COLLEGE of AMERICAN PATHOLOGISTS

May 11, 2020

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 latest Cures 2.0 concept paper. 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.

Yet while clinical laboratories are expanding testing, a recent study conducted by the CAP confirms that over 60 percent of laboratory directors report difficulties in obtaining critical supplies needed to conduct COVID-19 testing. Laboratory directors also reported increased stress on pathologists and laboratory professionals as a result of reduced work hours, reductions in pay, and increased burnout, among other factors. All laboratories are facing substantial financial stresses, regardless of whether they are providing COVID-19 testing. Nearly all laboratories surveyed reported substantial losses in revenues, including the need to furlough employees in some cases.[1]

As such, we strongly agree that the battle against COVID-19 has highlighted critical areas of concern that must be addressed today for our current response efforts and for future pandemics. While we continue to urge support for areas outlined here, as you consider Cures 2.0 provisions for potential inclusion in future COVID-19 legislation, the below should be included and implemented quickly to address immediate needs.

National Testing and Response Strategy for Current and Future Pandemics

As is noted in the paper and evident in today's COVID-19 response, much must be done to improve our nation's surveillance and testing capabilities to support the U.S. response to this and future pandemics. 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. During the

[1] https://www.cap.org/news/2020/cap-survey-of-laboratories-confirms-covid-19-testing-challenges-supply-shortages-and-excess-capacity

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COVID-19 crisis, 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.[2] Further, the CAP requested the agency 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 CAP and congressional appeals.

Moreover, given the infectiousness of COVID-19 and to meet the demand for COVID-19 testing of symptomatic patients, clinical laboratories established specimen collection drive-through testing locations. While we welcomed CMS providing flexibility 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 have the resources and support to provide needed 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 reporting infrastructure. While the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS)[3] 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 CMS without access to charges for the tests, and the Medicare Administrative Contractors (MACs) have not provided any methodology used to establish their 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 – and continue to be – 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 and many supplies and clinical labor are now being reported to be in erratic and short supply.Initial inappropriate test pricing for COVID-19 – and indeed, any pandemic disease – will lead to unnecessary delays and complications.

During future pandemics, the CMS must develop a highly transparent mechanism involving rate setting, including input from stakeholders such as the American Medical Association (AMA), and laboratories to establish adequate and appropriate national Medicare pricing of laboratory tests, medical procedures and/or services that are developed by the AMA's CPT Editorial Panel or by the CMS during future pandemics. The mechanism shall establish pricing 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

[2] https://documents.cap.org/documents/cap-hhs-coronavirus-laboratories-regulations.pdf
[3] https://www.cap.org/advocacy/latest-news-and-practice-data/april-21-2020#story4

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 appropriate treatment.[4] Unfortunately, laboratories are currently absorbing the cost of performing some of these tests, compounding their already significant financial burden. Further, while expanded coverage is needed immediately, it is also crucial in ensuring laboratories are equipped moving forward to provide an appropriately comprehensive laboratory test menu, as there is growing concern among epidemiologists that COVID-19 may reemerge, as other viruses have done after their initial outbreaks. Outside of a national public health emergency, the CAP remains committed to improving Medicare's local coverage process, as outlined below.

The existing reporting infrastructure commonly requires reporting to multiple state public health locations requiring different information which also needs to be addressed. With furloughed staff, the process is becoming cumbersome for smaller labs. Currently, each state has public health reporting requirements with differing required elements. For surveillance activities, it is important to have standardized data elements reported in order to identify "hot spots" and areas of need. While the CDC and FDA are attempting to address this problem during COVID-19, a standardized approach to data element requirements and reporting are important to identifying infected patients and managing resources effectively.

Finally, the CAP continues to support the establishment of a fund up to $5 billion to support pathology and laboratory frontline providers. It should provide assistance for pathologists and laboratories performing COVID-19 testing services, such as support for laboratory personnel, uncompensated testing, capital and supplies, research and development, and other costs associated with testing. Further, while funds would address current COVID-19 needs, they will also help ensure that pathology practices and laboratories remain viable and ready to respond to future pandemics. Pathologists are critical to the ability of the United States to succeed in slowing the spread of the pandemic by ensuring accurate and safe testing for all patients.

CMS Modernization

We agree that modern and systemic approaches to coverage and reimbursement are needed to allow for new technologies and treatments to benefit patients.

Pandemics impact every sector of the health care provider community, and any payment policies that may exacerbate the financial instability of health care provider practices should proceed with caution. However, during and after the pandemic, any payment policies implemented, should do so by waiving budget neutrality requirements stipulated in Section 1848(c)(2) of the Social Security Act. Specifically, changes to evaluation and management services (E/M) effective January 2021 will result in an 8% cut to pathology payment as well as sizable cuts to critical provider specialties as a result of the current requirement for budget neutrality. Together with other specialties, we urged Congress to waive the budget neutrality requirements for the finalized E/M code proposal slated for implementation on January 1, 2021. This much-needed action by Congress would provide a critical reprieve for all physicians facing substantial payment reductions during

[4] https://documents.cap.org/documents/Sign-On-Letter-to-CMS_Coverage-for-RVP-Tests_042820.pdf

and following future pandemics.[5]

Additionally, the local coverage determination (LCD) process is a vital part of ensuring Medicare patients receive optimal care through appropriate access to services and technologies. Despite recent changes to the Program Integrity Manual, the CAP continues to seek improvement in the LCD process through increased transparency and consistency in the use of medical and scientific evidence in coverage determinations.

Importantly, while national coverage decisions are appropriate during a national public health emergency and can provide timely coverage for necessary services/treatments, other coverage decisions often restrict access to care and therefore should be made at the local level after careful consideration of regional, geographic, and population-based differences. It is also critical that there is opportunity for thoughtful discussion and timely feedback from stakeholders and advocates who have unique insight into the actual nature of local practice and the needs of local patient populations.

Specifically, the CAP has advocated for a process for providers and suppliers to appeal a MAC's reconsideration decision to the CMS, rather than limiting reconsideration to the MAC that authored the LCD. The CAP has also requested that reconsideration requirements be broadened to include reasonable assertions that the MAC's conclusion misinterpreted existing evidence, as is currently allowed with national coverage determinations (NCD). We have seen how coverage decisions ignore medical evidence and Medicare program requirements. One local Medicare decision, for example, established an arbitrary utilization threshold for tests to evaluate chronic gastritis, which is associated with increased risks of ulcers and gastric lymphoma.[6] Yet it remains the case that, without new evidence, LCDs are functionally unreviewable once they become final, and that there is no independent review process.

Additionally, the CAP has argued that widespread adoption of replicated LCDs by MACs constitutes an evasion of the requirements of the more rigorous NCD process. The CAP continues to seek a solution that would prohibit a MAC from replicating LCD determinations without following in both form and substance the specified process for LCD development in its jurisdiction(s).

Finally, as the Program Integrity Manual changes have been implemented, the CAP has noticed several areas that could benefit from continued improvement. Most importantly, while the recent changes have made CAC meetings more transparent, they also have resulted in a decreasing – or even elimination – of these important meetings, as MACs now have the discretion to determine the frequency of the CAC meetings. CAC meetings are a vital opportunity for physician experts to provide advice and comment to Medicare contractors on coverage policies as they are being developed. The CAC also acts as a liaison in representing the opinions of the profession in the development of LCDs. We have communicated these concerns to CMS (https://documents.cap.org/documents/cap-letter-to-cms-jan-2020.pdf) and would urge you to work with us on ways to ensure this important opportunity for stakeholder input continues.

Support Funding to States for Medical Examiner Services

The CAP urges Congress to provide funding to assist state and local medical examiner

[5] https://documents.cap.org/documents/E.M-Position-Overview_Various-Provider-Types.AprilV2.4-17.FINAL.pdf
[6] https://www.statnews.com/2018/06/27/medicare-local-coverage-reform/

and coroner offices to support the COVID-19 related diagnostic services provided by forensic pathologists. Pathologists serve a unique role as medical examiners documenting the spread of disease through society. There is a severe shortage of forensic pathologists, and state and local governments have not been able to keep up with providing the funding needed to ensure adequate resources are available to provide these services. These physicians play a key role in understanding COVID-19 as well as contributing to public health of all Americans, and we urge the inclusion of additional funding to the states for these important services.

Other Areas of Concern for Cures 2.0

Reform Medicare Coding, Coverage, and Payment

For any consideration of reforms to coding, coverage, and payment, changes must continue to utilize a HIPAA-compliant code set, which requires all providers, clearinghouses, and payors to use the American Medical Association Current Procedural Terminology (CPT) code set. This includes CMS, which uses CPT codes as part of its system for reporting services provided to Medicare and Medicaid beneficiaries. The CAP supports the continued use of the CPT code set as it is developed with broad stakeholder input and ensures consistent, uniform, national coding.

In addition, the CPT Editorial Panel has the infrastructure and capacity to process code requests on a quarterly basis, provide transparency, and offer a public forum at regular intervals several times a year to convene interested and impacted stakeholders. This code set provides a uniform language that accurately describes medical, surgical and diagnostic services provided by physicians and other qualified health care professionals. The ongoing change and multi-stakeholder input to update the code set also ensures the facilitation of electronic transactions needed to ensure that patients continue to have accurate reporting and tracking of their medical services.

Increasing Use of Real Time Data and Evidence

Qualified Clinical Data Registries (QCDRs) play a vital role in improving quality of patient care by reporting medical and clinical data to CMS on behalf of clinicians for purposes of the Merit-based Incentive Payment System (MIPS) and for more general patient and disease tracking. Under CMS rules, QCDRs must demonstrate clinical expertise and quality measurement development experience. QCDRs collect and submit clinician data through traditional MIPS measures and non-MIPS/QCDR measures. QCDRs, which are typically part of broader clinical data registry efforts by national medical specialty societies, provide timely and actionable feedback to individual physicians and practices on their performance, and enhancing quality improvement opportunities. QCDRs allow for patient-centered, statistically valid and timely inter-practice and national benchmarking and comparisons. QCDRs can support the FDA's post-market surveillance and other regulatory efforts, as well as CMS drug and device-related reimbursement programs, by providing real time data on a broader population's experience with approved products. As such, the CAP supports legislation that would increase the use of real time data and evidence collected by QCDRs.

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 intraspecialty consultation.

Summary

Pathologists are physicians who specialize in the diagnosis of disease. 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 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. Now is not the time to erode that foundation.

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 and appropriate pricing and coverage for diagnostic testing, and 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, and coverage decisions should remain primarily local with necessary improvements to the LCD process. Finally, the CAP urges Congress to provide funding to assist state and local medical examiner and coroner offices to support the COVID-19 related diagnostic services.

Again, the CAP welcomes the opportunity to work with the Committee 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,

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