Kimberly Sanford, MD, MASCP, MT(ASCP)
President

October 5, 2020

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies (CMS-1734-P)

Dear Administrator Verma:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Physician Payment Schedule (PFS) for calendar year (CY) 2021, published in Federal Register on the August 17 (Vol. 85, No. 159 FR, pages 50074-50665).

ASCP represents the frontlines of laboratory diagnostics, and our membership of 100,000+ board certified pathologists, other physicians, and non-physician laboratory professionals lead the nation's efforts to diagnose and screen for COVID-19 and other diseases/conditions. ASCP 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.

I. Areas of ASCP Policy Concerns

This comment letter from the American Society for Clinical Pathology addresses the following issues:

1. **Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID–19 Pandemic (section II.F.)**
2. **Effect of Proposed Changes Related to Scopes of Practice**
3. **Update on Technical Expert Panel Related to Practice Expense**
4. **Molecular Pathology Interpretation (HCPCS Code G0452)**
5. **Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions**

ASCP is submitting a separate letter to provide comments on issues related to the Quality Payment Program.

II. Overview of Financial Impact

The Centers for Medicare & Medicaid Services (CMS) is proposing to reduce the Medicare conversion factor 11 percent, from $36.0896 to $32.2605. This reduction would lower the 2021 conversion factor below the 1994 Medicare conversion factor of $32.9050, which adjusted for inflation would be approximately $58.02 today.[1,2] The impact on pathology of all the policies outlined in this Proposed Rule is severe. The 9 percent overall cut in payments to pathologists would reduce reimbursements by $1.1 billion over 10 years. The burden in clinical laboratories is also steep, with a 5 percent reduction in overall payments expected.

III. Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID–19 Pandemic (section II.F.)

In the CY 2020 PFS Final Rule (84 FR 62844 through 62860), CMS finalized a policy for the office/ outpatient E/M visit code set (CPT codes 99201 through 99215) to adopt a new coding, prefatory language, and interpretive guidance framework that was provided by the AMA's CPT Editorial Panel and will become effective on January 1, 2021. The proposal focuses on a series of bundled services that are comparable to or include office/outpatient E/M visits. The implementation of CMS's E/M office/outpatient visit coding proposals would benefit physicians that provide these services. However, due to Medicare budget-neutrality requirements, pathologists and other hospital-based physicians that do not rely on these codes will experience massive reductions in overall payments to offset the costs associated with CMS's E/M proposal.

The increased spending on these services attributable to this proposal is $10.2 billion, and its impact on pathologists and clinical laboratories in terms overall reduced PFS reimbursements is estimated at 8 and 4 percent, respectively. In adopting the AMA RUC proposal, CMS did not fully follow the RUC's recommendations, a fact that has significantly enhanced the overall cost of the proposal and magnified the economic burden on pathologists and certain other physicians.

Comment Solicitation on the Definition of HCPCS code GPC1X: In the CY 2020 PFS final rule, CMS finalized the HCPCS add-on code GPC1X, which describes the "visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition." CMS stated the additional add-on code was to recognize additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits by primary care physicians. However, payment for this service is already incorporated in other codes and

[1] American Medical Association. History of Medicare Conversion Factors. Available at https://www.ama-assn.org/system/files/2020-01/cf-history.pdf.
[2] U.S. Bureau of Labor Statistics. Consumer Price Index Inflation Calculator. Available at https://www.bls.gov/data/inflation_calculator.htm.

goes beyond the AMA CPT/RUC recommendations. As a result, the existence of this HCPCS code adds significantly to the cost of the E/M coding proposals. In fact, this code alone accounts for 3 percentage points of the 11 percent reduction in the 2021 conversion factor. This unnecessary HCPCS code exacerbates the financial burden on pathologists, other physicians, and nonphysician providers who do not use this service and should be rescinded.

Global Surgery Codes: Another issue that is a topic of contention is whether the global periods for surgical codes should be increased to reflect the E/M changes. ASCP opposes this proposal as it would further increase the negative impact on pathology, by redistributing Medicare spending from non-patient facing services, such as pathology, imaging, etc. ASCP encourages CMS not to make changes to the global surgery codes when it finalizes this proposal.

Impact of Proposals on Pathologists/Clinical Laboratories: The reduction of the conversion factor, combined with the adoption of the add-on code, will result in huge cuts in payment rates for pathology, and at a particularly vulnerable time. The COVID-19 pandemic triggered a significant reduction in pathology and clinical laboratory referrals. Many pathology subspecialties experienced revenue reductions of 40-50 percent or more.[3] Some, like dermatopathology, witnessed reductions of close to 75 percent. While referrals have mostly rebounded--generally for clinical laboratory services--pathologists and clinical laboratories are still struggling with the financial impacts of the COVID-19 pandemic in many ways, including pay cuts from the loss of pathology referrals, salary reductions, furloughs, and layoffs.

The financial impacts of COVID-19 have also affected the non-physician laboratory professionals who work side-by-side with pathologists; they too have experienced pay cuts, furloughs, and layoffs. In a recent survey conducted by the ASCP, it was found that more than 50 percent of clinical laboratories reduced their staffs of pathologists and non-physician laboratory professionals, with 24 percent of laboratories furloughing personnel, 25 percent rescinding vacant positions or requisitions for staff, and 7 percent laying off staff. More than 60 percent of laboratories saw test volume decrease by 26 percent or more.

These impacts on pathology and the clinical laboratory are extremely troubling, not just because of their enormous financial impact on these professionals but because they present significant impediments to improving our nation's COVID-19 testing capacity. Not only have laboratories experienced massive reductions in revenues due to reduced referrals but pathologists and clinical laboratories have also encountered significant cost increases trying to obtain the scarce testing resources and testing equipment needed to perform COVID-19 tests and other laboratory services. Moreover, pathology and clinical laboratories are now being burdened with the significant financial costs associated with CMS's new Interim Final Rule mandating daily COVID-19 test reporting requirements.

Until an effective vaccine or treatment is found, the most important tool needed for a more effective pandemic response is robust laboratory testing capacity for COVID-19. Without it, the disease will

[3] XIFIN Press Release, New XIFIN Data Reveals Routine Lab Volume Down Approximately 60% but Coronavirus Testing Adds Back Nearly 20%. April 22, 2020. Access Sept. 24, 2020. https://www.xifin.com/news/press-releases/2020/new-xifin-data-reveals-routine-lab-volume-down-approximately-60-coronavirus

likely go undetected longer and will spread to more people before infected individuals are identified. But at a time when the federal government should be working to help pathology and laboratory medicine increase testing capacity, clinical laboratories are being asked to do far more, with far less. We do not think these expectations are fair or realistic, and could substantially diminish the ability of laboratories to respond effectively to the increased testing needs caused by this pandemic.

ASCP's Recommendations: ASCP believes that it is imperative that CMS and HHS minimize the financial impact of the E/M proposal on pathologists and clinical laboratories as well as other affected medical specialties. Consequently, we urge CMS/HHS to adopt the following recommendations:

- **Utilize its authority under the public health emergency declaration to preserve patient access to care and mitigate financial distress due to the pandemic by implementing the office visit increases as planned while waiving budget neutrality requirements for the new Medicare office visit payment policy.** ASCP believes that these proposals require additional funding, and we urge the Agency to work with Congress to secure these funds. Alternatively, CMS should adopt budget neutrality reductions uniformly across all services, so that all specialties, procedures, and service codes are uniformly adjusted.

- **Do not change physician work values for codes with a global period (10 and 90 day) to reflect the changes made to the values for office/outpatient E/M visits.**

- **Withdraw HCPCS code GPC1X.**

IV. Effect of Proposed Changes Related to Scopes of Practice

CMS outlines in its CY 2021 PFS NPRM "several policies consistent with the President's Executive Order 13890 on 'Protecting and Improving Medicare for Our Nation's Seniors' to modify supervision and other requirements of the Medicare program that limit healthcare professionals from practicing at the top of their license (84 FR 53573, October 8, 2019, Executive Order #13890). CMS states in its proposal that "We believe that physicians, NPPs *[nonphysician practitioners]*, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure, including education and training, to the extent permitted under the Medicare statute, as long as it is not likely to result in fraud, waste or abuse." ASCP is concerned that missing from this text are concerns that safeguard patient health and quality of care.

CMS is proposing to allow certain NPPs, such as nurse practitioners (NPs), certified nurse midwives (CNMs), certified nurse specialists (CNS), physician assistants (PA), to supervise the performance of "diagnostics tests," an extraordinarily expansive set of services, based on the notion that these providers may be so authorized under the scope of practice rules of certain states. ASCP is troubled by the exceptionally broad nature of the Agency's proposal. It appears that the Agency has not conducted a thorough review of state scopes of practice laws to determine how expansive the Agency's proposal is or whether state laws ensure appropriate education and training in these areas. This creates enormous potential for unintended consequences to adversely affect patient health.

ASCP is also concerned that the Agency has failed to clearly articulate what services NPPs would be allowed to supervise. CMS notes in the NPRM that "there is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as x-rays and cardiology procedures." The text indicates that CMS is considering including diagnostic laboratory tests into this permanent scope of practice expansion, without any clarification about the need for these healthcare professionals to meet applicable federal laws, such as the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CLIA specifies federal guidelines for test performance and includes provisions specifying educational and clinical training/experience requirements of individuals performing laboratory testing. State scope of practice laws for non-laboratory professionals do not always note that CLIA requirements must be followed, and they generally do not articulate what these standards are. As a result, ASCP is concerned that the wording of the PFS proposal could lead some to believe that they can perform laboratory testing without the need to comply with the CLIA mandates. ASCP strongly opposes allowing individuals who cannot satisfy applicable CLIA standards to perform or supervise diagnostic laboratory tests.

It is difficult for us to fathom that someone who isn't qualified to perform a diagnostic test would be qualified to supervise it.

In recognition of the CLIA's legal mandates, ASCP strongly urges CMS to ensure that for the remainder of the public health emergency and after its conclusion it will do the following:

- **Require all persons performing or supervising anatomic pathology or clinical laboratory tests to have satisfied the requisite CLIA requirements for the performance of those services.**
- **Mandate that all individuals performing laboratory tests are working under the auspices of a valid CLIA certificate and under the direction of an appropriately qualified laboratory director.**

In addition, ASCP recommends that the Agency rescind this proposal.

V. Update on Technical Expert Panel Related to Practice Expense

In this year's PFS NPRM, CMS specifically calls for comments on the best source of data for wage rates used in computing clinical labor costs, one of the direct practice expenses factored into PFS payment rates. CMS states that it currently uses data from the U.S. Bureau of Labor Statistics (BLS) to determine a per minute cost estimate for each of 50 different clinical staff professions. For example, CMS currently estimates the hourly wage for "lab technician" at $19.80 ($0.33 per minute).

BLS used to collect wage data for two levels of laboratory personnel, Clinical Laboratory Technologists (more frequently known as Medical Laboratory Scientists or Medical Technologists) and Clinical Laboratory Technicians (more frequently known as Medical Laboratory Technician). However, due to problems BLS was having obtaining data, it merged the wages for these two laboratory professional categories into a single composite wage. For 2019, BLS estimates the wage for clinical laboratory professionals at $25.54, or $0.43 per minute. It is our understanding from BLS staff that its wage estimate for the laboratory field is focused on *clinical laboratory professionals*, meaning that these wages do not reflect the costs of laboratory personnel providing *anatomic pathology services*, such as cytotechnologists and histotechnologists.

While ASCP strongly concurs that refining clinical labor costs on an annual basis would improve payment accuracy, we are concerned that the BLS data currently lacks the granularity necessary to accurately reflect, and appropriately price, anatomic pathology and clinical laboratory services. This needs to be corrected. We note that ASCP's own biennial wage surveys for the laboratory profession provides data on 13 different categories of anatomic pathology and clinical laboratory professionals.[4]

ASCP believes that BLS generally serves as a fair and transparent data source. That said, BLS must improve the granularity of its wage estimates for laboratory personnel. **As a result, we urge CMS to work with BLS to create distinct wage estimates for the following categories of personnel (at a minimum): medical laboratory scientists, medical laboratory technicians, histotechnologists, cytotechnologists, and laboratory assistants.** These personnel categories have a direct bearing on the pathology services reimbursed under the PFS and are needed to optimize payment accuracy. ASCP would welcome the opportunity to provide its expertise with the laboratory workforce to CMS and BLS.

ASCP would also be supportive of CMS hosting a Town Hall meeting in the near future to provide an open forum for discussion with stakeholders on research to update the PE methodology and the underlying inputs.

VI. Molecular Pathology Interpretation (HCPCS Code G0452)

In the 2021 PFS Proposed Rule, CMS is proposing to adopt the RUC-recommended work RVU of 0.93 and the RUC-recommended direct PE inputs for HCPCS code G0452 (Molecular pathology procedure; physician interpretation and report). The RUC had identified G0452, which had never previously been reviewed as potentially misvalued, at its October 2018 meeting of the Relativity Assessment Workgroup (RAW). **ASCP strongly supports CMS's proposal to adopt the RUC's recommendations for this service.**

VII. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

In response to section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Public Law 116-94, enacted on December 20, 2019, and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Public Law 116-136, enacted on March 27, 2020), CMS is proposing to make certain conforming changes to the data reporting and payment requirements to its regulations for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTS). CMS is revising §414.504(a)(1) to indicate that initially data reporting begins January 1, 2017 and is required every three years beginning January 2022. This revision delays the next data reporting period under the CLFS by 2 years. This means that the next data reporting will be the period January 1, 2022

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[4] Garcia, E. et al., The American Society for Clinical Pathology's 2017 Wage Survey of Medical Laboratories in the United States. *American Journal of Clinical Pathology*, Vol. 151, Issue 1, Jan. 2019, Pages 29–52, https://doi.org/10.1093/ajcp/aqy139

through March 31, 2022. As a result, the next private payor rate-based CLFS update would be effective January 1, 2023—not January 1, 2021.

CMS is also proposing conforming changes to its requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, CMS is proposing to revise its rules to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020. Further, for CY 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

ASCP supports this proposed change and urges the Agency to adopt them in its Final Rule.

I appreciate the opportunity to provide these comments. If we can be of any assistance in developing guidance on this matter or anything else, please do not hesitate to contact me or Matthew Schulze, Director of the ASCP Center for Public Policy, at (202) 735-2285.

Sincerely,

Kimberly Sanford, MD, MASCP, MT(ASCP)
President, American Society for Clinical Pathology