposal

In the Proposed Rule, CMS states that in some instances, payment for a service, when furnished in a physician's office setting, exceeds the total payment when the same service is furnished in a hospital outpatient department. CMS claims that this is not the result of appropriate payment differentials, but rather that it is due to anomalies in the data used under the PFS and OPPS.[3] CMS further argues that the information on which PE RVUs are based may be incomplete, outdated, or inaccurate, while OPPS payment rates are based on auditable hospital data and are updated annually.[4] As a result, CMS proposes to change the practice expense rate-setting methodology beginning in 2014. Henceforth, CMS would compare the PFS payment rate for a service furnished in the office setting to the total Medicare payment paid for the same service when furnished in a hospital outpatient setting. CMS proposes to limit the non-facility PE RVUs so that the total payment would not exceed the payment made in the facility setting. In performing this calculation, CMS applies the 2013 conversion factor to the unadjusted RVUs.

Thirty-eight codes for a variety of anatomic pathology services would be affected by this proposal.[5] The impact of the proposed policy on payment for these codes, if finalized, would be devastating. Not surprisingly, because the hospital APC payment compares directly to the practice expense component under the PFS, the most significant impact would be on payment for the technical component ("TC") of many pathology services. The chart below shows the percentage reductions in payment for selected codes between 2013 and 2014, assuming the conversion factor remains unchanged.[6]

[3] *Id*. at 43308.
[4] *Id*. at 43296.
[5] There is some question whether or not certain codes even should be included in the proposal, as it appears that fewer than five percent of the total services under those codes are furnished in a facility setting under the OPPS. CMS proposed to exclude "any service for which five percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services." 78 Fed. Reg. 43297. The codes in question include CPT codes 88120 and 88121, 88367, and 88368 ("FISH" testing), and 88184 and 88185 (flow cytometry). CMS has informally indicated that CPT 88120, at least, should not have been included.
[6] The American Pathology Foundation, *Special Bulletin* (Aug. 16, 2013).

HCPCS	Mod	Description	2014 PFS Proposed Payment	2013 Payment	Change in Dollars	Percent Change
88108	TC	Cytopath, concentration technique	23.82	56.82	(33.00)	-58%
88112	TC	Cytopath, cell enhance technique	23.82	51.37	(27.55)	-54%
88173	TC	FNA interp	38.45	79.95	(41.50)	-52%
88184		Flow cytometry, TC 1st marker	23.82	88.80	(64.98)	-73%
88185		Flow cytometry,TC Additional marker	12.93	54.10	(41.17)	-76%
88304	TC	Level III path exam	23.82	33.34	(9.52)	-29%
88307	TC	Level V path exam	60.90	215.37	(154.47)	-72%
88312	TC	Special stain, Grp 1	23.82	71.11	(47.29)	-67%
88313	TC	Special stain,Grp 2	23.82	55.80	(31.98)	-57%
88331	TC	Path consult, during surgery	23.82	38.45	(14.63)	-38%
88342	TC	Immunohistochemistry	38.45	73.15	(34.70)	-47%
88360	TC	Immunohistochemistry	38.45	74.85	(36.40)	-49%
88361	TC	Immunohistochemistry	38.45	99.35	(60.90)	-61%
88365	TC	In situ hybridization	38.45	120.44	(81.99)	-68%
88367	TC	In situ hybridization	38.45	198.35	(159.90)	-81%
88368	TC	In situ hybridization	60.90	170.46	(109.56)	-64%

As shown by the chart above, in some instances, the payment reductions would be more than 70 percent below current levels. While this represents the TC portion of many of these codes, the reductions still are significant when the code is billed globally. ACLA believes that Medicare should pay only a reasonable amount for any service, but it strains credulity to suggest that the Medicare program has been overpaying for these services by such a huge amount throughout the years, especially given the various tools that CMS has for reviewing potentially misvalued codes under the PFS.[7] The size of the proposed reimbursement reductions alone should give some pause concerning whether the policy underlying this approach is well-founded.

Further, these reductions would have grave implications for patient care. Many of these services, such as flow cytometry and in situ hybridization, are tests that are vital to the early diagnosis and treatment of cancer, including leukemia, lymphoma, and breast cancer. It is

[7] As a matter of fact, in recent PFS rules, CMS identified several of the codes in the chart as potentially misvalued codes and suggested that the American Medical Association Relative Value Scale Update Committee ("the RUC") should review them. These codes include CPT codes 88312, 88342, 88365, 88367, and 88368. The RUC has not yet reviewed these codes, and CMS should not be including these codes in the current proposal without having allowed the RUC to carry out its duties with respect to potentially misvalued codes. We note that CMS embraced the RUC's work with respect to misvalued codes when the Agency slashed reimbursement for CPT code 88305 by about 30 percent in the CY 2013 PFS final rule, yet the Agency now seems to have less confidence in the process. *See* 77 Fed. Reg. 68892, 69074 (Nov. 16, 2012).

unreasonable to expect that these services will continue to be available in the same manner as today if the reimbursement is cut in the draconian manner CMS proposes. These are not simple or inexpensive tests to perform, yet they are much less expensive and painful than later treatments at more advanced cancer stages that could have been avoided with early detection. The size of the proposed reductions, combined with the complexity and importance of the tests, suggest that great caution should be exercised before implementing such a flawed policy proposal as this.

B. CMS lacks a sound rationale for its proposal.

CMS has spent over two decades developing the PFS. The requirements of the PFS comprise thousands of pages in the Federal Register, as well as extensive sections in the Code of Federal Regulations. As mandated by Congress, CMS has developed a system of determining the PE RVUs. According to CMS's own regulations, the PE RVUs are computed "for each service or class of service by applying average historical practice cost percentages to the estimated average allowed charge during the 1991 base period."[8] While this formula has changed over time, the basic theory behind it has not. Practice expenses are based on historical practice cost percentages. Clearly, that historical practice cost cannot reflect the costs in the hospital setting as opposed to those furnished in an office setting. There simply is no basis that would permit CMS to use costs derived from the facility setting.

CMS does not cite any authority that would allow it to reject the data that it has developed over 20 years and utilize a new and distinct set of data to establish payment levels. CMS's only argument is that using the OPPS rate would result in lower payments than the PFS would. However, as discussed below, the rates established under the OPPS represent grouped codes that are not easily comparable to the individual CPT codes used in the PFS. Moreover, there is no basis for switching from the rates developed under one payment system to those developed under another. If this were permissible, CMS unilaterally could adopt *any* other payment system that it found attractive. CMS does not have the authority simply to jettison values developed under the PFS system simply because it prefers the rates that another system provides.

The arbitrary nature of CMS's proposal is underscored by the fact that it would use this approach only to lower payments when the PFS rate is higher than the OPPS rate. If CMS truly believed that hospital rates better reflected costs, then it also should have proposed to raise reimbursement under the PFS when the PFS rate is lower than the OPPS rate, as is the case for the relatively common CPT code 88305. CMS has made no such proposal here, however, which undermines the validity of its proposal.

Further, CMS's approach is based only on a comparison of the ***current*** payment amounts under the PFS and OPPS, as adjusted by CMS. CMS has based its proposal on a "snapshot in time" and compares what the PFS rates otherwise would be in 2014 (using the 2013 conversion factor) to what the 2013 payment levels for the same service under the OPPS would be. It then would adjust the RVUs for the 2014 PFS to ensure that the PFS rate would not exceed the OPPS

[8] 42 C.F.R. § 414.22(b).

rate. However, this comparison skews results based on this year's data. Hospital rates and PFS rates change relative to each other each year as adjustments are made under both systems.

For example, APC 0343, one of the APCs that includes many of the pathology services at issue here, will increase from a payment of $38.10 in 2013 to $277.56 in 2014, an increase of over 600 percent. This far exceeds the 2013 PFS payment for this same service. If CMS waited just one year to undertake this exercise and compared the projected 2014 APC payment rates with the PFS payment levels, the hospital payments would far exceed the amounts paid under the PFS. Would CMS then slash hospital payments to make them equal to PFS rates? Alternatively, would CMS raise the PFS rates next year to reflect the new higher payment in the hospital OPPS? In short, if CMS intends to implement this approach, it should review the results annually to ensure the two payment systems remain in some kind of equilibrium. Of course, this would be very costly and disruptive, and we do not believe that CMS intends to do this, nor should it, but the issue underscores the lack of foundation for the current approach.

C. This proposal uses an "apples to oranges" comparison.

As noted above, the PFS and the OPPS are two entirely different payment systems. The payment levels are different because they were designed to be different. They are based on completely different approaches to health care reimbursement. While the PFS pays for services on a code-by-code basis, the OPPS groups similar services together into bundled payments. This is significant because the bundling approach may underpay for certain services but it will overpay for others. This is not a problem under the OPPS system, because the theory behind the approach is that within a single hospital, the payment amounts will average out. As CMS itself has noted in this year's OPPS proposed rule, "Like other prospective payment systems, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. However, with the exception of outlier cases, overall payment is adequate to ensure access to appropriate care."[9]

It is inherently inappropriate to take an APC bundled amount and compare it to an individual CPT code paid under the PFS system. In this year's OPPS Proposed Rule, CMS itself has made this point. It states:

> As discussed above, the OPPS is a prospective payment system. *It is not intended to be a fee schedule, in which separate payment is made for each coded line item*…Our over-arching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule which pays separately for each coded item.[10]

---

[9] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals, 78 Fed. Reg. 43533, 43568 (July 19, 2013) ("OPPS Proposed Rule").
[10] *Id*. at 43569 (emphasis added).

The fallacy of CMS's approach is illustrated by a simple comparison of the APCs applicable to pathology and the CPT codes for the same services. There are more than 100 individual CPT codes paid for on the PFS as physician pathology services. However, all of those codes track to just five APC payment codes. Thus, these numerous CPTs are grouped together into a small number of APCs. As CMS itself notes, this grouping of various services means the payment may be "more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient." While the payment level may be low for some services, it will be high for others. However, overall, a hospital still should be reimbursed adequately to cover the cost of providing the items or service. Because the hospital is being paid for the mix of services, the price is considered to be fair.

When that average bundled price is applied to a single CPT code, however, the result unfairly penalizes the laboratory. If this price does not fairly compensate the laboratory for the service being provided (as is probable in many cases, given that the price is an average), then the laboratory cannot balance these losses with higher-priced services in the bundle, as a hospital can. The laboratory is being paid the appropriate PFS rates for those other services. In total, the APC payment represents an average payment for a bundle of services, and logically, there are some services included in that bundle that are paid at a level that is higher than the average. However, where the laboratory is not being paid for the bundle of services, it is unreasonable to apply that bundle-averaging payment to a single CPT code.

Reliance on the OPPS data results in payment levels that are unreasonable, just on their face. For example, CPT 88367, in situ hybridization, is used to detect the presence of the gene, HER2/neu, which is vital in determining whether a patient's breast cancer can be treated using Herceptin, a highly effective drug for some women. As a result of the OPPS cap, this service will be reimbursed at $38.00 (down from $198 in 2013), but according to CMS's own data, the cost of the kit used to perform the test is over $150.[11] Clearly, it will be impossible to perform the test at that amount. Thus, relying on the hospital data for these tests, many of which are not even routinely performed in the hospital, results in rates that obviously are unfair and unreasonable.

The unreasonableness of relying on the hospital costs also is shown by the fact that many of these services are not performed in hospital outpatient departments routinely. In the Proposed Rule, CMS states that it will not include any service for which five percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services. According to CMS's own data, in virtually all instances, the services at issue are performed in the outpatient department of a hospital less than 30 percent of the time. In many instances, the percentage is less than 20 percent. It seems inappropriate to base such a significant change in policy based on the cost reports for services that frequently are not performed in the outpatient department.[12]

[11] CMS, CY 2014 Proposed Rule Direct PE Inputs (supplies).

[12] In fact, it is not clear if even these percentages are correct, as they are based on Place of Service ("POS") codes reported on claims. There recently has been confusion about how to report the POS of pathology services furnished to inpatients and outpatients. It seems likely that some hospitals billing for these services may report the POS as a

D. CMS is wrong to assume that the data in facility cost reports more accurately reflect the cost of these services.

CMS also argues that the OPPS system yields more accurate and appropriate payment rates because rates are based on cost reports submitted annually by hospitals. However, the Agency's assumption about the accuracy of the costs is incorrect. To assist ACLA in formulating our comments on the Proposed Rule, ACLA contracted with the respected Moran Company to conduct its own study of the relevant inputs affecting CMS's proposal. As detailed in the resulting report, entitled "The Effects of CMS's Proposed Cross-Site Payment Caps on Reimbursement for Anatomical Pathology Services" ("the Moran Report), there are numerous problems with CMS's proposal and the underlying assumptions.

First, as CMS itself has recognized on numerous occasions, cost reports are not used to demonstrate the actual costs of supplying services. The Moran Report, which is attached, recounts the numerous times that CMS has made exactly this point. CMS consistently has acknowledged that the cost reports are used to determine the *relative* costs of various procedures furnished within a hospital so that Medicare payments for those services can be distributed appropriately among the various APCs. As CMS itself has noted, "the accuracy of the relativity is more important than whether the median cost derived from the claims data accurately reflect the cost of the services."[13] Subsequently, CMS said "we note that, in general, the median cost derived from this process may not represent the actual acquisition costs of the services being furnished, nor will they ever represent acquisition costs. They are estimated relative costs that are converted to relative weights, scaled for budget neutrality, and then multiplied by a conversion factor to result in payments that, as we have previously discussed, were designed in such a manner they are not expected to pay the full costs of the services."[14] In sum, it is wholly inappropriate for CMS now to argue that the APC payments represent a more accurate basis for payment, because they are based on cost reports that, by CMS's own admission, are not designed to reflect the actual full cost of providing the service.

Moreover, as the Moran Report also demonstrates, there are significant concerns with the cost reports as they apply to anatomic pathology services.

- The Uniform Bill 2004 format currently used by the Medicare program allows, but does not require, hospitals to report charges and costs in up to five distinct laboratory anatomical departments (*e.g.*, cytology, histology). However, most hospitals report these at an aggregate level, lumping all anatomic pathology services together.[15] Using these amounts and applying them to specific CPT codes is likely to result in skewed results.

---

hospital, even if the services were performed by an independent laboratory. *See, e.g., Trans. 2629, Chge Req. 7631,* Revised and Clarified Rules Place of Service Coding Instructions (Mar. 29, 2013) ("The correct POS code assignment shall be for that setting in which the beneficiary is receiving inpatient care or outpatient care from a hospital including the inpatient hospital (POS code 21) or the outpatient hospital (POS code 22).")

[13] 68 Fed. Reg. 63398, 63417 (Nov. 7, 2003).

[14] 70 Fed. Reg. 68516, 68621 (Nov. 10, 2005).

[15] More than 99 percent of the hospitals that reported data on which CMS based its 2013 rates aggregated charges and costs across all laboratory anatomical departments.

- The particular cost-to-charge ratios to which CMS applied its methodology included a large number of low ratios, which likely reflects the fact that hospitals may have spread the costs of certain laboratory equipment among several cost centers in their cost reports. This would undermine the accuracy of the particular costs reported for the anatomic laboratory center.

- Moran also found that there was significant variation in the costs used by CMS in setting the OPPS rates. Again, as Moran notes, this variation may not matter when setting hospital payments because the degree of variation "averages out over the entire system." However, using that data to set a cap on a PFS payment could in fact result in setting the dollar value significantly below cost. As Moran notes, "these costs are not representative of the actual costs of performing the procedures, and thus are not comparable to anything outside the OPPS."

Finally, ACLA commissioned the Moran Company to conduct a survey of clinical laboratory companies to determine how their costs compared to those used by CMS under the OPPS system. This survey included some of the nation's largest laboratory companies, as well as numerous companies that specialize in anatomic pathology services. In virtually all cases, the average costs reported by the companies were significantly higher than those reflected in the OPPS rates.[16] Moran notes that this could mean that ACLA laboratories have higher costs than those shown by the hospital data, but the report notes it is more likely that the hospital cost accounting practices underestimate the amount of direct and indirect costs associated with performing these procedures. As Moran concludes, "policymakers evaluating policies that rely on OPPS payment rates as a benchmark for payments in other settings should, at least in the case of the anatomic pathology services, approach such policies with healthy skepticism."

In summary, CMS should withdraw its proposal to cap payment for these anatomic pathology services and other services under the PFS to the corresponding OPPS rates. The policy basis for this approach is flawed at best, and the Agency's underlying assumptions cannot withstand scrutiny when applied to individual CPT codes under the PFS.

II. Proposals Regarding the Clinical Laboratory Fee Schedule

A. Summary of CMS's Proposal

CMS is proposing to implement a process to adjust payment amounts based on changes in technology. It would add the following definition of "technological changes" at 42 C.F.R. § 414.511: "changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used."[17] Each year, beginning with the CY 2015 PFS, CMS would review certain codes on the CLFS to determine whether they should be adjusted due to technological changes. It would identify a code, discuss how it has been

[16] In a few cases, the survey data mean costs were significantly lower than the OPPS mean costs. However, that occurred for codes such as 88185 and 88346, which usually include numerous units of service. Moran states that it appears that the OPPS data may reflect a line item that lumps all of the markers together, rather than the cost per marker, which is how the survey collected and reported the data.

[17] 78 Fed. Reg. 43351.

impacted by technological changes, and propose an associated adjustment amount. It also would list the codes for which it thinks there is insufficient information to support or establish an adjustment to technological changes and solicit comments. It would apply adjustments based on the Consumer Price Index – All Urban Consumers ("CPI-U") after it determines a new payment amount. CMS proposes to review the codes that have been on the CLFS the longest and work its way forward until it has reviewed all codes; it estimates that this would take approximately five years. After working its way through the current codes, it would start reviewing codes added after 2015 that have been on the CLFS at least five years.

B. Background on the CLFS

The CLFS was established in 1984, and it contains more than 1,200 codes for laboratory tests. Congress directed the Secretary of Health and Human Services to set the fee schedule for clinical laboratory tests for the 12-month period beginning July 1, 1984, adjusted annually by the CPI-U, and "subject to such other adjustments as the Secretary determines are justified by technological changes."[18] When it was established, the CLFS was based on the prevailing charges; it was not based on the cost to perform a given laboratory test.

In the Proposed Rule, in the context of explaining why payment amounts under the CLFS "are generally locked in place," CMS makes a cursory mention of adjustments based on changes in the CPI-U, productivity adjustments, and "adjustments required by statute." These adjustments have not been insignificant and should not be dismissed lightly. Taken together, these have been substantial payment adjustments – almost uniformly downward – for the services that ACLA's members provide.

- In at least 19 of the years from 1984 through 2011, laboratories received no fee increase or did not receive the full amount of the CPI increase that the statute otherwise would have required. In a few years, the fees actually decreased.

- There also have been seven reductions in the National Limitation Amounts ("NLAs") for laboratory services.[19] The net result is that a laboratory test that was reimbursed in 1984 at $10.00 was reimbursed at $8.71 in 2011, a 13 percent downward adjustment before inflation.[20]

- A provision in the health reform law applied a 1.75 percent annual downward adjustment for laboratory tests on the CLFS for each of the years 2011 through 2015.[21]

- A law passed in 2012 called for a 2.0 percent rebasing of the CLFS in 2013.[22]

---

[18] 42 U.S.C. § 1395l(h)(2)(A)(i).
[19] *See* 42 U.S.C. § 1395l(h)(4)(B).
[20] "What Should Keep You Up at Night: Lower Lab Pricing is Closer Than You Think," Nichols Management Group (Oct. 20, 2011).
[21] Pub. L. 111-148, Sec. 3401(l).
[22] Pub. L. 112-96, Sec. 3202.

- The across-the-board budget cuts known as "sequestration" reduced payments by an additional 2.0 percent.

As we show in the chart below, many common laboratory tests are paid today at lower rates in actual dollars than they were in the early years of the fee schedule. When the prices are adjusted for inflation, the reduction becomes even more significant. The chart below looks at 14 commonly ordered laboratory tests and compares the actual prices for 1994 and 2013, as well as the price after adjusting for inflation.[23] All of these tests are reimbursed significantly less today than they were in 1994, the earliest year for which we were able to locate data. After adjusting for inflation, most of the tests are reimbursed at a rate that is more than 40 percent lower today than the rate in 1994. And, by 1994, the fee schedule already had been reduced on several occasions since 1984, so even those figures most likely understate the cumulative reductions.

CPT	*Test Description*	*1994 NLA*	*2013 NLA*	*2013 NLA Adjusted for Inflation*	*% Change After Adjusting for Inflation*
80061	Lipid Profile	27.37	18.42[24]	11.69	**- 57**
81002	UA, non-automated w/o micro	3.80	3.52	2.23	**- 41**
82306	Vit D	42.86	40.70	25.83	**- 40**
82570	Urine creatinine	7.69	7.11	4.51	**- 41**
82607	B-12	22.40	20.72	13.15	**- 41**
82728	Ferritin	20.27	18.73	11.89	**- 41**
83036	Glycosylated hemoglobin	14.07	13.34	8.47	**- 40**
83540	Iron	9.63	8.90	5.65	**- 41**
83970	Parathormone	61.35	56.74	36.01	**- 41**
84153	PSA	27.33	25.29	16.05	**- 41**
84443	TSH	24.97	23.10	14.66	**- 41**
85025	CBC	11.46	10.69	6.78	**- 41**
85610	P time	5.86	5.40	3.43	**- 41**
87086	Urine culture	11.46	11.10	7.04	**- 39**

Any fee adjustment based on technological changes also should take into account the significant reduction in fees that already has occurred since the CLFS first was implemented. Failure to account for these reductions would end up unfairly penalizing laboratories by imposing additional reductions on top of those already borne.

---

[23] These tests are the same ones addressed by the Department of Health and Human Services Office of the Inspector General ("OIG") in its recent report on lab tests. The OIG noted that these tests accounted for 47 percent of the volume and 56 percent of the expenditures under the CLFS in 2010. *See* "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings," OEI-07-11-00010 (June 2013). The 1994 rates are from "1994 Medicare Reimbursement Manual for Clinical Laboratories and Pathologists, National Edition," published by Washington G-2 Reports. Two tests were not on the fee schedule in 1994, so they were not included. In addition, lipid profile (CPT 80019) does not have an NLA listed for 2013; therefore, the chart uses the amount most commonly paid by individual contractors.

[24] No NLA is listed for this code for 2013; therefore, the chart uses the fee level most commonly paid by individual contractors.

Furthermore, the health reform law applied a permanent "productivity adjustment" to the CPI-U for laboratories and other Part B suppliers in 2011 and subsequent years that has reduced and will continue to reduce the CLFS further every year in the future.[25] This productivity adjustment is designed to account for the "10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity." This productivity adjustment already captures the kinds of "technological changes" in laboratory codes CMS now proposes to review. The U.S. Bureau of Labor Statistics says that multi-factor productivity measures reflect "the joint effects of many factors, including research and development, *new technologies*, economies of scale, managerial skill, and changes in the organization of production."[26] Likewise, CMS's proposed definition would account for changes in "technologies" that may affect the cost of performing a test. It would be patently unfair for laboratories to have payments decreased twice for the same changes to the same technological advances, and it would discourage further technological innovation to improve patient care and reduce overall diagnosis-to-treatment cost per patient in the future.

C. General Trends in Technology Changes in the Laboratory Industry

The Agency solicits comment on "general trends in technology changes in the laboratory industry and the health care sector in general."[27] When considering "general trends in technology changes," it is important to recognize and account for the differences between laboratories of different sizes. Some labs may have the capital to make technology investments that other laboratories do not. Technology changes are not applied monolithically within the laboratory industry; a technology's availability is not the same as its widespread adoption, implementation, and affordability for all laboratories.

Many aspects of laboratory work are more automated now than they were decades ago, and the throughput and efficiency of laboratory instruments is greater. This has not obviated the need for laboratory technologists and technicians, however, and there is no doubt that the costs of labor and of the more automated laboratory instruments with improved methodologies have increased significantly. Also, with advances in technology, laboratories have incurred greater costs to maintain and service more sophisticated instruments.

Moreover, while there may be efficiencies available today that were not available in 1984, there often are costs to achieve those efficiencies. For example, information technology plays a huge role in how testing is performed in the laboratory, as well as in how tests are ordered and results reported. However, there is a significant cost to such technology that must be factored in when assessing the impact of this technology. Laboratory Information Systems ("LISs") in today's laboratories must communicate with automated instrument interfaces to enable faster turn-around times for test results, as demanded in quality patient care. In addition, these laboratory systems communicate with customers, including hospital EHRs, physician office EHRs, and patient portals, to facilitate electronic transmission of test orders and test

---

[25] Pub. L. 111-148, Sec. 3401(l).
[26] U.S. Bureau of Labor Statistics, Multifactor Productivity FAQs, *available at* http://www.bls.gov/mfp/mprfaq.htm#1 (emphasis added).
[27] 78 Fed. Reg. 43352.

reports and results. Advances in information technology also enhance laboratory operations by improved quality monitoring for patient safety. The investment by laboratories in information technology has been significant in the last 10 years, and future trends in esoteric testing algorithms requiring extensive databases for interpretation will demand even more. Lastly, advanced information technology is required during the billing process by payors, including CMS, when submitting claims and receiving electronic Explanations of Benefits ("EOBs") and payments. Information technology will continue to be a significant and growing expense for laboratories in the foreseeable future. Data from our member labs indicate that the cost per requisition of LISs, increased connectivity, and required billing system enhancements has more than tripled from 2000 to 2013. The increase from 1984 likely is even more significant.

D. General Principles for Adjustments Based on Technological Changes

As CMS contemplates adjustments to the CLFS based on technological changes, there are several ideas ACLA believes the Agency must keep in mind.

1. Adjustments to the CLFS cannot be unidirectional, whereby CMS only decreases prices.

CMS says that while some prices on the CLFS may increase, it begins with the presumption that most prices will decrease.[28] It is unwise and unfair for CMS's default position to be that technological changes must result in lower prices. CMS must remain open to the notion that technological changes have added costs to many tests. In addition, as suggested above, CMS also should take into account the other adjustments that already have occurred, both through actions by Congress and because of the impact of inflation. The impact of such other adjustments at least should be netted out of any proposed adjustments at the individual test code level that are based on technological changes.

CMS also must not make the error of looking to the recent molecular pathology gapfilling exercise as evidence that the cost of performing laboratory-developed tests ("LDTs") has decreased.[29] As ACLA has made known to CMS in the past, the recent gapfilling exercise has been an exceptionally flawed process, and it should not be used as evidence of anything other than the fact that pricing more than 100 tests at a time is difficult at best for CMS and its contractors. The prices derived through this gapfilling exercise bear little relationship to the actual cost of performing LDTs and other laboratory tests, and CMS should not assume any correlation between the gapfilled prices and the real costs to perform tests.

2. Independent clinical laboratories and other knowledgeable stakeholders must have a seat at the table.

Just as CMS relies on the RUC to determine appropriate changes to the PFS, it should assemble a panel of laboratory experts to advise it on determining changes to the CLFS. Such a

[28] 78 Fed. Reg. 43351.
[29] *See* 78 Fed. Reg. 43350 ("Further, our recent experience with using a gapfilling methodology to price molecular pathology tests, which are often LDTs, has shown that the costs of performing these tests has decreased since contractors initially established payment amounts for the tests, or compared to the code stack previously billed.").

panel must include representatives from the clinical laboratory industry, pathology, and independent clinical laboratories in particular. Additionally, CMS should host open meetings on the technology reviews – before and during the exercise – to solicit broad input and feedback.

3. CMS should not underestimate the complexity and enormity of this undertaking.

CMS has not fully articulated what process it would use to conduct its technology reviews, what information sources it would consult, where it would find those information sources, and how stakeholders will be involved. This process is far more complex than the high-level description in the Proposed Rule. And, based on the fact that there are more than 1,200 test codes on the CLFS and that CMS says it will take about five years to review all of the prices to account for technological changes, CMS is proposing to review about 250 codes a year for five years in a row. We urge CMS to proceed cautiously and thoughtfully as it fleshes out the process it will use for reviewing technology changes, and it should establish a longer timeline and a scope of work that is commensurate with the size and difficulty of this task. Our specific recommendations, as addressed further below, include: (1) start with a pilot project, reviewing no more than 10 to 20 codes in the first year; (2) extend the proposed review period to no less than 10 years and limit the maximum amount of codes reviewed during the first three to five years following the pilot to 100 codes per year; (3) balance the mix of high- and low-volume codes in each review cycle so that no more than 10 to 15 percent of total CLFS volume is reviewed per year; and (4) cap the amount of adjustment to no more than 15 percent of the current CLFS price in a year and phase in any remainder over a number of years.

4. The process must be fully transparent and consistent.

CMS has to be clear about what it is doing, on what basis, and how it is proceeding. In order to have the buy-in and full cooperation of the laboratory industry, it has to be able to "show its work." Our recent experience with gapfilling leads us to conclude that CMS should not use Medicare Administrative Contractors to carry out reviews of technological changes. Most contractors did not communicate with laboratories about their processes and inputs, and CMS was unable or unwilling to facilitate that communication. It may be appropriate for CMS to enter into an agreement with a contractor who is a subject matter expert, if stakeholders are involved enough so that they know what information and processes such a contractor is using, rather than simply being asked to comment on the subject matter expert's final product.

5. The process must have more time built in for give-and-take between the agency and the public.

CMS plans to propose adjustments to the CLFS based on technology changes in each year's Medicare PFS proposed rule, which typically is put on public display in early July with comments due in early September, roughly a 60-day period. For this process to work properly, and for adjustments to be based on a full range of factual information, the stakeholder input period must be longer than 60 days. Two months is an inadequate amount of time for laboratories and other stakeholders to assemble and distill information about the impact of technological changes on particular tests, and it certainly is not adequate to do so for roughly 250

codes at a time. CMS should build in a mechanism for giving stakeholders advance notice of the tests that CMS may propose for adjustment and for soliciting public input, even before the PFS is put on display in early July each year. Also, for such an advance notice period to be meaningful, it must be far enough in advance of the PFS proposed rule's publication for CMS to take stakeholders' views into account and make appropriate adjustments to the PFS proposed rule prior to its publication. We suggest that CMS post the codes that it expects to designate for scrutiny under this process at least 90 days prior to the issuance of the proposed rule. That would allow stakeholders to begin to gather the data and information necessary for an effective response.

E. Proposed Definition of Technological Changes

CMS proposes to define "technological changes" as "changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used." We agree that if CMS and stakeholders are to consider the way that technology has changed the cost of performing laboratory tests, the range of inputs must be wide enough to encompass not only changes that yield efficiencies and reduced costs, but also those that add to the cost of performing tests.

On the other hand, this broad definition could encompass almost any change to the way a test is done. For this to be a collaborative process that draws on the experience and expertise of the laboratory industry and other stakeholders, all parties have to use the term "technological changes" in the same way. Stakeholders and CMS alike could benefit from more specificity about what is encompassed by terms such as "technique" and "labor," to name just two terms in the proposed definition. Each of these terms could be construed extremely broadly or narrowly. For example, a "technique" could mean the whole body of specialized procedures and methods used in laboratory science, or it could mean a specific method of preparing a slide. Changes in "labor" may account for anything affecting the people who work at clinical laboratories and who touch specimens in any way, or it could be limited to the wages paid to the class of worker performing a specific job.

CMS should work with stakeholders to develop workable definitions and guidelines for what it means by each of the terms it uses in its proposed definition of "technological changes." While illustrations or examples can be helpful, they would be most helpful if they were developed in collaboration with the laboratory industry so that they reflect realistic and understandable changes in technologies.

F. Proposed Process

1. Stakeholder Input

CMS says that its proposed process "would best allow for the greatest amount of transparency in review and the most structured and consistent opportunity for the public to provide input."[30] However, it is difficult to discern as of yet what "the process" is. This process

[30] 78 Fed. Reg. 43351.

must be far more than announcing proposed adjustments to a group of codes in the PFS proposed rule in July and then allowing 60 days for the public to comment. It also encompasses the criteria for reaching the conclusion that pricing for a test should be adjusted in the first place.

While public input during the official comment period is essential, CMS must solicit input from the public before then on the following: (1) which codes will be up for review in a given year; (2) how to assess technological changes since the codes first appeared on the CLFS; and (3) how to estimate the increases or decreases in costs of those changes. CMS should develop its plan for engaging key stakeholders prior to the start of the official PFS comment period, and it should develop the plan with the input of stakeholders. When the Institute of Medicine recommended that CMS (then the Health Care Financing Administration, or "HCFA") should develop a data-driven consensus process for reforming the CLFS, it said:

> A consensus approach could lend legitimacy and credibility to the newly-developed values if it is designed in a manner acceptable to stakeholders. Unless care is taken in its design, however, it is vulnerable to criticism about the process for identifying participants, the method for combining information from different sources, and the possible impropriety of using subjective qualitative methods to measure what some think should be readily quantifiable.[31]

We believe that what the Institute of Medicine said in 2000 remains true today. The best way to perform this process is by ensuring that the industry is involved. One way to ensure that this occurs is for CMS to establish a negotiated rulemaking proceeding, which would set the original parameters of this process, determine what information sources should be considered, and address other issues that are likely to occur. The laboratory industry and CMS did work together in a negotiated rulemaking that was mandated by the Balanced Budget Act of 1997 and resulted in a final rule that resolved numerous coverage and administrative issues related to laboratory services.[32] That negotiated rulemaking process generally is considered to have been a success, and we believe it could serve as a model for resolving many of the issues that are likely to be raised by the current proposal.

Even if CMS does not establish a negotiated rulemaking, we believe it should create an Advisory Committee to work with CMS on reviewing data inputs and information used to determine whether technological changes have had an impact on the cost of performing tests. This Committee, with representation from the clinical laboratory industry and other key stakeholders, would work throughout the year, which would allow for an appropriate level of stakeholder involvement and give stakeholders more than just 60 days of input during the official comment period.

If CMS is unable to develop and implement a process for soliciting input from a broad variety of stakeholders prior to the publication of the CY 2015 PFS proposed rule, it should postpone the implementation of the CLFS code reviews for at least an additional year.

---

[31] Institute of Medicine, MEDICARE LABORATORY PAYMENT POLICY, NOW AND IN THE FUTURE (2000) at 149.
[32] *See* 66 Fed. Reg. 58788 (Nov. 23, 2001).

Regardless of the process CMS develops, it should include a reconsideration process and an appeal process after CMS finalizes a new price, with a requirement that CMS respond to such requests timely.

2. Information about Technological Changes

As proposed, each year in the PFS proposed rule, CMS would identify a group of codes, discuss how they had been impacted by various technological changes, and propose associated adjustments to the payment amounts for the test codes to reflect those changes.[33] ACLA believes that CMS should be more specific about its sources for information about technology changes. Because this process purports to compare technological changes that have occurred since a test code first appeared on the CLFS and was priced, it would require information about how a test was performed in 1984 (or whenever a code first appeared) and how it is performed currently. Most importantly, CMS should be willing to explain how it arrived at the amount of a specific adjustment in price by presenting the basis for its calculation. Otherwise, the integrity of the process will be undermined in the same way as the recent gapfilling process has been.

ACLA and its members are not aware of a ready source of information about how specific laboratory tests were performed in the mid-1980s, making it even more important that CMS has a good collaborative relationship with laboratories and other stakeholders who can help the Agency obtain that information. The Agency should work with stakeholders to determine the universe of possible data sources and evaluate them for their accuracy and objectivity.

3. Prices may go up or down, and CMS must be open to either possibility.

CMS begins with what we feel is a faulty presumption that prices are bound to go down because of technology changes ("We expect that most payment amounts will decrease due to the changes in technology that have occurred over the years since the payment amounts were established and the general downward trend in costs once technology has had an opportunity to diffuse.").[34] While some costs have decreased, it is important to consider the changes to technology and other changes that have caused costs to increase. For example, some laboratory instruments are more efficient, but they also are more expensive than predecessor technology. The cost to service and maintain the more sophisticated technology also has increased. Information technology requirements (barely extant when the CLFS was created) add costs to all tests, since virtually all laboratory instruments interface with LISs, and healthcare industry standards require that test results be reported out quickly. Lastly, advances in patient care have increased demands on laboratories with respect to the breadth of testing available and turn-around times. These improvements enhance patient care, but they increase costs, as well.

One significant change in the laboratory industry that is not discussed in the Proposed Rule is CMS's own requirements under the Clinical Laboratory Improvement Amendments ("CLIA"). When the CLFS was established, CLIA had not been passed, and clinical laboratories

[33] 78 Fed. Reg. 43351.
[34] *Id.*

were not as highly regulated as they are today. While CLIA and its implementing regulations themselves are not encompassed by CMS's proposed definition of "technological change," CLIA required changes in labor, skills, and techniques, all of which are included in the proposed definition. CLIA also requires laboratories to pay additional fees and, in some cases, to hire consultants to assist with compliance. Changes that laboratories have made to comply with CLIA requirements inarguably have increased the cost of performing any given test.

When CMS considers adjustments for a particular test code, it must address both technological changes that may have decreased costs and also countervailing changes that caused other costs to increase for the same test code. This should be part of the analysis for each test code, and it should be included in the published statement about the code in the PFS proposed rule.

4. Codes for Which There is Insufficient Information

In each PFS proposed rule, in addition to test codes for which CMS is proposing a price adjustment based on changes in technology, the Agency would list codes that it reviewed but for which there was insufficient information to support or establish an adjustment to the payment amount due to technological changes.[35] For the public to evaluate whether there is sufficient information to support or establish an adjustment, it will be important for CMS to share with the public what information it has consulted. We agree that it would be far better for CMS to acknowledge that its available information is not sufficient than for it to make a price adjustment based on scanty or incomplete information.

G. Proposed Identification and Prioritization of Codes to be Reviewed

1. CMS should start with a pilot project.

We recommend that CMS start its review of test codes with a pilot project, reviewing technological changes for 10 to 20 codes in the first year. This is an enormous and complex undertaking, and depending on how CMS proceeds and which codes it reviews, it has the potential to be extremely disruptive to the clinical laboratory industry. We are concerned about whether CMS has the resources, historical knowledge, and time to proceed thoroughly and transparently and consistently, especially in the first few years when the learning curve undoubtedly will be steep. Beginning with a pilot project would allow CMS to learn what does and does not work, what resources are available, and approximately how much time is necessary to review a test code. It also would allow laboratories and other stakeholders to learn about the process, suggest amendments, and prepare to allocate resources internally for commenting on test codes as they come up for review. For this process to maintain its credibility and legitimacy, CMS has to "get it right" the first time. A review of upwards of 250 codes in the first year cannot possibly yield that result.

[35] 78 Fed. Reg. 43351.

2. CMS should extend the amount of time it takes to review all of the codes on the CLFS and limit the annual review to 100 codes in the first post-pilot years.

CMS estimates that its review would take approximately five years, which averages out to a review of about 250 codes a year. The recent molecular pathology gapfilling exercise revealed how difficult it is for the Agency and/or its contractors to arrive at accurate, fair prices that are based on reliable data. But the recent gapfilling was for fewer than half as many codes as CMS is proposing to review each year, and it was a one-time event, instead of a process conducted annually for five years in a row and then repeated. CMS should strongly consider extending the number of years it proposes to move through all of the codes to at least 10 years, and it should not review more than 100 codes annually for the first three to five years after the pilot project.

Regardless of the process that CMS eventually develops for conducting technology review of the codes on the CLFS, we are skeptical that CMS can gather, analyze, and distill information about technological changes for 250 tests at a time. Addressing such a large number of tests each year also would put an enormous strain on laboratories and other stakeholders who will want to provide input on CMS's proposed adjustments, both during the formal comment period and prior to that.

3. The order in which codes are reviewed should not be purely chronological, and CMS should take test volume into account.

In addition to beginning with a small number of tests in a pilot review project and extending the length of time it would take to move through all of the codes on the CLFS, CMS should include a balanced mix of high-volume and low-volume codes in each review cycle so that no more than 10 to 15 percent of total CLFS volume is reviewed per cycle. Many of the oldest codes on the CLFS are for high-volume tests that represent a large part of many laboratories' work. Reviewing all of these high-volume codes at once could be extremely disruptive to many laboratories and could threaten beneficiary access to the most commonly used tests in medicine.

4. Cap the amount of adjustment in a year and phase in the remainder over a number of years.

To mitigate the potential disruptions to laboratories, physicians, and beneficiaries stemming from review and possible re-pricing of the codes on the CLFS, CMS should cap the total price adjustment for a negatively adjusted code in a given year to a percentage of the current CLFS price (*e.g.*, no more than 15 percent). Adjustment amounts in excess of the cap would then be phased in over a number of years at no more than that rate, until the adjustment is fully implemented. This approach has precedent in the Medicare "inherent reasonableness" context and also in the way CMS has implemented certain changes to its calculations for PE

RVUs.[36] This type of policy would be particularly helpful to a smaller laboratory or one with a smaller menu of tests so that a negative adjustment in any one year would not have an overly adverse financial effect on the laboratory.

5. CMS should amend its proposal for public nomination of codes.

CMS proposes to allow the public to nominate codes for technology reviews after the Agency has completed a review of the codes currently on the CLFS. CMS states that when a member of the public submits a nomination of a code for a technology review, it should include an explanation of "the technological change in the service and the way that change affects its delivery."[37] Instead, the nomination should include an explanation of the technological change and the way that change affects *the cost of performing the test*. This exercise is not about the way that clinical laboratory tests are delivered; it is about how the test codes are valued and their level of reimbursement.

III. Conclusion

In summary, we urge CMS to withdraw its proposal to use OPPS and ASC rates to limit practice expense relative value units under the PFS for codes with higher total Medicare payments in the office setting than in a hospital or ASC. This proposal is without a defensible legal or conceptual basis and would compromise diagnosis and treatment of cancer and other serious diseases in Medicare beneficiaries. ACLA is willing to work with CMS on its proposal to adjust the individual CLFS codes based on a review of technological changes, but it is essential that the process is transparent, that stakeholders have ample opportunity to provide input, and that CMS take into account the many reimbursement cuts endured by laboratories in recent years.[38] Thank you for your attention to ACLA's ideas and concerns.

Sincerely,

Alan Mertz

Alan Mertz, President
American Clinical Laboratory Association

---

[36] *See* 42 C.F.R. § 405.502(g)(vi) ("…a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year."); *see also* Medicare Program; 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; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007, 71 Fed. Reg. 69624, 69629 (Dec. 1, 2006).

[37] 78 Fed. Reg. 43352.

[38] Also of concern to ACLA members is the additional 22 percent cut that is proposed this year for CPT code 88305. *See* 78 Fed. Reg. 43517. Reimbursement for this code was reduced substantially last year based on the RUC's recommendations. This year's proposed additional reduction appears to result primarily from the planned recalculation of the Medicare Economic Index ("MEI"). Given the significance of the cut from last year, additional reductions are unwarranted and unfair. We expect that other codes are similarly impacted. Therefore, we urge CMS to delay implementation of proposed MEI changes.

The Effects of CMS's Proposed Cross-Site Payment Caps on Reimbursement for Anatomical Pathology Services

The Effects of CMS's Proposed Cross-Site Payment Caps on Reimbursement for Anatomical Pathology Services

In a Notice of Proposed Rulemaking promulgated on July 8, 2013, the Centers for Medicare & Medicaid Services (CMS) proposed to establish new payment limits for certain services rendered under the Medicare Physician Fee Schedule (MPFS). These limits would be imposed on individual services and procedures that were determined to have total payments under the MPFS that would be higher than the total payments for corresponding services under the Outpatient Prospective Payment System (OPPS).[1] CMS's stated rationale for this policy is that disparities in payment across these settings result from the use of inaccurate data to establish practice expense values under the MPFS.[2]

This "total payment" comparison would be based on comparing the sum of both professional and facility payments paid in either setting. Hence in defining the total payments in the office, CMS would add together the physician work and malpractice values under the MPFS with the non-facility practice expense value for each code. In the OPPS, by contrast, the facility portion of the total payment would be the sum of the OPPS payment amount for the applicable Ambulatory Payment Classification (APC), plus the amount of payment made to the physician when providing the service in the facility setting (i.e., work, facility practice expense, malpractice) payable under the MPFS.

The dollar values established in this comparison would be used by CMS both to identify procedures that would be subjected to limits in the MPFS, and also to calculate the amount of a downward adjustment to the practice expense component of the MPFS rate.[3] Services subject to other forms of cross-site payment limitation in either the MPFS or the OPPS would be exempt from these limits, as would procedures that are not separately payable under the OPPS. Services with very low OPPS volumes (less than 5% of combined OPPS and MPFS reimbursements) would also be exempt from this limitation.

In an addendum released by CMS shortly after release of the display copy of the 2014 MPFS Proposed Rule, CMS identified 211 Healthcare Common Procedure Codes (HCPCS) that met the proposed criteria for payment limitations. CMS indicated in its discussion that the adjustments proposed for those codes are already embedded in the proposed non-facility practice expense relative value units proposed for payment in 2014.

Of these 211 codes, 38 are codes for a variety of anatomical pathology services payable under the MPFS.[4] The Moran Company was engaged by the American Clinical Laboratory Association (ACLA), the national trade association of clinical laboratory companies, to assess this proposed policy, in order to determine whether the methodology CMS is proposing would,

[1] CMS is proposing to set payment limits for 2014 based on actual payment rates for both systems in 2013.
[2] CMS, *MPFS NPRM for 2014*, Display Copy, p. 53.
[3] Relative value units (RVUs) under each payment methodology would be converted to dollar values using the respective conversion factors of the two payment systems.
[4] In general, anatomical pathology services have Current Procedure Terminology (CPT)© codes in the range of 88###.

in fact, result in more accurate payments for anatomical pathology services. In addition to analyzing data made available by CMS, we were also asked to conduct a survey of ACLA member companies in order to generate procedure-level direct and indirect cost data for these 38 codes that can be directly compared to the valuations CMS is implicitly relying on in establishing practice expense values under these policies.

Our findings from this analysis are as follows:

- CMS's rationale for using OPPS values to cap MPFS payments explicitly contradicts a variety of prior CMS pronouncements regarding the comparative accuracy of OPPS valuations at the level of individual codes, and the utility of cross-system comparisons of absolute payment amounts. OPPS ratesetting allows for meaningful comparison of resource-intensiveness and costs of services within the OPPS system. But the methodology is not designed to allow for comparisons to services outside the OPPS.

- The cost accounting information CMS is explicitly relying on in making these cost comparisons is, for the 38 anatomical pathology under examination in this analysis, insufficiently granular to be reliable at the level of individual codes.

- The cost findings on which CMS is relying to set OPPS payment rates that will be used to cap MPFS rates are based on averages across data submitted by thousands of hospitals. When the distribution of actual hospital cost findings for these 38 codes is compared to the distribution of procedure-level costs from our survey findings, there is substantial overlap in the range of cost findings, calling into question whether costs are, in fact, sufficiently different in both settings to justify capping one set of payment rates with another.

- Policymakers evaluating policies that rely on OPPS payment rates as a benchmark for payments in other settings should, at least in the case of anatomical pathology services, approach such policies with healthy skepticism.

In the sections that follow, we present our rationale for these findings.

I. Prior CMS Comments Regarding the Accuracy of OPPS Payment Rates as Estimates of Actual Cost

In discussing the OPPS rate-setting methodology, CMS has repeatedly over the years described a system in which determining the relative resource-intensiveness of a procedure is more important than determining the exact cost of the procedure. In the final OPPS rule in 2004, CMS states:

> The OPPS seeks and uses relative costs to create weights that are used to distribute a fixed amount of Medicare payment for OPPS services appropriately among hospitals. Therefore, the accuracy of the relativity is more important than whether the median costs

> derived from the claims data accurately reflect the costs of the services.[5,6]

Similarly, in responding to comments in the 2006 OPPS final rule, CMS re-emphasizes that the purpose of the OPPS system is not to determine precise payment amounts for each code. CMS discusses the use of cost-to-charge ratios (CCRs) to calculate "costs" based on hospital charges for services.[7]

> We agree that the use of the hospital's average CCR results in computed costs and relative weights that may be more or less than specific actual costs and that this averaging is appropriate and desirable in a PPS and should continue. One of the principal purposes of determining median costs for weight setting in a budget neutral payment system is to determine the appropriate relativity in resource use among services, so that the fixed amount of money can be fairly and equitably distributed among hospitals based on case-mix. We note that, in general, the median costs derived from this process may not represent the actual acquisition costs of the services being furnished, nor will they ever represent acquisition costs. They are estimated relative costs that are converted to relative weights, scaled for budget neutrality, and then multiplied by a conversion factor to result in payments that, as we have previously discussed, were designed in such a manner that they are not expected to pay the full costs of the services. [8]

CMS also describes an imperfect system, in which relative weights and payments must be based on the best available information available—claims data and hospital cost reports—that CMS admits can be flawed. In the 2004 OPPS final rule, in another discussion about the CCRs used to determine the median costs for ambulatory payment classifications (APCs), CMS states:

> We recognize that the application of cost-to-charge ratios to charges for individual items as needed to develop median costs for APCs is imperfect. However, the only means at our disposal for determining costs from the charges on the claims was to calculate a cost-to-charge ratio using the cost report data that we believe is applicable to the OPD. We acknowledge that this system for determining relative values is imperfect…We believe that relative weights should generally be based on the claims data because, notwithstanding the weaknesses, claims data are the most complete and accurate source of information about all services furnished by all providers under the OPPS. [9]

In the OPPS final rule for 2005 CMS again discusses the potential flaws of claims data. In its discussion of the APC assignments for computed tomography (CT) and computed tomography angiography (CTA), CMS writes

> We acknowledge the commenters' belief that the claims are flawed and the hospitals' divergent charge structures do no result in consistent charging for CT scans, CTAs or image reconstruction, but note that those claims comprise the data on which the OPPS

[5] Federal Register / Vol. 68, No. 216 / pg. 63417
[6] Beginning in 2013, CMS switched from using median costs to mean costs to determine payment weights.
[7] The next section of this report provides a more detailed description of the OPPS rate-setting methodology, including the use of CCRs to determine costs for groups of services in APCs.
[8] Federal Register / Vol. 70, No. 217 / pg. 68621
[9] Federal Register / Vol. 68, No. 216 / pg. 63424

> relies for payment for wide variety of hospital outpatient services. We must rely on hospitals to manage their charge structures in a manner that accurately reflects the services provided.[10]

Despite these past discussions, in the 2014 MPFS proposed rule, CMS seems to take a different tack, and asserts that OPPS data is more accurate and reliable than the data used to determine MPFS payments.

> Given the differences in the validity of the data used to calculate payments under the PFS and OPPS, we believe that the nonfacility payment rates for the procedures that exceed those for the same procedure when in a facility result from inadequate or inaccurate direct PE inputs, especially in price or time assumptions, as compared to the more accurate OPPS data.[11]

In essence, throughout the history of the OPPS, CMS describes the ratesetting methodology as one that allows for meaningful comparison of cost relativities within the outpatient system. However, the payment rates set in the OPPS are not representative of true cost and thus are not comparable to costs outside of the OPPS system. Thus, CMS' new rationale for using OPPS values to cap MPFS payments explicitly contradicts the prior CMS pronouncements regarding the accuracy of OPPS valuations at the level of individual codes, and the utility of cross-system comparisons of absolute payment amounts.

II. Analysis of Cost-to-Charge Ratios Employed in Generating OPPS Cost Findings

Under the OPPS, relative values are assigned to ambulatory payment classification (APC) codes based on the average of the costs observed in hospitals for performing the services "packaged" into each payment code. Costs are imputed to individual claims for particular services at specific hospitals, and then averaged across all hospitals to compute payment relativities for services.

Costs are imputed to claims based on the standard Medicare "cost finding" methodology, which is based on data submitted by hospitals annually in Medicare Cost Reports. Each Cost Report presents a comprehensive cost accounting analysis of total hospital operations. In that analysis, costs associated with operating hospital departments that do not provide services to patients (e.g., the billing department) are allocated to departments that do render patient care services. The direct and allocated costs of running each patient care department are then compared to the total billed charges generated by that department in rendering patient care. A "cost to charge ratio" (CCR) is calculated for each department in each hospital.

In the OPPS payment methodology, CMS applies these calculated CCRs to impute costs to individual claims.[12] The charges for each line item on a claim are multiplied by the CCR

[10] Federal Register / Vol. 69, No. 219 / pg. 65723
[11] Federal Register / Vol. 78, No. 139 / pg. 43296
[12] In the OPPS methodology, CMS restricts its cost analysis to so-called "single bills" that permit allocation of "packaged" costs to individual services.

calculated for the department in that specific hospital in which charges were posted for that patient on that day. This multiplication converts the billed charge amount to an estimate of the cost incurred by the hospital in performing each service. It is these estimates that CMS uses as the data set employed to calculate payment relativities under the OPPS.

The accuracy of these cost findings as a measure of relative cost depends, in part, on the granularity of the departmental structure used to report costs. The Uniform Bill 2004 format presently used by Medicare permits hospitals to report charges and costs in up to five "Laboratory Anatomical" departments, with separate departmental designations for Cytology (311), Histology (312) and Biopsy (314).[13] When discrete CCRs are reported for these departmental categories, analysts can be certain that cost findings generated from claims billed for these services are based on historic charge-to-cost relationships for these exact services. If hospitals report CCRs for all anatomical pathology codes at a more aggregated level, e.g., using only the General Laboratory Anatomical code (310) for all anatomical pathology services, the accuracy of cost findings generated using such CCRs will vary code by code from the values that would be obtained by using more granular departmental cost findings.

To evaluate the importance of this issue in assessing the accuracy of the cost findings CMS used to cap practice expense RVUs for 38 codes in its proposed 2014 rule, we analyzed the cost report information CMS used to set the final 2013 payment rates for these 38 services.[14] These are the data that CMS says it used to compare total costs across sites of care.

We calculated the CCRs based on the costs and charges that CMS reported. The CCRs used by CMS to calculate the 2013 payment rates are derived from 1,763,757 claims lines containing any one of the 38 HCPCS codes for anatomical pathology services, as submitted by 2,885 hospitals. Of the observed CCRs used in ratesetting, 96% are matched to CCRs for revenue codes in the 031X family; the rest are matched to CCRs derived from other laboratory revenue codes.

Importantly, more than 99% of the hospitals reporting furnished CCRs for these revenue codes that are identical across all of the 031X revenue codes reported. This means that, in setting rates, CMS is using CCRs that are aggregated across all of the "Laboratory Anatomical" departments, rather than being specific to the type of anatomical pathology services being reported. Thus at the level of individual claims lines, the CCRs being used—and hence the resultant cost findings—may not be an exact match to the CCRs that might have been applied had hospitals reported information on a more granular basis.

Using these higher level CCRs means that many codes are grouped together under the same CCR. In the case of the 031X family, very high volume, but lower cost codes, such as 88305 (Level IV – Surgical pathology, gross and microscopic examination), will draw down the CCR. This subjects the codes to a lower CCR than if the more granular revenue center had been used, and the codes had not be grouped with a lower cost, but high volume code.

[13] The other departmental designations permitted under the UB 04 format are "General"(311) and "Other" (319).
[14] In this report, all references to cost findings used by CMS to set OPPS payment rates are based on The Moran Company's replication of the CMS 2013 OPPS Final Rule ratesetting methodology.

The CCRs CMS had available in applying its methodology contain a large number of very low CCR values. Reported CCRs have values lower than 0.100 in 20.3% of the cases; another 40.5% have CCR values between 0.100 and 0.200. In our experience, CCRs for ancillary departments such as pharmacy and medical supplies more typically run in the range of 0.250 to 0.350. The low CCRs for anatomical pathology services observed in these data imply that hospitals are applying very large charge markups to these services. Taken together with the lack of granularity in the CCRs being reported, one would expect that the specific cost findings CMS used in ratesetting in 2013 will vary materially around whatever average cost CMS finds for these services in the rate-setting process.

Another potential reason for low CCRs could involve the way hospitals allocate costs to particular cost centers. Of particular concern are capital costs, which may not be fully captured in the associated cost center, but instead spread over all the cost centers as part of overhead costs. Expensive lab equipment may fall into this category, and if so, the CCRs associated with laboratory departments may be artificially low.

III. The Distribution of Anatomic Pathology Cost Findings Used by CMS in Calculating PE Rate Caps

This inference is supported by examination of the line-level cost findings for these services contained in the "single bills" actually employed in ratesetting. For each of the 38 anatomical pathology codes affected by the practice expense cap policy proposed for the MPFS, we calculated cost findings for the single bills, and examined the distribution of cost findings for these services around the mean value used by CMS to set rates—and hence to establish the total payment amounts CMS is using to cap the PE values for these codes.

Appendix A presents our analysis of the range of variation in the costs findings used by CMS to set OPPS rates—and hence, implicitly, to establish caps on MPFS rates for these 38 codes. In addition to providing summary statistics on line counts and standard deviations of the observed data for each of the 38 codes, we show a decile distribution presenting the average cost observed for observations falling in each tenth of the total distribution.

As these data suggest, the range of variation is substantial. All codes exhibit meaningful variation around the calculated mean value. The standard deviations around the means are sizable relative to the means—and in fact exceed the mean value in 16 out of 37 cases.[15]

This degree of variation is significant, but not necessarily problematic in the context of calculating relative values within the boundaries of the OPPS. In that context, most or all claims lines used in ratesetting exhibit comparable variation in observed costs across hospitals, meaning that the degree of variations "averages out" to produce relativities that are proportional across the overall payment system. Comparison of costs within the OPPS can be valid, since the system is

[15] The data for CPT 88355 have been blinded to prevent disclosure of data for cells containing fewer than 11 observations.

designed to capture the relative resource-intensiveness of procedures, and distribute payments based on those relativities. But these costs are not representative of the actual costs of performing the procedures, and thus are not comparable to anything outside the OPPS.

In the present context, however, CMS is proposing to use the absolute dollar value of the relative weights calculated for each service as a point estimate of the maximum allowable cost for each service under the MPFS. In this context, variation means that a MPFS rate could be capped at a level meaningfully below the dollar value of the cost observed in a substantial number of outpatient hospitals for that service.

Because of the way the MPFS rates are set, there is no corresponding information in that system about the range of likely variation across practices around the "typical patient" cost values on which MPFS PE rates are set.

IV. A Survey of Clinical Laboratory Companies

To assist policymakers in evaluating the implications of CMS's proposed policy, The Moran Company was commissioned by the ACLA to conduct a survey of clinical laboratory companies designed to collect information about the direct and indirect costs they incurred in performing these 38 services. This survey was conducted in July, 2013. Companies were requested to provide current (2013) cost information on both the direct and indirect costs they incurred in performing each of these 38 services. Since most of these services have separate technical and professional components, companies were permitted to present separate data that could be added together to determine a corresponding global facility cost value.

Overall, we received 10 company responses to our survey.[16] One company furnished information about 34 of 38 codes; all other companies reported cost information on fewer services.[17] Two codes were not reported by any company. Overall, we received 154 discrete code/company responses—an average of slightly more than four responses per code. In eight cases, the information presented reflects a response of only one company. Because our sample included all of the nation's largest laboratory companies, we believe the data we received may well typify the economic reality of performing these procedures across the industry.

A summary of our survey responses, by HCPCS code, is presented in Appendix B.

As these data show, the survey results we are getting have, for most codes, means substantially higher than the mean cost findings used in the OPPS methodology. In six cases, however, the mean costs observed in our survey are meaningfully lower than the cost data CMS used to set the 2013 OPPS rates.

[16] One company provided high and low values for certain codes. We treated these two values as two separate data points in our survey analysis.

[17] Since not all lab companies furnish all anatomic pathology services, we infer that non-reporting reflected lack of data about some of these services.

There are also a few cases, such as code 88185 and 88342, where the survey data mean cost is significantly lower than the OPPS mean cost. In these cases, we believe the cost data is not necessarily comparable because survey respondents provided a per marker (or per unit) cost, while the OPPS data represents a line level cost, which can include multiple markers. Code 88185, for example, is an add-on code, which is submitted in conjunction with a primary code (in this case, 88184). The add-on code is used when multiple markers are being tested. The primary code represents the first marker test, and the add-on code is submitted for each additional marker to be tested. The OPPS data cannot easily be broken down to show a comparable per marker cost. This data anomaly further demonstrates that data in the OPPS is not easily comparable to costs outside of the system.

Interpreting these findings requires some amount of caution. If we take the OPPS as a baseline, our respondents may well have both direct and indirect costs for these services that are higher than those inferred in the hospital data. If we take our survey results as the baseline, hospital cost accounting practices may be substantially underestimating the amount of direct and indirect costs actually associated with performing these procedures.

The very low CCRs we saw in the preceding section—and the inference they provide about very high charge markups in anatomical pathology departments—are congruent with the latter interpretation. This interpretation is reinforced by the current controversy about the very low CCRs reported for CT and magnetic resonance services in radiology departments. In that context, critics have put forward evidence that hospitals may be systematically failing to allocate the cost of expensive diagnostic equipment in reporting costs in these departments.[18] That critique of hospital cost accounting practices may, upon further analysis, prove to be equally applicable here.

An alternative way of thinking about these data disparities informs the analysis presented in Appendix C.

In that presentation, we show how the reported survey means fall relative to the normal variance—as expressed by the standard deviation of the OPPS cost findings—around the mean OPPS value reported.

Of the 36 codes for which we have survey data, 22 fall within one standard deviation of the OPPS mean. Another 6 observations fall within 110% of one standard deviation above the mean. These facts support an interpretation that the cost findings in our survey may not be meaningfully different than the cost findings underlying the calculation of the OPPS means.

V. Conclusion

CMS has a variety of policy reasons to pursue more site-blind payment policies, and the policy under consideration moves squarely in that direction. Our concern in this analysis has been to

[18] See, for example, a letter from a coalition of radiology organizations concerned about the separate cost centers for CT and MR: http://www.acr.org/~/media/ACR/Documents/PDF/Economics/Medicare/Coalition%20Letter%20to%20CMS%20on%20Separate%20CT%20and%20MR%20Cost%20Centers.pdf.

determine whether the specific technical choice CMS has made—to use OPPS payment rates to cap MPFS payment rates—is justified by CMS's premise that OPPS data are inherently more accurate than the data used in setting MPFS payments.

Upon analysis, nothing we have looked at in this study supports that conclusion with respect to anatomical pathology services.[19] Several of our findings in fact cast doubt on whether the cost findings on which the OPPS rate structure are based have any value as estimates of the absolute cost of providing anatomic pathology services in any setting. In particular, the very low CCRs we are observing for anatomical pathology services in this analysis raise concerns about the face validity of hospital cost accounting practices, especially the incorporation of capital costs to specific cost centers. Policymakers evaluating policies that rely on OPPS payment rates as a benchmark for payments in other settings should, at least in the case of anatomical pathology services, approach such policies with healthy skepticism.

***

[19] Because of our focus on anatomic pathology services in this study, none of the conclusions we draw here should be extended to other types of service without further analysis.

Appendix A

		2011 OPPS Cost Decile Distribution													
		Number of Ratesetting Lines	COSTS												
CPT Code©	Short Descriptor		Mean	Std. Dev.	Minimum	10th Percentile	20th Percentile	30th Percentile	40th Percentile	Median	60th Percentile	70th Percentile	80th Percentile	90th Percentile	Maximum
88104	Cytopath fl nongyn smears	39,965	$27.24	$23.07	$0.76	$9.19	$12.27	$15.44	$18.16	$21.61	$24.29	$29.06	$37.50	$50.07	$633.78
88106	Cytopath fl nongyn filter	3,168	$30.04	$17.80	$1.73	$13.88	$15.82	$17.56	$18.12	$23.48	$32.23	$36.33	$49.20	$61.34	$148.54
88108	Cytopath concentrate tech	85,869	$27.64	$23.15	$0.09	$9.42	$12.82	$15.78	$18.64	$21.50	$25.50	$30.40	$37.30	$50.89	$586.21
88112	Cytopath cell enhance tech	207,019	$37.28	$29.02	$0.67	$13.86	$17.78	$22.18	$26.12	$31.56	$35.55	$43.18	$50.04	$68.57	$1,166.72
88120	Cytp urne 3-5 probes ea spec	2,154	$163.18	$157.75	$2.87	$38.24	$53.77	$72.11	$93.22	$107.73	$142.04	$185.22	$213.03	$429.23	$2,190.82
88160	Cytopath smear other source	5,634	$22.66	$20.11	$1.03	$6.45	$9.20	$11.45	$14.41	$17.57	$20.38	$24.53	$34.35	$41.04	$261.08
88161	Cytopath smear other source	6,424	$25.00	$25.00	$1.03	$8.85	$11.54	$13.25	$16.34	$21.37	$23.30	$28.68	$34.20	$45.77	$1,255.53
88162	Cytopath smear other source	2,068	$28.79	$17.97	$0.91	$12.88	$15.59	$18.63	$21.99	$25.91	$27.51	$31.84	$39.97	$49.78	$179.15
88173	Cytopath eval fna report	141,852	$47.67	$41.80	$0.00	$15.72	$21.78	$26.57	$31.90	$37.20	$44.41	$52.13	$62.88	$87.07	$1,389.52
88182	Cell marker study	5,709	$49.70	$41.41	$0.37	$12.94	$26.14	$43.14	$47.54	$47.54	$47.54	$47.54	$47.54	$74.12	$522.81
88184	Flowcytometry/ tc 1 marker	105,539	$34.98	$42.28	$0.10	$8.04	$12.62	$17.02	$21.08	$24.91	$29.58	$34.37	$45.22	$67.98	$1,646.75
88185	Flowcytometry/tc add-on	168,174	$161.22	$276.55	$0.00	$8.55	$13.38	$17.23	$20.60	$32.09	$76.41	$153.82	$260.99	$470.24	$4,533.40
88304	Tissue exam by pathologist	332,014	$37.00	$27.47	$0.00	$14.92	$19.58	$23.62	$27.34	$31.32	$35.37	$40.31	$48.60	$63.58	$2,152.62
88307	Tissue exam by pathologist	231,308	$93.34	$100.69	$0.00	$32.81	$41.24	$49.60	$58.79	$66.81	$77.99	$93.29	$117.36	$169.76	$4,707.25
88309	Tissue exam by pathologist	13,320	$96.41	$74.96	$0.00	$38.25	$49.53	$58.75	$68.55	$79.64	$89.65	$107.55	$129.83	$173.95	$2,782.90
88312	Special stains group 1	313,525	$31.26	$34.70	$0.00	$9.16	$12.80	$15.59	$19.34	$22.59	$26.44	$31.76	$41.89	$58.48	$2,335.93
88313	Special stains group 2	300,924	$39.82	$45.11	$0.00	$9.95	$14.14	$17.40	$21.60	$25.38	$31.69	$38.99	$54.47	$82.65	$1,050.74
88314	Histochemical stains add-on	4,776	$62.00	$108.79	$0.50	$10.43	$12.88	$15.94	$23.04	$26.39	$31.39	$45.72	$68.73	$157.60	$1,230.25
88319	Enzyme histochemistry	3,538	$127.71	$230.85	$3.19	$17.53	$23.95	$23.95	$34.80	$47.90	$71.85	$89.88	$175.28	$329.42	$2,985.38
88323	Microslide consultation	5,627	$53.99	$52.26	$1.00	$15.39	$22.74	$28.11	$37.20	$46.28	$53.07	$62.30	$67.55	$93.35	$1,615.64
88325	Comprehensive review of data	2,758	$91.52	$100.32	$0.01	$10.95	$27.90	$39.71	$48.65	$62.76	$81.35	$100.11	$152.62	$209.24	$1,811.75
88329	Path consult introp	5,101	$23.26	$23.20	$0.26	$7.38	$9.07	$10.90	$13.56	$16.26	$18.81	$23.97	$32.72	$41.72	$236.93
88331	Path consult intraop 1 bloc	115,183	$51.59	$64.48	$0.00	$15.40	$20.97	$25.65	$29.38	$34.71	$41.31	$51.02	$64.34	$97.68	$3,390.67
88333	Intraop cyto path consult 1	20,779	$28.73	$36.55	$0.10	$7.71	$11.25	$14.53	$17.49	$21.67	$27.32	$32.25	$38.40	$51.03	$1,334.99
88334	Intraop cyto path consult 2	5,803	$28.23	$36.42	$0.73	$5.73	$9.38	$11.63	$15.55	$18.68	$22.60	$28.90	$36.35	$56.06	$683.69
88342	Immunohistochemistry	448,197	$112.18	$169.11	$0.00	$21.71	$29.29	$36.23	$44.89	$55.34	$69.90	$102.27	$154.42	$260.40	$7,650.59
88346	Immunofluorescent study	20,072	$182.81	$219.62	$0.88	$23.75	$33.89	$43.38	$63.23	$96.62	$148.70	$212.34	$287.28	$456.65	$3,013.92
88347	Immunofluorescent study	16,760	$45.35	$38.60	$0.12	$13.91	$21.86	$24.72	$30.21	$36.38	$39.83	$46.56	$60.73	$83.50	$438.38
88348	Electron microscopy	7,191	$232.87	$206.40	$4.82	$73.36	$102.04	$129.71	$156.80	$189.58	$235.58	$267.12	$296.96	$427.40	$7,437.09
88349	Scanning electron microscopy	162	$112.60	$89.10	$0.21	$97.72	$97.72	$97.72	$97.72	$100.72	$100.72	$100.72	$102.59	$114.82	$842.16
88355	Analysis skeletal muscle	*	*	*	*	*	*	*	*	*	*	*	*	*	*
88360	Tumor immunohistochem/manual	37,846	$92.91	$85.51	$1.90	$25.29	$35.11	$45.09	$54.10	$67.72	$82.41	$106.33	$136.58	$190.90	$2,858.26
88361	Tumor immunohistochem/comput	19,282	$123.86	$115.90	$0.84	$32.28	$45.83	$56.65	$69.48	$84.48	$106.10	$137.65	$188.36	$273.25	$1,733.73
88362	Nerve teasing preparations	157	$103.84	$64.60	$8.93	$37.82	$53.20	$67.49	$83.82	$93.81	$111.02	$117.01	$120.55	$185.08	$345.50
88363	Xm archive tissue molec anal	1,267	$11.97	$11.54	$0.21	$3.22	$4.28	$5.77	$7.96	$9.48	$11.01	$12.09	$15.39	$23.43	$140.67
88365	Insitu hybridization (fish)	11,124	$99.80	$104.13	$0.14	$28.06	$37.10	$53.59	$61.26	$72.16	$88.06	$104.43	$128.37	$193.74	$2,786.90
88367	Insitu hybridization auto	4,444	$201.22	$330.61	$4.32	$32.70	$33.20	$55.31	$74.76	$93.91	$122.03	$174.44	$268.42	$435.42	$3,327.73
88368	Insitu hybridization manual	20,815	$151.74	$171.65	$4.49	$38.59	$56.59	$67.08	$72.24	$95.53	$121.36	$157.81	$205.09	$291.41	$2,691.74

** Data blinded because each cell represents fewer than 11 observations*

CPT copyright 2013 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Appendix B

		Survey			OPPS	
HCPCS Code	**Short Descriptor**	Mean	Median		Mean	Median
88104	Cytopath fl nongyn smears	$51.80	$51.80		$27.24	$21.61
88106	Cytopath fl nongyn filter	$53.50	$53.50		$30.04	$23.48
88108	Cytopath concentrate tech	$121.37	$75.08		$27.64	$21.50
88112	Cytopath cell enhance tech	$71.06	$65.19		$37.28	$31.56
88120	Cytp urne 3-5 probes ea spec	$422.94	$393.61		$163.18	$107.73
88160	Cytopath smear other source	$41.54	$41.54		$22.66	$17.57
88161	Cytopath smear other source	$53.23	$53.23		$25.00	$21.37
88162	Cytopath smear other source	$80.00	$80.00		$28.79	$25.91
88173	Cytopath eval fna report	$94.60	$75.79		$47.67	$37.20
88182	Cell marker study	$115.36	$72.37		$49.70	$47.54
88184	Flowcytometry/ tc 1 marker	$68.07	$39.11		$34.98	$24.91
88185	Flowcytometry/tc add-on	$22.59	$11.81		$161.22	$32.09
88304	Tissue exam by pathologist	$60.34	$57.47		$37.00	$31.32
88307	Tissue exam by pathologist	$202.09	$133.63		$93.34	$66.81
88309	Tissue exam by pathologist	$135.95	$182.66		$96.41	$79.64
88312	Special stains group 1	$55.13	$44.59		$31.26	$22.59
88313	Special stains group 2	$60.90	$55.04		$39.82	$25.38
88314	Histochemical stains add-on	$51.02	$51.02		$62.00	$26.39
88319	Enzyme histochemistry	$60.43	$60.43		$127.71	$47.90
88323	Microslide consultation	$141.91	$115.33		$53.99	$46.28
88325	Comprehensive review of data	$106.78	$106.78		$91.52	$62.76
88329	Path consult introp	$73.62	$73.62		$23.26	$16.26
88331	Path consult intraop 1 bloc	$69.20	$69.20		$51.59	$34.71
88333	Intraop cyto path consult 1	$55.38	$55.38		$28.73	$21.67
88334	Intraop cyto path consult 2	$62.88	$62.88		$28.23	$18.68
88342	Immunohistochemistry	$78.53	$66.82		$112.18	$55.34
88346	Immunofluorescent study	$122.19	$122.19		$182.81	$96.62
88347	Immunofluorescent study	$293.61	$293.61		$45.35	$36.38
88348	Electron microscopy	$691.40	$691.40		$232.87	$189.58
88349	Scanning electron microscopy				$112.60	$100.72
88355	Analysis skeletal muscle	$357.75	$357.75		*	*
88360	Tumor immunohistochem/manual	$114.22	$124.51		$92.91	$67.72
88361	Tumor immunohistochem/comput	$101.43	$110.08		$123.86	$84.48
88362	Nerve teasing preparations				$103.84	$93.81
88363	Xm archive tissue molec anal	$23.19	$23.19		$11.97	$9.48
88365	Insitu hybridization (fish)	$156.91	$132.96		$99.80	$72.16
88367	Insitu hybridization auto	$303.03	$192.92		$201.22	$93.91
88368	Insitu hybridization manual	$344.29	$265.49		$151.74	$95.53

** Data blinded because each cell represents fewer than 11 observations*

**For certain codes, such as 88185 and 88342, we believe that the survey data represents a per unit cost, while the OPPS data shows a per claim line cost, which can include multiple units. Therefore, the survey and OPPS data are not strictly comparable.

Appendix C

HCPCS Code	Short Descriptor	Survey Mean	OPPS Mean	OPPS Std. Dev.	OPPS + 1 s.d.	Survey % + 1 s.d.
88104	Cytopath fl nongyn smears	$51.80	$27.24	$23.07	$50.32	103%
88106	Cytopath fl nongyn filter	$53.50	$30.04	$17.80	$47.83	112%
88108	Cytopath concentrate tech	$121.37	$27.64	$23.15	$50.79	239%
88112	Cytopath cell enhance tech	$71.06	$37.28	$29.02	$66.30	107%
88120	Cytp urne 3-5 probes ea spec	$422.94	$163.18	$157.75	$320.94	132%
88160	Cytopath smear other source	$41.54	$22.66	$20.11	$42.77	97%
88161	Cytopath smear other source	$53.23	$25.00	$25.00	$50.00	106%
88162	Cytopath smear other source	$80.00	$28.79	$17.97	$46.76	171%
88173	Cytopath eval fna report	$94.60	$47.67	$41.80	$89.47	106%
88182	Cell marker study	$115.36	$49.70	$41.41	$91.11	127%
88184	Flowcytometry/ tc 1 marker	$68.07	$34.98	$42.28	$77.26	88%
88185	Flowcytometry/tc add-on	$22.59	$161.22	$276.55	$437.77	5%
88304	Tissue exam by pathologist	$60.34	$37.00	$27.47	$64.47	94%
88307	Tissue exam by pathologist	$202.09	$93.34	$100.69	$194.02	104%
88309	Tissue exam by pathologist	$135.95	$96.41	$74.96	$171.37	79%
88312	Special stains group 1	$55.13	$31.26	$34.70	$65.96	84%
88313	Special stains group 2	$60.90	$39.82	$45.11	$84.93	72%
88314	Histochemical stains add-on	$51.02	$62.00	$108.79	$170.79	30%
88319	Enzyme histochemistry	$60.43	$127.71	$230.85	$358.56	17%
88323	Microslide consultation	$141.91	$53.99	$52.26	$106.25	134%
88325	Comprehensive review of data	$106.78	$91.52	$100.32	$191.83	56%
88329	Path consult introp	$73.62	$23.26	$23.20	$46.46	158%
88331	Path consult intraop 1 bloc	$69.20	$51.59	$64.48	$116.06	60%
88333	Intraop cyto path consult 1	$55.38	$28.73	$36.55	$65.28	85%
88334	Intraop cyto path consult 2	$62.88	$28.23	$36.42	$64.65	97%
88342	Immunohistochemistry	$78.53	$112.18	$169.11	$281.28	28%
88346	Immunofluorescent study	$122.19	$182.81	$219.62	$402.44	30%
88347	Immunofluorescent study	$293.61	$45.35	$38.60	$83.94	350%
88348	Electron microscopy	$691.40	$232.87	$206.40	$439.27	157%
88349	Scanning electron microscopy		$112.60	$89.10	$201.70	
88355	Analysis skeletal muscle	$357.75	*	*	*	
88360	Tumor immunohistochem/manual	$114.22	$92.91	$85.51	$178.42	64%
88361	Tumor immunohistochem/comput	$101.43	$123.86	$115.90	$239.77	42%
88362	Nerve teasing preparations		$103.84	$64.60	$168.44	
88363	Xm archive tissue molec anal	$23.19	$11.97	$11.54	$23.52	99%
88365	Insitu hybridization (fish)	$156.91	$99.80	$104.13	$203.93	77%
88367	Insitu hybridization auto	$303.03	$201.22	$330.61	$531.83	57%
88368	Insitu hybridization manual	$344.29	$151.74	$171.65	$323.39	106%

** Data blinded because each cell represents fewer than 11 observations*