COLLEGE of AMERICAN PATHOLOGISTS

Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192) – Request for Information Department of Health and Human Services, Centers for Medicare & Medicaid Services

College of American Pathologists – June 10, 2025

Topic 1: Streamline Regulatory Requirements

1A. Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of the Medicare program?

The College of American Pathologists (CAP) appreciates the opportunity to comment on the request for information on "Unleashing Prosperity Through Deregulation of the Medicare Program." 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. The CAP appreciates HHS's efforts to improve the regulatory environment for physicians, and we look forward to working with the agency to provide regulatory relief for pathologists.

Merit-Based Incentive Payment System – the CAP suggests some regulatory requirements of the Merit-Based Incentive Payment System (MIPS), part of the Quality Payment Program, that could be modified without compromising the program. First, because CMS only utilizes data available in Medicare Part B Claims, cost measure scores, which are critical for practices to improve efficiency and reduce avoidable costs, are only available six months after the performance period closes. A practice has no way to obtain any feedback prior to that, which greatly limits their ability to improve. Therefore, we recommend that CMS remove the regulation (Social Security Act Section 1848(r)(5)(B)(i-ii)) that mandates cost measure development solely based on Part B Claims data.

MIPS Value Pathways – CMS's process for developing MIPS Value Pathways (MVPs) has resulted in increased burden for Medicare providers. Because MVPs are largely constructed by CMS without stakeholder input, as CMS states "almost all clinicians who reported an MVP also reported traditional MIPS" (2023 QPP Results at a Glance). Reporting twice through two different mechanisms is obviously increased effort by clinicians and necessitates additional administrative and IT support. We have serious concerns that the MVP framework runs counter to the language and spirit of MACRA. Therefore, we request that CMS maintain

traditional MIPS rather than transition to MVPs as the mandatory reporting option, as indicated by CMS' MVP transition diagram.

Coding and documentation – certain requirements for coding and documentation are both burdensome and ineffective, and thus could be waived without compromising patient safety. The CAP believes Medicare Administrative Contractors (MACs) should discontinue directing physicians/providers to report "unlisted" codes when a specific AMA Current Procedural Terminology (CPT) code exists. Such "unlisted" codes should not be required by the MACs, as established HCPCS/CPT codes are (per statute and regulation) adequate and proper for coverage and payment. Likewise, federal contractors should not be allowed to require physicians/providers to use additional "non-HIPAA" codes to report their services. For example, requiring molecular pathology providers to obtain and report non-HIPAA-compliant DEX Z-codes from the Palmetto DEX Registry, adds unnecessary requirements and complexity to claims for medically necessary services.

NCD and LCD revision processes – Medicare coverage policies, including National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), become outdated over time, with current studies and guidelines not always taken into account. Medicare's coverage of services can and should change, based on factors like medical advancements, patient needs, and policy changes. Keeping NCDs and LCDs updated is a complex process that requires ongoing monitoring and adjusting of coverage policies to ensure they remain effective and meet the needs of beneficiaries. One way to streamline this process and ensure policies remain current and reflect the latest medical evidence and best practices is for CMS and MACs to prioritize NCDs and LCDs that have a high volume of claims or those in rapidly evolving fields, such as molecular biology. The CAP supports CMS' effort to identify and remove NCDs that no longer reflect current medical practice or involve items or services infrequently used by beneficiaries. Similarly, MACs should regularly review and retire LCDs that are infrequently used or no longer supported by current evidence.

Laboratory date of service (DOS) policy – aligning the current Hospital Outpatient Prospective Payment System (HOPPS) laboratory DOS exception across the inpatient setting would allow laboratories to bill directly for molecular pathology tests and ADLTs, rather than indirectly receiving payment from the hospital, which would reduce administrative and billing complexity for hospitals, clinical laboratories, treating physicians, and Medicare beneficiaries. Regardless of the location or date of the testing, the services performed during an inpatient or outpatient encounter are typically unrelated to those driven by molecular testing. For example, if blood is drawn at the same time a cancer patient receives chemotherapy during an outpatient encounter (e.g., for the purposes of assessing potential for metastasis or minimal residual disease) the results of testing completed on that specimen will inform treatment during a future, not the current, encounter. For these tests, the process of seeking payment from the hospital has long proven burdensome for clinical laboratories, hospitals, treating physicians, and Medicare beneficiaries, which may negatively impact patient care, particularly in the cancer setting where large genomic sequencing panels are increasingly used and timely access to

test results can guide treatments the patients receive. Tests on tissue samples acquired from patients during hospital stays are critically important for determining future treatment planning and optimal patient care. We urge CMS to allow laboratories to directly bill Medicare for molecular pathology tests and ADLTs in the inpatient setting as well.

1B. Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?

In the opinion of the College of American Pathologists (CAP), the most significant process that increases burden on clinicians is constant change to the MIPS program itself. This includes both regulatory changes such as modifying the weight of performance categories or removing Improvement Activities as well as changes to the performance adjustment amount. While we acknowledge that the MACRA statute mandates budget neutrality, we encourage CMS to consider ways to fairly compensate clinicians for their time and effort while reducing the modifications to the program each year.

In addition to the burden of participating in the MIPS program itself, regulations around MIPS impose additional unseen burdens on clinicians. While the CAP applauds CMS' desire that all quality measures be appropriate, reliable and valid, the testing requirements imposed on measures necessitate significant effort from clinicians and cost from nonprofit medical specialty societies. Some societies, especially smaller ones, have ceased measure development due to the associated costs, leaving some Medicare providers with extremely limited choice of quality measures. Given the extensive expert involvement in measure development at medical specialty societies, CMS' requirements go above and beyond what is required for a valid, reliable measure. Therefore, we suggest that 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3) should be rescinded in favor of a more flexible approach that ensures high-quality valid measures. For example, approval of a measure testing plan that applies to all relevant measures, or acceptance of real-world evidence of reliability and validity rather than relying on narrow statistical definitions.

In addition to effort required to participate in testing of measures, clinicians are burdened by constant changes to the available measures as CMS removes quality measures with high performance ("topped out" measures). This not only complicates the program for participants, it also fails to acknowledge the significant time and effort clinicians spend in maintaining high quality. Achieving excellent patient outcomes is not a one-time activity but requires constant ongoing monitoring, evaluation, and process improvement. Measures with high performance should not be arbitrarily removed as long as they remain priorities of the program. We urge CMS to rescind 42 C.F.R. §§ 414.1305, 414.1400(b)(4)(iv)(D).

1C. Are there specific Medicare administrative processes, quality, or data reporting requirements, that could be automated or simplified to reduce the administrative burden on facilities and other providers?

The College of American Pathologists (CAP) suggests the following:

Quality measure scoring – to earn the maximum number of points on quality measures, the measures must have a benchmark, which CMS generates when sufficient data has been submitted from program participants. However, the amount of data required appears arbitrary and the points a measure is worth can change on a yearly basis, thus leading to confusion among practices. To simplify this, we suggest that CMS rescind 42 CFR § 414.1380(b)(1)(ii)(A) and instead apply the scoring policy indicated in 42 CFR § 414.1380(b)(1)(ii)(E) to all quality measures.

Prior authorization – prior authorization processes are not only administratively burdensome, but also costly, inefficient, opaque, responsible for patient care delays, and typically indiscriminately applied. Specific to pathology is the issue of laboratory benefits management programs, which dictate or limit health care provider decision-making in the use of clinical laboratory/pathology services. For well-established clinical laboratory/pathology testing, the CAP believes such programs pose an unnecessary and counterproductive procedural encumbrance upon the practice of medicine with the potential to improperly limit medically necessary testing. Laboratory benefits management programs and other prior authorization protocols should be transparently based upon peer-reviewed, published evidence, with routine and timely updates based upon accepted standards of medical practice, amenable to prompt overrides based on the medical judgment of the physician, and prohibited from facilitating business conduct adversely impacting claims of a pathology/laboratory provider acting on a lawful order for services from a health care provider. In any context, clinical decisions undertaken by prior authorization programs or protocols should be administered by providers who are at least as qualified as the prescribing/ordering physician whose decision-making is subject to utilization review. The CAP urges CMS to limit prior authorization requirements to those novel and emerging tests and services where they may be needed most, and to streamline prior authorization processes, including in Medicare Advantage plans, to help ensure unimpeded access to medically necessary services and care. Additionally, we strongly urge CMS to incorporate appropriate protections ensuring health carriers cannot deny or reduce reimbursement for pre-authorized health care services after they have been completed. Especially for pathologists and clinical laboratories who often render health care services at the request of an exempt ordering provider, it is critical to ensure plans cannot retroactively deny coverage after provision of services, thereby adding administrative burdens or payment reductions for physicians, and ultimately harming patient care. Finally, we also encourage CMS to prohibit Medicare Advantage plans from denying a prior authorization request on the basis of the date of service: this is not compatible with how lab tests are used to guide patient care. Under Medicare, the “date of service” is the date of specimen collection, which often is earlier

than when the laboratory receives the specimen for testing. If a health care provider does not get prior authorization before ordering the test or before the date that the sample is collected, the laboratory will attempt to get prior authorization once it receives the order. However, this frequently results in a denial because the "date of service" has passed, creating an unnecessary burden of appeal for all parties involved. Instead, prior authorization requests for clinical diagnostic laboratory tests should be accepted at any time during which a timely claim for reimbursement can be submitted, and requests should not be denied because they were made after the "date of service." The laboratory date of service should not be misused as a reason to deny coverage or restrict access to appropriate services.

The Protecting Access to Medicare Act (PAMA) – the CAP seeks to minimize disruption to the laboratory community and ensure the ongoing provision of laboratory services to Medicare beneficiaries. However, the CAP and many other stakeholder groups have identified data reporting requirements that have resulted in an inappropriate skewing of the PAMA payment rates to reflect disproportionate weighting of large commercial clinical laboratories. We remain concerned about the impact this will have on availability of quality patient care through access to medically necessary laboratory testing. Thus, we urge CMS to maintain current CLFS rates in 2026, using flexibility in the statute to hold off the further reductions of up to 15 percent on 800 tests scheduled to begin January 1, 2026. Rates should not be reduced until at least after the next data collection and data reporting cycle. Additionally, CMS should change the applicable PAMA data collection period from January 1 – June 30, 2019, to January 1 – June 30, 2025. Using 2019 data to set today's rates will only exacerbate existing payment rate issues. Finally, CMS should conduct an education campaign to ensure that all applicable laboratories (physician office, hospital outreach, and independent) know about and understand their obligations under PAMA to report information to CMS for purposes of rate-setting.

Topic 2: Opportunities to Reduce Burden of Reporting and Documentation

2A. What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?

Audit requirements for MIPS Improvement Activities – as noted above, the College of American Pathologists (CAP) believes the MIPS program includes both the stated burden of reporting requirements and unstated burdens that are mandated to participate in the program but do not increase quality improvement or MIPS scores. A notable example of this is the audit requirements for Improvement Activities (IAs). While the CAP recognizes the value of true, accurate, and complete data particularly in the Quality category, IAs have a fundamentally different structure and only require attestation rather than ratio and case count-type data submission. Auditing an attestation-based activity is by its nature a subjective exercise and the arbitrary nature of such an audit leads to confusion on the part of participants. Because each practice can interpret a given IA differently, there is no way to standardize the audit

requirements. Therefore, we suggest the rescission of 42 CFR § 414.1400(b)(3)(v)(B) and replacement with a requirement only to audit the Quality category.

Alternative Payment Models – although the intention of the QPP was to eventually transition all clinicians to value-based care arrangements, ongoing changes and barriers to participation in Alternative Payment Models (APMs) are impeding this process. A notable barrier is CMS' decision to establish separate data intake mechanisms for each model constructed by the Center for Medicare and Medicaid Innovation Center (CMMI). This not only increases effort and time for CMMI's to roll out a new model, it also forces participants to access and learn a new system in order to transition from MIPS into an APM, which represents a significant outlay of administrative and IT resources. Instead, we suggest allowing qualified APM participants to report quality measures and data elements via existing registries rather than restricting reporting to custom-built CMS solutions unique to each APM. Registries, including QCDRs, have extensive experience supporting physician groups in extracting data and have the most current data integration mechanisms. Given this and their subject matter expertise, registries are best placed to assist physician groups, a fact which CMS recognizes for the MIPS program but not for APMs. This would also eliminate the redundant effort on the part of CMS.

NCCI coding guidance – the CAP is concerned with coding guidance provided in the National Correct Coding Initiative (NCCI) Policy Manual that is inconsistent with the American Medical Association (AMA) Current Procedural Terminology (CPT) code set for laboratory services. Addressing these inconsistencies, by removing from these Manuals and other related NCCI methodologies (i.e. MUE and PTP edits) information that contradicts AMA CPT coding structure or guidance, would reduce the burden on laboratory providers, and address ongoing compliance issues and reimbursement denials for clinical laboratories and other medical service providers. We urge CMS to resolve this conflict and ensure that laboratories are able to code claims consistently and correctly, and be reimbursed appropriately for medically necessary services.

2B. Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers?

The College of American Pathologists (CAP) also suggests that in order to reduce the complexity of MIPS reporting, some activities in the program should be counted for multiple performance categories. Many clinical actions improve both quality and efficiency (e.g. value metrics) or quality and clinical practice improvements. Therefore, CMS should implement mechanisms by which stakeholders can nominate activities to gain cross-category credit, such as both Quality and Improvement Activities.

Topic 3: Identification of Duplicative Requirements

3A. Which specific Medicare requirements or processes do you consider duplicative, either within the program itself, or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)?

Price transparency – The College of American Pathologists (CAP) believes strongly that patients must be able to make informed decisions about their health care, which includes having access to price information. However, we have concerns with overlapping requirements and increasing complexity around the provision of price information and good faith estimates for pathology services. In addition to risk for patient harm from any delays, there is significant – and particular – difficulty in determining the cost of pathology services in advance. For instance, a surgical or invasive diagnostic procedure performed by a dermatologist, surgeon, gastroenterologist, urologist, or other clinician may result in no specimens obtained or it may result in one or multiple specimens requiring evaluation. Additionally, anatomic pathology services typically involve a pathologist performing microscopic examination of tissues or body fluids to determine whether cancer or other disease is present and, if so, its characteristics. The type of specimen(s) or complexity of required analysis is often not known in advance of the initial microscopic examination conducted by the pathologist, and in fact often precedes the patient's surgical procedure, precluding a reliable estimate of charges or costs. It is in this setting of multiple levels of complexity that pathologists are potentially asked to provide a good faith estimate of costs, and in which we in turn are in need of guidance how to advise them. The CAP has been continually engaged with CMS on this issue, including a March 22, 2022 meeting, an April 2022 follow-up letter, an October 12, 2022 listening session at which we provided additional details from the co-provider perspective, and November 2022 formal comments. We urge CMS to continue to work with us to determine how to best include pathologists in the good faith estimate process and other price transparency requirements.

Topic 4: Additional Recommendations

4A. We welcome any other suggestions or recommendations for deregulating or reducing the administrative burden on healthcare providers and suppliers that participate in the Medicare program.

The College of American Pathologists (CAP) offers recommendations related to the Clinical Laboratory Improvement Amendments (CLIA). Since inception of CLIA, the quality of laboratory testing has improved with the changes in technology. The CLIA statute provides an important foundation to help ensure the accuracy and reliability of clinical laboratory medicine. The notice-and-comment rulemaking process is vital to enable interaction with the laboratory community and provide more timely updates to accommodate today's medical practice. We

value the opportunity to work with CMS and the laboratory and health care communities to help ensure the practice of high-quality pathology medicine.

In the context of this RFI, the CAP recommends rescinding specific provisions that CMS finalized in the December 28, 2023, final rulemaking entitled "CLIA Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories" (848 FR 89976). The CAP believes – consistent with CMS' request – that specific provisions within the final rulemaking (listed below) posed "unnecessary administrative burdens and costs" and unintended consequences to CLIA-certified laboratories. CMS should rescind specific provisions – some of which resulted in dramatic changes, as well as unintended consequences. Given the stresses that clinical laboratories are facing with escalating costs and shortages of skilled professionals, rescinding some of the regulatory changes will help attain CMS' goal of avoiding regulatory burdens that "divert resources from patient care, contribute to inefficiencies, and can create financial strain on providers." The CAP recommends that these sections of the regulations revert to the version that was effective on December 27, 2024 (prior to the final rule going into effect):

- §493.1405(b)(2)(ii)(A) Standard; Laboratory director qualifications for laboratories performing moderate complexity testing
- § 493.1443 Standard; Laboratory director qualifications" for laboratories performing high complexity testing.
- § 493.1449(d) Standard; Technical supervisor qualifications for Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology in laboratories performing high complexity testing.

For the change made at §493.1405(b)(2)(ii)(A), the previous regulation (which was in place since 1993) recognized that licensed physicians have the requisite 20 continuing education hours in laboratory practice because of their medical training. To that end, the CAP believes the changes made to this provision are unnecessary and would cause an undue burden and cost to clinical laboratories.

Regarding the changes made at § 493.1443, we appreciate CMS' effort to align the CLIA regulations among doctorate-level degrees, but as CMS acknowledged in the final rule publication, pathologists are different due to their training as physicians. We remain concerned about the inclusion of the Doctor of Clinical Laboratory Science (DCLS) degree to qualify for high-complexity laboratory director positions and urge CMS to reconsider this allowance. Because DCLS programs are relatively new (beginning in 2014-2019), the CAP is concerned that the academic standards are still evolving and insufficient to determine whether graduates can serve as directors of high-complexity laboratories. CMS chose to recognize the DCLS degree relatively early in the degree's development process. Few DCLS programs exist. Accreditation of these programs and board certification are in development along with consideration given to state licensure requirements. Individuals who obtain this degree may not

consult with clinicians about complex medical diagnoses. The training is not comparable to the standards for others that qualify to be a laboratory director. We believe that additional information and evaluation of the practical, on-site, in-laboratory component of DCLS training programs, as well as the demographics, performance data, and placement experiences of DCLS graduates are required. As practicing physicians, pathologists apply expert medical knowledge, judgment, and experience to clinical laboratory tests results, examinations of anatomic pathology specimens, a patient's medical history, and other relevant clinical information. Pathologists prepare a diagnostic report and/or recommendation to guide and inform the management, treatment, or prevention of disease for a specific patient or determination of medical findings for decedents. The CAP supports the advancement of clinical laboratory professionals in the field of laboratory science, and we look forward to learning more about the technical, clinical, and leadership roles that DCLS graduates assume as their numbers and types of experiences continue to grow.

For § 493.1449(d), the December 2023 rule change lowered the technical supervisor (TS) requirements for immunohematology. The regulation in place on December 27, 2023, required that the TS for immunohematology be a doctor of medicine or osteopathy. CMS cited the need to change this requirement because fulfilling the competency assessment requirements (for example, direct observation) can be challenging in rural facilities as the TS may not be onsite as the individual(s) may cover a large geographic area. The CAP strongly opposes the removal of physicians from the role of TS for immunohematology and believes it would constitute a risk to public health and individuals served the clinical laboratory. This field is evolving into emerging uses and hazards of therapies in the field of transfusion medicine (e.g., cellular therapy), which require the expertise of a physician to oversee.

The CAP also recommends rescinding the cytology proficiency testing (PT) program (42 CFR 493.855) and replacing it with a requirement for participation in accredited education. CLIA statute required that the HHS Secretary establish "national standards for quality assurance (QA) in cytology services" (42 USC 263a(f)(4)). When CMS enacted the CLIA regulations in 1992, CMS implemented the cytology QA program as an annual requirement that individuals who interpret pap smears in CLIA laboratories undergo PT. This is the only CLIA requirement that applies PT standards to the laboratory professional, rather than the validity of the test. Requiring individuals to take tests every year is burdensome and not what Congress intended. Pathologists and cytotechnologists acknowledge the value of cooperative interaction for the interpretation of difficult cytology slides. Educational programs encourage this approach, but individual PT testing requirements are not based on this approach. The CAP would be pleased to work with CMS and other medical and cytology organizations to develop national standards for QA in cytology services to replace the cytology PT requirement in current regulations.