September 10, 2018

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, Maryland  21244

RE:  Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Proposed Rule (CMS-1693-P)

Dear Ms. Verma:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comments on the Center for Medicare & Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) on the Physician Fee Schedule (PFS). The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation’s largest medical specialty societies and is the world’s largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

ASCP’s comments on the Proposed Rule are focused primarily on the Proposed Rule’s provisions related to the revaluation of the Clinical Laboratory Fee Schedule (CLFS), per Section 216 of the Protecting Access to Medicare Act of 2014 (“PAMA”); proposed updates to Supply and Equipment pricing; and CMS’s proposed refinements to several pathology services.

I. Proposals Concerning PAMA and the Clinical Laboratory Fee Schedule (CLFS)

In the NPRM, CMS indicated that it is responding to stakeholder concern “that the CY 2018 CLFS payments rates are based on applicable information from only a relatively small number of laboratories. Some stakeholders stated that, because most hospital-based laboratories were not applicable laboratories, and therefore, did not report applicable information during the initial data reporting period, the CY 2018 CLFS payment rates do not reflect their information and are inaccurate.” CMS states in the NPRM that “In determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities.” CMS further states that it “believe[s] it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities.”

In this NPRM, CMS outlines one proposal to the current regulations implementing Section 216 of Protecting Access to Medicare Act (PAMA) that it says would help it achieve its goal in increasing data submissions. This proposal would remove Medicare Advantage payments from the
denominator of the “majority of Medicare revenues” threshold calculation. Additionally, CMS solicits in this NPRM comments on “other approaches that have been requested by some stakeholders who have suggested that such approaches would result in CMS receiving even more applicable information to use in establishing CLFS payment rates.”

A. Statutory Framework in Brief

Before outlining our comments on the Agency’s proposal and solicitation for comments, I am summarizing here the key statutory requirement of PAMA: “applicable laboratories” are required to report to CMS private payer data for laboratory tests reimbursed under the Clinical Laboratory Fee Schedule (CLFS). Applicable laboratories are “laboratories” that receive the majority of their Medicare revenues under the CLFS, or Physician Fee Schedule (PFS), or new section 1834A of the Social Security Act (these new provisions were added to the Social Security Act by PAMA (specifically section 216) and provide the Agency with the statutory authority to re-price the CLFS).

The term “private payer” refers to “a health insurance issuer and a group health plan,” a Medicare Advantage plan, or a Medicaid managed care organization. These laboratories must then report data on the payment rates and corresponding test volume for laboratory tests furnished during the data collection period. The data collected by the Agency is then used to calculate weighted median payment rates, which are currently in use today despite widespread concerns about the accuracy of these rates.

B. Has CMS Met Congress’ Market Rate Requirement?

In the CMS Final Rule on the Medicare Clinical Diagnostics Laboratory Test Payment System (CMS_1621-F), CMS purposely opted to exclude hospital laboratories from the definition of an applicable laboratory, despite the fact that this position is contrary to congressional intent. During Congressional action on PAMA, Senators Orrin Hatch (R-UT) and Richard Burr (R-NC) engaged in a Senate floor discussion to clarify for the record congressional intent as to what laboratory data was to be included in the data submission requirements. In that “colloquy,” Senator Burr asked: “It is my understanding that the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services (emphasis added), and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the CLFS.” Senator Hatch responded: “The Senator is correct.”

Given the Senators’ clarification that PAMA requires CMS to “reflect true market rate,” CMS’s efforts to reprice the CLFS are inconsistent with congressional intent.

It is not surprising that the information collected from the first data reporting period in early 2017 is not reflective of actual market pricing for laboratory services as the data obtained from hospital, physician office, and independent laboratories is completely out-of-sync with their respective market shares. According to the June 2017 issue of Laboratory Economics, “Hospital labs account for 48.2% of the total 9.2 billion lab tests performed annually in the United States” yet they account for only one percent of the applicable data on which CMS has based its revised payment rates. Independent laboratories account for 29.5 percent of the U.S. market for laboratory services yet
they account for 90 percent of the applicable data used to calculate new weighted median prices.\(^1\) These data suggests that CMS’s efforts to construct a “market rate” price structure for the CLFS are woefully insufficient and that significant work is needed to improve the reliability and accuracy of these payment rates.

Furthermore, we agree with CMS that the data on which it bases its new payment rates needs to be more robust. We are similarly concerned with the small sample size CMS obtained from applicable laboratories is insufficient to assure the accuracy and reliability of its payment rates. CMS received data from less than 2,000 of the 261,524 laboratories receiving payments under Medicare Part B in 2015.\(^2\) Moreover, only 21 hospital outreach laboratories submitted applicable information to CMS. That’s less than one half of one percent of all hospital laboratories reimbursed for lab services under Medicare Part B in 2015 and roughly one percent of all entities providing data. This point is especially relevant to those tests for which the Agency received insufficient data (data from fewer than 30 reporting entities) to price the service. As a result, the data on which CMS has based its preliminary payment rates is inherently skewed toward the lower payment rates typically obtained by large independent reference labs with significant economies of scale.

C. CMS Effort to Improve the Collection of Applicable Information

ASCP appreciates that CMS has articulated acquiring “as much applicable information as possible from the broadest possible representation of the national laboratory market,” including from hospital outreach laboratories, as one of its objectives on which to base payment rates. We also concur that it is important to minimize reporting burdens and are eager to work with the Agency to ensure CMS has sufficient data on which to calculate laboratory test payment rates that accurately reflect their true market rate.

One proposal put forth by the Agency to accomplish this is to remove Medicare Advantage payments from the “Medicare revenues” test used to determine whether a lab is considered an “applicable laboratory.” ASCP strongly supports CMS’s proposal to exclude Medicare Advantage revenues. It is also our belief that the inclusion of these revenues status is inconsistent with the statute. These revenues have no bearing on laboratory services and likewise prevent CMS from its charge of developing a true market based fee schedule. Only reviews from Medicare Part A and B should be included. For the same reason, we urge CMS to likewise remove Medicare Part D revenues from the “Medicare revenues” test.

If CMS truly hopes to increase the amount of applicable data it collects, it must consider policy changes that will result in data that is truly reflective of the national market for laboratory services, which is what is required by the statute and congressional intent. In accordance with this mandate, ASCP urges CMS to remove the requirement that an applicable laboratory is an entity that bills Medicare Part B under its own NPI. CMS does not have authority to impose this requirement. Per PAMA, the only authority CMS has to exclude laboratories from the need to submit data is on the basis of the low expenditure/volume thresholds. The NPI requirement has almost completely

---

1 In contrast, POLS perform 9.3% of testing volume, which is relatively consistent with the data provided from this sector of the market for laboratory services.
removed hospital outreach laboratories from being considered as applicable laboratories. As a result, ASCP believes CMS is obligated to look at the laboratory as a separate, distinct and identifiable revenue/cost center.

D. **Use of 14X Bill Types for Test Majority of Medicare**

In addition to removing the NPI from the definition of an applicable laboratory, ASCP urges CMS to clarify the Medicare payments for the claims submitted to the Agency by clinical laboratories. On this request, ASCP concurs with and urges adoption of a proposal from the American Clinical Laboratory Association (ACLA) concerning the use of 14X bill types by hospital outreach laboratories. This proposal would recognize payments for claims submitted on a CMS 1500, a CMS 1450 using a 14X bill type, or their electronic equivalents. As noted by ACLA, “the 14X bill type is used only to submit claims for hospital laboratory outreach (non-patient) claims, so this approach would account only for hospital laboratory business that competes in the marketplace with independent clinical laboratories. The revised definition would not have the effect of excluding from the definition of “applicable laboratory” any laboratory that already reported private payer data to CMS.”

E. **Calculation of the Weighted Mean and Burden Reduction**

PAMA requires that for each laboratory test the Secretary shall calculate a weighted median. The purpose of the weighted mean is to ensure that new payment rates are an accurate reflection of current market payment rates. ASCP believes that it is imperative for prices to accurately represent rates in accordance with their respective market share. Therefore, ASCP respectfully urges CMS to weight the data received in accordance with that laboratory type’s respective market share. If hospital laboratories represent 20 percent of the market for testing services, then the data for these facilities should be weighted to 20 percent. This will help adjust the data to ensure that CMS’s calculated median pricing accurately reflects the true market median price—which is the central task of Section 216 of PAMA.

In the NPRM, CMS has suggested lowering the expenditure/volume thresholds from $12,500 to $6,250 as a means to increase the amount of applicable data it receives. We believe that if CMS adopted market-share weighting, it would negate the need to reduce low expenditure/volume thresholds thus reducing the potential reporting burden, particularly on those laboratories less well-equipped to provide CMS with applicable data.

Another policy ASCP requests that CMS adopt to minimize reporting burden concerns the reporting of “applicable data” from manual (hard-copy) remittances. Individual test-level payment information is generally not included in the laboratory’s billing system. While the amount of data found on these remittances is relatively small, the amount of resources expended trying to translate this into test-level information in an electronic format is significant. Allowing this data to be excluded would be helpful for smaller laboratories that face a disproportionate burden when it comes to reporting. That said, we believe CMS should allow for applicable laboratories to submit such data if they so choose.
ASCP also would encourage CMS to allow applicable laboratories to report aggregated data, as authorized by Section 1834A(a)(6) of the Social Security Act.

II. Pathology Supply and Equipment Pricing Update

In the NPRM, CMS initiated a comprehensive review of the direct practice expense (PE) inputs for supply and equipment pricing for CY 2019, using the consulting firm StrategyGen to conduct the research. As CMS states in the Proposed Rule, it has not performed a comprehensive review of supply and equipment prices since 2004-2005. That said, CMS reprices equipment and supplies on an item-by-item basis, using invoices submitted by medical specialties. Based on the report from StrategyGen, CMS is proposing updated pricing recommendations for more than 2,000 supply and equipment items currently used as direct PE inputs. Market research resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis. CMS is proposing to update supply and equipment pricing over a 4-year phase-in. Ultimately, StrategyGen determined the recommended price based on the researched-commercial prices, which were gathered from subscription-based benchmark databases as well as publically available commercial pricing data.

While the RUC PE Subcommittee does not evaluate pricing, it has collected and submitted information to CMS as part of the RUC recommendation process. This process, although not comprehensive, represents collaboration between physicians and CMS. ASCP agrees and appreciates CMS’s efforts to initiate the comprehensive review of supply and equipment pricing and, in general, supports CMS’ efforts to this effect. That said, ASCP concurs with the RUC and other medical specialty societies about a number of concerns about the approach, data, and methodology used to develop these new supply prices. We are concerned, for example, that pricing information obtained from subscription-based databases is not publically available and therefore cannot be easily analyzed to evaluate pricing.

While we are appreciative to CMS for updating these prices, we believe that the RUC, medical specialty societies, and other stakeholders should be able to review the data before adopting these new rates. Accordingly, we urge CMS to postpone adoption of these new rates for one year to allow for this review. Further, we urge CMS to allow stakeholders and interested parties to continue to review and provide comment and/or alternative pricing information during the course of CMS’s four-year phase in of these new rates. To enable this, ASCP urges CMS to provide detailed information about StrategyGen’s sources and methodologies.

III. Individual Pathology Services

ASCP wishes to relate our concerns about several pathology services, Blood Smear Interpretation (CPT code 85060) and Bone Marrow Interpretation (CPT code 85097) and several Fine Needle Aspiration codes. ASCP shares the concerns voiced by the RUC and the College of American Pathologists (CAP), the medical specialty society representing pathology before the RUC, and similarly urges CMS to utilize the RUC’s recommended work RVUs and Direct PE recommendations.
A. Blood Smear Interpretation (CPT code 85060)

<table>
<thead>
<tr>
<th>Code</th>
<th>Long Descriptor</th>
<th>CMS Proposed work RVU</th>
<th>RUC Recommended work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>85060</td>
<td>Blood Smear, peripheral, interpretation by physician with written report</td>
<td>0.36</td>
<td>0.45</td>
</tr>
</tbody>
</table>

For CPT Code 85060, CMS disagreed with the RUC recommended work RVU of 0.45 for CPT code 85060 Blood smear, peripheral, interpretation by physician with written report, and is proposing a work RVU of 0.36 based on the time ratio between the current and survey intra-service time. ASCP does not agree that the difference of three minutes between the current and survey intra-service time for code 85060 constitutes a “significant decrease,” as CMS states. Especially when examining such a small amount of time, a time ratio should not be used because any decrease will result in a large ratio and a corresponding but inappropriate decrease to the physician work RVU. Rather than using time ratios CMS should examine the magnitude estimation between the physician work, time and intensity. We note that the RUC unanimously approved a work RVU of 0.45 for CPT code 85060.

CMS states that the recommended work value of 0.45 is higher than “nearly all of the other global XXX codes with similar time values.” However, a review of the RUC database contradicts this finding showing that thirteen XXX codes with 12 minutes of intra-service time have values the same or higher than 0.45 RVUs whereas only eleven such XXX codes have values lower than 0.45. ASCP urges CMS to accept a work RVU of 0.45 for CPT code 85060.

B. Bone Marrow Interpretation (CPT code 85097)

<table>
<thead>
<tr>
<th>Code</th>
<th>Long Descriptor</th>
<th>CMS Proposed work RVU</th>
<th>RUC Recommended work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>85097</td>
<td>Bone Marrow, smear interpretation</td>
<td>0.94</td>
<td>1.00</td>
</tr>
</tbody>
</table>

For CPT code 85097, CMS disagreed with the RUC’s recommended work RVU of 1.00 and is instead proposing a work RVU of 0.94 based on the current work value. CMS states that “significant decreases in time should be reflected in decreases to work RVUs.” However this criticism seems oddly placed considering that the AMA RUC survey respondents indicate that the service requires 25 minutes to perform rather than the current time of 30 minutes and that CMS proposes to maintain the current work value. Additionally, the current time is “CMS/Other,” which means that the time was not based on a survey and the code was not reviewed by the Harvard studies or through the RUC process. It is unclear to us how CMS determined this time and what it actually represents. “CMS/Other” time has historically been deemed invalid as part of the RUC review process. The RUC agreed with the CAP that incorrect assumptions were made in the previous valuation of this service because it was based on a CMS crosswalk of indeterminate significance. The RUC also agreed with CAP that it is inappropriate to compare the surveyed time to the current CMS/Other time. The RUC also concurred with CAP that given the total work, time, intensity, and complexity of the patient case, the current work RVU of 0.94 was too low a value for the physician work involved. As a result, ASCP urges CMS to accept a work RVU of 1.00 for CPT code 85097.
For the direct PE inputs, ASCP urges CMS to consider pathology clinical staff activities apart from the standard PE clinical activities. This is because the RUC PE Subcommittee determined that separate and distinct pathology clinical activity codes were needed when the PE Spreadsheet Update Workgroup developed the codes for clinical activities. The clinical activity description for PA001 accession and enter information and PA008 file specimen, supplies and other materials appear to describe data entry and filing activities. In the pathology laboratory, however, these tasks are very different than in other settings. These clinical activities are integral elements performed by health care professionals in order to analyze a specimen and are not administrative tasks that go into the indirect PE. These clinical activities are allocable to a particular patient for this service and should not be considered a form of indirect expense. ASCP urges CMS to accept direct PE clinical activity inputs, PA001 and PA008, for CPT code 85097.

C. Fine Needle Aspiration

Our comments here center on three of the codes in the Fine Needle Aspiration family of codes. The RUC thoroughly analyzed this family of fine needle aspiration services by review of the history, survey data and magnitude estimation to other similar services. We note that the RUC unanimously approved the work RVUs for all services in this family and urges CMS to accept the RUC recommended values.

<table>
<thead>
<tr>
<th>Code</th>
<th>Long Descriptor</th>
<th>CMS Proposed work RVU</th>
<th>RUC Recommended work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>10021</td>
<td>Fine needle aspiration biopsy; without imaging guidance; first lesion</td>
<td>1.03</td>
<td>1.20</td>
</tr>
<tr>
<td>10X12</td>
<td>Fine needle aspiration biopsy, including ultrasound guidance; first lesion</td>
<td>1.46</td>
<td>1.63</td>
</tr>
<tr>
<td>10X16</td>
<td>Fine needle aspiration biopsy, including CT guidance; first lesion</td>
<td>2.26</td>
<td>2.43</td>
</tr>
</tbody>
</table>

For CPT code 10021, CMS disagrees with the RUC recommended work RVU of 1.20 and proposes a work RVU of 1.03 based on a direct crosswalk to CPT code 36440 Push transfusion, blood, 2 years or younger (work RVU= 1.03, intra-service time of 15 minutes, total time of 35 minutes). Code 10021 is a revised service that has a new reporting structure. Currently, this service is reported per lesion. Given that CMS’s rejection of the RUC recommendation is based on a flawed budget neutrality interpretation, ASCP urges that CMS accept the RUC’s recommended work RVU of 1.20 for CPT code 10021.

For CPT code 10X12, CMS disagrees with the RUC recommended work RVU of 1.63 and proposes a work RVU of 1.46 based on adding the incremental difference between the RUC recommended work RVUs for codes 10021 and 10X12 (0.43 work RVU difference) to the CMS proposed work RVU for code 10021. The RUC recommendations were based on valid survey data, not on an incremental difference in work RVUs between codes 10021 and 10X12. The RUC used magnitude estimation valuing these services compared to the physician work, time, intensity and complexity and CMS
should not pick out the increment to go forward with valuing this service. ASCP urges CMS to accept RUC’s recommended work RVU of 1.63.

For CPT code 10X16, CMS disagrees with the RUC recommended work RVU of 2.43 and proposes a work RVU of 2.26 based on adding the incremental difference between the RUC recommended work RVUs for codes 10021 and 10X16 (1.23 work RVU difference) to the CMS proposed work RVU for code 10021. The RUC recommendations were based on valid survey data, not on an incremental difference in work RVUs between 10021 and 10X16. The RUC used magnitude estimation valuing these services compared to the physician work, time, intensity and complexity and CMS should not pick out the increment to go forward with valuing this service. ASCP urges CMS to accept RUC’s recommended work RVU of 2.43.

ASCP appreciates the opportunity to comment on this proposed rule. Please refer any questions to Matthew Schulze, Director, Center for Public Policy at 202-735-2285 or Matthew.Schulze@ascp.org.

Sincerely,

James Wisecarver, MD, PhD
President, American Society for Clinical Pathology