COLLEGE of AMERICAN PATHOLOGISTS

September 11, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1784-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1784-P; Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program; (August 7, 2023)

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-1784-P entitled "Medicare Program; CY 2024, 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. Medicare Economic Index (MEI) and the Physician Practice Information (PPI) Survey
2. CY 2024 Clinical Labor Pricing Update Proposals
3. Updates to Prices for Existing Direct PE Inputs
4. Technical Corrections to Direct PE Input Database and Supporting Files
5. Potentially Misvalued Services
6. Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation
7. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively
8. Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services
9. Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services
10. Expand Diabetes Screening and Diabetes Definitions
11. CY 2024 Updates to the Quality Payment Program (QPP)
12. Requests for Information for the Quality Payment Program (section IV.)
13. RFI: Histopathology, Cytology, and- Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section III.P.)

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1. Medicare Economic Index (MEI) and the Physician Practice Information (PPI) Survey

To ensure Physician Fee Schedule (PFS) payments appropriately reflect the relative work, practice expense, and malpractice resources, the CMS believes that the cost share weights used in the PFS rate setting process should reflect the most recent cost shares from the Medicare Economic Index (MEI).

In CY 2023, the CMS proposed to rebase and revise the Medicare Economic Index (MEI) to reflect more current market conditions faced by physicians. However, the CMS delayed the adjustments to PFS rate setting cost share weights in order to balance payment stability and predictability. Many commenters requested the CMS further delay the update based on the AMA's intentions to collect practice cost data through the upcoming Physician Practice Information (PPI) Survey. In light of the PPI Survey and to preserve payment stability, the CMS is proposing to further delay the implementation of the finalized MEI cost weights for CY 2024. **The CAP agrees with CMS' proposal to postpone the implementation of the updated MEI weights until additional practice cost data is available.**

The CAP is concerned that the PPI Survey does not fully capture the breadth of pathology practice. Notably the PPI survey excludes independent laboratory practices (specialty code 69). Independent laboratory was also excluded in the original PPI Survey, and the CMS continues to use supplemental PE survey data provided by the CAP in CY 2005. It is important that the practice expense data for independent laboratory is updated during the PPI Survey data collection effort. If CMS continues to rely on outdated data for independent laboratory, patient care services will be adversely impacted due to potentially improper or outdated allocation of practice expense across services. **The CAP urges the CMS to ensure that specialties excluded from the PPI Survey, such as independent laboratory, have their updated practice costs included when developing proposals related to practice expense.**

2. CY 2024 Clinical Labor Pricing Update Proposals

For CY 2022, the CMS implemented an update to clinical labor rates for services paid through the PFS. The CMS used Bureau of Labor Statistics (BLS) wage data to generate a cost per minute for each clinical labor type. In situations where the wages of clinical labor types were not referenced in the BLS data, the CMS used wage data from Salary Expert. The Salary Expert data served as a proxy to crosswalk to a BLS labor category rate. The update to clinical labor rates will occur over a four-year transition period and will be completed in 2025. During the transition period, clinical labor rates will remain open for public comment.

In CY 2023, the CMS increased the clinical labor rates for vascular interventional technologist, mammography technologist, and CT technologist by replacing their crosswalk with 2022 wage survey data. This update created a rank order anomaly; leaving the cytotechnologist labor type (L045A) undervalued. To demonstrate this rank order anomaly, the CAP reported to the Agency that the CT technologist has a Salary Expert valuation of $0.71, while a Cytotechnologist has a Salary Expert valuation of $0.78. The CMS originally valued both these labor types at $0.76 through a crosswalk to MRI technologist. Following the CY 2023 radiology pricing updates, a CT technologist is now priced above a cytotechnologist at $0.78. This issue is even more pronounced for the mammography technologist which has a salary expert value of $0.67 but is now valued at $0.79.

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To ensure appropriate valuation, the CAP believes that the cytotechnologist labor rate should be cross-walked to genetic counselors (BLS 29-9092). This revised crosswalk is supported by wage survey data, Salary Expert valuation, and more accurately reflects cytotechnologist education, job duties, and workforce shortages and recruitment challenges.

According to Salary Expert data, the cytotechnologist should be valued 10% more than the CT technologist. Based on the revised CT technologist labor rate of $0.78, an appropriate valuation for cytotechnologist would be $0.86. **A crosswalk to BLS 29-9092 genetic counselors ($0.85) corrects this rank order anomaly and is also supported by the 2021 American Society of Clinical Pathologists (ASCP) Wage Survey of Medical Laboratories in which the average cost per minute for cytotechnologists is $0.86.**

Education and Certification Requirements:
The ASCP Board of Certification is responsible for certifying cytotechnologists and ensuring that they demonstrate the knowledge and skills to perform the essential tasks in the medical laboratory. The certification requirements for a cytotechnologist include:

- Baccalaureate degree from an accredited college/university,
- Successful completion of a CAAHEP accredited Cytotechnology program (ex: a one-year, post-baccalaureate graduate program**),
- Successfully pass the certification exam, and
- Complete the Credential Maintenance Program (CMP) every three years.

An MRI technologist requires an associate degree and additional training to demonstrate competencies in didactic coursework and clinical procedures. A genetics counselor requires a bachelor's degree with additional training that qualifies as a master's degree. Therefore, cytotechnologist education is undervalued based on its current crosswalk to MRI technologist. **The education requirement for cytotechnologist is more consistent with genetic counselor.**

Job Duties
Under the direction of a radiologist, the MRI technologist is responsible for preparing the best images possible for a radiologist to evaluate the MRI results and render a diagnosis. Whereas, under the direction of a pathologist, a cytotechnologist is responsible for both preparing and evaluating human cellular samples from all body sites, to detect and highlight for the pathologist's attention cells with pre-cancerous changes, cancer cells, benign tumors, infectious agents, and inflammatory processes. **Therefore, the crosswalk to MRI technologist does not appropriately recognize a cytotechnologist's ability to evaluate human specimens.**

Workforce Shortages and Recruitment Challenges
In the 2023 CAP Practice Leaders Survey, 89% of respondents indicated that it is difficult to recruit and retain cytotechnologists. This is consistent with a 2023 survey by the International Clinical Cytometry Society (ICCS) in which 88% of respondents rated the recruitment process for cytotechnologists as "difficult" or "very difficult". Recruitment difficulties have translated into higher wage rates - 80% of respondents indicated they had to increase wages in the past 24 months to recruit and retain workers. Additional benefits and bonuses are also being offered in addition to increased wages. Of those who increased wages, 60% of respondents indicated they also implemented additional benefits or other bonuses not included in the wage rate in the past 24 months.

The CAP urges the CMS to crosswalk the cytotechnologist labor type (L045A) to genetic counselor (L057A) (BLS 29-9092) ($0.85). This crosswalk will correct the rank order anomaly

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among labor types, appropriately value cytotechnologist education and job duties, and is supported by Salary Expert and ASCP wage survey data.

3. Updates to Prices for Existing Direct PE Inputs

For CY 2024, on Table 15, the CMS proposes to update the price of 16 supplies and two equipment items in response to the public submission of invoices. **The CAP supports the updates of the following supplies and equipment items; SC084, SC085, SM008, SL491, EP034, EP111, SA110, SL077, SL495, SL475, SL488, SL474, and SL486 and urges the CMS to finalize the updates as proposed.**

4. Technical Corrections to Direct PE Input Database and Supporting Files

In response to the CY 2023 PFS final rule, the CAP notified the CMS that CPT code 86153 was missing its work time in the Physician Work Time public use file. The CMS determined that this was an unintended technical error. For CY 2024, the CMS is proposing to add the correct 20 minutes of intra service work time to CPT code 86153. **The CAP agrees with the correction of this error and urges the CMS to finalize the update of 20 minutes of intra service work time to CPT code 86153.**

5. Potentially Misvalued Services

The CMS is seeking comment on an interested party nomination of three apheresis codes as potentially misvalued. The codes are:

- 36514 - Therapeutic apheresis; for plasma pheresis,
- 36516 - Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion, and
- 36522 - Photopheresis, extracorporeal.

The nominator stated that the clinical labor type of RN/LPN ($0.63 per minute) does not appropriately reflect the staffing involved in these procedures. In response, the nominator proposed a new labor type of therapeutic apheresis nurse specialist with a rate of $1.06 to $1.14 per minute.

The nominated apheresis codes were valued based on the existing clinical labor types recognized by the CMS. In comparing the existing clinical labor types, the CAP believes that L042A RN/LPN is the most appropriate staff type and reflects current practice. **Based on the existing clinical labor types, the CAP <u>does not</u> believe that CPT codes 36514, 36516, and 36522 are misvalued.**

The CAP does not believe that the nominator has identified misvalued services but rather has potentially identified a gap in the clinical labor types recognized by the CMS. **Therefore, the CAP urges the removal of CPT codes 36514, 36516, and 36522 from the potentially misvalued code list and it would be more appropriate for the CMS to instead address the nominator's concern though the clinical labor pricing portion of the proposed rule.**

6. Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation

In the CY 2020 proposed rule, the CMS proposed HCPCS add-on code G2211 (originally GPC1X) based on their belief that the time, intensity, and practice expense involved in furnishing services to a patient on an ongoing basis that results in a comprehensive, longitudinal, and continuous

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relationship and involves the delivery of team-based care that is accessible, coordinated, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set. The CMS believes that the work reflected in G2211 is inherently distinct from existing E/M codes including those that describe preventive and care management services. To allow for significant time to complete implementation activities, the CMS proposed an effective date of January 1, 2021.

In the CY 2021 final rule, the CMS established payment for G2211 and updated their utilization assumptions. However, Congress delayed payment for G2211 until January 1, 2024, through the Consolidated Appropriations Act. With the Act's upcoming expiration, the CMS is proposing to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024.

The CAP echoes the concerns raised by the AMA RUC that, overall, there is not clarity on the purpose, use and reporting of this code. The CAP and the AMA RUC also believe that the physician work of G2211 is already described by existing CPT codes. In situations where the practitioner provides G2211 on the same date as an E/M encounter, the E/M coding structure allows for a physician to report a higher code level when medical decision-making or time on the date of encounter warrants a higher level. In other situations, the physician work of G2211 could be described by other codes such as prolonged services (99358, 99359, and 99417), online digital management services (99421-99423), telephone E/M services (99441-99443), interprofessional telephone/internet/electronic health record consultations services (99446-99452), chronic care management services (99490, 99491, 99437 and 99439), complex chronic care management services (99487 and 99489), principal care management (99424 - 99427) or transitional care management services (99495 and 99496).

The CAP urges the CMS to discard payment of G2211 as the work is already described and accounted for within the existing E/M CPT code set. Implementation of G2211 would essentially mandate duplicate billing.

7. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

Over the last several years, the CMS has received comment identifying the need for a different approach for valuing services that relies on research and data other than the AMA RUC's specialty-specific valuation recommendations. Commenters suggested convening expert panels that might review research and recommend resource recalibrations for purposes of updating relative values under the PFS. The commenters suggest that such independent assessments could help address what they perceived as growing distortions in resource allocations under the PFS for certain types of services, including evaluation and management (E/M) visits and other non-procedural/non-surgical services.

In response, the CMS is seeking public comment regarding potential approaches to improve the accuracy of valuing services. The CMS is especially interested in how they might improve the accuracy of valuation for services, including how they could evaluate E/M services with greater specificity, more regularly and comprehensively. The CMS is also interested in whether the current AMA RUC is best positioned to provide recommendations to the CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if

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another independent entity would better serve the CMS and other interested parties in providing these recommendations.

The methods used by the RUC are appropriate to accurately value E/M and non-E/M codes. The underlying resource-based relative value scale (RBRVS) methodology remains relevant today and the RUC valuation process continues to improve with the developed of numerous standards/policies/conventions to improve relativity and ensure consistency. Standard packages for pre-service time, post-service time, practice expense direct input benchmarks, and pre-service clinical staff time packages have been implemented, allowing for enhanced relativity and comparison among all services. To identify potentially misvalued services, the RUC identifies, maintains, and reviews a list of new services and services that use new technology, develops objective screens based on defined criteria, and examines all services in which utilization estimates are more than expected. **The CAP stands in full support of the RUC process. There is no need for another independent entity to provide recommendations regarding the valuation for services that are reported on the Medicare Physician Fee Schedule.**

8. Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services

The CMS is exploring ways to better identify and value practitioners' work when they incur additional time and resources to help patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with the practitioner's ability to execute a medically necessary plan of care.

For CY 2024, The CMS is proposing to create five new G-codes to identify and value these services for PFS payment and distinguish them from current care management services. This new coding builds on to the CY 2013, 2015, and 2017 PFS final rules, where the CMS finalized new coding to provide separate payment for transitional care management services, chronic care management services, and behavioral health care management services to improve payment accuracy and better recognize resources involved in care management and coordination for certain patient populations.

The CMS is proposing two new G-codes describing CHI services performed by certified or trained auxiliary personnel incident to the professional services and under the general supervision of the billing practitioner.

- GXXX1 - Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:
- GXXX2 – Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1)

The CMS is proposing to establish a code to separately identify and value a social determinants of health risk assessment that is furnished in conjunction with an E/M visit.

- GXXX5 - Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months.

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The CMS is proposing two new G-codes for when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease.

- GXXX3 - Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:
- GXXX4 – Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

The CAP commends the CMS for recognizing the need for health-related social needs services, social determinant of health risk assessments, and principal illness navigation services. However, the CAP is not only concerned with the work valuation of GXXX1, X2, X3, and X4, but also believes that GXXX5 is already captured by and is duplicative of existing E/M codes.

As described, GXXX1, X2, X3. X4 are non-physician services, but reflect services provided by trained auxiliary personnel under the direction of a physician or other practitioner. The physician work of these services is already captured in the initiating E/M visit code. **Therefore, the CAP disagrees with the assignment of any work RVU to GXXX1, X2, X3, and X4 as these services do not involve physician work that is not already captured by existing E/M coding. In regards to the practice expense component of GXXX1, X2, X3. and X4, the CAP also urges the agency to consider the current constraints on PFS funding and believes that any expansion of Medicare to cover non-physician services should be funded and paid through a separate program independent of the physician fee schedule.**

As proposed, GXXX5 must be furnished by the practitioner on the same date they furnish an E/M visit. It is noted that the E/M coding structure allows a practitioner to report a higher code level when medical decision-making or time on the date of encounter warrants a higher level. **Therefore, the CAP disagrees with GXXX5 as it is duplicative. The 5-15 minutes required to complete the SDOH assessment can instead be captured by reporting a higher-level E/M code.**

The CAP is concerned that the CMS continues to introduce and value new codes outside of the CPT and RUC processes. The CAP believes that the CPT process can identify new technology and gaps in coding and valuation as the practice of medicine evolves. Since the CPT process is open to the public, any interested party can submit a code application if they believe the current E/M codes do not accurately capture work or practice expense resources. **The CAP believes that the work of the proposed HCPCS G-codes is already accurately defined within the full range of CPT E/M services and that the CMS should follow the CPT Editorial Panel process to describe any new E/M services as they arise. In addition, to preserve relativity and to ensure validity of the RUC process, the CMS should allow the RUC to review any new service placed on the physician fee schedule for both physician work and practice expense valuation.**

Therefore, the CAP disagrees with the implementation of GXXX1, X2, X3, X4, and X5 in CY2024 and recommends that these codes be referred to the AMA's CPT Editorial Panel and if necessary, then to the AMA RUC for consideration of valuation..

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9. **Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services**

Expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth is generally precluded from payment under Medicare Parts A or B. However, in the CY 2023 PFS final rule, the CMS identified certain clinical scenarios where payment is permitted for certain dental services where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. For the CY 2024 rulemaking process, the CMS sought submissions for additional clinical scenarios where dental services may be required to diagnose and treat the individual's underlying medical condition and clinical status.

Based on the evidence contained in the received submissions, the CMS is proposing to amend their regulation and to permit payment under Medicare Parts A and Part B for:

1. Dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered: chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and the administration of high-dose bone- modifying agents (antiresorptive therapy) when used in the treatment of cancer; and
2. Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer, CAR T-cell therapy when used in the treatment of cancer, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

The CMS is also proposing payment for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room as currently described in regulation.

Dental services are inextricably linked to covered CAR T-cell medical services and improve clinical outcomes for CAR T-cell patients. Untreated oral or dental infections can complicate or compromise the clinical outcome of the CAR T-cell medical service. For this reason, clinical practice guidelines recommend dental services prior to initiating the CAR T-cell therapy and other lymphodepleting therapy. **The CAP supports the CMS' proposal to allow payment for dental services inextricably linked to CAR T-cell therapy, when used in the treatment of cancer. However, the CAP again urges the CMS to consider the current constraints on PFS funding and believes that any expansion of Medicare to include dental services should be paid through a separate program independent of the physician fee schedule.**

10. Expand Diabetes Screening and Diabetes Definitions

For CY 2024, the CMS is proposing to:

- expand coverage of diabetes screening tests to include the Hemoglobin A1C (HbA1c) test;
- expand and simplify the frequency limitations for diabetes screening, and
- simplify the regulatory definition of "diabetes" for diabetes screening, Medical Nutrition Therapy, and Diabetes Outpatient Self-Management Training Services.

The HbA1c test is clinically appropriate for diabetes screening and has unique advantages compared to existing covered tests that should be considered by the practitioner and patient when choosing a

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diabetes screening test. **The CAP supports the expansion of coverage to include the HbA1c test for diabetes screening. The CAP also supports the expansion and simplification of the frequency limitations as it removes barriers for medically necessary screening.**

11. **CY 2024 Updates to the Quality Payment Program (QPP)**
    Advanced APMs

As CMS explains in the proposed rule, the Quality Payment Program includes two participation tracks for clinicians providing services under the Medicare program: MIPS and Advanced APMs. We appreciate CMS's "commitment to support providers in the transition from traditional MIPS to APMs and Advanced APMs" and we acknowledge CMS's goal that all traditional Medicare beneficiaries "be in a care relationship with clinicians accountable for quality and total cost of care by 2030." To that end, we support efforts to improve health equity in addition to advancing value and we urge CMS to ensure that also includes consideration of clinicians in small or single-specialty practices or in rural and underserved areas. Additionally, we support CMS's goal of modifying CEHRT use criterion for Advanced APMs to promote flexibility in adopting CEHRT that is clinically relevant to participants, emphasizing the importance of interoperability and health information technology (HIT). The CAP has previously commented on the unique challenges that pathologists face in meeting many of the typical electronic health record and HIT requirements.

However, we oppose CMS's proposal to transition to individual QP determinations as we have concerns that this change will drive some clinicians out of APMs and increase the complexity of the program for physicians. Specifically, CMS is proposing to calculate QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an Advanced APM, rather than having eligible clinicians receive their QP determinations at the APM Entity level, as is the current policy. We have not yet seen data or other specifics about the impact of this policy change on physicians in all specialties and APMs, nor have we seen data to support CMS's assertion that any of the issues raised are happening with appreciable frequency. Also, as we have expressed before, the Quality Payment Program regulations are already exceedingly complex and difficult to understand and interpret. Significant administrative infrastructure is currently needed to help physicians interpret regulations and make decisions about participation pathways. Making these rules even more complex and nuanced will disenfranchise physicians from participation in the Quality Payment Program.

We strongly agree that it is not beneficial for an APM Entity to exclude certain specialists. In fact, as CMS earlier noted, a provider who is not furnishing direct services may be making other important contributions to practice such as consultation or training of new clinicians. Yet, the proposed change to individual QP determinations does not consider the breadth of roles and responsibilities of clinicians within an APM and instead goes against the idea team-based care. Previously, CMS itself recognized this when it made its initial decision, stating that QP determination at the Advanced APM Entity group level aligns with the goals of the Advanced APMs themselves and ultimately "is more beneficial for a wider range of eligible clinicians who might not have an opportunity to be QPs individually or in smaller groups."

Instead, we urge CMS to continue with and improve the process of making QP determinations at the APM Entity group level, minimizing administrative burden on physicians and furthering team-based care. As commenters have expressed before, this approach is supportive of "care coordination, organization cohesiveness, and the different clinician types supporting an Advanced APM Entity regardless of whether or not their services are tied directly to attribution." Especially for pathologists, who apply their expertise to the diagnosis and management of a wide variety of medical conditions

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and thus are integral to any care coordination initiatives, it is imperative that they are recognized in APMs and not disenfranchised from participation in the Quality Payment Program. We believe there are other ways CMS could address the issue of APM Entities "removing or otherwise not including eligible clinicians who may technically contribute less to the APM Entity-level Threshold Score" (for example, introducing the ability of clinicians to appeal their QP determination if they so choose during a defined window after the first snapshot) and we urge CMS to explore those alternatives rather than making broad programmatic changes. We also again ask CMS to work with the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and all relevant stakeholders to design specialty-focused APMs and APMs that meaningfully capture a diverse variety of specialties' contributions to team-based care.

12. Requests for Information for the Quality Payment Program (section IV.)

The CAP looks forward to continuing engagement with the CMS on multiple aspects 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 ensure flexibility for pathologists in a way that recognizes and accounts for the value pathologists contribute to patient care as non-patient facing clinicians in an inherently patient facing program. These considerations will be especially important as CMS moves forward with implementation of MIPS Value Pathways. The CAP continues to support explicit consideration of how non-patient facing providers are enabled to participate and be fairly recognized for the value of care they provide, via accommodations or alternate measures as necessary to meet the clause[1] in the Medicare Access and CHIP Reauthorization Act (MACRA) that requires CMS to give consideration to non-patient facing clinicians. The CAP outlines specific concerns below in its comments on the Quality Payment Program (QPP).

Medicare Shared Saving Program

Proposal for Shared Savings Program ACOs to Report Medicare CQMs

While we appreciate the challenges inherent in deduplicating patients and combining data from multiple electronic health records (EHRs) into one coherent, true, accurate and complete data set, we do not believe that introduction of new types of quality measures advances the goals of the Quality Payment Program. Creating a new type of quality measure, especially with a generic name like Medicare CQMs, at this point in the evolution of the Quality Payment Program will likely lead to confusion among clinicians and administrative staff working on the program. Combined with the rollout of a new reporting pathway for MIPS-eligible clinicians (MIPS Value Pathways), Medicare CQMs only add complexity to the QPP without evidence they will drive noticeable quality improvements.

[1] 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.

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Furthermore, amending the definition of "collection type" to include Medicare CQMs layers on additional confusion as these measures are not available to many clinicians who are currently reporting other collection types of quality measures such as MIPS CQMs and eCQMs. Medicare CQMs are only available to Shared Saving Program ACOs and should not be categorized the same as MIPS CQMs/eCQMs available to all MIPS-eligible clinicians. Put another way, a Shared Savings Program ACO participant could choose to report MIPS CQMs but an individually-MIPS-eligible clinician could not choose to report Medicare CQMs.

Request for Feedback for the Quality Payment Program

Promoting Continuous Improvement in MIPS

We thank CMS for the opportunity to weigh in on future policies to promote continuous improvement in the Quality Payment Program. We understand CMS' desire to evaluate existing policies to determine whether there are additional opportunities for quality improvement, a component of the MIPS program. However, we have significant concerns about the underlying assumptions governing the approaches described in this RFI. Many of these considerations are based on potentially flawed premises; the end result could lead not only to increased burden for clinicians but to decreased quality of care for Medicare beneficiaries.

Briefly, we believe that continuous improvement should not be the *primary* goal of the MIPS program. There are many programs in existence across the health care system that promote continuous improvement for all clinicians, such as Ongoing Professional Practice Improvement (OPPE) and Continuing Medical Education requirements plus CLIA, Proficiency Testing, and Laboratory Improvement Programs in the case of pathology and laboratory medicine. Continuous improvement for clinicians is embedded in the health care system; adding new requirements to MIPS in order to achieve the same ends is redundant and unnecessary. Furthermore, if continuous improvement is a major goal of MIPS, some mechanisms to promote this are already present in the program, such as removal of topped out measures. Constant change increases burden for clinicians; constant change without significant change in outcomes is a disincentive to meaningful improvement.

Therefore we believe a balanced approach to MIPS reporting and quality improvement is more appropriate. MIPS should reward clinicians for improving their quality of care and maintaining that high quality. MVPs should be focused on areas where improvement is possible and the transition to an APM is clear. Finally, CMS and CMMI should also re-evaluate the APM portfolio to ensure appropriate representation of all clinicians before pushing clinicians into these models.

Please find below our specific responses to the questions included in this Request for Feedback:

1. What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?

As noted above, we respectfully contest the assumption that clinicians need to constantly improve---once they reach a high level of performance-- as measured by MIPS. MIPS is a limited program, whose quality measurement is based on a relatively narrow set of actions that can be developed into measures meeting programmatic requirements. It is not realistic to define continuous improvement by these metrics alone. Furthermore, the fact that many clinicians perform well in MIPS should not be taken as evidence of the need for change. Many clinicians provide high-quality care to their patients. While they may have areas of improvement, not everything can be measured by MIPS quality measures, such as rare (even rare catastrophic) events or events that are attributable to no individual clinician.

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Furthermore, the evidence available currently suggests that improvement is occurring: per the 2021 PUF a third of the NPI-TINs in MIPS received quality improvement bonus points. Considering that a significant number of clinicians applied for the Extreme and Uncontrollable Circumstances exception, this indicates measurable improvement among those who remain. What's more, some clinicians would not be eligible for the improvement bonus because they did not report the same measure at the same practice for two consecutive years, again, especially in light of the public health emergency. Therefore the data shows that clinicians are improving in quality. Additional changes to policies of the MIPS program are unnecessary, unless they are designed solely to recognize participation in other continuous improvement programs, such as those that pathologists are required to do.

2. Should we consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?

We do not support such programmatic changes. We also disagree that improvement is more important than maintaining quality. Encouraging constant change increases burden and devalues the ongoing work clinicians put in to remaining at high performance. Change is difficult, system wide change is even harder; it takes time and energy to implement and to maintain. Clinicians should be rewarded for the effort they put in to ensure they continue to provide the highest quality care year after year.

In addition, the MIPS program is already unduly complex for clinicians; the program's scoring system and other programmatic requirements are already difficult to understand and implement. Adding complexity in scoring and tracking will add significant confusion and additional undue burden. CMS should focus policy changes on simplifying the program instead of making it more complex.

3. Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?

We believe it would be arbitrary to impose additional requirements on MIPS-eligible clinicians. Even if there were a measure or set of measures that could be reported by all clinicians in MIPS, which is unlikely given the diversity of clinician types in the health care system, there is no reason to believe that forcing all clinicians to report the same measures would drive continuous improvement. Some clinicians may already be performing well on such measures; others may not be able to affect circumstances that would allow them to perform well. Furthermore, if use of these measures did drive improvement, the measures would top out quickly, necessitating further change which only adds burden to the program. Increasing reporting requirements makes a program that is already onerous for many practices even more complex and frustrating.

More specifically, we believe that changing requirements for measures or use of measures is not a mechanism to drive continuous improvement. Consider a situation where five practices report a quality measure; one practice scores 100% while the other four score less than 20%. Should the high-performing practice, who has likely put in additional time and effort to improving on this measure, be punished because they are significantly out-performing the other practices? Barring this practice from reporting this measure in the future does not drive improvement among the four practices who are performing poorly. Instead, it only punishes one practice for their excellence. Furthermore, given the time and effort required to develop and test quality measures, it is unreasonable to assume that practices will have a constant supply of new measures to choose from, particularly as CMS seeks to reduce the number of measures in MIPS.

4. Should we consider creating additional incentives to join APMs in order to foster continuous

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improvement, and if so, what should these incentives be?

The idea that APMs automatically promote continuous improvement is not supported by available data. In fact, APMs may not even drive improvement as much as MIPS: a given APM, for instance the Enhancing Oncology Model (EOM), has only one set of measures for the entire length of the model. A practice that signs up for EOM will use the same measures for the duration of the model or their participation in it. Furthermore, there is no expectation that a practice demonstrate a performance gap in these measures to qualify for the APM.

The quality measures in APMs are fundamentally no different than MIPS measures; in fact, the EOM uses some actual MIPS measures such as QID 134. It is true that APMs have a limited set of measures, which aligns with CMS' proposal to require that specific measures are mandatory for reporting. However, APMs are almost entirely voluntary and practices who join them do so knowing what measures will be expected of them and that the practice is able to report these measures.

Finally, there is little evidence that APMs broadly speaking drive quality. The recent report regarding the Oncology Care Model, for example, showed no change in quality measures over the duration of the model. The report acknowledges that patient-reported metrics were high to begin with and quality improvement is only a secondary goal of many APMs.

5. What changes to policies should CMS consider to assess continuous performance improvement and clinicians interested in transitioning from MIPS to APMs?

First, we appreciate CMS' recent Request for Information regarding specialty participation in MVPs and the Request for Information in this proposed rule regarding MVP Reporting for Specialists in Shared Savings Program ACOs. Most specialists are currently not meaningfully captured in APMs, a fact which CMS and CMMI are acknowledging and attempting to address. However, this limits the useful policy levers for clinicians transitioning from MIPS to APMs; if few clinicians are eligible for APMs, even a robust transition pathway that promotes continuous improvement would not be useful if there is nothing to transition to. Given this limitation, changes to policies seem premature. Furthermore, the MVP program has only just begun to roll out. Until it is fully implemented, it would be difficult to see how meaningful policy changes could be enacted. If CMS feels the need for an additional transition between MIPS and APMs beyond MVPs, that could be explored in partnership with societies and other stakeholders.

Specifically regarding MVPs as a vehicle to transition from MIPS to APMs, we suggest the following policies which would shift MVPs from being an extension of MIPS specialty measure sets to a real bridge to APMs:

a. Focus on the outcome of the MVP as it relates to patient care, not the specific activities and component parts
b. Incentivize MVP participation by offering an MVP bonus and additional flexibility for new MVP participants; consider making MVPs upside-only for first-year MVP participants
c. Ensure that MVPs address social determinants of health and reflect the higher costs of caring for low-income or dual-eligible patients
d. Adapt MVP payment adjustments to be in line with APM and other value-based payment mechanisms: monthly bonus payments as included in the Enhancing Oncology Model

If a large percentage of clinicians continue to be not ready for the transition to APMs, or APMs are not ready for them, additional effort should be put into whatever the transition between MIPS and APMs is, not in distorting the parameters of MIPS to demonstrate "improvement" that may not be

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clinically relevant. If CMS wants to re-evaluate whether some clinicians should stay in MIPS forever due to the fact that APMs are not relevant for them, we support this effort and would be pleased to discuss more.

6. We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?

CMS' continued increasing of the data completeness threshold adds to the burden of reporting and we suggest that this increase not be finalized. We believe there is a lack of understanding of the maturity of health information technology standards to seamlessly aggregate data from electronic health records, laboratory information systems and registries from physicians who practice at multiple sites.

Until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings, and providers, it is premature to continue increasing data completeness and doing so on top of increasing reporting or performance standards would be unmanageable for many small or rural practices. Technology, standards, costs, and implementation decisions made by health IT developers will continue to impact the completeness of quality reporting; none of these are within the control of individual clinicians. The state of data available for automated reporting must be a primary consideration in any policy to increase reporting burden
For this reason and those previously described, we believe quality measures are not the mechanism by which CMS should look to drive improvement, if that is even a major goal. We suggest instead that Improvement Activities could be used to foster continuous improvement, such as an Improvement Activity targeting a specific improvement threshold.

7. While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

We suggest that CMS be mindful that emphasizing continuous improvement over maintenance of quality has the potential for significant downsides. We reiterate that this is not an optimal approach, particularly attempting to drive continuous improvement by increasing burden on clinicians. Making the MIPS program harder or more complex will conversely lead to less time for clinicians to spend on patient care and more time on administrative tasks. However, if CMS were to move forward with these policies, it would be critical to develop mechanisms to easily assess whether maintenance of quality is occurring.
This includes straightforward pathways to revive measures once considered topped out and bonus points for practices who are still scoring well on measures they have not reported for several years if they choose to use them again.

MIPS Value Pathways (MVPs)

Subgroup Reporting

While the CAP is supportive of CMS' policy that allows a group to form subgroups in whatever way

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seems appropriate (e.g. not limiting subgroups to a single specialty), we are concerned about limitations placed on subgroups with respect to reweighting. While CMS may not be mandating that subgroups are a single specialty, this option may appeal to groups in order to streamline reporting of meaningful measures for all clinicians. In that instance, subgroups may have different reweighting needs than the affiliated group. We understand the challenges outlined by CMS regarding the time needed to ascertain the data submission requirements of a group or subgroup but feel this decision is best left to the group/subgroup, who are most aware of their own circumstances. **Therefore, we do not support the policy disallowing reweighting at the subgroup level**.

Furthermore, CMS is proposing that a facility-based score will not be determined at the subgroup level and complex patient bonus points will not be assigned at the subgroup level. Taken together, these policies make comparing scores at the subgroup level and the group level less meaningful. It is our belief that these policies make it more likely that a clinician will receive a score at the group level since the addition of complex patient bonus points will likely increase the group level score. While subgroups have the potential to be a meaningful way for large complex multi-specialty groups to report MVPs that are relevant to different sets of clinicians, CMS' proposed policies reduce the utility and motivation to form subgroups. We encourage CMS wherever possible to promote subgroup formation rather than disadvantage clinicians who choose to report through subgroups.

Quality Data Submission Criteria

Data Completeness Criteria for Quality Measures

The CAP appreciates CMS' desire for the most complete quality measure data to evaluate clinicians. Given the critical goals of MIPS to improve health care quality, a certain level of data completeness is needed. Furthermore, we applaud CMS for acknowledging that increasing the data completeness requirements represent a burden on clinicians. This is especially true of clinicians in complex practices patterns; our experience shows that a high number of MIPS-eligible pathologists practice in multiple locations with multiple electronic health information systems. Ownership of and access to this data varies significantly across practices. We therefore support CMS' proposal to maintain data completeness at 75% through PY 2026.

However, we encourage CMS to consider that, even setting aside the operational challenges of data access, a data completeness threshold of 100% is not feasible. CMS has stated that cases that cross performance years cannot be submitted as part of either year's data. Therefore some data will always be excluded from reporting. This is only one example of data that cannot be part of MIPS reporting. A data completeness threshold of 75% is more than representative of a group's performance on quality measures. In instances where case volume is low, groups are already incentivized to submit more than 75% of their data to ensure they are meeting case minimums. Unless CMS has reason to suspect a group or individual MIPS eligible clinician of "cherry-picking", a data completeness threshold of 80% is added burden without adding value. Therefore, **we encourage CMS to reconsider raising the data completeness threshold in 2027 or for subsequent years**.

CMS has also stated that EHR adoption and reporting of eCQMs should promote higher rates of data completeness. However, pathologists largely do not use EHRs that are eligible for CEHRT therefore they cannot report eCQMs. Laboratory information systems (LIS) are fundamentally different than EHRs and not eligible for CEHRT. Specialties like pathology who are not eligible for eCQMs should therefore be excluded from increased data completeness thresholds given that they lack the necessary components that would promote higher rates of data completeness, as indicated

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by CMS. Such specialties can be identified based on reweighting of the Promoting Interoperability performance category.

Selection of MIPS Quality Measures

The CAP strongly appreciates CMS' retention of the 6 pathology-specific MIPS CQMs in the Pathology Specialty Measure Set. A stable measure set is critical to streamline options and reduce administrative burden by allowing clinicians to predict reporting requirements for subsequent years. However, t**he CAP asks that CMS remove measure 440, Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician from the proposed 2024 pathology measure set.** The CAP has identified multiple feasibility issues that pathologists face while trying to report on this measure. This measure was written for dermatologists who read their own biopsies, is stewarded by the American Academy of Dermatology (AAD) and has not been tested for feasibility for pathologists because of significant implementation challenges. Notably, AAD has requested that each biopsy be reported separately as an individual denominator instance. This does not align pathology practice. Multiple specimens are given the same Accession ID and treated as a single case or report. Although we appreciate the addition of a Denominator Exception for measure 440 in PY 2023, this measure is out of alignment with pathology practice patterns and is so fraught with implementation issues that the data should not be considered valid to use for benchmarking or comparison purposes for pathology practitioners.

For these reasons, the CAP believes that measure 440 be removed from the pathology measure set going forward. **The CAP strongly recommends that measures from one specialty not be added to another specialty's measure set unless and until they have been fully tested in that other population of providers.** Given that the Pathology Specialty Measure Set now contains 6 pathology MIPS CQMs and the fact that we think it highly likely that QID 491 will earn a performance year benchmark for PY 2023, we believe measure 440 is no longer needed and only adds complexity for pathologists and lack of data standardization for MIPS.

The CAP has discovered that CMS is not applying the Eligible Measure Applicability (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 has also discovered that when a practice reports less than 6 measures via Medicare Part B claims, CMS does the look-back on Medicare claims to see if the practice could have reported on other measures to determine if EMA should be applied. However, when the data is submitted via a qualified registry, the burden is placed on the practices to provide CMS with a list of all CPT codes billed as part of their Targeted Review to have CMS apply EMA and correct their scores. Given that practices report zero cases in the numerator and denominator to CMS, we encourage CMS to thoroughly apply EMA before final scores are released. **For these reasons, the CAP urges CMS to apply the EMA process automatically to all practices who are unable to report a minimum of six measures as determined by Medicare Part B claims.** Otherwise, the practices are subject to erroneous scoring and are unable to achieve their maximum MIPS final score.

In addition, determination of clinically-related measures should be subject to rulemaking and comment, because the subregulatory process for determining these has led to inefficient groupings. The following pathology clinically related measures were identified in CMS' 2023 EMA and Denominator Reduction Guide:

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Clinical Topic	MIPS CQM	Medicare Part B Claims
Pathology 1	**249:** Barrett's Esophagus **250:** Radical Prostatectomy Pathology Reporting **395:** Lung Cancer Reporting (Biopsy/Cytology Specimens) **396:** Lung Cancer Reporting (Resection Specimens) **397:** Melanoma Reporting	**249:** Barrett's Esophagus **250:** Radical Prostatectomy Pathology Reporting **395:** Lung Cancer Reporting (Biopsy/Cytology Specimens) **396:** Lung Cancer Reporting (Resection Specimens) **397:** Melanoma Reporting
Pathology 2 (N)	**249:** Barrett's Esophagus **395:** Lung Cancer Reporting (Biopsy/Cytology Specimens) **397:** Melanoma Reporting **491:** Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma	**249:** Barrett's Esophagus **395:** Lung Cancer Reporting (Biopsy/Cytology Specimens) **397:** Melanoma Reporting
Pathology – Skin Cancer	**397:** Melanoma Reporting **440:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	**397:** Melanoma Reporting

We appreciate the modification of the clinical clusters to represent somewhat more related procedures; the "Pathology 2" group may assist practices who do not see resection specimens, a common issue for practices. We also support grouping of skin cancer measures together, as dermatopathology groups cannot report any other measures. However, we feel the "Pathology 1" clinical cluster does not represent a meaningful group of measures and is a source of confusion for practices. Therefore, we request that this cluster be terminated.

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 for reporting purposes. Most importantly, we reiterate that EMA should be uniformly applied across all practices reporting MIPS CQMs without the need for practices to provide extensive documentation.

The CAP also encourages CMS to exercise caution when partially removing MIPS quality measures. While we understand the intent of maintaining measures with specific purposes and their importance in certain MVPs, the overall goal of MVPs is to streamline and simplify MIPS. By creating different sets of quality measures available in "traditional" MIPS and MVPs, CMS risks confusing clinicians wishing to report both options. We also believe that partially retaining quality measures does not align with the intent of the program: this indicates that quality in an MVP is not the same as quality in traditional MIPS. If anything, we suggest that MVPs should be more stringent than traditional MIPS. MVPs are intended to be the most important, parsimonious set of quality measures for a given specialty or condition; a measure that lacks value in the broader traditional MIPS program cannot be considered part of a parsimonious set.

Finally, we do not support removal of measure QID 138, Melanoma: Coordination of Care. This measure is critical as a companion to measure QID 397, Melanoma Reporting, to ensure appropriate diagnosis, treatment, and follow-up for patients with melanoma. We urge CMS to retain this measure to maintain continuity of care across the patient journey.

Improvement Activities Performance Category

Changes to the Improvement Activities Inventory

As above, we urge caution when adding or removing activities from MVPs when those changes do not apply to traditional MIPS. This extends to creation of MVP-specific Improvement Activities (IAs). Since MVPs have the same quality improvement goals as traditional MIPS, an IA linking a formal quality improvement model to an MVP seems unnecessary and potentially confusing. MVPs are intended to streamline the program into the most meaningful activities for a condition or specialty.

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Adding new unfamiliar requirements does not advance that goal. In fact, adding MVP-specific requirements or activities could lower adoption of MVPs since clinicians are more likely to continue reporting what they know instead of learning a new set of activities.

Establishing the Performance Threshold

Proposal to Modify Policy for Establishing the Performance Threshold

The CAP appreciates that CMS is taking into consideration the burden placed on clinicians by raising the performance threshold rapidly. The updated understanding of what constitutes a prior period is important to allow increased flexibility as the program becomes more challenging and the public health emergency winds down completely. However, using data from 2019 even as part of the calculated prior period could lead to skewing of the data. This is due to both the reweighting policies that were applied to 2019 data as well as to the higher scores that were likely due to different scoring policies in place early in the program. CMS has acknowledged that a number of policies were in place to ease clinicians into MIPS participation. Given that those policies, such as bonus points for measures and a three-point floor for quality measures, are no longer in effect, it does not seem accurate to set the performance threshold based on those scores. Furthermore, even if scoring policies were the same, using data that is seven years old is likely not comparable to current data. Therefore, while we overall appreciate CMS' policy to update the definition of "prior period", **we strongly oppose raising the performance threshold to 82 points**. Given the expanded understanding of prior period and the requirements imposed by this wording, we suggest that 75 points is a performance threshold set based on a prior period and the threshold could therefore be left unchanged.

Targeted Review

Given the tight timeline described for completing QP determinations, the CAP understands the desire to move targeted reviews earlier in the year. Since preliminary performance feedback has been released earlier in the summer for the past several years, we do not anticipate major issues with moving release of final scores earlier in the year. However, it is critical that all scores be available at that time to ensure that clinicians have an accurate assessment of their score. This includes not only MVP and traditional MIPS scores but also facility scores where applicable. If facility scores are not available earlier in the summer, we suggest leaving the timeline for targeted review as is.

In addition, we recognize the need to shorten the timeline. However, the CAP feels that 15 calendar days may be insufficient time for clinicians to provide additional information if requested as part of targeted reviews. The MIPS program presents a significant administrative burden for many practices; adding unnecessary urgency will only increase the burden. Furthermore, the validity of the MIPS program relies on scores that are accurate. Shortening the timeline for targeted reviews risks this accuracy if practices are not able to provide information that could materially affect their score. **Therefore, the CAP suggests keeping the timeline for providing additional information if requested at 30 calendar days.**

Third Party Intermediaries General Requirements

Self-Nomination and Program Requirements
The CAP appreciates CMS' understanding that third party intermediaries are only required to support quality measures that apply to the clinicians they support. Similarly, third party intermediaries should only be required to support subgroups if they are supporting MVP reporting since subgroups can

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only report through MVPs. If this was in the intention of the current policy, we recommend clarifying the language to indicate that third party intermediaries *who are supporting MVPs* must support subgroup reporting.

Attestation of Data Access Capabilities
The CAP applauds CMS for recognizing the uneven way in which data validation was previously being conducted, especially as it relates to health IT vendors. However, the proposed language regarding changes to data access capabilities is overly broad and would increase the burden on MIPS-eligible clinicians and practices as well as third party intermediaries. There is a significant difference between requiring third party intermediaries to have access the data required for data validation audits and requiring third party intermediaries to have the data itself. **We suggest that the language be modified to require third party intermediaries to attest that they have access to the data** so it is clear that intermediaries are not expected to maintain all data necessary for an audit at all times.

Third Party Intermediary Support of MVPs.
As MVPs continue to roll out, the CAP is supportive of CMS' continued efforts to improve the program. While we still have concerns about requiring third party intermediaries to support all MVPs that are relevant to the specialties they support, **we agree with the proposed policy indicating that intermediaries must only support relevant measures**. This represents a significant step forward in reducing the burden and associated confusion of the program for MIPS-eligible clinicians and third party intermediaries. However, we also suggest that CMS clarify that third party intermediaries are only expected to support the categories that are pertinent to the specialty of their clinicians. That is, a third party intermediary who has not been supporting Promoting Interoperability in traditional MIPS due to the fact that their clinicians are exempt should not be expected to support Promoting Interoperability in an MVP.

Proposal to Remove Health IT Vendor Category
The CAP appreciates CMS' ongoing assessment of differences within third party intermediary categories. Given the importance of data accuracy, the reduced expectation of data validation by health IT vendors as compared to qualified registry and QCDRs is a significant concern for the integrity of the program. **We therefore support removal of this category of third party intermediaries.** However, given CMS' statement that the data submitted by health IT vendors was in some cases incorrect or inaccurate, we suggest that CMS pause raising the performance threshold until all parties have full confidence in the data. Similarly, in instances where CMS has evidence pointing to incorrect data for specific MIPS CQMs, we suggest that the relevant benchmarks be reset given the lack of confidence in the data.

Terms of Audits
The CAP understands CMS' need to establish impartial criteria for determining which third party intermediaries will be audited in a given year, in addition to the random audits. We agree with the idea that certain behaviors could be considered a red flag triggering a targeted audit. However, we disagree with one proposed criterion cited as an area of concern: a continuing pattern of Quality Payment Program Service Center inquiries or support call questions. Given the increased complexity of the program, third party intermediaries need the opportunity to clarify requirements and ensure they are complying with all parts of the MIPS program. Discouraging questions to the service center or on support calls is contrary to the goals of the program to reduce burden on clinicians. If anything, CMS should be encouraging questions to ensure that all intermediaries have the same understanding of details of the program. If there is reason to believe that an intermediary lacks understanding of the program or is operating in error, this should be determined by the content of the

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questions to the service center, not the volume. We suggest that CMS clarify that submitting questions on support calls or to the service center is not a trigger for an audit unless those questions demonstrate a pattern of poor behavior (such as cherry-picking of data) or lack of understanding of the MIPS program.

13. RFI: Histopathology, Cytology, and- Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section III.P.)

Introduction

Technology and the wider healthcare sector have changed dramatically in the decades since the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and its implementing regulations were enacted. To better meet the needs of clinical laboratories, CLIA should be modernized. However, CLIA modernization must focus on streamlining regulatory and business processes and making laboratory testing - and patient results - more accessible and less costly to patients, while adapting to and encouraging new ways of working. For example, establishing new regulations for remote testing allows laboratories to go into communities where they are needed most while ensuring safe and accurate testing. On the other hand, instituting additional requirements for laboratory personnel at a time when laboratories and hospitals struggle to hire staff while balancing ever-reduced reimbursements from public and private payers will exacerbate workforce problems. There can be no benefit to clinical quality or patient satisfaction if facilities are unable to hire enough qualified workers.

Whether, and how, CLIA should provide oversight of histopathology preparation and processing of tissue samples for slide staining, specifically related to guidance for routine histopathology slide staining and complex IHC staining.

The CAP recommends that the current practice be maintained: that histology labs remain outside of the scope of CLIA regulations. Currently, the CAP provides oversight for over 100 laboratories that conduct histopathology preparation and processing in addition to higher-complexity testing which is in scope of regulatory oversight. Although these high-complexity labs may not necessarily be representative of the wider laboratory community, the CAP through our oversight of these laboratories has not identified issues with quality originating in slide staining and preparation. Instituting CLIA oversight of histopathology would mean both increased regulatory burden for laboratories while reducing the flexibilities available to laboratory directors, who must make decisions on laboratory workflow based on the best interest of the patient balanced with the realities of constricting financial resources. In addition to adapting to workforce challenges, technology is rapidly changing the field of histology, and it may be premature to develop regulations as practices remain in flux and issues with quality have yet to be identified.

What criteria (for example, training programs, on-the-job training, experience, or academic degree) would interested parties recommend for personnel performing high complexity automated IHC staining?

The CAP recommends no change from the current requirements stating that personnel should be required to complete training on the tasks performed, and Laboratory Directors should be responsible for ensuring that this training is performed and kept current. Adding new requirements for individuals seeking to work in a laboratory at a time when laboratories are struggling to find qualified workers will add to workforce challenges.

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How does the categorization of automated staining systems impact personnel who are currently performing this task but do not meet the qualifications for performing high complexity testing?

The automated staining systems have a dual purpose: staining and diagnostics. Histotechnologists use only the staining functionality of this equipment, not the diagnostics. The practice of slide staining and preparation has become more automated and mechanized as technology advances. While slide preparation still greatly depends on human personnel, this mechanization reduces the amount of variability in the tasks performed. Some laboratories use histology personnel with high complexity testing qualifications while others do not. This has led to confusion. Technical solutions and training guidelines are being developed but are not ready to be implemented. With current laboratory personnel shortages, prescriptive regulation in this area could have a significant impact on laboratory operations and workforce. The CAP has requirements for ensuring the quality of the staining and preparations. The pathologists that review these slides evaluate the quality of the preparations before any results are reported for patient care. The CAP recommends no change in this area for the time being, as technology is moving slide staining and preparation towards a more standardized, less variable practice.

What is an acceptable timeframe between the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides to protect the integrity of the macroscopic tissue?

The CAP opposes setting a prescriptive timeframe for the review of the macroscopic gross tissue examination, and the review and confirmation of these tissue findings by a pathologist prior to the microscopic review of slides. Current guidelines protect the integrity of the macroscopic tissue and allow the pathologists and laboratory teams the flexibility to make lab workflow decisions, and the clinical decisions they support, in the best interests of patients. Our position is that there is a reasonable medical certainty that there is no risk of patient harm if gross descriptions are reviewed more than 24 hours after transcription and respectfully request that this not become a requirement under CLIA.

What education and experience or training requirements should be required for individuals to qualify as a general supervisor (GS) for histopathology? If qualified, what is an acceptable timeframe for the GS to review and evaluate gross examinations under the specialty of histopathology?

Histology personnel are not considered high-complexity personnel. If current practice is maintained and they remain outside the scope of regulation, then there is no need to provide any requirements for these personnel. A pathologist (technical supervisor) is responsible for supervision of non-pathologists that qualify as high complexity testing personnel to assist with gross examination. The pathologist is also responsible to assess the competency of those individuals at least annually. The pathologist is the licensed provider who is responsible for overseeing the lab, its personnel, and its performance as per CLIA. As such, the CAP recommends against instituting educational, experience, or training requirements for general supervisors in histopathology. Additionally, specifying a timeframe for the general supervisor to review and evaluate gross examinations is unnecessary. In CAP's oversight of histopathology labs, we have not seen issues with quality that

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would be fixed by setting timeframes, and the current practice allows for flexibility in workflow while protecting material integrity and the quality of results.

What education and professional experience, or training requirements should be required for individuals performing gross tissue examination that have an associate degree from a histotechnician program or a PA who has training from an accredited program and is certified as a PA?

The CAP recommends no changes to current workforce requirements. Current requirements define the qualifications for individuals to assist with grossing that state that they need to meet high-complexity testing qualifications, and there are separate requirements for personnel training and competency assessment. With current laboratory personnel shortages, adding new training, qualification, and educational requirements will hinder laboratories to hire the workforce they need, and serve as a barrier to individuals seeking to join the laboratory workforce.

General Comments

The CAP supports the modification of CLIA regulations to allow for remote testing as well as remote viewing and sign out of digital materials, while establishing appropriate controls to ensure patient safety and clinical quality. Ensuring pathologists can review materials, and sign out remotely, means that they can verify laboratory results where and when needed, reducing the amount of time that patients and providers have to wait for results.

However, the applicability of extending remote workability to a broader range of non-physician clinical laboratory personnel would need to be evaluated by examining the specific tasks associated with each individual service that could be safely performed remotely and with appropriate safeguards in place.

How should "remote testing location" be defined?

The CAP proposes the following definition: a remote testing location is one not physically connected with the testing facility at the address listed on the CLIA certificate but under the same Laboratory Director listed on the CLIA certificate and connected to the hospital system of the same via secure internet connection (i.e., VPN). This will allow for remote testing while ensuring responsibility for clinical accuracy and patient safety sits with a licensed provider and under CLIA regulatory oversight. "Remote sign out" should be defined as well. The CAP suggests that remote sign-out should be defined by the pathologist review and signing out on the materials while physically in a location other than the address listed on the CLIA certificate and connected to that location's system via a secure internet connection.

How should the CLIA regulations be revised to allow pathologists to examine histopathology and cytology slides/images at a remote testing location?

To allow pathologists to examine histopathology and cytology slides/images at remote testing locations while maintaining the safeguards instituted by CLIA, the CAP recommends that CLIA regulations be revised to ensure the following:

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- There is a method for the individual reviewing cases to ensure correct patient identification for slides/images and data files submitted for review.
- The individual reviewing cases has access to pertinent clinical information at the time of slide/image(s) or remote data file review.
- The laboratory validates digital whole slide imaging (WSI) used for clinical diagnostic purposes by performing its own validation studies, including approval for use by the laboratory director (or designee who meets CAP director qualifications) before the technology is used for the intended diagnostic purpose(s).
- The laboratory ensures that sites engaging in telepathology (defined as “the practice of remote pathology using telecommunication links to enable the electronic transmission of digital pathology images”) and remote data assessment provide reasonable confidentiality and security.
- The laboratory trains all users of the telepathology system as appropriate to their role.
- The telepathology records include diagnoses made and statements of adequacy assessment, preliminary diagnosis, or recommendations for additional studies provided at the time of evaluation.
- Telepathology services are included in the laboratory's quality management system.

What conditions (including, location(s)) should apply for a pathologist to examine histopathology or cytology slides/images remotely without obtaining a separate CLIA certification?

The items listed in the response above would need to be addressed.
In addition, the laboratory would need to ensure that these individuals are listed on the laboratory's personnel roster and that they have appropriate records of their qualifications. The roster should also indicate who is eligible to work remotely: there should be an understanding who is working remotely, and when. A remote policy must be in place - with written agreements about maintaining security, HIPAA, etc. Include requirements for the laboratory director to ensure the professional competency for all pathologists that provide interpretive services, and that individuals be trained within the specialty where they will be leveraging remote sign-out.

Under what conditions should a primary location cease permitting testing at the remote location?

The CAP recommends a cease testing protocol where a laboratory’s overall performance and deficiencies are taken into account. If there are certain deficiencies that originate at a given remote testing location, then remote testing must cease at that location until those deficiencies are assessed and corrected. Additionally, if issues with overall quality are detected, then personnel that have repeated citations and problems as well as the Laboratory Director should not be allowed to work remotely until those issues are corrected.

How should the remote location be included on the final patient report?

It should be noted that testing was performed at a remote site, identified with a code. The CLIA-certified location should maintain a database of the remote locations mapped to the location codes.

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This will ensure that results can be tracked back to where testing was performed, while protecting the privacy of individuals that may live at that location if it is a residential address.

How should CMS, SAs, or Accreditation Organizations perform onsite surveys at remote locations?

Pathologists and other personnel at remote locations under the laboratory's CLIA certificate must be listed on the laboratory's personnel roster. The inspector would evaluate qualifications, patient reports, and other records as they perform the inspection regardless of the testing location. The CAP would also use Laboratory General Telepathology and Remote Data Assessment requirements as described above. The inspector should also assess security protocols and understand if there were any data breaches/cybersecurity attacks - software issues, down systems - where the hospital and/or laboratory systems may be compromised.

Under what circumstances should CLIA allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification?

CLIA should allow remote locations or testing facilities to examine clinical cytogenetics images without obtaining a separate CLIA certification as long as the same requirements listed above for remote testing and review are met. The same principles and thus requirements should apply in order to safeguard patient safety, clinical quality, and accuracy of results.

Under what circumstances would the examination of clinical cytogenetics images be unacceptable for the remote location scenario?

Under the following circumstances:

- Use of systems that do not maintain proper patient identification throughout the entire testing process.
- When pertinent clinical information needed to properly review data and images is not available.
- If using a system that has not been properly validated for remote use.
- Use of a system that personnel have not been trained on.
- Use of systems or testing processes that do not maintain the confidentiality of patient data.
- Lack of records of remote activities.
- If any of these have been violated, testing should cease until deficiencies are corrected.

What clinical cytogenetics testing processes should the primary laboratory have in place to ensure the remote site complies with the CLIA requirements?

Results generated by personnel remotely need to be included under the laboratory's quality management system, with investigation of any errors identified, and the proper oversight of these personnel by a technical supervisor and general supervisor. The CAP requires the final report for conventional cytogenetics and FISH analyses to be reviewed and signed by the cytogenetics section director or qualified cytogeneticist designee. A designee needs to be a MD or PhD that completed a fellowship in clinical cytogenetics, or with four years of training or experience in human medical genetics or pathology, with at least two in clinical cytogenetics. The testing performed remotely is subject to proficiency testing and alternative performance assessment requirements.

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What "conditions" or "criteria" would be necessary for the remote location to ensure quality testing for the examination of clinical cytogenetics images?

The following conditions must be met:
1) There is a method for the individual reviewing cases to ensure correct patient identification for slides/images and data files submitted for review.
2) Telepathology services are included in the laboratory's quality management system.

The College of American Pathologists is pleased to have the opportunity to comment on these issues and appreciates your consideration of our comments. Please direct questions related to items 1-10 of these comments to James Carver at jcarver@cap.org , Maurine Dennis at mdennis@cap.org or Todd Klemp at tklemp@cap.org; for items 11-12 contact Colleen Skau at cskau@cap.org and Elizabeth Fassbender at efassbe@cap.org and for item 13 contact Andrew Northup at anorthu@cap.org

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