COLLEGE of AMERICAN PATHOLOGISTS

To: The Trump Presidential Transition Team and 119th Congress
From: College of American Pathologists (CAP)
Date: January 21, 2025
Re: First 100 Days Success and Ongoing Priority Issues for Pathologists

On behalf of the members of the College of American Pathologists (CAP), we congratulate President Donald J. Trump on his victory in the 2024 presidential election and welcome the members of the 119th Congress. 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. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists deliver high quality diagnostic services to patients and other physicians. For almost 80 years, the CAP has been the advocate for pathologists, patients, and the public when it comes to improving laboratory quality and assuring that patients receive the right test, at the right time, and with the right result.

We look forward to working with the Trump Administration and 119th Congress to improve our nation's health by addressing six important policy and regulatory issues impacting the delivery of high-quality diagnostic services to patients. The CAP would like to work with the Administration and Congress to enhance the nation's health care system by quickly and comprehensively addressing these priorities in the months ahead:

1. **Streamline Laboratory Regulations and Reduce Administrative Burden**
   Rescind the Food and Drug Administration's arbitrary and capricious Final Rule on Laboratory Developed Tests (LDTs) and ensure patient access to critical diagnostic tests using a risk-based regulatory framework for LDTs and focused updates to existing regulations.

2. **Ensure Sustainable, Appropriate Reimbursement for Pathology and Laboratory Services**
   Stabilize the Medicare payment system to protect patient access to essential pathology services and mitigate cuts that threaten laboratory operations.

3. **Strengthen the Pathology and Laboratory Workforce**
   Address critical workforce shortages by expanding physician training programs and the number of federally-supported training slots for pathologists to meet growing patient care demands and the health care needs of an aging population. Options for federal action could also include increasing the number of training programs for laboratory medical technologists and histotechnologists,

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encouraging individuals to train for in-demand laboratory positions by offering financial support such as tuition or loan relief, and raising awareness of laboratory medicine as a career opportunity and highlighting the importance of laboratory workers in providing health care.

4. **Increase Competition and Oversight in Private Payor Health Insurance**
   Promote fair insurance practices by ensuring network adequacy, prohibiting anticompetitive contracts, and supporting locally coordinated care.

5. **Finalize Protections Around Surprise Billing and Price Transparency**
   Streamline billing dispute processes and implement good faith estimate requirements to protect patients and ensure fair physician reimbursement.

6. **Ensure Appropriate Regulation of Artificial Intelligence**
   Support innovation and patient safety in laboratory AI applications while maintaining the critical leadership role of pathologists in clinical decision-making.

Each of these priorities is described in more detail below. We look forward to following up with you at the start of your term and the new Congress to address these issues and learn more about how we can support advancing a productive healthcare policy agenda.

1. STREAMLINE LABORATORY REGULATIONS & REDUCE ADMINISTRATIVE BURDEN

The CAP's highest priority concern is to rescind the FDA's proposed regulation of laboratory-developed tests (LDTs). We have many concerns about the final FDA rule, most importantly because of its impact on patient access to critically important diagnostic tests. We are also concerned about the timeline for implementation and the unsustainable costs that will hinder the development of LDTs. Pathologists and laboratories fear these regulatory restrictions from the FDA will make it difficult for laboratories to continue to develop and provide LDTs and, thus, would impair and delay the diagnosis of disease and treatment of patients.

The CAP's position on LDTs is guided by what is in the best interest of patients. The CAP and many patient advocates strongly support FDA oversight of some LDTs. Oversight is necessary because of medical decisions being made based on the results of LDTs, as well as the risks associated with some extraordinarily complex LDTs, the quality of which is difficult to independently verify. For more than a decade, the CAP has advocated for the adoption of a new statutory framework for LDT regulation that would enhance patient safety, maintain quality laboratory testing, and promote innovation without creating unnecessary regulatory burdens on pathologists, clinical

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laboratories, and other professionals involved in laboratory testing. Most recently, the CAP supported proposed legislation, the Verifying Accurate Leading-edge IVCT Development Act of 2023, the VALID Act, which would create a three-tiered risk-based system, expressly authorizing FDA to fully regulate the highest-risk LDTs, while leveraging existing structures to improve and promote patient safety with all other LDTs.

The CAP has opposed proposals that would vest the CMS with exclusive jurisdiction over LDTs. CMS oversees laboratories under the *Clinical Laboratory Improvement Amendments of 1988* (CLIA). However, CLIA does not regulate the scientific principles behind, or the clinical validity of, laboratory tests and the CMS does not have the expertise to ensure these tests work clinically. Rather than expanding CMS's oversight under CLIA, the CAP believes that a proper framework for LDT regulation would allocate authority between the agencies. This approach would leverage FDA's expertise in ensuring the effectiveness and safety of highly complex tests and CMS's expertise in overseeing general laboratory operations.

CLIA needs periodic, focused regulatory updates to keep pace with recent technology – not a broad, disruptive legislative overhaul that would threaten patient access to clinical laboratory tests. Reopening CLIA legislatively could have far-reaching and unintended consequences that could undermine the framework under which all clinical laboratory testing is done in the U.S. CLIA "modernization" legislation could have a disastrous effect on community laboratories and those serving rural areas where new unfunded mandates and regulatory burdens could threaten to close laboratories.

The CAP recommends the following:

- Rescind the current FDA Final Rule to regulate all LDTs and work with Congress to establish a risk-based FDA regulatory framework for highly complex LDTs to ensure the availability of safe and effective tests, and
- Retain current CLIA statute, which ensures the continuity and quality of clinical laboratory medicine practice, and continue issuing focused, targeted regulatory updates to CLIA to enable laboratory practice to keep pace with current technology.

2. ENSURE SUSTAINABLE, APPROPRIATE REIMBURSEMENT FOR PATHOLOGY AND LABORATORY SERVICES

The CAP requests the Trump Administration and Congress begin the process of stabilizing the Medicare payment system. More specifically, the CAP urges the Administration to: (1) provide an inflationary update to the Medicare Physician Fee Schedule (MPFS) by amending Title XVIII of the Social Security Act to provide for an inflationary update to the MPFS that is based on the Medicare economic index; (2)

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work with Congress to pass legislation to eliminate, revise, or replace the MPFS' budget neutrality requirements in Medicare; (3) mitigate the impact of the projected 2.83% cut to the MPFS conversion factor in 2025; and (4) stop the payment cuts in the Medicare Clinical Laboratory Fee Schedule (MCLFS) mandated by the *Protecting Access to Medicare Act* (PAMA).

Since enactment of PAMA, 72 percent of tests on the CLFS have faced payment cuts. Collectively, these cuts threaten access to laboratory services for diagnosing and treating seniors with a wide range of conditions, including diabetes, heart disease, liver disease, kidney disease, cancer, anemia, viral and bacterial infections, and opioid dependency, among others. Additional cuts would weaken the clinical laboratory infrastructure, making it more difficult to deliver routine health care and respond to the inevitable next public health crisis.

The CAP recommends the following:

- Provide an inflationary update to the Medicare Physician Fee Schedule (MPFS) by amending Title XVIII of the Social Security Act to provide for an inflationary update to the MPFS that is based on the Medicare economic index,
- Work with Congress to pass legislation to eliminate, revise, or replace the MPFS' budget neutrality requirements in Medicare,
- Mitigate the impact of the projected 2.83% cut to the MPFS conversion factor in 2025, and
- Work with Congress to pass legislation to stop the CLFS payment cuts from the implementation of PAMA and implement an appropriate inflationary update process to stabilize Medicare's CLFS payment rates.

In addition to the above, we request that the Administration and Congress preserve the current procedural terminology (CPT) and relative value update committee processes. The MPFS is comprised of discrete activities and services that are currently well suited to support the entire house of medicine. There are two professional volunteer processes, organized by the American Medical Association (AMA), which require involvement by the entire physician community and must remain unaltered by Congress and the Administration.

First, health care services performed by physicians and nonphysician providers are continuously reviewed and updated by the AMA's Current Procedural Terminology (CPT) Editorial Panel. The CPT Editorial Panel provides a uniform process for the coding of medical services. It streamlines reporting and increases accuracy and efficiency throughout our healthcare systems. Since 1966, physicians and other health care professionals have relied on CPT to communicate with colleagues, patients, hospitals, and insurers about the procedures and services they have performed. This system of terminology is the most widely accepted medical nomenclature used to

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report medical procedures and services under public and private health insurance programs. CPT is also used for administrative management purposes such as claims processing and developing guidelines for medical care review and is recognized by the federal government as a HIPAA mandated code set. The CPT processes are open to the public and highly transparent. Anyone can request a new code, attend the meetings held three times a year, and contribute to the process of updating the medical terminology.

If a physician service is under-reimbursed or non-reimbursed on the MPFS, there are well-run processes in place to propose new codes and revise existing ones for reimbursement. The start is through the non-government funded CPT Editorial process so that the service or procedure is accurately codified. Next there are processes in place, discussed below, to assure that the incremental work that each provider contributes is appropriately reimbursed with an eye on potential waste and inappropriate use. Representatives from the CMS are highly involved with each step in the process, with significant participation at the CPT Editorial Panel meetings and in their processes. These highly qualified CMS representatives provide helpful insights and recommendations, and make decisions that assist in the overall coding, payment, and policy regulation that governs our health care system.

Second, when Medicare transitioned to a physician payment system based on the resource-based relative value scale (RBRVS), the AMA, anticipating the effects of this change, formulated a multi-specialty committee. This committee, known as the AMA/Specialty Society RVS Update Committee (RUC), provides the whole of medicine a powerful voice in describing the resources required to provide physician services. The RUC is an independent entity, composed of volunteer physicians and staffed and funded by the AMA, national medical specialty societies and other health care professional organizations. The RUC's recommendations are provided free of charge to the U.S. government.

Since 1991 the RUC has submitted numerous recommendations to the CMS that enhance the underlying data used to create relative values units (RVUs). The RUC, in conjunction with the CPT Editorial Panel, has created a process where physicians can develop relative value recommendations for new, revised, and potentially misvalued codes as well as update RVUs to reflect changes in medical practice. The RUC's annual cycle for developing recommendations is closely coordinated with both the CPT Editorial Panel's schedule for annual code revisions and CMS's schedule for annual updates in the Medicare Payment Schedule. The CPT Editorial Panel meets three times a year to consider coding changes for the next year's edition. The RUC meets soon after the CPT Editorial Panel meetings to consider the relative value of codes that are changed or added by the Editorial Panel. CMS publishes the annual update to the Medicare RVS in the Federal Register every year, at about the same

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time the AMA publishes the new CPT book for the coming year. The updated CPT codes and relative values go into effect annually on January 1. Due to the close coordination between RUC and CPT and the timely submission of recommendations to CMS, physicians have the benefit of organized medicine's input into relative values for new codes in the same year that the coding changes appear in CPT.

Through its unique structure, the RUC has created the best possible resource for physician payment determination: physicians. It is the work of these dedicated physicians who contribute their time, energy and knowledge that make the RUC process a success that benefits all practicing physicians and care delivery throughout our health care system.

The CAP recommends the following:

- Allow the AMA CPT and RUC processes to continue to assist HHS and CMS as they do now and not impede or interfere with any additional governmental action.

In addition, the CAP requests that the Administration and Congress work with the CAP and other physician groups to stabilize the Medicare physician payment system and related quality programs. The *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) was originally passed to end a cycle of Medicare payment cuts and reward value-based care. However, 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. The Medicare Payment Advisory Commission (MedPAC) has questioned the value of the Merit-based Incentive Payment System (MIPS) program due to its design and measurement methods. Indeed, the Government Accountability Office's (GAO) 2021 report on provider performance and experiences under the MIPS described many of the challenges physicians experience, 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. Unfortunately, both the MIPS and MVP quality programs continue to pose challenges. Furthermore, the proposed upsides of MIPS participation have not materialized even for the highest performers. The cost and burden of MIPS participation has been higher than anticipated and likely significantly outweigh any marginal improvement in quality. Most concerning, uncertainty remains about whether scores on MIPS quality measures actually represent improvements in outcomes for patients. While alternative payment models (APMs) have potential to reduce burden, the current structure of APMs significantly incentivizes participation by multi-specialty practices, especially large

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health systems. It is unclear how single-specialty community-based practices can participate in APMs. Since consolidation of physician practices appears to drive higher prices, ensuring that independent practices are valued in APMs is critical. Incentives must recognize that high quality care is provided in both rural and urban areas, as well as large and small practices. Overall, the burden of data entry and other administrative requirements continues to impede the effectiveness of MACRA instead of improving care for patients.

The CAP recommends the following:

- Reduce administrative burden on clinicians while maintaining stable payment systems during the transition to value-based care, and
- Embolden the role of the Physician-Focused Payment Model Technical Advisory Committee to ensure that decisions about services and care, including in value-based care models, are made by clinicians, not administrators.

3. STRENGTHEN THE PATHOLOGY WORKFORCE

The demand for trained pathologists continues to far exceed the supply provided by the existing number of residency positions. Data from the CAP's 2021 Practice Leader Survey suggests a nationwide need of at least 1,000-1,200 pathologists to fill open employment positions in recent years. In 2023, only 30% of pathology practice leaders who were seeking to hire one or more pathologists reported that they expected to fill all open positions. CMS has not done enough to address the issue of physician shortage.

Pathologists drive patient care decisions. When other physicians need more information about a patient's disease, they turn to pathologists to provide specific diagnoses and/or consultations for each patient. The critical importance of timely and accurate pathological diagnosis is recognized throughout the care continuum. Pathologists are professionally responsible and legally accountable for the laboratory results upon which most patient care relies. Pathologists serve as laboratory directors, ensuring compliance with all laboratory, regulatory, and accreditation standards. The influence of pathologists' services on clinical decision-making is pervasive and constitutes the critical foundation for appropriate patient care. The CAP urges the CMS to create opportunities and incentives for the pathologist workforce to expand as needed to meet population growth and aging.

Older adult patients require higher levels of care due to greater incidence of chronic disease. As the US population ages, this will increase the demand for physician services on a smaller pool of available physicians. Therefore, it is imperative to grow the physician workforce. The Association of American Medical Colleges (AAMC) is

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projecting that the U.S. will face a shortage of up to 124,000 physicians by 2034. Section 4122 of the Consolidated Appropriations Act of 2023 requires the distribution of an additional 200 Medicare-funded residency positions to train physicians. The law requires CMS to notify hospitals receiving residency positions under section 4122 by January 31, 2026.

While we understand that the statute requires that half of the additional residency positions are dedicated to psychiatry and its subspecialties, the CAP is concerned that specialties such as pathology are experiencing significant workforce shortages that need to be addressed, especially in rural areas. The pathology workforce is not keeping pace with patient growth and population changes.

The CAP recommends the following:

- Invest a portion of the federal investment in physician training programs to the specialty of pathology, especially necessary in rural and under-served areas. Specifically, the Resident Physician Shortage Reduction Act would provide 14,000 new Medicare-supported GME positions over seven years. While this would not be enough to remedy the full physician shortage, it is a critical step in the right direction.
- Legislation to incentivize international medical graduates to practice in the US, such as the Conrad State 30 and Physician Access Reauthorization Act, would also help address the problem by enabling more qualified non-US citizens to practice in underserved communities.

4. INCREASE COMPETITION AND ENFORCEMENT IN PRIVATE HEALTH INSURANCE

Private health insurance is a critical component of our health care system, with nearly two-thirds of the country's population covered by private health insurance. However, insurers are increasingly relying on inadequate networks of contracted physicians, hospitals, and other providers, which can disrupt care coordination, add burdens, and lead to lower quality care. This is a particular concern for the most vulnerable patient populations, including those with low income and/or chronic conditions. In fact, these kinds of requirements prevent the local pathologist from participating in care coordination at the time of initial diagnosis or correlating these critical initial findings with subsequent surgical specimens obtained in the hospital.

The CAP is committed to improving care and addressing health care costs, but disrupting care coordination can negatively affect a patient's timely diagnosis, treatment, and outcome.

The CAP recommends the following:

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- Implement network adequacy requirements that mandate adequate numbers of in-network hospital-based physicians, such as pathologists, and that ensure meaningful, competitive contracts to protect local care,
- Enact prohibitions on the use of tiered and narrow physician networks that deny patient access to, or attempt to steer patients toward, certain physicians/facilities based primarily on cost of care factors,
- Restrict anticompetitive "exclusive" or "preferred" contracts that are in opposition to local, coordinated care in the patient's community, and
- Strengthen enforcement of requirements that manage insurer interference and continue to support the physician-led health care team.

5. FINALIZE PROTECTIONS AROUND SURPRISE BILLING AND PRICE TRANSPARENCY

The CAP continues to strongly support the protections that keep patients out of the middle of billing disputes. However, as we have previously explained, our members have reported significant difficulties in resolving payment disputes for certain out-of-network services since the launch of the federal independent dispute resolution (IDR) portal. From the burdensome open negotiation process to the large number of disputes still awaiting payment determinations, the IDR process has been fraught with interruptions, complications, misuse, and confusion.

The Trump Administration has an opportunity to finalize regulations that will implement new disclosure requirements, centralize the open negotiations process, increase flexibility around batching, and promote equitable access to IDR for low-dollar disputes. These changes will ensure important clarification and consistency while ensuring all physicians can appropriately access the federal IDR process and receive fair reimbursement for their out-of-network services.

Additionally, the CAP has been continually engaged in the implementation of the good faith estimate (GFE) requirements for uninsured or self-pay patients. Still, despite additional guidance and education, our members continue to express concerns and confusion about how to comply with these requirements.

As the Trump Administration moves forward with implementation of the *No Surprises Act*, we wish to stress that the requirements for GFEs for covered individuals (1) add further administrative burden and increased complexity, (2) present potential for misuse by insurers, and (3) are a threat to patient access to, and quality of, care. We urge the Trump Administration to work with us, engage other provider stakeholders, and gradually and carefully implement the additional requirements with maximum flexibility.

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The CAP recommends the following:

- Finalize IDR regulations that will implement new disclosure requirements, centralize the open negotiations process, increase flexibility around batching, and promote equitable access to independent dispute resolution for low-dollar disputes; and
- Work with the CAP and other provider stakeholders to implement the good faith estimate requirements with maximum flexibility.

6. ENSURE APPROPRIATE REGULATION OF ARTIFICIAL INTELLIGENCE

Artificial Intelligence (AI) may present both significant opportunities and substantial, evolving challenges for the field of pathology and has the potential to affect the way pathologists practice medicine. Pathologists are critical thought leaders with special expertise in laboratory operation and have responsibility for the selection, analytic verification or validation, clinical validation, integration, and performance monitoring of laboratory tests. The expansion of pathologists' responsibilities to include AI will constitute an important new element in pathologists' role as CLIA laboratory directors and section directors. The CAP supports and encourages the professional and critical role of pathologists in the development, implementation, and maintenance of AI systems within the laboratory.

The CAP recommends the following:

- Ensure that federal regulations on AI are reasonable and not overly burdensome from a laboratory perspective, prioritize patient safety, ensure clinical validity, allow innovation, and preserve the role of pathologists as physicians and advocates for patients.
- Review any new regulatory requirements to ensure they are not duplicative with existing regulations and do not infringe on the practice of medicine.
- Recognize the leadership role that pathologists must have in the selection, configuration, deployment, application, and monitoring of AI systems involved in the pre-analytical, analytical and post-analytical phases of laboratory workflow.

SUMMARY & NEXT STEPS

We appreciate your considerations of these priority items and look forward to a strong partnership with you as we advance America's health. We believe a meeting with our pathologist leadership and key members of your new health policy team would be a critical next step in assuring these items are considered in your first 100 days in office. We look forward to coordinating this meeting at your earliest convenience.

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Senate and House Leadership
Chairman and Ranking Member, Senate Finance
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