COLLEGE of AMERICAN PATHOLOGISTS

August 2, 2024

The Honorable Diana DeGette
House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Larry Bucshon, MD
House of Representatives
2313 Rayburn House Office Building
Washington, D.C. 20515

Re: Request for Information – 21st Century Cures Next Steps

Sent via email to cures.rfi@mail.house.gov

Dear Representatives DeGette and Bucshon,

The College of American Pathologists (CAP) is pleased to provide feedback on how Congress can build upon the successes of the 21st Century Cures Act and Cures 2.0. 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 have a long track record of delivering high quality diagnostic services to patients and other physicians.

The CAP appreciates the opportunity to share our views with you regarding ways to further modernize coverage and ensure patient access to the right tests at the right time. We've reviewed the questions for consideration and have provided responses which are focused on local coverage process improvements, meaningful access to federal health plan claims data, increasing use of real time data and evidence, ensuring Medicare coding consistency, and continuing pandemic preparedness efforts. As you consider a new set of reforms under the banner of the broader 21st Century Cures initiative, we urge you to consider these comments and work with us to continue improving treatment options and increasing important research for patients.

LCD Process Improvements

As you know, the 21st Century Cures Act added language directing the Secretary of the Department of Health and Human Services (HHS) to improve the transparency of the local coverage determination (LCD) process. In addition to the statutory mandates, the Centers for Medicare & Medicaid Services (CMS) solicited stakeholder input, all of which led to revisions to Chapter 13 of Medicare's Program Integrity Manual, which outlines the LCD process and now serves as a roadmap for Medicare Administrative Contractors (MACs). When the Cures 2.0 Act was being drafted, the CAP submitted comments noting that additional improvements were needed to allow for new technologies and treatments to benefit patients. Since that time, we have continued to observe several issues of concern

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regarding development and delivery of sound and timely Medicare local coverage policy. These issues include:

1. Restricted Stakeholder Engagement – It is critical to the coverage development process that there is thoughtful discussion and timely feedback from stakeholders and advocates who have unique insight into the nature of local practice and the needs of local patient populations. In the past, this insight was provided by Contractor Advisory Committee (CAC) members, who are health care professionals and other stakeholders that serve in an advisory capacity as representatives of their constituency. However, as a result of the 21st Century Cures Act, MACs are still required to establish CACs, but CAC meetings are now optional and restricted to "experts" who only "review evidence that will inform policy development."

   Prior to the 2019 revisions to the LCD guidelines, CMS defined the purpose of the CAC meeting as a formal mechanism for physicians to "*be informed of and participate in the development of an LCD in an advisory capacity*." MACs were required to communicate to CAC members that *the focus of the CAC was LCDs and Medicare administrative policies*." However, the 2019 revised LCD guidelines describe the role of the CAC as a formal mechanism for health care professionals "*to be informed of the evidence used in developing the LCD"* and that CAC members now serve in an advisory capacity as representatives of their constituency "*to review the quality of the evidence used in the development of an LCD."*[1] In response to our inquiry about this change, CMS stated that it is due to the 21st Century Cures Act and the fact that "MACs are required to post publicly a summary of evidence that they considered during the development of LCDs, including specific citations, and an explanation of the rationale supporting the LCD."

   While we understand the interest in evolving the role of the CAC, this restriction to solely "review evidence" represents an overinterpretation of the 21st Century Cures Act by CMS, resulting in a loss of the clinical knowledge that physician panel members uniquely bring to the local coverage process as experts who daily engage in patient care with various patient populations. Our CAC members and other physician panelists have observed that even when their expertise is offered it does not appear to be meaningfully considered by the MACs. This failure to hear the expertise that practicing physicians bring to coverage policy development can result in suboptimal coverage policies and reduced access to care for patients. Instead, we recommend that MACs take a more aggregate view of LCD development and provide specific time for open discussion at CAC "evidentiary" meetings, which would allow panel members and others (including non-panel CAC members) to comment, ask questions, and actively participate. The required open meetings, held after the LCD is made public, would also benefit from this kind of open, meaningful discussion from all stakeholders.

[1] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf

2. Lack of Transparency and Consistency – With the changes to the role of the CAC member and the various meetings held by the MACs, we are concerned that there is more confusion than clarity around how stakeholders are expected to participate in the LCD process. In addition to open meetings, there are the CAC "evidentiary" meetings expanded on above, as well as CAC "engagement," "impact," and "touch base" meetings, all of which are optional and vary by MAC. Clearly and consistently outlined terminology/identification and operations of meetings across MACs would greatly improve stakeholder engagement. Additionally, MACs should publicly announce plans to convene panels (for CAC "evidentiary" or other meetings) and utilize an open and transparent nomination process. MACs should also define and employ objective criteria in vetting and selecting panel members.

3. Lengthy and Limited Reconsideration Process – Current LCD guidelines do not provide a timeframe for MACs to complete a reconsideration request for a revision to an LCD. We understand that due to "overstrained resources at the MACs," CMS believes it is best "to allow the MACs flexibility to ensure an evidentiarily sound LCD is developed that meets the needs of Medicare beneficiaries." However, reconsideration requests can take months or even years, as illustrated by the example below. Additionally, the process lacks transparency regarding the status of reconsideration requests. As oftentimes the only method of addressing issues with existing LCDs, the reconsideration process must appropriately balance the need for an evidentiarily sound LCD with the need to provide appropriate access to reasonable and necessary care for Medicare patients. This is especially true when contemplating a "modernized system of developing new cures" and a "delivery system capable of getting them to patients in need."

   On December 31, 2021, the CAP filed a formal reconsideration request for revisions to the Special Histochemical Stains and Immunohistochemical Stains ("special stains") LCD. The request was sent independently to four MACs with identical special stains LCD, and included important coverage changes, including to remove outdated age-based and clinical criterion-based selection for testing colorectal cancer patients. It took more than two years for any MAC to finalize changes to the flawed LCD, and as of June 2024, two MACs have yet to finalize any revisions. Meanwhile, the outdated coverage policies currently in effect continue to deny critical cancer tests to Medicare patients.

   Additionally, the CAP has also requested that the reconsideration process be broadened to include requests to correct an LCD when sufficient evidence exists to convincingly refute misinterpretation of evidence by a MAC. We have seen how certain coverage decisions ignore medical evidence and Medicare program requirements. One local Medicare decision, for example, established an arbitrary utilization threshold for a test to evaluate gastric biopsies for a known carcinogen, Helicobacter pylori, which is associated with increased risks of gastric cancer and lymphoma. Yet it

remains the case that, without "new evidence," LCDs are functionally unreviewable once they become final.

4. Insufficient MAC Metrics – The Medicare Access and CHIP Reauthorization Act of 2015 set forth a provision in Section 509 that requires contractor performance transparency to the extent possible without compromising the process for entering into and renewing contracts with MACs. Under this section, the Secretary shall make available to the public the performance of each MAC with respect to such performance requirements and measurement standards.

   The LCD process is a large component of each Part A/B MAC contract with CMS, and as such, the CAP believes that CMS should implement and publicly report performance metrics that hold MACs accountable for adhering to applicable LCD guidelines outlined in Chapter 13 of the Medicare Program Integrity Manual. Current performance metrics for MACs do not include measures to assess if a MAC is fulfilling these requirements in substance or in form only. Therefore, we recommend that CMS add key LCD process measures to the current MAC performance metrics to assess performance effectiveness and adherence to specific LCD guidelines and as outlined in MAC contracts.

The LCD process is a vital part of ensuring Medicare patients receive optimal care through appropriate access to services and technologies. While the 21st Century Cures Act and resulting CMS changes made important progress towards a more transparent process that incorporates stakeholder input, elements that are essential for further progress include, as outlined above: appropriate stakeholder engagement that allows for consideration of clinical knowledge, increased transparency and consistency across MAC meetings and operations, a timely and broadened LCD reconsideration process, and the addition of MAC metrics for adhering to the LCD process.

Meaningful Access to Federal Health Plan Claims Data

One section of the Cures 2.0 Act that was not advanced but the CAP views as a necessary reform is the Cures 2.0 Act's Sec. 411, Meaningful Access to Federal Health Plan Claims Data. As noted in the text, "ensuring clinician-led clinical data registries meaningful access to claims data will enable such entities to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide them with the information necessary to assess the cost-effectiveness of therapies." The current program to access Claims data is inadequate because the cost and burden of accessing data on an ongoing basis are prohibitive for clinician-led clinical data registries. This data is necessary to allow registries to conduct longitudinal and other data analyses essential for enhancing quality of patient care. The CAP supported H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act of 2021, which would solve this long running problem and advance the goals of the Cures 2.0 Act. As such, we support Congress including language similar to this in any legislative package that moves forward.

Ensuring Medicare Coding Consistency

As the 21st Century Cures initiative moves forward, we want to stress that 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.

Unfortunately, additional coding requirements within Medicare as well as commercial plans are increasingly adding unnecessary burdens and impeding patient access to medically necessary tests. For example, we continue to have serious concerns with UnitedHealthcare's requirement for reimbursement that molecular pathology claims contain a DEX Z-code, which is obtained from the Palmetto DEX Registry (see attachment 1). We believe pathologists and laboratories will experience unnecessary strain from the administrative burdens and operational difficulties of this requirement, which risks interfering with the ability for a patient to receive timely and appropriate services.

Continuing Pandemic Preparedness Efforts

The battle against COVID-19 highlighted critical areas of concern that must be addressed to better prepare for future pandemics. Throughout the pandemic, laboratories around the world relied on the CAP for quality in proficiency testing and accreditation. We also worked to address the critical supply chain issues impacting laboratories around the country. The CAP has further provided guidance on national testing strategies and policy proposals for health equity, improving access to care for all patients. As such, the CAP appreciates the Public Health section that was included in Cures 2.0 and requests that Congress consider the following recommendations as you deliberate legislation pertaining to the 21st Century Cures initiative.

First, the CAP urges Congress to consider policies to standardize electronic laboratory reporting and authorize funding to enhance laboratory information systems to ensure critical data on disease spread can be shared with public health agencies. The CAP

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believes more should be done to establish a uniform and standardized system for data sharing with public health agencies, and that Congress should ensure that burdens on data providers are manageable and streamlined given the critical role that such providers play during a PHE.

The pandemic highlighted the need for standardized data reporting to public health agencies for officials to access comprehensive and nearly real-time data to inform decision making in their response during the PHE. As such, the CAP supports the creation of national standardized minimum data reporting requirements and formats in which clinical laboratories would be required to report only to the state in which the laboratory is located. The minimum data required to be reported should include only those data typically available to clinical laboratories. The same national standards could be used by state public health agencies to report data on out-of-state patients to the state public health agency of the patient's residency. Alternatively, the federal government could establish a national data hub for public health, during a PHE, for use in distributing public health-related results to various locations in a standardized format.

Further, better coordination at the federal and state levels and funding for laboratories to purchase and/or enhance laboratory information systems would improve data collection and strengthen our nation's response to public health crises. More specifically, federal funding should be made available to laboratories to fully cover the costs of installation, validation, maintenance, and any required updates of electronic public health reporting software and interfaces, as the nation's laboratories cannot continue to absorb these "unfunded mandates" during future PHEs. Ultimately, it is the responsibility of HHS and state (and local) agencies to develop and adopt uniform standards and common pathway solutions for reporting and sharing all public health data (and not limited to a PHE), to prevent this unreasonable burden on laboratories or other required reporting entities from occurring again.

Finally, the CAP supports ensuring there is a mechanism to provide for adequate coverage and reimbursement of tests during a PHE so that the public can access tests as needed and laboratories have enough revenue to continue operating.

The CAP appreciates your work in this space. We look forward to working with you on legislation to support the 21st Century Cures initiative. Please contact Hannah Burriss at hburris@cap.org if you have any questions regarding these comments.

Sincerely,

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President

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