COLLEGE of AMERICAN PATHOLOGISTS

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

Attention: CMS-1734-P, RIN 0938-AU10

Subject: **Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy**

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1734-P entitled “Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies.” As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Our comments in this letter focus on the following subjects included in the proposed rule:

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.)
    A. Revaluing Services That Are Analogous to Office/Outpatient E/M Visit (2b.)
    B. Comment Solicitation on the Definition of HCPCs Code GPC1X (2c.)
    C. Waive Budget Neutrality for New CPT Code 99072
2. Proposed Valuation of Specific Codes for CY 2021 (Section II.H.)
    A. (1) Fine needle aspiration (CPT codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 100010, 10011, and 10012)
    B. (51) Molecular Pathology Interpretation (HCPCS Code G0452)
3. Changes to Direct PE Inputs for Specific Services (3)
    A. Update on Technical Expert Panel Related to Practice Expense (e)
4. Proposal to Remove Selected National Coverage Determinations (Section III.J, Page 523)
5. Scope of Practice and Related Issues (Section II.G.2 & 3)
    A. Supervision of Diagnostic Tests by Certain NPPs
    B. Pharmacists Providing Services Incident to Physicians’ Services
6. Clinical Laboratory Fee Schedule (A)

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A. Revised Data Reporting Period and Phase-in of Payment Reductions (1-4)
B. Comment Solicitation on Payment for Specimen Collection for COVID-19 Clinical Diagnostic Tests (5)

7. Medicare Shared Savings Program (Section III.G.)
8. CY 2021 Updates to the Quality Payment Program

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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.)

Effective Jan. 1, 2021, CMS will implement payment rate increases for office/outpatient E/M codes and simplified coding and billing requirements for E/M visits. CMS finalized this policy in the CY 2020 PFS Final Rule but delayed implementation until 2021. The office visit payment increases are required by statute to be offset by reductions to other services, in this case resulting in an unsustainable reduction of nearly 11% to the 2021 Medicare conversion factor of which 3% is directly related to the creation of the GPC1X add-on code. Specialties like pathology that do not generally bill office/outpatient E/M visits will experience significant decreases as result of this revaluation.

Beyond the challenges caused by the pandemic, it is important to note that Medicare payments have failed to keep up with inflation since the inception of the PFS in 1992. The planned decrease in the 2021 conversion factor rolls back the conversion factor to below the original1994 conversion factor of $32.9050 (worth approximately $58.02 in today's dollars.[1]) Other sectors of the health care delivery system do not face this same problem, as hospitals and others do not operate under a budgetary cap and receive market-based payment updates. It is also important to point out that other payers, including in the private sector, use the Medicare PFS when setting payment rates. Therefore, the cuts have far-reaching consequences well beyond the Medicare program.

For pathology, these cuts are significant. The 2021 proposed regulation predicts a 9% cut in pathology payments and a 5% cut for independent laboratories. Pathologists are essential professionals, integrally involved in directly addressing the COVID-19 crisis as directors of clinical laboratories responsible for accurate and timely SARS-CoV-2 detection for diagnosis and treatment, as well a public health role through surveillance activities. These cuts will have a significant impact on pathology at a time when patients and their treating physicians are relying on the expertise of pathologists. The regulatory misalignment between FDA and HHS has highlighted the role pathologists fill as laboratory medical directors in providing safe and effective testing for SARS-CoV-2 during this ongoing coronavirus pandemic. There are ongoing challenges in increasing COVID testing and supply chain management which will be further complicated by the coming influenza season. When you combine those critical issues with the 9% cuts pathologists are facing in 2021, the impact on practices and ultimately patient care will be devastating. Clearly, the CAP should be concerned that a significant financial instability will be created for our specialty during this public health crisis when budget neutrality adjustments are enacted when CMS implements the Medicare office visit payment policy finalized for 2021. **Therefore, the CAP strongly urges CMS to utilize its authority under the public health emergency declaration to preserve patient access to**

[1] Using the U.S. Bureau of Labor Statistics inflation calculator, the conversion factor in 1994, $32.9050, is worth approximately $58.02 today. This means that the proposed CY 2021 cut of the conversion factor to $32.2605 is an even steeper cut when adjusted for inflation and is by far the lowest conversion factor since its inception in 1992. https://www.bls.gov/data/inflation_calculator.htm.

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laboratory care and mitigate financial distress due to the pandemic by waiving budget neutrality requirements for the new Medicare office visit payment policies.

A. Revaluing Services That Are Analogous to Office/Outpatient E/M Visit (2b.)

In the CY 2020 PFS proposed rule, the CMS recognized that there are services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes. Some of these services always include an office/outpatient E/M visit(s) furnished by the reporting practitioner as part of the service, and therefore, CMS believes it may be appropriate to revalue the following services upwardly to parallel changes in the office/ outpatient E/M visits. These services include: (1) ESRD monthly capitation payment services, (2) transitional care management services, (3) maternity services, (4) assessment and care planning for patients with cognitive impairment, (5) Initial Preventive Physical Examination and Initial and Subsequent Annual Wellness Visits, (6) Emergency Department visits, (7) therapy evaluations, and (8) behavioral health care services.

The CAP has noticed that CMS is also proposing to apply the office visit increases to other sets of services where office visits may not be specifically bundled. CMS employs a variety of reasons and methodologies to apply the office visit increases to specific services. CMS proposes to apply increases to services simply because an office visit was referenced as supporting rationale, but not a direct crosswalk in developing a work RVU. CMS proposes adjustments using a variety of methodologies such as applying general percentage increases. These methodologies are not resource-based and do not accurately account for the physician or qualified healthcare professional's work, time and intensity required to perform these services. The most egregious methodology is a blanket increase percentage based on a broad-based estimate of the overall change in the work associated with assessment and management with the overall increase in the work of the office visits. Applying increases via these various methodologies is causing anomalies in relativity among services and ignores the long-established RUC process. Along these lines, most of the codes proposed for increases have not been reviewed by the RUC process for current practice or surveyed for physician work for over 10 years and some have never been reviewed. The accuracy of the work values, and for some codes, the accuracy in the number and level of office visits for these codes, should be fully evaluated and reviewed through the RUC survey process, as the office/outpatient E/M codes were. The CAP believes that the application of any additional work value applied to these codes at this time is premature. **These additional E/M increases will further erode payment to all other non E/M physician services during the ongoing public health emergency and urges the Agency to postpone these updates and request that the RUC individually value them at a later date.** Valuing these services at this time, without current practice information from specialty societies, is reckless and undermines the pillars of the resource based relative value system.

B. Comment Solicitation on the Definition of HCPCs Code GPC1X (2c.)

In the CY 2020 PFS Final Rule, CMS established the add-code GPC1X for office/outpatient E/M visit complexity with an effective date of CY 2021. Since the code was established, CMS has received stakeholder feedback that the code definition is unclear, as are the rules on when it is appropriate to report the code. The CMS continues to believe that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. The CMS is appropriately soliciting comments providing additional, more specific, information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, and how they might refine the utilization assumptions for the code.

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We concur with others that code GPC1X is unclear and not well defined. For one, the code descriptor for GPC1X is different throughout different sections of the proposed rule. It is difficult to respond to a call for comment when the descriptor is unclear. Secondly, in previous comments to the Agency, the CAP requested that CMS withdraw HCPCS code GPC1X as the physician work for this service is redundant with existing revised CPT Editorial Panel revised codes and goes beyond the AMA CPT/RUC recommended revisions in the 2021 Medicare Proposed Rule. Thirdly, the time, intensity and practice expense to address any conditions associated with medical care and all health care services of patients are already inherently included in the revised office visits service codes and there is no need for this HCPCS add-on code. Finally, if there was a component of physician work missing at the time of the CPT review of these E/M codes, we are sure it would have been found and accounted for. **The CAP urges the CMS to cease its efforts to establish this add-on service GPC1X through its immediate deletion.**

In the Proposed Rule for 2020, CMS originally assumed that GPC1X would be reported with over 50% of all office visit claims, resulting in $2.6 billion increase in Medicare allowed charges and a 3% decrease to the 2021 Medicare conversion factor. CMS received comments that their 50% assumption overstated utilization. However, in CMS's most recent utilization projections for add-on code GPC1X, CMS assumes the code would be applied to 75% of all office visit claims, costing the Medicare program $3.3 billion annually. This add-on code alone will account for a 3.5% reduction in the conversion factor. CMS does not explain why the utilization assumptions were increased from 50% to 75%. Instead, the 186,549,518-utilization assumption for GPC1X is found within utilization projection tables on the CMS website. CMS states that stakeholders have not submitted specific comments or alternative recommendations on the utilization of this "service," however, CMS's assumptions are not explained and the service itself is not clearly described. **Given the budget impact and significant confusion regarding the definition and use of HCPCS code GPC1X, the CAP recommends that CMS stop implementation of this add-on code and cease any efforts to do so in the future.**

Additionally, if the agency does move forward with implementation of this add-on code, the CAP urges CMS to reexamine and lower its' current utilization assumption associated with GPC1X. Finally, the CAP urges that the Agency adhere to its long-established association with the RUC process that assures transparency in both process and methodology used to arrive at updated utilization assumptions.

C. Waive Budget Neutrality for New CPT Code 99072

The AMA recently created, valued, and submitted to CMS a recommendation for a new CPT code 99072 *Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease.* The CAP believes the implementation of this new code, if budget neutrality is applied, will only exacerbate the budget neutrality impacts of the coding and revaluation of the office/outpatient E/M codes for CY 2021 and beyond. **The CAP urges the CMS to waive budget neutrality for CPT code 99072 when implemented.**

2. Proposed Valuation of Specific Codes for CY 2021 (Section II.H.);

A. (1) Fine Needle Aspiration (CPT Codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 100010, 10011, and 10012)

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Following the publication of the CY 2019 final rule, the CMS communicated to the AMA RUC that the codes in the Fine Needle Aspiration family could be nominated as potentially misvalued, the CMS indicated that they were open to receiving new information about the valuation of these codes. After reaffirming its recommendations from CY 2019 in January 2020, the CMS stated that the RUC has not provided any new information that was not already presented for the previous CMS review of these codes. Therefore, the CMS is not proposing any changes to the codes in the Fine Needle Aspiration family, as the reaffirmed CY 2021 RUC recommendations are identical to the CY 2019 RUC recommendations that already went through notice and comment rulemaking. The CMS welcomes the submission of new information regarding these services that was not part of the previous CY 2019 review of the code family.

CMS's Errored Utilization Assumptions

In November 2018, following the Agency's disclosure of Table 12 *Fine Needle Aspiration Work Pool Comparison* in the CY 2019 Final Rule, AMA RUC staff discovered that CMS erroneously double-counted the utilization for new codes that had image guidance bundled, causing the Agency to incorrectly assert that the RUC was recommending a 20 percent increase in physician work for the Fine Needle Aspiration code family, stemming from a misinterpretation of the AMA's utilization crosswalk recommendations. Based on the Agency's rationale articulated in rulemaking for CY 2019, it appeared that this was a foundational reason CMS rejected the RUC recommendations for the codes in this code family.

The source utilization for the two existing FNA codes 10021 and deleted code 10022 of a collective volume of 210,210, was greatly exceeded by the utilization destination column for 10021, 10004-10012 of a collective volume of 400,450. **Those two numbers should have instead been identical in CMS's analysis.** Under the previous code structure, reporting FNA under image guidance with a certain modality for a single lesion would involve both reporting deleted code 10022 and the corresponding image guidance code; under the current code structure only the new FNA code with bundled image guidance would be reported. Due to a misinterpretation of the RUC's utilization crosswalk recommendations, the Agency inadvertently double counted each bundled image guidance code during their RUC recommendation evaluation. After correcting for double counting the utilization for the newly created bundled codes, the work pool based on the RUC recommended values would have been instead resulted in a decrease by 15 percent using the CMS utilizations from the CY 2019 NPRM. Based on the CMS proposed reductions, the work pool for the family would decrease by 23 percent based on the utilization data available during the CY 2019 rulemaking**.**

AMA RUC Staff clarified the error on a call with CMS officials in December 2018 and the three Agency officials verbally concurred that the Agency's analysis had a utilization crosswalk error and the AMA RUC staff and CMS officials jointly worked together to ensure this confusion would not occur for future tabs going forward. AMA RUC staff requested for the Agency to reconsider their rejection of the RUC recommendations for CY 2019. The CMS Officials declined to do so for CY 2019, noting that their utilization projections in the NPRM addenda materials were available for public comment. However, the CMS officials offered that the surveying specialties could write a letter to CMS to nominate the affected codes from these families as being potentially misvalued. Eight specialty societies submitted a letter to CMS in January 2019 to nominate these services as potentially misvalued. In the CY 2020 Medicare Physician Fee Schedule Proposed Rule, the Agency identified two of the codes in this code family for review via their public nomination process for potentially misvalued services and the RUC added this code family to its agenda for the January 2020 RUC meeting.

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After presenting the error to CMS when CAP representatives met February 3, 2020, and with the RUC Staff working closely with CMS on this issue to ensure this situation does not repeat itself going forward for other families of services, it is very concerning that the Agency reverted back to its previous statement that they "…do not believe that utilization was erroneously double-counted for this code family."

Pertinent new information available now is the actual claims data from CY 2019 to assess how accurate the Agency's RVU pool estimates were during the CY 2019 rulemaking process. CMS's projected RVU pool for CY 2019 for the updated FNA code family is over twice as high as what actually occurred in 2019 even though the utilization for the newly created codes is largely identical to the source utilization from 10021 and 10022. Separately, as CMS was not aware of the double counting issue during CY 2019 rulemaking, all information regarding the utilization crosswalk assumptions misinterpretation, as explained above, would also represent new information.

New Additional Support for RUC Recommendations

The RUC recommended physician work values for CPT codes 10005 *Fine needle aspiration biopsy, including ultrasound guidance; first lesion* (RUC recommended work RVU = 1.63, 10 minutes pre-service, 20 minutes intra-service, and 9 minutes post-service) and 10021 *Fine needle aspiration biopsy, without imaging guidance; first lesion* (RUC recommended work RVU = 1.20, 10 minutes pre-service, 15 minutes intra-service, and 8 minutes post service). **These work values are supported by close relativity comparison of the following physician fee schedule services that have not been considered to date.**

The work value of CPT code 10005 can be appropriately estimated or cross-walked to CPT code 76978 - Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion (Work RVU = 1.62, 5 minutes pre-service, 20 minutes intra-service, and 5 minutes post-service). Based on the identical intra-service time, intensity and complexity similarities, and ultrasound service similarities, codes 10005 and 76978 should have similar physician work RVUs. An ultrasound-guided FNA biopsy of the lesion has very similar overall physician work of a targeted dynamic ultrasound microbubble sonographic contrast evaluation. **Based on the above code comparison rationale, the CAP agrees with the RUC's recommended Work RVU of 1.63 for CPT code 10005.**

The work value of CPT code 10021 can be accurately estimated and cross-walked to CPT code 95866 - *Needle electromyography; hemidiaphragm* (Work RVU = 1.25, 10 minutes pre-service, 15 minutes intra-service, and 10 minutes post-service) is also similar in total physician work, intensity and complexity, and identical intra-service time as 10021, and code 95866 has a very similar total time as code 10021. **Based on the above code comparison rationale, the CAP agrees with the RUC' recommended Work RVU of 1.20 for CPT code 10021.**

Based on the clarification on the Medicare volume misunderstandings, and all of the above new information, the CAP urges CMS to accept a work RVU of 1.20 for CPT code 10021, and a work RVU of 1.63 for CPT code 10005.

B. (51) Molecular Pathology Interpretation (HCPCS Code G0452)

At the October 2018 RUC Relativity Assessment Workgroup (RAW) meeting, HCPCS code G0452 (*Molecular pathology procedure; physician interpretation and report*) was identified as potentially misvalued on a CMS/Other screen. In 2019, the CAP conducted a robust physician work survey and then developed physician work and practice expense recommendations for the October 2019 RUC

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meeting. The RUC unanimously agreed with our recommendations based on a greater complexity of analysis and longer overall time spent interpreting modern molecular/personalized medicine assays, and for CY 2021, the CMS has proposed the RUC-recommended work RVU of 0.93 and the RUC-recommended direct PE inputs for HCPCS code G0452. **The CAP agrees with CMS's proposal and urges the agency to finalize and implement the RUC recommended physician work value of 0.93 and the direct practice expense inputs for HCPCS code G0452 for CY 2021.**

3. Changes to Direct PE Inputs for Specific Services (3);

A. Update on Technical Expert Panel Related to Practice Expense (e)

Physician Practice Expense Data Collection

CMS provides a brief update on a January 2020 convened Technical Expert Panel (TEP) and analyses performed by the RAND Corporation. While not currently proposing changes to the practice expense methodology or data collection process, CMS states that comments on the RAND reports are welcome during the comment period, or anytime thereafter via email. CMS notes that they intend to convene a Town Hall with all stakeholders in the future to discuss the practice expense methodology and data collection effort. We encourage CMS to do so before proposing any changes and initiating further research.

In its first phase of its research, RAND concluded that the Physician Practice Information Survey (PPIS) data are outdated and may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries. To follow-up on some of these issues, RAND convened a technical expert panel (TEP) on January 10, 2020 to obtain input from stakeholders. Topics included, for example, how best to aggregate PE categories if there were to be new survey instrument; ways to maximize response rate in a potential new survey; and ways to use existing data to inform PFS PE rates. RAND also issued results from its subsequent phase of research. Based on the results of the TEP and RAND's other ongoing research, CMS states that it is interested in potentially refining the PE methodology and updating the data used to make payments under the PFS. **The CAP agrees that some PE refinements are needed and requests that any changes be fully transparent with advance notice of any and all methodological changes, allowing the AMA RUC and each specialty opportunity to provide input and feedback.**

Clinical Labor Costs

CMS states that stakeholders have expressed an interest in updating the clinical labor data used for direct PE inputs based on current salaries and compensation for the health care workforce. CMS specifically calls for comments on the best source of data for wage rates used in computing clinical labor costs. It currently uses data from the Bureau of Labor Statistics (BLS) to determine a cost per minute estimate for each of 50 different clinical staff professions. **The BLS is the most reliable and transparent source of data available and the CAP urges the CMS not to use any other source of clinical labor cost data in its practice expense methodology. However, CMS should keep the data up-to-date and should use the most recent year of available BLS data to determine clinical labor costs.**

RAND Reports and Activities

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CMS continues to rely on the RAND Corporation to provide research and analysis regarding potential data collection and methodological changes related to the practice expense relative values. RAND has focused on the following three issues:

- Updating and/or improving the data used in the indirect cost-allocation process
- Refining the current indirect cost-allocation process
- Using hospital outpatient costs to inform or replace the current process to establish the physician practice expense relative values

The CAP urges CMS to begin working with the AMA the RUC, and specialties immediately to initiate a new data collection process and to discuss any potential changes to the underlying PE methodology.

Updating and/or Improving the Data used in the Indirect Cost-Allocation Process

RAND conducted a thorough review of physician surveys, literature and data sources and determined that there is not an adequate source of existing data to replace the practice cost information currently utilized in the indirect cost-allocation process. RAND includes a suggested survey in an Appendix to the latest report. The survey is complex and attempts to collect information that is not essential to the existing methodology. The previous PPIS was also too lengthy and requested information not imperative to the indirect cost methodology. The next survey must be refined to collect only the absolute required information.

RAND and CMS also imply that data collection should be less granular with fewer specialties surveyed to simplify their processes. Any changes only to "simplify" should not disadvantage our practicing physicians. **The CAP strongly urges CMS to work with the AMA, the specialties, and other stakeholders to plan an effective, transparent and fair data collection effort.**

4. Proposal to Remove Selected National Coverage Determinations (Section III.J.)

The CAP appreciates CMS's need to periodically review its national coverage determinations (NCDs) to maintain clinically relevant policies that reflect current technology and prevailing medical practice.

While we support CMS's effort to identify and remove NCDs that that no longer reflect current medical practice or that involve items or services that are used infrequently by beneficiaries, we believe that removal of the following three NCDs would have serious negative consequences for Medicare beneficiaries and may result in limited and inconsistent access to care if left to local contractor discretion. Therefore, the CAP recommends retaining these national policies with updates according to the latest evidence-based guidelines and terminology.

1. Apheresis (Therapeutic Pheresis) (110.14) – The need for most of therapeutic apheresis (TA) procedures is still highly relevant. In many of the indications listed in the national coverage determination *NCD), TA is a first-line treatment and provides effective mitigation. Pathologists treating patients with therapeutic apheresis highly respect the American Society for Apheresis guidelines for TA. In the most recent 2019 edition, nine of the 13 indications listed are Category I indications, meaning that TA is a first-line therapy, alone or together with other therapies. Two indications, leukapheresis for leukemia and systemic lupus are Category II indications (second-line

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therapy alone or with other therapies). Only two are in Category III (optimal role not established), pruritis of cholestatic liver disease and scleroderma and polymyositis.

There are numerous other Category I and Category II indications for TA which are not listed in the NCD. For example, indications involving renal diseases. Currently, Medicare covers dialysis for many patients, so it would benefit patients to cover medically indicated TA therapies which prevent the need for dialysis or renal transplants.**In the best interest of patient care, the CAP recommends that CMS provide uniform coverage for therapeutic apheresis through national policy and, if coverage is to be maintained through national policy, the CAP further recommends CMS revise its NCD to align with the latest ASFA guidelines and other scientific evidence. Alternatively, if CMS cannot incorporate these guidelines and evidence into the NCD and thereafter update its policy regularly, then we recommend CMS sunset the NCD to allow for coverage of this treatment through local coverage determinations by Medicare Administrative Contractors.**

2. Cytogenetic Studies (190.3) – The clinical importance of this test remains as pertinent today as when it first came into widespread practice decades ago. Conventional cytogenetic analysis ("the microscopic examination of the physical appearance of human chromosomes") continues to play a crucial role in genomics. Many newer genomic techniques have become prominent in recent years (e.g., chromosomal microarray and next-generation sequencing), each providing increasingly detailed views of the genome. However, cytogenetic analysis is readily accessible, can be interpreted without the need for specialized equipment, conveys critical information with a much more rapid turnaround time, and for some abnormalities (e.g., balanced rearrangements such as translocations and inversions) remains not only the best but the only means of visualization.

The following clinical scenarios illustrate the relevancy of cytogenetic studies:

- *Provides rapid results:* Although NGS can provide information regarding sequence and structure of the whole genome, it is a complex and expensive technique for elucidating genomic abnormalities, requiring very specialized technical and bioinformatic expertise currently available only at large institutions. In contrast, cytogenetic studies are relatively cost-effective in established genetic laboratories. In addition, and more importantly, cytogenetic studies can provide results to the referring physician within 2-3 days of specimen receipt in the laboratory. This is particularly important when:
    - Ruling out common chromosomal aneuploidy in newborns with multiple congenital anomalies (e.g., evaluating for the presence of trisomy 13, trisomy 18, trisomy 21 (Down syndrome), or other numerical abnormalities)
    - Ruling out structural chromosomal rearrangements in couples with recurrent pregnancy losses (particularly those who are currently pregnant)
    - Evaluating the sex chromosome complement in newborns presenting with atypical or ambiguous genitalia
    - Evaluating for the presence of recurrent chromosomal rearrangements in neoplasia (e.g., t(9;22) in chronic myeloid leukemia, t(15;17) in acute promyelocytic leukemia). Diagnoses of some hematologic neoplasms and solid tumors cannot be made without proof of the underlying chromosomal abnormality; without this proof, treatment of the patient cannot be initiated.
- *Accurate whole-genome assessment:* Numerical (chromosomal gain or loss) and structural (e.g., translocation, inversion, insertion, duplication) rearrangements are readily detected at the microscope, with a resolution of ~5-10 Mb. NGS-based approaches are currently not validated in any diagnostic laboratory to detect completely balanced translocations with non-

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recurrent breakpoints, which are implicated in infertility and recurrent pregnancy loss, and can be a cause of single-gene disorders. Conventional cytogenetic studies remain the only clinically available testing method to identify these abnormalities.

- *Able to detect mosaicism and neoplastic clonal evolution:* Cytogenetic analysis permits the detection of abnormalities that are present in mosaic form (i.e., present in some but not all cells), even if present in only a single cell (examples of abnormalities often seen in mosaic form are sex chromosome abnormalities such as Turner and Klinefelter syndromes, and abnormalities due to structural abnormalities such as Pallister-Killian syndrome). Depending on the level of mosaicism present, techniques such as chromosomal microarray may not be able to detect and/or quantify the level of mosaicism. In neoplastic studies, the finding of additional abnormalities, even if present in only a single cell, may be the harbinger of disease progression. Chromosomal microarray and NGS lack the sensitivity to detect single-cell abnormalities.
- *Recommended for use by other professional genomics societies for cytogenetic studies:* Publication of technical standards as well as evidence-based reviews have highlighted the importance of cytogenetic studies. (e.g., American College of Medical Genetics; American College of Obstetricians and Gynecologists; Association for Molecular Pathology; and others. These publications, written by experts in the field of cytogenetics provide the clinical community, data-driven algorithms for accurate test utilization, and are approved and supported by various national and international genomics societies (examples of these publications are available upon request).
- *In widespread use in national and international CAP-accredited laboratories*: The CAP/American College of Medical Genetics Cytogenetics Committee continues to provide proficiency testing for cytogenetic analysis to laboratories in the United States and internationally. There has been no appreciable decrease in participation of laboratories in these proficiency tests.

Cytogenetic analysis has been in routine clinical use for over 60 years, during which time it has become a cornerstone of genomic testing. The first “whole-genome” screen, it remains one of the most readily accessible and widely used genomic tests. Clinical geneticists, oncologists, and pathologists need the data provided by cytogenetic analysis for diagnosis, prognosis, and treatment determination. Although it is true that cytogenetic analysis alone cannot detect DNA sequence changes, it can and does provide critical information that sequencing alone cannot. Just as the “simple” X-ray remains a critical component of the radiologic testing armamentarium, so too will the “simple” cytogenetic analysis remain an essential method in the increasingly complex field of genomics.

As our understanding of genomics has evolved over time so has the nomenclature associated with both constitutional and neoplastic diagnoses. In reviewing the NCD for Cytogenetic Studies, the CAP noted that a number of terms used are very outdated (“FAB L1-L3”) and, in some cases, currently understood to be offensive (“mongolism,” “failure of sexual development”). **The CAP is concerned about the outdated terminology in this NCD and would like to partner with CMS to revise the policy terminology to reflect the advances made in our understanding of genomic conditions.**

3. Histocompatibility Testing (190.1) – The importance of histocompatibility testing (antibody detection and identification, crossmatching and high-resolution HLA typing) is indisputable science and there is strong evidence supporting its use. Histocompatibility testing results are one of the most important decision points in donor selection and post-transplant immune suppression and monitoring. There is also emerging evidence supporting the use of histocompatibility testing in

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cancer immunotherapy. Removal of consistent national coverage standards would not be in the best interest of any transplant patient.

Although the methods have changed over the years, identifying compatible transplants, pre-transplant and monitoring post-transplant remain critical to ensuring good outcomes and appropriate post-transplant management. This is broadly true for solid organ and stem cell transplants. In addition, there are increasing uses of histocompatibility testing to identify safe use of pharmacotherapies, and disease associations. More recent works suggest that histocompatibility testing might be of importance in immunotherapies for certain cancers. **The CAP recommends that CMS retain this NCD and update the policy to reflect the current scientific literature.**

5. Scope of Practice and Related Issues (Section II.G.2 & 3)

A. Supervision of Diagnostic Tests by Certain NPPs

During the COVID-19 public health emergency, CMS implemented flexibilities to "ensure that an adequate number of health care professionals are available to support critical COVID–19-related and other diagnostic testing needs and provide needed medical care." Here, CMS is proposing to make permanent those changes, including a policy that allows certain non-physician providers (NPPs) to supervise diagnostic tests as allowed by state law and scope of practice. While we agree that certain actions were required to respond to the COVID-19 emergency, the CAP has serious concerns about efforts to permanently eliminate or weaken Medicare's physician supervision requirements for diagnostic testing. As we have commented before, the CAP strongly believes that diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, and under the supervision of licensed physicians, or consistent with non-waived testing requirements under CLIA 88.

While all laboratory and other health care professionals share an important role in providing care to patients, non-physician providers do not have the same education and training as a fully trained and licensed physician. As was noted in a recent coalition letter led by the American Medical Association (AMA), physicians must complete seven or more years of postgraduate education and more than 10,000 hours of clinical experience, compared to only two to three years of graduate level education and 500-720 hours of clinical training for nurse practitioners (NPs), and a two-year program and 2,000 hours of clinical care for physician assistants (PAs). Currently, as CMS explains, nurse practitioner and clinical nurse specialist are authorized to perform tests under applicable state laws without physician supervision. However, a number of other non-physician providers, including nurses, technologists, and other laboratory professionals, regularly furnish diagnostic tests and require the level of oversight and supervision provided by licensed physicians.

Additionally, without the appropriate level of physician supervision for most testing, we agree with CMS that "there could be induced utilization that would increase costs." While CMS dismisses this concern because "this might be offset by reduced payment rates," we would emphasize that there are patient safety issues, potential clinical problems, and quality of care complications that accompany increased and unnecessary testing. No test is so simple and straightforward to perform that erroneous results or outcomes cannot occur, and no incorrect test result is "risk free" or inconsequential with regard to potential harm. Further, inappropriate ordering and provision of diagnostic testing (particularly when dealing with expensive molecular testing) can mean increased cost not just to Medicare, but to patients and laboratories as well.

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Washington, DC 20001
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Removing physician supervision of diagnostic testing could also increase the burden on physicians, including pathologists, and create further challenges for our already overworked and understaffed laboratory technologists. It takes time away from patients and other responsibilities for physicians to educate NPPs and rectify testing or ordering/interpretation errors. In addition, the vast majority of NPPs are not held to the same standards as physicians when it comes to "after hours" or on-call responsibilities, which can make it difficult to reach NPPs with critical values requiring immediate attention. This can result in laboratories and pathologists spending hours trying to identify someone to confirm the critical results have been acknowledged, and could also put unfair responsibility on laboratories and pathologists when patients are waiting for critical laboratory results that have not been addressed by their provider.

Finally, as we have expressed before, the CAP continues to have concerns about any changes that could incentivize over-utilization, increase abusive practices, and/or contribute to unfair contractual arrangements. For example, even as CMS has taken steps to close ambiguities to deter pod labs and other abusive referral practices, provider groups continue to create new arrangements structured around any technical requirements to retain the ability to profit from highly selected pathology services. Removal of physician supervision requirements may further contribute to inappropriate self-referral practices. We maintain that an exclusion of anatomic pathology services from the in-office ancillary services exception to the self-referral law is the most effective means of preventing program abuses and protecting quality care for patients

Physician oversight and supervision of diagnostic testing ensures high-quality care, including appropriate and safe testing for patients. NPPs are critical members of the care team, but the best interests of patients require that a physician direct the course of the diagnostic and therapeutic care of the patient and that a physician determine appropriate clinical and anatomic laboratory services. We urge CMS not to finalize this proposal and to allow these scope of practice flexibilities to expire when the public health emergency ends.

B. Pharmacists Providing Services Incident to Physicians' Services

CMS notes that it is current policy for pharmacists to provide services incident to the services of the billing physician or NPP, and the agency believes clarification in this area "may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training, licensure and scope of practice." As an example, CMS states that this clarification was helpful in recently addressing the ability of pharmacies to enroll as laboratories and work with physicians in the assessment of clinical information, specimen collection and reporting results of COVID-19 clinical diagnostic laboratory tests.

In this area, we would also find it helpful for CMS to provide additional clarification that pharmacists are not able to offer laboratory testing without the requisite CLIA certification and that pathologist supervision is necessary.

The CAP believes that the interpretation of laboratory tests, used for the diagnosis, prevention, treatment, or assessment of human disease, or for purposes of drug therapy management, constitutes the practice of medicine, for which pharmacists should not be licensed. The CAP, therefore, recommends that any regulation addressing the ability of pharmacists to order, perform or evaluate laboratory tests should be based on the following principles:

- Except for individuals requesting a test for themselves as authorized by state law, the ordering of clinical laboratory tests should be limited to licensed physicians, licensed dentists, or licensed health care practitioners under the supervision of a licensed physician

College of American Pathologists
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Washington, DC 20001
202-354-7100

or licensed dentist who is providing treatment for the patient. Further, diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, and under the supervision of licensed physicians, or consistent with moderate and high complexity testing requirements under CLIA 88. As we articulated above, outside of the COVID-19 public health emergency, physician oversight and supervision of diagnostic testing must be maintained.

- The interpretation of clinical laboratory tests is the practice of medicine and should, therefore, be done solely by licensed physicians.
- All clinical laboratory testing used for the diagnosis, prevention, treatment or assessment of human disease, and laboratory testing for purposes of drug therapy management should be subject to quality control and proficiency testing.
- When individuals perform any test on a person other than themselves, it should be construed as the practice of laboratory medicine, subject to all of the above listed principles, unless such test is approved by the Food and Drug Administration (FDA) as an "over-the-counter" test that is available for use to the general public without a prescription and used by a home health care attendant or caregiver under the supervision of a licensed physician.

6. Clinical Laboratory Fee Schedule

A. Revised Data Reporting Period and Phase-in of Payment Reductions

As is explained by CMS in this proposed rule, the Protecting Access to Medicare Act (PAMA) required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). Recently, section 105(a) of the Further Consolidated Appropriations Act (FCAA) and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) made revisions to the CLFS requirements for the next data reporting period and the phase-in of payment reductions. Together, these statutory revisions result in a delayed reporting period (now starting in January 2022) and a freeze in payment reductions for CY 2021. The freeze in payment reductions is especially important as pathology practices and laboratories are in serious jeopardy across the nation right now as a result of the COVID-19 public health emergency. Here, CMS proposes to revise current definitions and make other conforming changes to reflect the statutory revisions.

Given the integral roles pathologists play in ensuring availability of clinical laboratory services, overseeing the quality and appropriateness of laboratory testing in their medical communities, and developing laboratory tests, the CAP and its members have a significant stake in the continued implementation of PAMA and any revisions. Thus, as you know, we have consistently called for changes to CMS's data reporting requirements that ensure a broad representation of the laboratory market and more accurate payment rates. In particular, CMS's earlier definition of applicable laboratories subject to data reporting, which excluded the overwhelming majority of hospital laboratories, resulted in a skewing of the PAMA payment rates to reflect a disproportionate counting of large commercial clinical laboratories. As hospital laboratories typically receive higher rates from private payers than do independent laboratories, the exclusion of these data undermined the accuracy of CMS's calculations and future reimbursements for these and all other laboratories providing clinical laboratory services. It also contradicted the statute Congress enacted. The CAP is committed to improving patient care and addressing escalating health care costs, but we have been significantly concerned about the impact this failure will have on quality patient care and access to medically necessary laboratory testing.

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Washington, DC 20001
202-354-7100

While the payment cuts already implemented remain problematic, the CAP appreciates CMS's changes in the CY 2019 Medicare PFS final rule to the definition of "applicable laboratory," which will hopefully result in additional laboratories of all types reporting data to CMS during the data reporting period. As outlined above, we believe that efforts to include hospital outreach laboratories are especially important in ensuring an accurate, market-based payment system for laboratories paid through the CLFS.

As CMS makes its conforming changes to reflect the recent statutory revisions, the CAP urges the agency to take advantage of the delayed reporting period to ensure that all laboratories required to report do so and that the data accurately reflects all segments of the laboratory market. We understand that some actions have already been taken by the agency, but CMS should direct additional communication and outreach efforts at hospital outreach laboratories and provide adequate education and resources to ensure these laboratories have the awareness and infrastructure needed to collect and report applicable data to CMS.

B. Comment Solicitation on Payment for Specimen Collection for COVID-19 Clinical Diagnostic Tests

In response to the COVID-19 public health emergency the CMS established that Medicare would pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients.

The CMS established two new level II HCPCS codes to track and pay for these services for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the COVID–19 public health emergency (PHE).

- G2023, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source.

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

CMS requests comments on whether they should delete HCPCS Codes G2023 and G2024 once the COVID-19 PHE ends. Specifically, CMS is seeking public input on why these codes, and their corresponding payment amounts ($23.40), which are higher than the nominal fees for specimen collection for other conditions, would be necessary or useful outside of the context of the PHE. CMS is particularly interested in why separate, increased payment for specimen collection specifically for COVID-19 tests, in contrast to other tests, might be needed following the end of the PHE.

The optimal specimen for SAR-CoV-2 detection is a nasopharyngeal swab which must necessarily be collected by an experienced healthcare professional. The importance of this specimen type will be underscored during the impending influenza season. Influenza virus detection also utilizes a nasopharyngeal swab specimen. While several laboratories have proposed alternate specimens for SARS-CoV-2 testing (eg, nasal swabs, saliva) published studies indicate that even those specimens are sub-optimal unless collected under healthcare professional supervision. At a minimum, nasopharyngeal swabs will remain the required specimen type for SARS-CoV-2 detection through the 2020 – 2021 influenza season.

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Washington, DC 20001
202-354-7100

As CMS knows, a separate, increased payment was required during the PHE to expand SARS-CoV-2 testing and ensure Medicare beneficiaries, especially for those who are unable to travel, have access to testing in a manner that prevents exposure for both patients and health care workers. However, beyond the PHE, increased payment for specimen collection for COVID-19 tests may still be helpful, as resources required to collect these specimens – such as increased training, time, expenses, and personal protective equipment – will still be limited. Further, there may continue to be a need to reduce Medicare patients' exposure to the general population and alleviate patients' unease with leaving the home, despite an official end of the PHE. As we have explained above, no test is so simple and straightforward to perform that erroneous results or outcomes cannot occur, and the COVID-19 PHE has highlighted the importance of prompt and accurate testing for patients. Thus, we believe that HCPCS Codes G2023 and G2024 will help ensure safe and accessible pathology and laboratory services for patients, even beyond the official PHE. **Therefore, the CAP recommends that CMS retain HCPCS codes G2023 and G2024 after the PHE ends as the service will continue to be beneficial into the foreseeable future.**

7. Medicare Shared Savings Program (Section III.G.)

The Medicare Shared Savings Program (MSSP) was established to "facilitate coordination and cooperation among health care providers to improve the quality of care of Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B." Specifically, providers may participate in the MSSP through Accountable Care Organizations (ACOs), which incentivize on the basis of outcomes rather than the number of services. As diagnosticians, pathologists apply their expertise to the diagnosis and management of a wide variety of medical conditions, and thus are integral in any care coordination initiatives. By virtue of their capabilities and roles, many pathologists already coordinate care and undertake efforts targeted at increasing integration to improve patient care and the patient care experience overall. However, we have continually commented to CMS that pathologists face challenges participating in many alternative payment models (APMs), including ACOs. [2]

Yet, despite the challenges that continue to exist for pathologists and other specialists, CMS in this proposed rule is suggesting potentially disruptive changes to MSSP quality measurement and reporting requirements. We agree with CMS that efforts should be made to reduce reporting burden, offer more flexibility, and create a more meaningful measure set, but we are concerned that the changes proposed here do not actually accomplish these goals. Moreover, pathologists and many others remain on the frontline of the current COVID-19 crisis. It strikes us as an especially poor time to introduce substantial changes to an important value-based care program.

In particular, CMS's proposals to increase the quality performance standard and replace the current MSSP quality measure set with those from the proposed APM Performance Pathway (APP) could cause further confusion and hurdles to participation in the program. Valid and less burdensome measurement of the quality of care provided through ACOs is essential to ensure the ACO's success and that the promotion of higher quality of care and cost savings are not the result of limiting necessary care. Yet pathologists and other specialists already face challenges demonstrating value with limited and less relevant quality measures – use of the narrower APP quality measure set may only exaggerate this issue. The CAP continues to believe considerable accommodations or alternate measures are necessary for non-patient-facing clinicians. Further, we continue to have questions about how the not-yet-finalized MIPS Value Pathways and APP proposals will work in practice, which makes it difficult to assess these MSSP changes, and it certainly makes it difficult for providers to

[2] https://documents.cap.org/documents/CAP-Medicare-Shared-Savings-Program-CMS-1701-P-Comments.pdf

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Washington, DC 20001
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understand how they will implement the changes. Finally, while we agree that CMS has discretion to pursue efforts that improve the quality of care furnished by ACOs over time, the CAP believes it is still important to focus on increasing – and not decreasing – opportunity and incentives for specialty physician involvement in APMs.

The CAP is committed to increasing the availability and adoption of innovative payment models, like ACOs, that afford an opportunity for the participation of pathologists. Indeed, pathologists are key to ensuring the quality of laboratory tests by collecting, surveying, analyzing, and using patient population clinical results to guide therapy, best practices, and safety for individual patients and patient populations. These activities provide the infrastructure and foundation for effective and appropriate care. Still, increased performance standards and disruptive changes to quality measurement may only add to challenges that continue to exist for pathologists and other specialists. More is needed to increase opportunity for pathologist involvement in APMs, including the MSSP program, and to appropriately incentivize and recognize the role of pathologists in successfully achieving the ACO goals of reducing costs and improving quality and safety.

8. CY 2021 Updates to the Quality Payment Program

The CAP is looking forward to continuing our engagement with the CMS on elucidating the challenges of the Merit-Based Incentive Payment System (MIPS) in order to determine how to appropriately measure providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. Through the years, the CAP has advocated to increase flexibility for pathologists in a way that recognizes and accounts for the value pathologists play in patient care as non-patient facing clinicians in an inherently patient facing program. The CAP continues to believe considerable accommodations or alternate measures are necessary to meet this clause[3] in the Medicare Access and CHIP Reauthorization Act (MACRA) as the CAP outlines below in its comments on the Quality Payment Program (QPP).

Transforming MIPS: MIPS Value Pathways

MVP Implementation

The MIPS Value Pathways (MVP) is an extremely significant and important transition for the MIPS program from the current formulation of reporting on four separate categories to the new framework where measures and activities across the four performance categories will be aligned. As specialty societies move forward with creating MVP candidates, the CAP encourages CMS to be open to innovative thinking and have a willingness to test new ideas rather than simply reshuffling the current program**.** While the CAP agrees that the MIPS program must move to a more coherent and simplified state, the CAP appreciates that CMS is delaying implementation of MVPs to 2022. This delay provides specialty societies a much-needed reprieve to consider developing an MVP while

[3] In carrying out this paragraph, with respect to measures and activities specified in subparagraph (B) for performance categories described in subparagraph (A), the Secretary—
"(I) shall give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient; and
"(II) may, to the extent feasible and appropriate, take into account such circumstances and apply under this subsection with respect to MIPS eligible professionals of such professional types or subcategories, alternative measures or activities that fulfill the goals of the applicable performance category.
In carrying out the previous sentence, the Secretary shall consult with professionals of such professional types or subcategories.

College of American Pathologists
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Washington, DC 20001
202-354-7100

ensuring their members are able to prioritize addressing the spread of COVID-19 within their practices and communities.

In addition, the CAP appreciates the additional CMS proposals to refine the MVP framework's guiding principles and development criteria. **While the additional guidance and criteria are helpful, the CAP believes that further clarifications are needed for specialty societies as they work to develop MVP candidates.** For example, in the proposed rule CMS states that it will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year prior to the publication of the proposed rule. This creates a lack of transparency for specialty societies that take on the burden of developing MVP candidates with no indication of whether their MVP candidate will be accepted by CMS. The CAP hopes that development of MVPs can be a collaborative and iterative process working closely with CMS instead of a siloed activity that could lead to investment of numerous resources on the part of specialty societies with no assurances from CMS of a successful MVP candidate.

Another obstacle to developing MVPs is the timeline for implementing a measure into MIPS. Multiple stages in the measure development timeline and CMS's requirements for measure developers to propose a measure for MIPS significantly delay acceptance of a new measure. For example, to propose a measure for the 2021 MIPS program, a measure developer must have submitted their application to CMS by June 1, 2019. **We urge CMS to consider changes to the existing timelines for reviewing clinician measures to shorten the review time and better align with Physician Fee Schedule/QPP rulemaking cycle.** The Measure Application Partnership (MAP) is set up to align with the Inpatient Prospective Payment System rulemaking cycle. We welcome a conversation with CMS on ways to improve the MAP process, including better ways to enhance engagement and physician specialty involvement and feedback.

MVPs for Non-Patient Facing Clinicians

The CAP believes that there are several aspects of the proposed MVP framework that do not take non-patient facing, diagnostic specialties such as pathology into account. For example, CMS envisions that an MVP would include the entire set of Promoting Interoperability (PI) measures. However, pathologists as non-patient facing clinicians are automatically reweighted for the PI category since the category requires the use of Certified Electronic Health Record Technology (CEHRT) and pathologists practice in Laboratory Information Systems (LIS) which are not CEHRT. In addition, the current PI measures are patient-facing and not applicable to pathologists. The CAP believes that a physician should be able to attest that they (or at least 75% of the eligible clinicians in their group) are using certified electronic health records technology (CEHRT) or health IT that interacts with CEHRT, rather than reporting on individual PI measures for MVP purposes. Doing so would engage clinicians who are non-patient facing that are currently exempt from the category.

The CAP is concerned that CMS wants to increase the number of population health measures that utilize administrative claims data in the MIPS program while reducing the number of specialty specific measures. This would put pathologists at a significant disadvantage since administrative claims-based quality measures are not applicable or relevant to pathologists. Trying to apply the same measure across different specialties would result in intrinsically inequitable performance comparisons between clinicians, which is especially important in a program that is budget neutral like MIPS.

The CAP urges CMS to maintain the current and necessary special statuses for MIPS as it moves to the MVP framework. This will allow non-patient facing clinicians such as pathologists to have the option to develop and participate in MVPs. This flexibility is especially important for pathologists as

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Washington, DC 20001
202-354-7100

they are already subject to additional quality oversight. While these special status clinicians are unable to participate in some measures and activities for MIPS such as PI and cost, they can continue to demonstrate their value to patient care in MVPs within the afforded special statuses.

Streamlining Reporting of Measures and Activities for MVPs

The CAP believes that the MVP pathway needs to be structured appropriately to effectively improve the relevance of MIPS to clinical practice and reduce unnecessary paperwork burdens. While the MVP framework bundles measures together in a specific clinical area, we are concerned the framework still requires clinicians to report in each performance category and maintains the status quo with Promoting Interoperability (PI) and Improvement Activities (IA) categories. **CMS should eliminate the need for clinicians to report in four separate performance categories and revise the PI and IA to eliminate reporting for the sake of reporting.** Rather than a clinician having to attest to IAs, the developer of each MVP should note to CMS which IAs clinicians are inherently performing as part of a particular MVP, and corresponding IA credit should be automatic. This is similar to how MIPS alternative payment models (APMs) and recognized patient-centered medical homes are currently scored in the IA performance category. In addition, as stated earlier, the CAP believes that a physician should be able to attest that they (or at least 75% of the eligible clinicians in their group) are using CEHRT or health IT that interacts with CEHRT, rather than reporting on individual PI measures for MVP purposes. Doing so would engage clinicians who are non-patient facing that are currently exempt from the category.

MVP Assignment for Clinicians and Groups

The CAP encourages CMS to carefully consider how to assign clinicians and groups to an MVP, to make MVP participation voluntary and to incentivize clinicians to opt-in to MVPs. Clinicians should have the choice to opt-in to participate in an applicable MVP, if available, or remain in traditional MIPS. CMS should notify clinicians of an applicable MVP through multiple avenues, including the QPP Participation Status Tool, QPP submission portal, and the QPP performance feedback reports. CMS should base its MVP suggestions for each clinician and group practice on a combination of past MIPS reporting data, physician specialty designation, and claims data.

The CAP is encouraged that CMS is proposing to modify its MVP guiding principles to indicate that MVPs will allow subgroup reporting. However, it is unclear how CMS will operationalize this, especially as some clinicians may not have the resources within a multispecialty group to report on a separate MVP and may prefer to report on the multispecialty group measures instead. It is imperative that CMS establish a mechanism for subgroup reporting within multispecialty groups to decrease clinician burden of reporting and not cause unnecessary complications in identifying which clinicians within a group should report on which MVP.

<u>MIPS Performance Category Measures and Activities</u>

Quality Performance Category

The CAP does not agree with the 2021 pathology measure set as proposed by CMS. **The CAP asks that CMS remove measure 440, Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician from the proposed 2021 pathology measure set.** This measure is stewarded by the American Academy of Dermatology (AAD) and is not tested for feasibility for pathologists. This measure creates significant implementation challenges for pathologists, as the measure was specified without consideration to how general pathology practices code information. In addition, AAD has recognized that there should be certain exclusions to this measure (e.g., wide excision and re-excision), but this

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Washington, DC 20001
202-354-7100

is not considered in the approved specifications. Measures should not be added to another specialty's measure set unless they have been fully tested in that other population of providers.

Additionally, the CAP is disappointed that CMS has not published further guidance on the Eligible Measure Applicability (EMA) process if a practice will be unable to report on a minimum of 6 measures or unable to report on a high priority/outcome measure. The CAP has discovered that CMS is not applying the EMA process automatically to practices who are unable to report on a minimum of 6 measures or on a high priority/outcome measure. **The CAP urges CMS to apply the EMA process automatically to these practices. Otherwise, the practices are subject to erroneous scoring and are unable to achieve the maximum MIPS final score**.

In addition, based on the previously released pathology clusters for the 2019 EMA process, the CAP has discovered that these are not necessarily clinically related measures.

We identified two pathology clinical clusters for Medicare Part B Claims collection type:

Quality ID	Outcome/ High Priority	Quality Measure Title
249	N/A	Barrett's Esophagus
250	N/A	Radical Prostatectomy Pathology Reporting

AND

395	High Priority	Lung Cancer Reporting (Biopsy/ Cytology Specimens)
396	High Priority	Lung Cancer Reporting (Resection Specimens)

We also identified one pathology clusters for MIPS CQMs:

Quality ID	Outcome/ High Priority	Quality Measure Title
395	High Priority	Lung Cancer Reporting (Biopsy/ Cytology Specimens)
396	High Priority	Lung Cancer Reporting (Resection Specimens)

While these clusters may appear related in scope, due to diverse practice settings and case mixes these clusters are negatively impacting many pathologists and/or practices that simply do not examine specimens that pertain to all the clustered measures and therefore are unable to report on one or more of the clustered measures. In other words, just because a pathologist can report on one measure, does not indicate he/she can report on the others. The CAP asks that CMS NOT include these clusters as part of the EMA process for the 2020 and 2021 MIPS performance years, especially if CMS is not automatically applying the EMA process.

- Case Example: If a pathologist is performing measure 249 (Barrett's Esophagus) in the

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Washington, DC 20001
202-354-7100

claims data submission, it does not mean that he/she could also report on measure 250 (Radical Prostatectomy Pathology Reporting) which is in the same cluster. This pathologist would be unfairly penalized under the EMA methodology using this cluster.

- Case Example: A practice may primarily receive biopsy type specimens and no cancer resections. In this example, the group could possibly report on measure 395 but would be unable to report on measure 396 because they do not handle lung cancer resection cases. This group would then be unfairly penalized under EMA methodology using these clusters.

The CAP asks that CMS take the above into account before finalizing the EMA pathology clusters for the 2020 and 2021 MIPS performance years. Further, the CAP urges to use the formal rulemaking process for publishing the EMA clinically related measure clusters. This would allow appropriate input from specialty societies and MIPS eligible clinicians so that measure clusters are related in scope.

Cost Performance Category

CMS is proposing to increase the weight of the cost performance category to 20% in 2021 in order to incrementally increase the weight to meet the requirements of the statute that the quality and cost performance categories must be equally weighted at 30% each beginning in the 2022 MIPS performance year. The CAP urges caution and encourages CMS to be cognizant of the many clinicians including pathologists who have not had much experience in the cost category of MIPS. While there are a few pathology practices who have been attributed to the Medicare Spending Per Beneficiary (MSPB) measure in previous performance years, most practices have not been attributed to any cost measures. Even these practices have had a difficult time understanding why they were attributed to the MSPB measure. As such, the CAP encourages CMS to provide detailed and transparent data to practices if they are attributed to any cost measures to provide an opportunity for improvement and to learn how exactly they were attributed to cost measures. This is especially important as the cost category will continue to be weighted more in future performance years of MIPS.

Improvement Activities Performance Category

The CAP appreciates our ongoing and productive collaboration with the CMS regarding the Improvement Activities (IA) category and the CMS's recognition that non-patient facing MIPS clinicians and groups will have a limited number of measures and activities to report in this category. The pathologist specific IA guidance that the CAP has worked with CMS to provide for its members is invaluable and will go a long way in educating pathologists on this category and activities. We appreciate CMS's continued policy to allow non-patient facing clinicians and groups to report on a minimum of one activity to achieve partial credit or two activities to achieve full credit (regardless of the weight of the activities) to meet the IA submission criteria.

Promoting Interoperability Performance Category

The CAP appreciates the CMS's recognition that many of the measures under the Promoting Interoperability (PI) performance category require face-to-face interaction with patients and that sufficient measures are not applicable to non-patient-facing MIPS clinicians. We appreciate the recognition of the non-applicability of the PI category to pathologists by CMS and ask that CMS confirm that non-patient facing clinicians will continue to be automatically reweighted for the PI category.

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202-354-7100

MIPS Final Score Methodology

Quality Measure Benchmarks

The CAP supports CMS's proposal to use performance period benchmarks for the 2021 MIPS performance period, using the data submitted during the 2021 performance period rather than baseline period historic data. The CAP agrees that using 2021 performance period benchmarks for the year where there are gaps in baseline data will ensure that data continues to be reliable and accurate. This will also allow accurate results for benchmarking purposes for the 2021 performance period and could capture any changes in care that have occurred because of the national COVID-19 public health emergency.

Assigning Measure Achievement Points for Topped Out Measures

For the 2021 performance year CMS is proposing to apply the seven measures achievement point cap to measures that (1) have been topped out for two or more years based on the published 2020 performance year historic benchmarks (which are based on submissions for the 2018 performance year); and (2) remain topped out after the 2021 performance year benchmarks have been calculated. The CAP believes that CMS should suspend the topped out measure scoring caps altogether rather than revising the criteria for the 2021 performance year. This would provide further relief to clinicians dealing with the COVID-19 public health emergency.

Third Party Intermediaries

Data Validation Audit by QCDRs

Beginning with the 2021 performance period, CMS is proposing that Qualified Clinical Data Registries (QCDRs) would conduct data validation audits, with specific obligations on an annual basis prior to submitting any data to CMS for purposes of the MIPS program. This places a significant burden on registry practices as yet another requirement into a tightly wound timeline that is not practical and would be overly disruptive of the primary work of caring for patients. In addition, as the CAP has stated previously, such a requirement would be exceedingly difficult with respect to auditing improvement activities because CMS has provided very limited guidance as to what constitutes appropriate documentation for each Improvement Activity. This creates operational challenges in auditing such activities. We believe the requirement that QCDRs validate the Improvement Activities shifts an undue burden to QCDRs to perform an activity that CMS should be conducting.

In addition, QCDRs have no official role, delegated authority, or guidance from CMS as a CMS auditor. As such, if a practice disagrees with the decision of a QCDR audit, there is no clear path as to how a QCDR could respond and be supported in their decision by CMS. There could also be financial and legal consequences in a situation where a practice passes the QCDR audit but subsequently fails a CMS audit. This exposes the QCDR to financial and legal action from practices that perceive an error on the QCDR's part. In order to protect QCDRs from additional financial and legal burdens, CMS should allow Improvement Activities submissions that QCDRs receive be sent to CMS's QPP helpdesk so that the helpdesk can provide guidance to QCDRs on whether each submission can be accepted/approved. This QPP review could then serve as a final determination on any future audit.

Finally, the CAP believes that CMS should not require collection of more protected health information (PHI) than is necessary to achieve its purpose. Like many other medical registries, our registry is

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Washington, DC 20001
202-354-7100

designed to collect only that PHI which is needed to achieve the objectives of improving the quality of care through our data analysis. We are concerned that the codification of multiple auditing requirements related to clinical documentation and patient information could jeopardize our business model and trust that we have built with pathologists over the years. We believe CMS should narrowly define what should be collected via an audit, with such criteria preserving the confidentiality of patient information and not subjecting QCDRs to additional risks that they would not otherwise assume.

For these reasons, we urge CMS to refrain from requiring QCDRs to perform pre-submission data validation audits of the improvement activities performance category of MIPS. Not only does CMS's proposed mandate impose additional burdens on QCDRs, it puts them in a position of having to decide whether practices have successfully met criteria and documentation that are not sufficiently defined by CMS.

QCDR Measure Testing Requirements

The CAP was pleased by CMS's decision to delay the QCDR measure testing requirements until the 2022 performance period due to the COVID-19 public health emergency. However, CMS is proposing that QCDR measures that were approved for the 2020 performance period must be face valid prior to being self-nominated for the 2022 performance period and that QCDR measures approved for the 2022 performance year with face validity must be fully tested prior to being self-nominated for any subsequent performance periods (that is, 2023 performance year and beyond) in order to be considered for inclusion in the MIPS program. In addition, CMS proposes that for a *new* QCDR measure to be approved for the 2022 performance year, the measure must be face valid. Face validity measure testing must be completed prior to submission. To be approved for the 2023 performance year and future years, CMS proposes that a *new* QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. Under the Proposed Rule, QCDR measures that are not fully tested by the second self-nomination date would not be considered for approval for the second year.

As noted in our comments on the 2020 QPP Final Rule, the CAP strongly opposes this overly burdensome proposal because we firmly believe it is not attainable for most, if not all, QCDRs and will, therefore, either cause QCDRs to submit far fewer measures or drop out of the MIPS program altogether. We understand CMS's desire that all QCDR measures be reliable and valid, but quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, providing rigorous face validity for each measure. Currently, QCDRs typically review performance data before and after implementing a measure in the registry. Also, as finalized in the Medicare and Medicaid Interim Final Rule with Comment (IFC) published on May 8, 2020 (CMS-5531 IFC), starting with the 2022 performance period QCDRs must provide performance data prior to submitting a QCDR measure that can help demonstrate that QCDR measures are feasible and reliable.

The CAP continues to believe that CMS's measure testing requirement will impose unreasonable cost and other burdens on QCDRs and that such costs will impede measure development, lead to increases in licensing fees or registry participation fees for clinicians, and may cause QCDRs to cease measure development altogether. This requirement fails to recognize the many steps used in developing QCDR measures to ensure their reliability and validity. For these reasons, we continue to believe that this rule is contrary to the Medicare Access and CHIP Reauthorization Act of 2015's (MACRA's) requirement to encourage the use of QCDRs for reporting measures, especially given that MIPS measure developers are not subject to this testing requirement.

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Performance Feedback

While data included in CMS's 2017 and 2018 QPP Experience Reports provided useful information (i.e., overall participation rates by specialty), the reports lack key details about specialists' specific engagement in the MIPS and A-APM tracks of the QPP. For example, specialty-specific MIPS data on scoring and payment adjustments (including exceptional performance), reporting mechanisms used, measures most often reported, and breakdowns of group vs. individual reporting, as well as detailed A-APM participation by model, is essential to our overall understanding of specialty participation in QPP and how we can best tailor educational materials for specialty physicians.

In addition, because CMS will take the highest score if a clinician has multiple MIPS submissions for 2019, in the 2019 Experience Reports the CAP would also like CMS to publish on which submission clinicians were scored, i.e. individual, group, facility-based score etc. The CAP also encourages CMS to publish timely updates for facility-based score previews on the CMS QPP participation lookup tool. This is especially important for clinicians as their facility-based scores may change based on changes in the attributed facility's Value Based Purchasing score as well as the MIPS program scores for the quality and cost categories.

To address these concerns and in the spirit of transparency, we ask that **as part of the QPP Experience Reports and/or annual notice-and-comment rulemaking for the QPP, CMS provide detailed specialty-specific data and information on:**

- **MIPS scoring and payment adjustments (including exceptional performance);**
- **MIPS reporting mechanisms;**
    - **quality measures reported;**
- **group vs. individual reporting as well as details related to Opt-In and Voluntary Reporting**
- **on which submission the clinician received his/her final score (i.e. individual, group, facility-based etc.)**

Public Reporting on Physician Compare

As the CAP has stated in prior comments to the CMS, we believe that all physicians should have an opportunity to review their personal information that will be included on the CMS Physician Compare website prior to posting. Prior review by physicians will give physicians the opportunity to improve their processes when deficiencies are identified; and is aligned with the stated program goals of improving health care quality. The CAP encourages the CMS to develop educational tools for patients viewing the Physician Compare website, especially with MIPS and as it moves to MVPs. The CAP believes it will be important to note when a physician could not participate in a specific performance category listed due to circumstances beyond his/her control, (e.g. Cost or PI due to lack of applicable measures). The absence of this explanatory information is potentially misleading and could imply a lack of interest in quality when the issue is actually lack of applicability of the program to that physician. The CAP reiterates the need to indicate clearly on the website when a program does not apply to a particular physician.

MIPS Reporting Burden

In the proposed rule, CMS has estimated that clinicians would spend about 9 hours and $900 per participant to report on quality measures via a QCDR or registry. The CAP believes that this a woefully low estimate of the amount of time and cost that CAP members spend on MIPS reporting. This also does not take into account the burden and cost of administering this program that is being

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placed on physicians, via their societies with registries. One example is the new requirements of fully testing QCDR measures prior to submission. Some estimates from vendors that perform measure testing set the cost of testing *each* QCDR measure in a range between $30,000 and $100,000. For QCDRs that steward numerous measures, the cost of fully testing each one could be in the millions of dollars. This is an expense that nonprofit medical societies cannot bear without any assistance and funds from CMS for these activities. Measure development and maintenance are onerous, costly, and unsustainable processes for specialty societies with limited resources.

CMS has continued to shift costs and burden of administering the MIPS program onto physicians, via their specialty societies that create measures and have QCDRs. This is a hidden cost of the program that is ultimately being borne by physicians. **Specialty societies responded to CMS when the QPP was initiated by investing heavily in QCDRs and in measure development. These investments to support our physicians in MIPS continue to increase, without recognition of the costs of administering the program.** The positive payment adjustment to physicians is already incredibly low, and when the costs of QCDR investment ad infrastructure are added in, this make MIPS a significant cost to physicians that is not accounted for.

Advanced APMs

As CMS explains, under the Advanced APM track, the QPP provides a 5 percent APM Incentive Payment in payment years 2019 through 2024 to Qualifying APM Participants (QPs) for achieving threshold levels of participation in Advanced APMs. The APM Incentive Payment is a critical component in rewarding high-quality treatment of patients and in increasing participation in Advanced APMs. Payments are made based on the clinician's QP status in the QP Performance Period that is two years prior. We understand that the two-year lag makes it difficult for CMS to ensure that payments are made in a "routine and efficient" manner, and we share CMS's desire to reduce uncertainty and delays for the QPs. Certainly, given the significant investment and work required to reach QP status under the Advanced APM track, every effort should be made to quickly and accurately disburse the payment to QPs. Additionally, when required, CMS must provide adequate notification and opportunity to QPs to identify the appropriate means of disbursing the APM Incentive Payment. Further, in addition to any revised hierarchy or other approach to disbursement – and we wonder about the feasibility of making payment directly to NPIs rather than TINs – we also encourage CMS to consider policies that increase opportunity and incentives for specialty physician involvement in Advanced APMs to ensure more providers can earn the bonus payment for delivering high-quality value-based care to patients.

As we continue with implementation of the QPP, the CAP acknowledges CMS's work to reduce barriers to clinician participation in Advanced APMs, to promote efficiency and effectiveness, and to respond to stakeholder feedback. As we emphasized above and in earlier comments, pathologists are integral in any care coordination initiatives – including Advanced APMs – as they apply their expertise to the diagnosis and management of a wide variety of medical conditions and undertake efforts targeted at increasing integration to improve patient care. We reiterate our general support for changes that facilitate more APMs achieving Advanced APM status and that create more opportunities for specialty providers of all kinds to become QPs under the Advanced APM track of Medicare's Quality Payment Program.

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The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions related to items 1-3 of

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these comments to: Maurine Dennis (202) 354-7136 / mdennis@cap.org, or Todd Klemp (202) 354-7105 / tklemp@cap.org; items 4-7 to Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org, and for all other items, contact Loveleen Singh (202) 354-7133 / lsingh@cap.org.

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