ASCP STRONGERTOGETHER

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

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–1751–P. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide comments on several policy proposals outlined in the CY 2022 Medicare Physician Fee Schedule (PFS) Notice of Proposed Rulemaking (NPRM). ASCP is the world's largest organization representing the field of laboratory medicine and pathology. We represent 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's comments areas of concern with the following items addressed in the PFS NPRM:

- **Practice Expense Relative Value Units: Clinical Labor Pricing Update**
- **Physician Self-Referral Updates**
- **Pathology Clinical Consult (CPT Codes 80XX0, 80XX1, 80XX2, and 80XX3)**
- **Comment Solicitation for Codes Involving Innovative Technology**
- **Clinical Laboratory Fee Schedule: Specimen Collection and Use of Electronic Travel Logs**
- **General Comments on Evaluation and Management Services Valuations**

I. Practice Expense Relative Value Units [FR section H.B.]: Clinical Labor Pricing Update

CMS is proposing to update the clinical labor pricing (direct practice expenses) for CY 2022. CMS's current clinical labor wage rates were last updated in 2002 and are out of date. To update these rates, CMS is proposing to use wage data from the Bureau of Labor Statistics (BLS), using a methodology the Agency outlined in its CY 2002 PFS Final Rule. ASCP concurs that the BLS wage data may be the most appropriate single data source to use as the basis for identifying clinical labor wage costs for all non-physician staff types involved in providing services reimbursed under the PFS.

In the Proposed Rule, CMS recognizes that BLS wage data does not cover all staff types (such as histotechnologists and cytotechnologists) contained in CMS's direct PE database. To approximate these

wages, CMS proposes crosswalks or extrapolates wage data using supplementary data sources for verification whenever possible. ASCP has reviewed the CMS proposals in comparison to our own wage surveys and believes that CMS's proposed crosswalks and supplementary data sources provide acceptable approximations for these wages.

As CMS notes in the Proposed Rule, "the potential effects of the clinical labor pricing update on specialty payment impacts are largely driven by the share that labor costs represent of the direct PE inputs for each specialty. Specialties with a substantially lower or higher than average share of direct costs attributable to labor would experience significant declines or increases, respectively, if this proposal is finalized." This puts a huge burden on pathology, which is heavily dependent on expensive supplies and other direct costs (non-labor costs) compared to other providers.

ASCP notes that while CMS's estimate of the impact of the change in clinical labor pricing may only be -1 percent for pathology and -3 percent for independent laboratories*, this impact will not be uniform across the specialty of pathology as some pathology subspecialties should be expected to be more vulnerable to payment changes on a code-by-code basis*. Many pathology subspecialties may be served by a fraction of the overall family of pathology Current Procedural Terminology (CPT) codes and, as a result, a significant change in one or more of the few codes that certain pathologist subspecialists bill for could have catastrophic impacts on the viability of their practice. Similarly, some, particularly smaller, independent (clinical) laboratories may similarly focus on a small subset of laboratory services and may be particularly vulnerable on a code-by code basis.

While we support CMS's proposal to update the clinical laboratory values, **ASCP strongly urges CMS to phase in these changes, preferably over four or more years, such that no single code is exposed to more than a 5 percent reduction in payment in any single year. Moreover, we urge CMS to work with Congress to secure sufficient funds to provide funding to ensure a positive update to the Medicare conversion factor for 2022 and beyond. Lastly, we urge CMS to update its BLS data as that agency recently released its 2020 data.**

II. Physician Self-Referral Updates: The Physician Self-Referral Statute and Regulations

In commenting on this proposed regulation, ASCP wishes to convey that we strongly support efforts to prevent self-referral, kick-backs, mark-ups and other abusive billing practices that adversely affect the quality of patient care, spur overutilization of health services, and increase costs. ASCP appreciates CMS's interest in modifying the Physician Self-Referral regulations to deter program and patient abuse.

In line with this goal, CMS is proposing to revise the Physician Self-Referral regulations to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves compensation *for anything other than services that he or she personally performs*. This will mean that the compensation for the rental of office space, such as for in-office laboratories, or equipment may not be determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessee to the lessor in order for the indirect compensation arrangement to qualify for the indirect compensation

arrangement exception at 42 C.F.R. § 411.357(p). ASCP hopes that this proposal, if finalized, will help lessen the financial incentives for providers to attempt to profit on their referrals.

A. Definition of "services that are personally performed"

CMS is also proposing to define "services that are personally performed." Under the NPRM, services that are performed by someone other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members or persons supervised by the physician (or the immediate family member) are not considered to be personally performed by the physician. ASCP generally supports this definition.

One of the services frequently abused under physician self-referral arrangements is pathology services, which has wrongly been equated with clinical laboratory services as part of the Physician Self-Referral Law's In-Office Ancillary Services Exception. ASCP has long supported reform of the Stark Law's to exclude pathology services from the In-Office Ancillary Services Exception.

Some physicians, in order to profit on their referrals for these services, have sought to provide these services in-office. Unlike clinical laboratory services, these services cannot be performed in the physician's office while the patient is on-site. Not surprisingly, as is typically the case with services abused under self-referral arrangements, this can lead to overutilization, poor quality and increased healthcare costs for payers and patients.

The technical component for most pathology service, including surgical pathology services, should only be performed by highly trained and skilled professionals, called histotechnologists or histotechnicians. Unfortunately, one of the glaring gaps in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) is that the *processing* of patient specimens—even anatomic specimens—is not covered under CLIA's oversight. As a result, there are no standards for the performance of this highly complex medical service, such as personnel or supervision requirements when it is performed outside of a CLIA high-complexity clinical laboratory. This should not be permitted, as it fosters the potential for substandard patient care.

ASCP believes that to address this problem two policy prescriptions are necessary:

- **CMS should clarify that the processing of an anatomic pathology specimen must be performed in a CLIA-certified high complexity laboratory, performed by an individual meeting the qualifications of 42 CFR 493.1487 and under the supervision of a pathologist board certified in anatomic pathology, or other physician qualified under 42 CFR 493.1447(l) to serve as both a laboratory director and technical supervisor of a high complexity laboratory; and**
- **Anatomic pathology services should be removed from the Physician Self-Referral Law's In-Office Ancillary Services Exceptions.**

With regard to the first of these two proposals, we believe that one way to accomplish this change would be to update the CPT-4 and HCPCS Codes Subject to CLIA Edits List to include Codes 88304 (TC), 88305 (TC) and G0143 (TC). We note that with the exception of these two codes, all other

codes in the surgical pathology code family (88300-88309) can be found on this list, *even for services of lesser complexity*.

III. Proposed Valuation of Specific Codes for CY 2022: Pathology Clinical Consult (CPT codes 80XX0, 80XX1, 80XX2, and 80XX3)

A. Pathology Consult Code Work RVUs and Times

Among the codes addressed in the CY 2022 PFS are the new pathology consult codes (CPT codes (80XX0, 80XX1, 80XX2, 80XX3). These new codes were created as a result of a RUC review of CPT codes 80500 and 80502. During the review it was determined that there was no clear typical patient or service connected with the then existing consultation codes. It was also determined that the then existing codes could not be accurately surveyed and that it appeared from historical data that these services were not properly understood. As a result, the RUC referred review of these codes to the CPT Editorial Panel to better define the services and descriptors. In October 2020, CPT codes 80500 ad 80502 were replaced by the CPT Panel with new codes to describe pathology consultation services: 80XX0, 80XX1, 80XX2, and 80XX3.

In presenting these codes to the RUC, it was noted that the new codes required updated valuations. First, the evidence used to value the previous services was based on flawed assumptions, including the use of an unknown crosswalk. Moreover, the new codes better reflect the current needs of physicians seeking pathology consultations. In the 25 years since the old codes were created, there has been an explosion in the number and complexity of available laboratory tests. There is also an increasing number of new drugs (and corresponding assays) and patients dealing with chronic diseases. These factors, particularly the increasing reliance on molecular diagnostic testing (precision medicine), has made it more challenging for many physicians, as they have expressed uncertainty about what tests to order for their patients and how to integrate the results into patient care.

In accounting for the resource costs of these services, ASCP appreciates that the Agency concurred with most of the RUC recommendations for these services. Accordingly, we offer the following comments on the individual codes involved here:

Code 80XX0: In the NPRM, CMS states: "The RUC recommended a work RVU of 0.50 for CPT code 80XX0 based on the 25th percentile of the survey. The RUC-recommended 15 minutes of intraservice and total times for CPT code 80XX0 are 2 minutes above the current instraservice and total times for CPT code 80500. This represents a 15 percent increase in the respective times. However, the RUC-recommended work RVU of 0.50 is 35 percent higher than the current work RVU of 0.37 for CPT code 80500." CMS further states that it believes that "the increase or decrease in times should be commensurate with the increase or decrease in the work RVU. Therefore, [CMS is] proposing a work RVU of 0.43.

In response, ASCP urges CMS to reconsider its proposed work RVU of 0.43. For the reasons outlined above that these new codes are separate and distinct from the old codes, comparing these codes does not provide a reliable benchmark for comparison. The RUC recommendations, based on the survey's 25th percentile work RVUs, provides a more appropriate data point to value this code.

Code 88XX1: In the NPRM, CMS state that it proposes to accept the RUC's recommendation of 0.91 for the work RVU without refinement for CPT code 80XX1. ASCP supports the Agency's proposal to finalize the RUC recommendations for this code.

Code 80XX2: In the NPRM, CMS states: "The RUC recommended a work RVU of 1.80 for CPT code 80XX2 based on the 25th percentile of the survey. The current intraservice and total times for CPT code 80502 are 42 minutes. The RUC-recommended times for CPT code 80XX2 are 54 minutes. Similar to the scenario described above for CPT code 80XX0, the intraservice and total times for CPT code 80XX2 increased 28.6 percent while the work RVU increased 35 percent. As stated above, we believe the increase or decrease in time should be commensurate with the increase or decrease in the work RVU. Therefore, for CPT code 80XX2 we are proposing a work RVU of 1.71, which is the current total time ratio of CPT code 80502 compared to the RUC-recommended total time for CPT code 80XX2."

In response, ASCP urges CMS to reconsider its proposed work RVU of 1.8. For the reasons outlined above that these new codes are separate and distinct from the old codes, comparing these codes does not provide a reliable benchmark for comparison. The RUC recommendations, based on the 25th percentile work RVUs, provides a more appropriate tool for valuing this service.

Code 80XX3: In the NPRM, CMS state that it proposes to accept the RUC's recommendation of 0.80 for the work RVU without refinement for CPT code 80XX3. ASCP supports the Agency's proposal to finalize the RUC recommendations for this code.

B. Proposed Changes to Recommended Direct Practice Expense Inputs

CMS states in its NPRM that it is proposing the RUC-recommended work RVU of 0.80 for CPT code 80XX3 without refinement.

CMS states in its NPRM that "for the direct PE inputs of CPT codes 80XX0, 80XX1, and 80XX2, [it is] proposing to refine the time associated with the clinical labor activity PA001 (Accession and enter information) from the RUC-recommended time of 4 minutes to 0 minutes as we believe the time is duplicative with clinical labor activity PA008 (File specimen, supplies, and other materials)."

In response, ASCP notes that for these codes clinical labor activity PA001 is recommended as a pre-service clinical labor task to document the physician's request for the pathologist's consult and its underlying rationale. PA008 is included in the RUC recommendation to cover the *post-service* clinical labor associated with this service. As a result, these two clinical labor tasks are recommended to cover separate and distinct aspects of this service. The inclusion of these two items is not duplicative. **Accordingly, ASCP requests that CMS accept the RUC recommendation of 4 minutes for PA001 for codes 80XX0, 80XX1, and 80XX2.**

In addition, CMS notes it proposes to remove "the RUC recommended 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80XX0, 80XX1, 80XX2, and 80XX3, respectively." CMS states that "there is no indication from the code descriptors that the pathologist is reviewing physical slides. The code descriptor and description of work indicate that the pathologist is reviewing paper records and/or EHR and therefore we are proposing to remove the equipment time associated with EP024 (microscope, compound) from CPT codes 80XX0, 80XX1, 80XX2, and 80XX3."

When pathologists are requested to provide a consult on a patient case, all relevant information including the slides is reviewed. We note that the physician work descriptions found in the summary of the RUC recommendations state, "All applicable diagnostic material, slides, primary analytical data are retrieved/unarchived for the pathologist's examination and review." These slides would be reviewed by the pathologist using a high-quality professional microscope. During these services, the microscope would remain in use by the pathologist and not be available for use by others.

The need for the pathologist to examine patient slides is also referenced in the RUC's NF practice expense summary of recommendation form as follows: "Such data includes but is not limited to patient medical history records, retrieval of patient specimen slides, laboratory data, images…" **Consequently, ASCP respectfully requests that CMS reconsider its position and accept the RUC recommended equipment times of 15, 30, 54, and 30 minutes for EP024 (microscope, compound) for CPT codes 80XX0, 80XX1, 80XX2, and 80XX3, respectively.**

C. The Role of the Independent Historian in the Pathology Consult Codes

In the Proposed Rule, the Agency has opted not to allow the RUC recommended "Assessment requiring an independent historian" as an element the Agency would recognize as an element of medical decision making. In explaining its position, CMS states that "neither the code descriptors nor the descriptions of work indicate that this type of assessment is typical in a pathology clinical consult as was discussed for the office visit Levels of Decision-Making table. ASCP notes that this assessment is identified in the CPT prefatory language.

To provide further rationale as to why this assessment should be allowed, ASCP supports the explanation outlined by the College of American Pathologists in their comments on the Proposed Rule. We have included an excerpt of these comments at the end of this letter as Appendix 1. **We urge CMS to accept and finalize the RUC recommendations for the "Assessment requiring an independent historian."**

IV. Comment Solicitation for Codes Involving Innovative Technology: Resource costs for services involving innovative technologies such as software algorithms and artificial intelligence

Rapid advances in innovative technology are having a profound effect on every facet of the economy, including in the delivery of health care. Emerging and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. In this Proposed Rule, CMS is soliciting public comment to better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and artificial intelligence (AI).

ASCP appreciates that the Agency recognizes the importance of paying for innovative technologies, such as software algorithms, machine learning, and artificial intelligence and that it is actively engaged in gathering information from stakeholders to determine accurate resource costs. We recognize that considerations around these technologies are complex and their impact on payment important. These advanced technologies can provide critical new tools to enable physicians and other health care

professionals to provide better patient care and to improve outcomes. They are transforming quality, efficiency, accessibility, and patient, as well as physician, experience within the health care system.

From ASCP's perspective, Medicare should factor in the costs of these new tools in setting payment rates for patient services, whether through the PFS, Clinical Laboratory Fee Schedule, or other Medicare fee schedules. Sound payment policy should not only incentivize their use, but also their development, and can be linked to demonstrable improvement in patient care. While relatively new in terms of its application to medicine, the use of algorithms and other similar advanced technologists is well on its way to being integrated into a number of pathology and clinical laboratory services, used not just for patient diagnosis, screening and prognosis, but also to minimize laboratory test ordering (i.e., eliminate unnecessary testing) without compromising quality of care.

Digital pathology is one example of a new technology that is expanding rapidly, and it is on the verge of becoming a mainstream option for routine diagnostics. Digital pathology broadly refers to a discipline in which digital tools are used to advance the practice of pathology. These tools include digital imaging technologies (e.g., whole-slide imaging), telepathology, and data science methods such as data mining, digital image analysis, and artificial intelligence. Like other advanced technologies, digital pathology can provide improvements in patient care, particularly in remote and underserved areas.

ASCP appreciates CMS's interest in the resource costs of new technologies like digital pathology. To encourage expansion and enhancements in digital pathology, we urge CMS to ensure payment rates appropriately account for the costs of these services. That said, as the adoption of digital pathology is in its early stages, the data available on which to set sound payment policy is limited. **Accordingly, we would urge the Agency to continue studying digital pathology and not to develop any prescriptive overarching payment policies that may deter its advancement.**

Another area of technological advancement applied to laboratory science pertains to tests known as Multianalyte Assays with Algorithmic Analyses (MAAAs). These tests combine results from two or more assays, such as biochemical or molecular markers, along with patient demographics and clinical information, into an algorithm to generate diagnostic, prognostic, or predictive information for a disease. MAAAs tests, like other tests using algorithms to provide their results, provide new insights into a patient's health that were not previously available.

Historically, however, when these tests were added to the Medicare CLFS, the Agency did not provide payment to account for the cost of the algorithm—instead paying only for the component tests. ASCP notes that CMS recently adhered to this payment approach for a new MAAAs test that required the laboratory to purchase (per test) a third-party proprietary algorithm needed to provide the patient service. Not reimbursing for the algorithm results in lower payment to laboratory than if it just used the component tests and thus disincentivizes its use in patient care. ASCP is concerned that maintaining this approach to pay for these technologies will undermine the development of new diagnostics, which ultimately does not benefit quality patient care.

In the PFS NPRM, CMS proposes to use a crosswalk to account for the use of an algorithm in CPT code 92229. CMS states that it continues "to believe that the software algorithm present in the analysis fee for CPT code 92229 is not well accounted for in our PE methodology." Moreover, CMS states that it "recognize[s] that practitioners are incurring resource costs for purchase of the software and its ongoing use." As a result, CMS proposed to utilize its crosswalk approach to reimburse the cost of the algorithm. While ASCP cannot speak to the appropriateness of that particular crosswalk, we appreciate the Agency's effort to provide payment to cover the cost of the algorithm. **Accordingly, ASCP urges CMS work to ensure that as digital technologies, algorithms and other advanced technologies are increasingly integrated into medical practice that the Agency includes payment to cover the added costs of these services, not just in the PFS but in the CLFS as well.**

V. Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

CMS is soliciting comments on two issues affecting the CLFS. The first issue concerns the PHE-specific specimen collection fees and travel allowances. The second concerns the use of electronic travel logs to document travel mileage.

A. Clinical Diagnostic Laboratory Tests

As part of its response to the COVID-19 public health emergency, CMS created a nominal specimen collection fee and travel allowance as part of the CY 2021 PFS NPRM so that independent laboratories could recoup the costs associated with the collection of patient specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients. This policy involved creating two new HCPCS codes to pay for these services for the duration of the COVID–19 public health emergency (PHE). These codes were:

- G2023, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source, and
- G2024, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a (skilled nursing facility) SNF or by a laboratory on behalf of a (home health agency) HHA, any specimen source.

In this year's PFS NPRM, CMS proposes to delete HCPCS Codes G2023 and G2024 once the COVID-19 PHE ends and is seeking public input on the proposal. These codes have been necessary because the ideal specimen for SAR-CoV-2 detection utilizes a nasopharyngeal swab which must be collected by a skilled healthcare professional. This type of swab is also key for the detection of influenza and other respiratory viruses. While several laboratories have proposed alternate specimens for SARS-CoV-2 testing (e.g., nasal swabs, saliva) studies support the idea that nasopharyngeal swabs are the gold standard for producing accurate test results. Moreover, as CMS is aware the new HCPCS codes were established to expand SARS-CoV-2 test capacity; to improve access to testing services for Medicare beneficiaries (particularly those unable to travel), and to reduce the potential for infection that travel may pose, both to the patient and/or healthcare workers.

While there have been significant advances in the types of COVID-19 clinical laboratory tests that are available, the gold standard remains polymerase chain-reaction (PCR) testing, a test best performed in a

high-complexity laboratory certified per CMS's regulations for the Clinical Laboratory Improvement Amendment (CLIA) program. We note that some alternatives to the PCR tests can be prone to false positive or negative test results (See attachment), particularly when used by those lacking proper training in laboratory testing techniques, or may have more limited time windows during which the test is most likely to detect the presence of the SARS-CoV-2 virus.

While we hope that the pandemic ends soon, infectious disease experts have warned that COVID-19 may become a permanent, endemic disease, similar in some ways to influenza. As new variants emerge, there is increased likelihood that a new variant could emerge that could evade current COVID-19 vaccines and bring about new outbreaks. During the course of the PHE, clinical laboratories across the U.S. have struggled with staffing issues created by a long-term shortage of laboratory personnel. The health and safety of pathologists and laboratory professionals are critical to the ability of our nation's clinical laboratories to meet the testing needs of our patients. We firmly believe that the potential for future outbreaks after the conclusion of the PHE supports strict adherence to appropriate safety protocols, appropriate use of personal protective equipment (PPE), and special training for specimen collection beyond the immediate PHE, and this is better enabled with the two HCPCS codes. **As a result, ASCP believes that eliminating these codes at this time is premature. Doing so could slow response times and/or limit patient access to testing from any new future outbreaks that occur.**

B. Electronic Travel Logs

As described in the March 2020 COVID-19 Interim Final Rule (IFC) (85 FR 19256), CMS is required to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital).

In accordance with the March 2020 COVID-19 IFC (85 FR 19256), Medicare has established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. Medicare Administrative Carriers (MACs) calculate travel allowances for each claim, and in some cases, they have required laboratories to maintain *paper logs* of miles traveled to receive the travel allowance. CMS indicated in the CY 2020 IRC that, for the duration of the PHE for the COVID-19 pandemic, paper documentation (Logs) of miles traveled would not be required and that laboratories could maintain electronic logs if they preferred.

CMS is proposing that it will allow electronic logs as a *permanent option*, not just for COVID-19 testing but for all clinical laboratory diagnostic services requiring travel to the patient. In allowing for electronic logs, CMS notes that "maintaining paper logs of miles is burdensome, whereas maintaining electronic logs is less burdensome, especially with the development of GPS systems and various applications for cellular phones in recent years that can track miles traveled." ASCP supports CMS's proposal and its conclusions about the clear administrative benefits of electronic logs. **We urge the Agency to adopt its proposal to allow electronic logs as a *permanent option* in its final regulations for the PFS.**

VI. General Comments on Evaluation and Management Services Valuation (FR section II.F.): Visits Included in Codes with a Surgical Global Period

CMs is proposing not to apply the increased 2021 valuation of the office Evaluation and Management (E/M) services to the visits added to the surgical global packages. **ASCP concurs with this proposal and urges the Agency to adopt it in its final regulations. In addition, ASCP asks CMS not to make any adjustment to the physician work values for codes with a global period (10 and 90 day) to reflect changes made to the values of the office/outpatient E/M visits**.

ASCP appreciates the opportunity to provide these comments and looks forward to working CMS to finalize these recommendations for CY2022. If there is anything we can do to assist with your efforts, please do not hesitate to contact me or Matthew Schulze, Director of the Center for Public Policy at Matthew.Schulze@ASCP.org or at 202.735.2285.

Sincerely,

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

Attachment

Appendix 1. As drafted by the College of American Pathologists

C. Role of Independent Historian in Pathology Clinical Consult Codes

In the 2022 NPRM, CMS states that they will not include the element of "Assessment requiring an independent historian" as part of an element of Medical Decision Making (MDM). Although this element is included in the CPT prefatory language, CMS states below that they do not believe that pathologists interact with independent historians in the typical scenario. The agency is also concerned that interaction with independent historians is not included in the Pathology Consult Codes descriptors or description of work. *NPRM Excerpt:*

> *The proposed Levels of Decision Making for Table for Pathology Clinical Consult codes includes "Assessment requiring an independent historian(s)" as an element of "Amount and/or Complexity of Data to be Reviewed and Analyzed * - Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below." Neither the code descriptors nor the descriptions of work indicate that this type of assessment is typical in a pathology clinical consult as was discussed for the office visit Levels of Decision-Making table. For these reasons, CMS proposes that this element not be included as an element that CMS would recognize as an element of medical decision making. We note that CMS will monitor the use of these replacement codes per our usual practice to ensure appropriate billing and inform future rulemaking as needed. We are also seeking comment on how these replacement codes would most typically be billed relative to use of existing pathology coding. Such information would also inform future rulemaking as needed.*

It is important to state that the Pathology Consult Codes were valued based on the assumption that pathologists would be able to use elements from the MDM table stated in the following CPT introductory language **(*The appropriate level of pathology clinical consultation services may be based on either the total time for pathology clinical consultation services performed on the date of the consultation; or the level of the medical decision making (MDM) as defined for each service)*** when it *was* appropriate. Below we have listed the following scenarios where the pathologist needs to utilize the independent historian:

Complex toxicology cases –

- Independent historians (e.g., spouse/significant others, other family members, close friends, external treating physicians/QHPs, clinical staff and counselors, outside lab providers involved in treatment monitoring programs, etc.) often provide valuable information in pathology clinical consultations on complex and unexpected toxicology results and the evaluation of drug-drug interactions.

- This is most common in individuals who have been undergoing chronic pain management, substance abuse treatment, or both, where clinical and medication history from the patient may be poor, incomplete, or deemed unreliable (and, especially, when the patient is acutely confused, delirious, unresponsive or in a comatose state).

- Gaining as much insight as possible on specific types/doses of prescription and over-the-counter medications, potential use of illicit drugs and/or herbal and other supplements (that enhance pharmacologic effects or alter drug metabolism)—as well as past patterns of misuse/abuse and non-compliance with treatment programs—are critical in the overall assessment of the patient's clinical condition and correlation of diagnostic findings.

- When unknown substances may have been ingested, independent historians are frequently helpful as they may have access to the patient's source material.

- Discussions with clinical and technical staff at external laboratories performing prior testing as part of ongoing treatment monitoring programs, may be necessary when complex, atypical or clinically inconsistent findings are observed by current definitive testing (eg, liquid chromatography/mass spectrometry) or should more detailed information be required than typically provided in outside lab reports.

Genomic testing cases –

Genomic testing scenario 1 - oncologist requests a consultation from a molecular pathologist to assist in the care of a patient with stage 3 ovarian cancer, including tumor genomic profiling results. After reviewing the patient's medical, surgical, pathologic and treatment history, he reviews the genomic test results. The results identify specific mutations relevant to the efficacy of specific therapies and to the patient's overall prognosis. In addition, the pathologist notes a specific mutation that suggests a heritable condition. However, the true somatic or germline status of the variant cannot be confidently determined by the somatic-only sequencing that was performed on the tumor. Furthermore, the available medical record did not include the necessary level of detail for personal and family history to determine whether suspicion for a hereditary cancer syndrome was warranted.

- During the patient's next clinic visit, the pathologist interviewed the patient and the patient's sister to obtain information to better interpret the genomic test result.

Genomic testing scenario 2 - An oncologist requests a consultation from a molecular pathologist to assist in the care of a patient with metastatic colon cancer, including tumor genomic profiling results. After reviewing the patient's medical, surgical, pathologic and treatment history, he reviews the genomic test results. The results identify specific mutations relevant to the efficacy of specific therapies and to the patient's overall prognosis. In addition, the pathologist notes a specific mutation that suggests a hereditary cancer syndrome not usually associated with colon cancer. However, the true somatic or germline status of the variant cannot be confidently determined by the somatic-only sequencing that was performed on the tumor. Furthermore, the available medical record did not include the necessary level of detail for personal and family history to determine whether suspicion for a hereditary cancer syndrome was warranted.

- During the patient's next clinic visit, the pathologist determined that the patient was not reliable and interviewed the patient's caretaker and family to obtain information to better interpret the genomic test result and determine whether genetic counseling and germline evaluation are warranted.

Other clinical scenarios –

- An elderly Russian speaking patient with Alzheimer disease presented with soft tissue bleeding and normal conventional laboratory assays (PT, aPTT, TT) and abnormal TEG (significant fibrinolysis). Patient was accompanied by his wife who was the patient's historian.

- Newborn with congenital heart disease, on aspirin and with intracranial bleeding. Question was raised about possible Bernard -Soulier syndrome, congenital bleeding disorder. Parents provided relevant personal history.

- Young woman with multiple "strokes" and positive MTHFR mutation was accompanied by her husband who contributed to her history. Referred patient for a second opinion to re-review imaging. As a result, diagnosis was MS and not strokes.

Kimberly Sanford, MD, MASCP, MT(ASCP)

President

September 11, 2020

Stephen M. Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Jeffrey E. Shuren, MD, JD
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn and Director Shuren:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing in regards to the important role that test setting plays in determining whether testing for the coronavirus (COVID-19) can accurately identify true positives for the virus.

New advancements in laboratory testing for COVID-19 are poised to substantially increase U.S. test capacity, with the expectation that this could help better manage the pandemic and restore some semblance of normalcy to everyone's lives. The Abbott BinaxNOW COVID-19 rapid antigen test, the subject of a recent U.S. Food and Drug Agency's (FDA) Emergency Use Authorization, is one example. Many others are under development, including a number seeking a share of a $5 million NIH competition for new COVID-19 rapid tests.

But whether these tests can improve our ability to accurately detect disease depends on how they are used and whether the right tests are used in the right patient care settings, keeping in mind how test performance characteristics and the prevalence of disease affect the positive and negative predictive values. Even a very good test's positive predictive values plummets when it moves from a diagnostic setting (relatively high prevalence of infected individuals) to a screening setting (relatively low prevalence of infected individuals). We note that there have been a number of cases of individuals who tested positive for COVID-19, only for it to be determined later that their initial test results were false positives. Ohio Governor Mike DeWine, is one example, but there have been many others, including a number of relatively high-profile cases involving prominent sports figures.

The following example outlines the impact that the test setting can have on likelihood of a false positive result. In a case where the prevalence of disease is 50 percent (patients are symptomatic) and test sensitivity and specificity are both 95 percent, then 95% of the time a positive result is truly positive; the false positive rate is only 5 percent. But if that same test is used in a setting where individuals are more likely to be asymptomatic, such as screening sites, the false positive rate changes dramatically. In a setting with 1% prevalence, only 16 out of 100 positives are correct; the false positive rate would be 84 percent. Attached are the data for these examples.

False positives can result in harm to individuals and to COVID-19 response efforts. Individuals who receive false positive results may suffer from loss of income resulting from an inability to work. They may receive unnecessary treatment, which carries with it the possibility of patient harm and unnecessary medical costs. False positive rates can also confound COVID-19 pandemic response efforts as it adversely affects the quality of data on which our response is based.

As noted previously, the testing setting is of critical importance to test performance and one that we believe requires guidance from the Agency. Consequently, we believe that FDA should specify that positive results obtained in a low prevalence population (e.g., asymptomatic individuals) should be initially classified as "provisionally positive." Good medical practice dictates that this guidance should note that all such "provisionally positive" results should be followed with confirmatory testing, preferably using a RT-PCR test, to eliminate the reporting of false positives.

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.

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,

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President, American Society for Clinical Pathology

cc: Elizabeth Hillebrenner, CDRH, FDA
William H. Maisel, MD, MPH, OPED, CDRH, FDA
Timothy Stenzel, MD, PhD, OIVDRH, CDRH, FDA
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Attachments

Clinical Calculator 2

Predictive Values and Likelihood Ratios

Given the prevalence of a condition within the population and the sensitivity and specificity of a test designed to indicate the presence of that condition, this page will calculate the predictive values of the test (probabilities for true positive, true negative, false positive, and false negative) and its positive and negative likelihood ratios.

To proceed, enter the known or hypothetical values of prevalence, sensitivity, and specificity into the designated cells, then click the «Calculate» button. To perform a new calculation with a new set of values, click the «Reset» button. All values should be entered as decimal fractions.

Prevalence =	.5
Sensitivity =	.95
Specificity =	.95

Prevalence, sensitivity, and specificity must each be entered as a proportion.

Calculate Reset

For any particular test result:

probability that it will be positive	0.5
probability that it will be negative	0.5

For any particular positive test result:

probability that it is a true positive ["positive predictive value"]	0.95
probability that it is a false positive	0.05

For any particular negative test result:

probability that it is a true negative ["negative predictive value"]	0.95
probability that it is a false negative	0.05

likelihood Ratios: [definitions]

Conventional Positive	19
Conventional Negative	0.052631579
Positive [weighted for prevalence]	19
Negative [weighted for prevalence]	0.052631579

Note that conventional positive and negative likelihood ratios can be quite misleading when prevalence substantially differs from .50.

Clinical Calculator 2

Predictive Values and Likelihood Ratios

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To proceed, enter the known or hypothetical values of prevalence, sensitivity, and specificity into the designated cells, then click the «Calculate» button. To perform a new calculation with a new set of values, click the «Reset» button. All values should be entered as decimal fractions.

Prevalence =	.01
Sensitivity =	.95
Specificity =	.95

Prevalence, sensitivity, and specificity must each be entered as a proportion.

Calculate Reset

For any particular test result:

probability that it will be positive	0.059
probability that it will be negative	0.941

For any particular positive test result:

probability that it is a true positive ["positive predictive value"]	0.161016949
probability that it is a false positive	0.838983051

For any particular negative test result:

probability that it is a true negative ["negative predictive value"]	0.99946865
probability that it is a false negative	0.00053135

likelihood Ratios: [definitions]

Conventional Positive	19
Conventional Negative	0.052631579
Positive [weighted for prevalence]	0.191919192
Negative [weighted for prevalence]	0.000531632

Note that conventional positive and negative likelihood ratios can be quite misleading when prevalence substantially differs from .50.