COLLEGE of AMERICAN PATHOLOGISTS

August 27, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman DeGette and Congressman Upton:

The College of American Pathologists (CAP) is pleased to provide feedback on the Cures 2.0 legislative discussion draft. 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. Further, pathologists are on the frontline of the current COVID-19 crisis, responsible for developing and selecting new test methodologies, validating and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs. Now more than ever, patients and their treating physicians rely on the expertise of pathologists and the availability of appropriate testing.

The discussion draft outlines many areas that the CAP supports, including improvements to the vaccine and immunization programs, increasing diversity in clinical trials, support for developing antimicrobial innovations, a national testing strategy, and additional funding for independent research institutions, public laboratories and universities. Additionally, there are areas of the discussion draft that the CAP has concerns that will be elaborated upon below.

National Testing and Response Strategy for Current and Future Pandemics

As is noted in the discussion draft and evident in today's COVID-19 response, much more is to be done to improve our nation's surveillance and testing capabilities to support the U.S. response to this and future pandemics. The supply chain has been fragile throughout the COVID-19 pandemic. There needs to be a comprehensive strategy that includes testing supplies, test kits, plastic pipette tips, specimen acquisition swabs, and transport media. The CAP appreciates that the Cures 2.0 draft includes provisions that address these critical issues. A comprehensive strategy should allow for regulatory flexibility, quick development of and appropriate pricing and coverage for diagnostic testing, and funds to support testing services and laboratory frontline providers.

During a public health emergency, a swift process for relaxation of Clinical Laboratory Improvement Amendments (CLIA) restrictions will allow laboratories the necessary discretion to determine what is best for their staffs to manage the pandemic. Laboratories sought to employ appropriate protocols to reduce the risk of infection among their own teams and to avoid hindering their ability to test and treat patients. The CAP specifically requested a temporary waiver of CLIA requirements so pathologists and other licensed health care professionals could utilize remote review and sign out.[1]

[1] https://documents.cap.org/documents/cap-hhs-coronavirus-laboratories-regulations.pdf

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100

Further, the CAP requested that the Centers for Medicare and Medicaid Services (CMS) postpone inspections of accredited laboratories, which would allow personnel to devote the necessary time to fully verify and validate new coronavirus testing assays and redesign operations to accommodate emerging technologies and testing. We are pleased that both these issues were addressed, but they may not have been were it not for the CAP and congressional appeals.

Moreover, given the high infectivity of COVID-19 and to meet the demand for testing of symptomatic patients, clinical laboratories established specimen collection drive-through testing locations. While we welcomed the CMS providing flexibility for on-site locations, the waiver was granted on March 26, 2020 – two weeks after the national emergency declaration, delaying critical testing. Importantly, while we support efforts to streamline administrative procedures for personnel, the CAP strongly believes the current CLIA personnel requirements for testing should be maintained.

In addition, appropriate processes and infrastructure should be in place to ensure that patients have timely access to diagnostic testing and laboratories must have the resources and support their need for testing. Specifically, this should include quick deployment of the emergency use of laboratory developed tests (LDTs), adequate pricing for diagnostic testing, full coverage of diagnostic testing, and the presence of a reporting infrastructure. While the Food and Drug Administration (FDA) and the CMS[2] have made recent improvements in this area, initial delays and shortcomings continue to affect the prevalence of testing in the United States.

For example, the payment rates for COVID-19 diagnostic testing (HCPCS codes U0001 and U0002) were set by the CMS without the understanding of the significant costs for the tests, and the Medicare Administrative Contractors (MACs) did not provide any methodology used to establish reimbursement rates. Based on our review of costs from our members providing or seeking to offer the tests in their laboratories, it is clear that the payment amounts set by the CMS were woefully inadequate. The cost of the reagents, supplies, and labor involved to perform one test as well as the incremental equipment and other fixed capital costs, far exceed the current MAC-reported payment amounts. Cost estimates vary greatly between laboratories, many supplies and labor. Initial inadequate reimbursement for COVID-19 – and indeed, any pandemic disease – will lead to unnecessary delays in testing and further complications. During future pandemics, the CMS must develop a highly transparent mechanism involving reimbursement including input from stakeholders such as the CAP, the American Medical Association (AMA), and laboratory stakeholders to establish adequate coding and appropriate national Medicare reimbursement of laboratory tests, medical procedures and/or services that are codified by the AMA's CPT Editorial Panel or by the CMS during future pandemics. This mechanism must establish reimbursement amounts for the newly created tests, procedures, and/or services within 30 days of CPT and/or HCPCs code creation.

Further, a national public health emergency is a situation that demands quick national coverage for a range of diagnostic testing. The CAP has requested immediate national coverage for multiplex polymerase chain reaction (PCR) respiratory viral panel (RVP) tests, which are critical for ruling in/out COVID-19 patients with other viral respiratory conditions and helping to guide immediate treatment.[3] While expanded coverage is

[2] https://www.cap.org/advocacy/latest-news-and-practice-data/april-21-2020#story4
[3] https://documents.cap.org/documents/Sign-On-Letter-to-CMS_Coverage-for-RVP-Tests_042820.pdf

immediately needed, it is also crucial to ensure laboratories are equipped moving forward to provide an appropriately comprehensive laboratory test menu as different variants of COVID-19 emerge. While some progress has been made with local carriers, the proposed revisions do not apply to COVID testing, falling short of required action to best protect patients. Outside of a national public health emergency, the CAP remains committed to improving Medicare's local coverage process, as outlined below.

Other Areas of Concern for Cures 2.0

Medicare Coverage for Precision Medicine Consultations

The CAP opposes genomic precision medicine consultations provided by a qualified clinical pharmacist. The CAP believes that the interpretation of laboratory tests constitutes the practice of medicine, for which pharmacists are not licensed. The CAP also believes that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect test result is "risk free" or inconsequential with regard to potential harm. The CAP strongly supports physician-led health care teams, since they are the most highly educated and trained health care professionals, so that each member of the team can use their specific strengths together for the benefit of the patient. The CAP strongly believes that patients' best interests require that a physician member of the team directs the course of the diagnostic and therapeutic care of the patient and that a physician determines appropriate clinical and anatomic laboratory services.

Further, pathologists direct clinical and anatomic pathology laboratory services; perform biopsies; evaluate surgical, cytology, and autopsy specimens; interpret laboratory tests; and serve as laboratory consultants to other physicians. While all laboratory and other health care professionals share an important role in providing care to patients, their skillset is not interchangeable with that of a fully trained and licensed physician. Likewise, the role of pathologists' assistants is to facilitate the practice of medicine by pathologists, but not to make diagnoses or determine treatment for patients. Those functions, defined as the practice of medicine, are the responsibility of physicians alone. The CAP urges you to reconsider allowing genomic precision medicine consultations provided by clinical pharmacists.

GAO study and report regarding enhancing Medicare Coverage and reimbursement for innovative health technologies

The CAP is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. The CAP has continually advocated for regulatory frameworks that enhance patient safety, maintain quality laboratory testing and innovation without creating a significant regulatory burden on laboratories. We have also regularly worked with the CMS on coverage issues ranging from National Coverage Determinations (NCDs) to Program Integrity Manual (PIM) updates.

Under the CMS's Proposed Rule CMS-3372-P entitled "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary', the CMS allows manufacturers to elect at any point within two years of receiving breakthrough designation to start receiving Medicare coverage for a four-year period. This ensures earlier reimbursement and patient access while preserving device manufacturers' incentive to collect additional data to prove the device is reasonable and necessary. By creating this coverage period, the CMS streamlined local coverage

determinations for innovative devices and eliminated some of the current coverage variations by Medicare Administrative Contractors (MACs). There are improvements still needed in this area. Our members have and continue to face a multitude of challenges under the current Medicare coverage paradigm. While the CAP strongly believes that the quality of care provided to Medicare beneficiaries depends on access to treatments appropriate to their needs, including new technologies, we have concerns about the creation of new coverage pathways that may undermine or circumvent the current processes. The CAP recommends that data be collected on the consistency (or inconsistency) of coverage among MACs for innovative technologies and encourages efforts to increase consistency among existing Local Coverage Determinations, where needed, for new technologies. The CAP expresses caution that innovative technologies cannot and should not replace physician medical decision making. In fact, these technologies may enhance patient care and increase rather than reduce physician work.

Further Understanding the Implications of Long COVID

While the CAP is supportive of further research and support for patients who have long-COVID, the CAP would like to highlight a concern with collecting data from patients who self-identify symptoms. This method can result in skewed data. The CAP suggests providing some filter(s) for distinguishing symptoms as COVID related vs. related to other causes or conditions. More objective data may be obtained from physicians treating (or having knowledge of) patients with long-term COIVD related symptoms.

Digital Health

The CAP appreciates the recognition of the promise of digital health technologies in modernizing health care in the United States. In some cases, pathologists currently practice medicine whereby diagnosis is achieved through digital or electronic communication technology where a physician is not in the physical presence of the patient's specimen. As such, the CAP is opposed to any legislation that would preempt or undermine state medical licensure requirements. Notwithstanding the imperatives of the current public health emergency in which state licensure laws have been of necessity waived on a temporary basis, the CAP believes pathologists interpreting specimens, slides, or images sent through interstate commerce should be licensed in the state where the patient presents for diagnosis, except for an interspecialty consultation.

Post-Approval Study Requirements for Accelerated Approval

The CAP cautions on the use of alternative data sources until clinical interoperability has been addressed. Despite technical advances and adoption of electronic health record (EHR) systems funded through CMS Promoting Interoperability Programs ("Meaningful Use" legislation), the mechanisms and standards necessary to support clinical interoperability of laboratory data remain incomplete. As a result, laboratory data generated by varying in vitro diagnostic (IVD) instruments for the same kinds of measurements cannot be intermingled or directly compared across existing EHR systems without risk of medical error and patient harm. This problem also limits the secondary use of laboratory data for public health surveillance and clinical research and may lead to inconsistent or incorrect conclusions. Foundational efforts in laboratory informatics made laboratory test result data readily machine processable but not always comparable to similar data generated by disparate laboratories with differing IVD analyzers. Unless, clinical interoperability is addressed, it will be difficult to use broader

data sources to support post-approval studies.

Summary

Pathologists are physicians who specialize in the diagnosis of disease. This includes every aspect of laboratory medicine. The expertise they provide drives treatment decisions that optimize outcomes for patients. They play an integral role in the diagnosis of diseases such as cancer, hepatitis, cirrhosis, and the novel coronavirus (COVID-19). Indeed, the current pandemic has brought to the forefront the vital role of pathologists and the value that they bring to medicine. Pathologists are integrally involved in direct mitigation of the COVID-19 crisis by providing accurate and timely diagnosis, directing every aspect of medical laboratories, as well as developing potential cures. Pathologists and the services they provide, including ensuring laboratory quality in communities across the United States, are at the foundation of our health care system. We must now strengthen that foundation further to meet the challenges of today and tomorrow.

As Congress works on further COVID-19 and Cures 2.0 legislation, we urge you to consider our recommendations, including the need for regulatory flexibility, quick development of appropriate pricing and coverage for diagnostic testing, as well as funds to support testing services and laboratory frontline providers in any comprehensive testing strategy. We also agree that modern and systemic approaches to coverage and reimbursement are needed but that payment policies should not exacerbate the financial instability of health care provider practices. Finally, the CAP urges you to reconsider allowing genomic precision medicine consultations provided by clinical pharmacists. Although clinical pharmacists play a very important role in providing care to patients, the CAP firmly believes that the interpretation of laboratory tests constitutes the practice of medicine, for which pharmacists should not be licensed.

Again, the CAP welcomes the opportunity to work with your offices on these and other identified issues to accelerate the discovery, development, and delivery of cutting-edge medicine and treatments for all Americans. Please contact Sarah Bogdan via email at sbogdan@cap.org or via phone at (401) 316-5144 if you have any questions regarding these comments.

Sincerely,

Patrick Godbey, MD, FCAP
President

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100