COLLEGE of AMERICAN PATHOLOGISTS

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To Whom It May Concern:

Thank you for the opportunity to provide comments on actions Congress can take to stabilize the Medicare payment system while furthering a successful transition toward value-based care. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. The CAP's pathologists have direct experience in nearly all the payment pathways offered under MACRA's Quality Payment Program (QPP), as well as the underlying Physician Fee Schedule (PFS). Thus, our comments in this letter focus on our direct experiences with the effectiveness of MACRA; barriers that need to be addressed for MACRA to fulfill its purpose of increasing value in the U.S. health care system; and more specific recommendations to improve MIPS and APM programs, including how to improve provider participation.

The CAP is encouraged by your interest in addressing the challenges presented by MACRA, and we agree that serious and immediate improvements are needed to our nation's health care payment structure. In the broader context, we encourage a dialogue that looks at waste and consolidation in the health care system as the primary drivers of escalating health care costs. As you know, physicians continue to be asked to do more with fewer resources each year[1], which simply does not

[1] https://www.ama-assn.org/system/files/ama-medicare-reform-grassroots-insert.pdf

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reflect the needs of nor address the waste within our health care system. For example, the largest source of health care spending in the U.S. is administrative, with over $265 billion a year in waste according to some studies[2]. This includes time and resources devoted to meeting billing and reporting requirements for insurers and public programs, which has only been exacerbated by MACRA's incredible complexity. Add on top of that our unstable payment system, numerous other state and federal rules, and managing electronic health records and utilization management programs, and it is no surprise that we are seeing a national burnout rate of more than 50 percent among physicians in practice[3], at a time when health care delivery is critical.

The CAP is committed to improving patient care and addressing escalating health care costs – yet as is stated in the RFI, "in order to keep our patients safe and our workforce strong, we need a payment solution that is consistent and that pays for health outcomes." As we will describe, we believe Congress can make significant progress by extending the exceptional performance bonus pool for the MIPS program as well as the 5 percent Advanced APM Incentive Payment; passing the Supporting Medicare Providers Act of 2022 and waiving the 4 percent PAYGO sequester; ending the statutory freeze in annual Medicare physician payments and providing updates based on the Medicare Economic Index (MEI) in 2023 and beyond; and mandating stakeholder participation in development of new payment models while maintaining traditional MIPS options. We look forward to working with you to address these common goals and improve today's Medicare payment system.

1. Effectiveness of MACRA

MACRA was originally passed to end a cycle of Medicare payment cuts and reward value-based care, yet today we are faced with continued financial instability within the Medicare physician payment system and value-based care that is not incentivized or attainable for most physicians.

As you recognize already, there has been a chorus of dissatisfaction with the Merit-based Incentive Payment System (MIPS). The Medicare Payment Advisory Commission (MedPAC) has questioned the value of the MIPS program due to its design and measurement methods. Indeed, the Government Accounting Office's (GAO) 2021 report on *Provider Performance and Experiences under the Merit-based Incentive Payment System* described many of the challenges physicians experience in the MIPS program, including the question of whether MIPS meaningfully improved quality of care or patient outcomes. It further indicated that the design of the program may incentivize reporting over quality improvement. CMS's response to the GAO report was that a new pathway in MIPS, called MIPS Value Pathways (MVPs) would address many of these challenges. Although MVPs are new in 2023, it is already clear that CMS has added complexity to the MIPS program rather than decreasing it.

Alarmingly, significant portions of the cost of the MIPS program have fallen on the backs of physicians. The CAP has previously asked GAO to consider a follow up report to its 2019 *Study on CMS Quality Activities* that found that CMS did not maintain complete and detailed information on its

[2] The Role of Administrative Waste In Excess US Health Spending, " Health Affairs Research Brief, October 6, 2022
[3] https://www.ama-assn.org/amaone/ama-recovery-plan-america-s-physicians-reducing-physician-burnout

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funding for quality measurement activities. The GAO stated that CMS's information showed it had carried over from each year to the next large amounts of available funding—known as unobligated balances—for quality measurement activities from fiscal years 2010 through 2018. Meanwhile, specialty societies such as the CAP have taken on the responsibility of developing quality measures to comply with CMS's payment programs and are in dire need of funding for these activities.

Additionally, the CMS-proposed meaningful "upsides" of MIPS participation have not materialized, even for the highest performers. The potential 9 percent positive payment adjustments that accompanied a flat PFS have not materialized and the cost and burden of participation in MIPS has been higher than anticipated. Thus, within MIPS, the administrative and financial burden of participating far outweighs any marginal improvements in cost and quality that could possibly be ascribed to MIPS participation.

Within the Advanced Alternative Payment Model (APM) track, there is an equivalent lack of meaningful results, with increased and unnecessary complexity built into the system. CMS recently acknowledged in its own *Synthesis of Evaluation Results across 21 Medicare Models, 2012-2020* that most of the current models created by the Center for Medicare and Medicaid Innovation (CMMI) are not meeting quality and savings goals. When accounting for shared savings, some APMs actually increased net costs and only two on CMS's list of 21 improved the patient experience of care.

Despite there being hundreds of APMs, there have been very limited options for physicians to participate, much less for them to receive Qualifying APM Participant status from meeting the Advanced APM participation threshold. Per the recently-released MedPAC data book (July 2022), the vast majority of clinicians participating in Advanced APMs were in accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). In fact, of the clinicians who qualified for the 5 percent Advanced APM bonus, over 75 percent were in MSSP, and four other Advanced APMs made up most of the remaining eligible clinicians. Just 3.4 percent participated in an Advanced APM other than those four or MSSP. One look at the CMMI website for available APMs, their associated rules, dates for sign-up, data reporting and other requirements demonstrates an extraordinary amount of complexity for models that are hardly being utilized. In addition, it is clear that single-specialty practices are disenfranchised from being able to participate in most APMs. And incentives for physicians to participate in Advanced APMs should recognize that high-value care is provided by both small practices and large systems, and in both rural and urban settings.

CMS's policies and the evolution of MACRA threatens single-specialty, community-based practices. As currently envisioned by CMS, both MVPs and APMs significantly favor multispecialty practices. Furthermore, while CMS wants to see all Medicare beneficiaries and most Medicaid beneficiaries enrolled in an accountable care relationship by 2030, it is unclear how single-specialty, community-based practices can participate in CMS's vision. CMS has not explicitly articulated how this transition will occur, nor what they see as the primary accountable care relationship model for specialists. In the recently released proposed rule, CMS acknowledges broad concerns among participants that the path from MVPs to APMs remains particularly unclear for specialties other than primary care.

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Finally, the underlying PFS has created significant financial instability for physician practices, and dissatisfaction with MACRA that may further discourage participation in value-based care models in the future. The Medicare PFS is the only payment system within Medicare without an annual inflationary update. This is particularly destabilizing as clinicians, many of whom are small business owners, contend with a wide range of shifting economic factors when determining their ability to provide care to Medicare beneficiaries. According to an American Medical Association (AMA) analysis of Medicare Trustees data, when adjusted for inflation, Medicare physician payments have declined by 22 percent from 2001–2021. This is in contrast to other areas of the health care system, such as hospitals and ambulatory surgical centers, which are not seeing such significant decreases in payment.

The long-term consequence of failing to avert the cuts is decreased patient access to care. In fact, the 2021 Medicare Trustees Report expressed concern that, although the physician payment system put in place in 2015 avoided the significant short-range physician payment issues, it "nevertheless raises important long-range concerns that will almost certainly need to be addressed by future legislation." The Trustees further stated, "In addition, the law specifies the physician payment updates for all years in the future, and these updates do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases. Absent a change in the delivery system or level of update by subsequent legislation, the Trustees expect access to Medicare-participating physicians to become a significant issue in the long-term." In fact, according to a Medical Group Management Association report, the majority of practices (92 percent) said that 2022 Medicare reimbursement rates already do not adequately cover the cost of care provided, and that nearly 60 percent of groups are considering limiting the number of new Medicare patients they accept, while 66 percent have considered reducing charity care. Additionally, they found that 58 percent of respondents said they might have to reduce the number of clinical staff and 29 percent are considering closing satellite locations.[4]

MACRA and the QPP are not addressing the true drivers of cost in the health care system, and are instead perversely incentivizing market consolidation, which further increases health care costs. The lack of adequate model pathways for single specialty physicians plus the cost and complexity of participation is too burdensome for many practices. The net effect is driving physicians out of rural and underserved areas. Between what it costs to run a physician practice and actual payment combined with the administrative and financial burden of participating in QPP, MACRA is ultimately destabilizing the care delivery system.

2. <u>Regulatory, statutory, and implementation barriers that need to be addressed for MACRA to fulfill its purpose of increasing value in the U.S. health care system</u>

For MACRA to fulfill its purpose of increasing value in the health care system, Congress must consider reforms to the budget neutrality requirement within the current PFS system. Indeed, budget

[4] https://mgma.com/getmedia/b0716bbf-d21f-4ead-b1cb-9371485e62ff/09-21-2022-Impact-of-Payment-Reductions-to-Medicare-Rates-in-2023-Full-Report.pdf.aspx

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neutrality is a major barrier to achieving high-quality, high-value health care, as these requirements lead to arbitrary reductions in reimbursement unrelated to the cost of providing care, forcing physicians and other health care providers into adversarial roles, leading to an unpredictable reimbursement system (clinicians cannot predict their reimbursement year after year, even if they maintain the same quality of care). As you know, the changes to the evaluation and management (E/M) codes in 2019 would have resulted in a 9 percent cut in reimbursement to all pathologists had Congress not intervened. This kind of essentially arbitrary reduction to reimbursement and continued uncertainty prevents clinicians from making financial decisions or investing in innovation in the best long-term interest of their patients and the overall health care system. While we acknowledge that budget neutrality is a politically appealing option to control rising health care costs, we encourage Congress to think more creatively and expansively about ways to manage health care costs which do not generate such significant instability for health care providers, threatening beneficiary access to essential health care services.

Budget neutrality within MACRA (and in particular, MIPS) also poses barriers to high-quality, high-value care, as it encourages clinicians to leave the program rather than compete with other physicians for a small pool of funds. Again, while we recognize that budget neutrality has been considered an important component of controlling costs within the health care system, its impact on individual clinicians fails to address the real sources of waste in the system. Slightly higher Medicare reimbursement to MIPS-eligible physicians is simply not the main driver of increasing health care costs. Therefore, we recommend that Congress consider eliminating, revising, or replacing the budget neutrality requirements in MACRA.

Another major barrier concerning implementation of MACRA is the associated administrative burden, particularly as it relates to the current state of health care data. While electronic health records are critical for advancing care accuracy, timeliness, and coordination, one size does not fit all with respect to health information technology (health IT). Even within a single specialty, different physician practices have different levels of fluency with technology, and between specialties, the maturity of health IT varies widely. Therefore, when it comes to implementing the requirements of a system-wide program like MACRA, we suggest regulations acknowledge the varying states of data availability and encourage flexibility to accommodate differing health IT readiness. Furthermore, rather than impose health IT requirements across the board, CMS and other agencies should work with stakeholders to move from the current state to an improved future state that promotes greater health data interoperability.

Data entry remains a major burden to complete implementation of MACRA, as it requires significant time and effort on the part of physicians and/or administrative staff: an average of more than 200 hours a year in one study[5]. One proposed alternative is quality measurement based on administrative claims. However, while these measures reduce data entry burden, they do not represent a complete fix; downsides of administrative-claims-based measurement include limited available data, retrospective evaluation, and oftentimes limited clinician control over the processes

[5] Khullar D, Bond AM, O'Donnell EM, Qian Y, Gans DN, Casalino LP. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. *JAMA Health Forum.* 2021;2(5):e210527.

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being measured. CMS acknowledges the need for real-time evaluation and feedback, which cannot be accomplished based on administrative-claims-based measurement. We recommend that Congress encourage innovation around solutions that minimize physician administrative, financial, and technological burdens of participation which do not improve the quality of patient care and do so without arbitrarily reducing the opportunities for clinicians to demonstrate quality of care. To this end, we suggest reducing the complexity of complying with MIPS, and of MIPS scoring, by working with stakeholders to assess burden-reduction mechanisms that acknowledge variability among different specialties.

Similarly, we are encouraged by CMS's dedication to reducing burden and increasing interoperability in working with ONC to ensure alignment between requirements of different programs. However, we strongly encourage CMS and ONC to avoid moving too quickly with technological requirements that are arbitrary or infeasible for large swaths of the physician population. Initial efforts towards all-electronic measurement and reporting are still being assessed; requirements in the digital health space should be evidence-based, following the model of other standards in medicine. As with other aspects of MACRA, we also encourage CMS to solicit input from end users and other stakeholders in the field, to ensure that any requirements align with current capabilities and are financially sound, rather than employ a one-size-fits-all method that increases costs and burden of implementation.

3. Recommendations to improve MIPS and APM programs

While the concerns outlined above require longer-term and systemic changes, there are more immediate issues related to the QPP that Congress and CMS could address. Today, Congress must provide stability in the Medicare payment system, ensure improved financial incentives for quality and value, mandate involvement of stakeholders in development of new payment models, and increase transparency and flexibility. Additionally, traditional MIPS options must be maintained for single specialty practices to ensure that private/independent practices of all sizes remain viable as options for physicians.

In addition to addressing the financial instability of the Medicare physician payment system outlined above, Congress can ensure better financial incentives for quality and value. For example, CMS itself acknowledges that, starting next year, "the statutory incentive structure under the Quality Payment Program for eligible clinicians who participate in Advanced APMs stands in contrast to the incentives for MIPS eligible clinicians." Additionally, physicians have been reporting quality measures in the MIPS program for several years, but the available set of measures is constantly changing. This creates the impression that the actions detailed in the quality measures are only important when physicians are not doing them; in fact, maintaining a high standard of quality is essential for patient safety and satisfaction. Physicians should be recognized and compensated for ongoing efforts not only constantly to improve but also constantly to maintain a high level of quality; this requires substantial effort from clinicians, administrative staff, and allied health professionals. Therefore, we ask that Congress extend the exceptional performance bonus pool for the MIPS program, which rewards the highest performers with additional funds, supporting them in continuing to provide the highest quality care.

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Similarly, practices who have joined Advanced APMs must undertake significant practice redesign activities in order to provide enhanced services to beneficiaries including 24/7 access to care, patient navigation, care planning, and more. Advanced APM participants also take on significant downside financial risk by participating, thereby demonstrating their commitment to value in health care. As with practices in MIPS, the burdens associated with these activities are significant. Specifically, the consequences of the loss of the APM Incentive Payment, which was a critical component in rewarding high-quality treatment of patients and in increasing participation in Advanced APMs, cannot be underestimated. Without the incentive payment, providers will be less able to afford continued participation in Advanced APMs (considering operating costs and needed infrastructure) and will be less likely to take on any new participation (given significant transformation investment costs). Not only does it appear this will further constrain pathologists' ability to participate in Advanced APMs but, like CMS, we are concerned about what this could do to "the availability and distribution of funds in the budget-neutral MIPS payment pool." To address this issue, Congress should extend the 5 percent Advanced APM Incentive Payment, ideally by passing the Value in Health Care Act (H.R. 4587).

Further, CMS has indicated that the MIPS program will sunset in the near future. As a transition from MIPS to APMs, CMS has instituted the MVP program. However, as conceived by CMS, this program requires significant resources to implement, from the perspective of both physicians and the national specialty medical societies who develop MVPs. If CMS continues to believe that the MVP program is essential for the transition from fee-for-service to value-based payment, it will be essential to fund the necessary infrastructure associated with this transition. We suggest CMS consider development grants or cooperative agreements that would promote meaningful engagement of all stakeholders in the MVP development, implementation, and assessment process. As mentioned above, the GAO found that CMS was carrying significant unobligated balances for quality measurement activities. Outside of one set of cooperative agreements that were put in place four years ago, CMS has not invested these funds in measure development for traditional MIPS, MVPs, or APMs, all of which could benefit from increased investment.

Just as important as providing better financial incentives is ensuring that the Medicare payment system is stable for the future. As explained above, the constant cycle of fiscal uncertainty represents a major point of instability in the health system and is a threat not only to provider participation in value-based payment but to broader care access across the American health system, as physicians who are unable to keep up with the increasing costs of running a practice leave the system. This is a particular concern in rural and underserved areas where physicians are already in short supply. Most immediately, Congress should pass the Supporting Medicare Providers Act of 2022 to ensure relief from scheduled budget neutrality cuts and, in addition, should waive the 4 percent PAYGO sequester triggered by passage of the American Rescue Plan Act.

On top of the scheduled cuts and sequester, physicians are the only Medicare providers who do not receive annual updates for inflation. While MACRA was an agreement between Congress and organized medicine that resulted in a frozen fee schedule in return for an upside potential with MIPS (mostly) and bonuses for Advanced APM participation, the upside potential under MIPS has not materialized and Advanced APM participation remains extremely limited. To help reduce fiscal

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uncertainty and the ever-increasing financial burden of running a physician practice, Congress must end the statutory freeze on annual Medicare physician payments and provide updates based on the Medicare Economic Index (MEI) in 2023 and beyond.

While appropriate incentives are necessary for participation in Advanced APMs, it is also critical that Congress mandate involvement of stakeholders in development of new payment models. The CAP has been continually concerned that models are being submitted to the Physician Focused Payment Model Technical Advisory Committee (PTAC) and developed by CMMI that dramatically change providers' clinical decision-making without considering the input on specialties impacted by these models. The CAP has sought to ensure physicians, especially the societies that represent physicians participating in and affected by new payment models, have input into new model development. Specifically, in carrying out its statutory duties of testing innovative health care payment and delivery models that lower costs while "preserving or enhancing the quality of care," CMMI is required to consult clinical and analytical experts with expertise in medicine and health care management. Amongst those clinical experts and those with expertise in medicine and health care management, CMMI should be required to include associations representing physician specialties whose services are directly impacted in primary and/or supporting roles by the Center's models. Consultation with specialty associations will help ensure that models developed in a manner that is transparent, consistent with sound clinical input and practices, and focused on the best interests of the patient.

Similarly, while the CAP is supportive of the PTAC's role in the review and recommendation of models developed by physicians, we believe that model submitters should be required to consult participating and affected specialties prior to model submission. PTAC provides an important opportunity for specialists to develop their own models and submit them for review and recommendation to the Secretary. However, at least three models recently submitted to the PTAC have included pathology services, yet the CAP was not consulted or even aware they encompassed pathology services until the models were posted for public comment. Model submitters should be required to provide evidence of consultation and concurrence from specialties participating in their models prior to their submission, so that the PTAC can make recommendations on models that are truly physician-focused and enable meaningful contribution of their participants in enhancing the care of patients.

Finally, traditional MIPS, though burdensome, allows single specialty pathology practices to obtain full incentives. Many pathologists in independent practice choose to stay in MIPS for that reason. The CAP believes the replacement of traditional MIPS with MVPs and Advanced APMs advantages larger, multispecialty practices, as the clinical alignment envisioned by these programs is often achieved via physician employment or practice consolidation. Indeed, consolidation among physician practices and between hospitals and physician practices has accelerated in the past decade, with participation in APMs cited as reasons for consolidation[6]. Traditional MIPS options must be maintained for single specialty practices to ensure that private/independent practices of all sizes remain a viable option for physicians.

[6] Medicare Payment Advisory Commission. 2022. March 2022 Report to the Congress: Medicare Payment Policy; Ch 4. Washington, DC: MedPAC

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Again, the CAP welcomes the opportunity to work with you on these and other identified issues to reform the nation's Medicare payment system. Especially as we emerge from the current public health emergency, it is critical that we address the challenges presented by MACRA, which will require longer-term and systemic changes. However, Congress can take significant steps by immediately extending the exceptional performance bonus pool for the MIPS program as well as the 5 percent Advanced APM Incentive Payment; passing the Supporting Medicare Providers Act of 2022 and waiving the 4 percent PAYGO sequester; ending the statutory freeze in annual Medicare physician payments and providing updates based on the Medicare Economic Index (MEI) in 2023 and beyond; and mandating stakeholder participation in development of new payment models while maintaining traditional MIPS options. Finally, while this conversation continues, we hope to also see a dialogue that looks at waste and consolidation in the health care system as the primary drivers of escalating health care costs. Please contact Darren Fenwick at dfenwic@cap.org / 202-354-7135 if you have any questions regarding these comments.

Sincerely,

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