COLLEGE of AMERICAN PATHOLOGISTS

January 4, 2021

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016

Subject: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-9123-P, which seeks to "improve the electronic exchange of health care data, and streamline processes related to prior authorization, while continuing CMS' drive toward interoperability, and reducing burden in the health care market." 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 you know, pathologists are physicians whose timely and accurate diagnoses drive care decisions made by patients, primary care physicians, and surgeons. Pathologists are acutely aware that the right test at the right time can make all the difference in a patient's diagnosis, treatment, and outcome. Policies or programs, including prior authorization, that interfere with a patient's ability to receive timely and appropriate services/care risk negatively affecting patients, providers, and the entire health care system. Thus, we generally support CMS's efforts to reduce burden on patients, providers, and payers, while moving towards greater interoperability. Importantly, we urge CMS to move forward with changes that streamline the process of submitting a prior authorization request and ensure expedited prior authorization timeframes.

Outside of the context of prior authorization, the CAP has previously provided comments to CMS on improving interoperability and access to health care data.[1] In particular, challenges remain for pathologists and laboratories as a result of their reliance on Laboratory Information Systems (LISs) to support the work of analyzing patient specimens and generating test results. As we have explained before, it is via an LIS that EHR or enterprise-wide clinical information systems exchange laboratory and pathology data. While this certainly adds complexity to prior authorization issues for

[1] https://documents.cap.org/documents/cap-comments-on-cms-interoperability-proposed-rule.pdf

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

pathology and is worth considering as CMS evaluates electronic prior authorization solutions, here we focus our comments more generally on other prior authorization concerns/gaps and barriers for pathology. We urge CMS to consider the unique position of pathologists and their laboratories as the agency moves to increase data sharing and reduce overall payer, provider, and patient burden through proposed changes to prior authorization practices.

C. Request for Information: Reducing Burden and Improving Electronic Information Exchange of Prior Authorization

As CMS explains, prior authorization is a process "through which a provider must obtain approval from a payer before providing care and prior to receiving payment for delivering items or services." While prior authorization processes may help payers to help control costs and ensure payment accuracy, more often the resulting barriers can do more harm than good. Prior authorization and other utilization management programs often inappropriately dictate or limit health care provider decision-making and patient care, impinging on the practice of medicine and improperly encumbering medically necessary laboratory and pathology services. According to the American Medical Association (AMA), about one-quarter of physicians report that prior authorization has led to a serious adverse event for a patient in their care.[2] Wait times and care delays are also significant issues for patient care, while the burden on physicians can lead to dissatisfaction and burnout.

The CAP is committed to improving patient care and addressing escalating health care costs. Yet, it is imperative that cost-control measures balance other care considerations and continue to ensure access to timely and appropriate services. Accomplishing this includes streamlining/automating prior authorization processes in such a way that takes into account the unique position of pathologists, targeting requirements where they are needed most and in a way that is least burdensome on providers, ensuring transparency based upon updated and appropriate evidence, and guaranteeing administration of these processes by providers who are at least as qualified as the prescribing/ordering physician whose decision-making is otherwise subject to utilization review.

Specific to pathology, prior authorization can be especially complex, as pathologists generally do not have the information needed to complete required forms and are not in a position to appeal decisions. Moreover, oftentimes when the specimens are received, there is not the time or availability to pause for prior authorization processes. Specimens obtained by invasive procedures have a limited time period of viability and unnecessary delays could result in repeat procedures or wasted samples. Ordering physicians also resist pausing for prior authorization out of concern that the patient may not return. Further, due to the invasive nature of the biopsy (brain, etc.) or severity of a patient's condition and need for an immediate pre-treatment specimen, there may be only one chance to obtain a specimen. In these instances, the pathologist must proceed with the tests before obtaining approval, or compromise the entire process with significant negative effects on the patient, and could end up shouldering the costs. Finally, insurer-imposed utilization management policies that restrict, deny, or steer services for patients may disrupt coordination, add burdens, or lead to

[2] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

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

lower quality care. This is a particular concern for the most vulnerable patient populations, including those with low income and/or chronic conditions.

More directly, pathologists have been confronted with challenges from laboratory benefits management programs (LBMs), which are health insurance payer protocols or programs that are administered by a health insurance payor or another entity under contract with the payer. These programs dictate or limit health care provider decision-making relating to the use of clinical laboratory/pathology services. The CAP has argued that regulation of LBMs is fundamentally needed to prevent conflict of interests by entities that administer these programs and to ensure that these programs do not conflict with, subordinate, or unduly encumber the practice of medicine.

Streamlining or automating prior authorization and other utilization management processes is critically important and must take into account the fact that pathologists generally do not have the information needed to complete prior authorization forms and are not in a position to appeal decisions as they may not have access to the complete medical record. Further, prior authorization requirements should be targeted where they are needed most, and the burden on health care providers eased as much as possible. Other considerations the CAP believes must be included in any prior authorization process or utilization management program include that they be:

- transparently based upon peer reviewed, published evidence in medical literature;
- subject to routine and timely updating based upon accepted standards of medical practice and the most current medical knowledge;
- amenable to a physician's immediate over-ride in the ordering of pathology/laboratory services based upon the medical judgment of the physician regarding the patient;
- prohibited from facilitating business conduct by a health insurance payer that would have an adverse claims impact upon a pathology/laboratory provider who receives an order for services from a health care provider in accordance with law.

Furthermore, it is imperative that clinical decisions undertaken by these programs or protocols be administered by providers who are at least as qualified as the prescribing/ordering physician whose decision-making is otherwise subject to utilization review, as is called for under policies espoused by the AMA. In addition, the CAP regards any such prior authorization or utilization review activities of physician judgment applicable to patient care undertaken by health insurance payers, or other entities under contract with payers, to be tantamount to the practice of medicine and subject to corporate practice of medicine laws in states where applicable.

* * * * *

The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions to Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.

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