AMERICAN CLINICAL LABORATORY ASSOCIATION

March 10, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attn: CMS-0057-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program (CMS-0057-P)

Dear Administrator Brooks-LaSure,

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide comments on the abovementioned rule (Proposed Rule).[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving healthcare needs and provide vital clinical laboratory tests that help identify and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of healthcare delivery through policies that expand access to testing services that improve and save lives.

ACLA's comments on the Proposed Rule focus on the following areas:

A. Prior authorization: time frames, denial reasons, publication of metrics, and "gold carding" programs

B. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

C. Request for Information: Improving the Exchange of Information in Medicare Fee-For-Service

[1] 87 Fed. Reg. 76238 (Dec. 13, 2022).

A. Prior Authorization

ACLA shares the Centers for Medicare & Medicaid Services' (CMS's) interest in improving and increasing the efficiency and transparency of the prior authorization process for patients, providers, and payers. Regulatory changes designed to improve the prior authorization process should work for all stakeholders in the process, including clinical laboratories. At present, the prior authorization process may suit payers, yet significant challenges are the norm for healthcare practitioners, other service providers, and patients as existing prior authorization requirements often result in administrative denials for medically necessary covered services. We are grateful that CMS recognizes that the burdens of prior authorization requirements should not be borne solely by healthcare practitioners and other service providers. Indeed, burden is often borne by clinical laboratories that frequently are faced with the need to seek prior authorization for a test after a specimen has been drawn and sent to the laboratory, because the ordering healthcare practitioner did not do so. Clinical laboratories typically do not have face-to-face interactions with patients, they often lack information that is essential to prior authorization requests, lack access to medical documentation maintained by ordering healthcare practitioners, and face the absence of incentive for healthcare practitioners to obtain prior authorization for laboratory tests because there are no negative repercussions for them if they fail to obtain it. In these circumstances, it is laboratories that experience repercussions in the form of lack of payment for tests that require prior authorization if it is not obtained, not practitioners who order them.

An additional way regulatory changes could improve the prior authorization process for all stakeholders would be to ensure that laboratories are permitted the option of requesting prior authorization for a service it will perform. Often, a laboratory is best positioned to know which tests require prior authorization for different types of patients and they know what kind of documentation is required to secure prior authorization. This experience can help expedite a timely response to a prior authorization request. Payers should not be permitted to allow only the ordering practitioner to seek prior authorization. CMS should address this in the final rule by clearly stating that clinical laboratories must be permitted to seek prior authorization for a test when it is required.

1. Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations

ACLA supports the proposal to require a payer to provide a specific reason for denying a prior authorization request, regardless of the delivery method of the decision.[2] The reasons should be standardized and should be specific enough to allow the patient, the ordering healthcare practitioner, and the provider of the services to understand why an item or service will be denied. It also is important for a provider to know whether a prior authorization request was denied because the payer believes that an item or service is not medically necessary (in which case the requestor may appeal the decision) or because the payer requires additional information or documentation to render a decision (in which case the ordering practitioner, payer, laboratory, and patient can attempt to gather more information). A benefit of such a policy may be to increase understanding of the ordering healthcare practitioner about the circumstances under which an item or service will or will not be covered by a particular payer.

---

[2] *Id*. at 76292.

We appreciate that CMS recognizes that under the Medicare Advantage (MA) program, the actions that constitute an "organization determination" include a prior authorization decision.[3] We ask for CMS to confirm that when a healthcare practitioner who is contracted with an MA plan orders laboratory testing and makes a referral to a non-contracted laboratory without securing prior authorization for the testing, it is "plan-directed care" and results in a favorable organization determination (and therefore coverage and payment for the testing).[4]

2. Requirements for Prior Authorization Decision Timeframes and Communications

CMS proposes that beginning January 1, 2026, payers must provide notice of prior authorization decisions "as expeditiously as a patient's health care condition requires, but no later than seven days for standard requests" or 72 hours for expedited requests.[5] We appreciate that the proposed decision timeframe is shorter than the current federal requirements for some payors, which are 14 days or longer. However, ACLA is concerned that seven days is still too long in the case of prior authorization for many laboratory tests. When a healthcare provider collects a specimen and sends it with an order to a laboratory without requesting prior authorization (if required), the laboratory is put in an untenable position. The laboratory cannot delay testing, because of specimen integrity and degradation issues, the importance of timely test results to treatment decisions, and quick turn-around time expectations. Yet, it is the laboratory's payment for testing that is at stake if prior authorization is not forthcoming. Similarly, when a patient presents at a laboratory patient service center, the laboratory may not have any insight into whether prior authorization was requested, and it would not be reasonable for the laboratory to decline to collect a specimen for testing that requires prior authorization. To address these issues, we propose that MA plans, Medicaid managed care plans, CHIP fee-for-service and managed care plans, and qualified health plans (QHPs) on a federally-funded exchange should be required to provide notice of prior authorization decisions for laboratory testing in real time, but no later than 72 hours after a standard request or one day after an expedited request.

ACLA further recommends CMS modify its proposal to institute a penalty for a payer that failed to provide the notice within the applicable timeframe. The burden would remain with the provider to contact the payer to get a status update—and this outreach from the provider already would be after the applicable timeframe of the original request had elapsed.[6] We urge CMS to adopt specific and meaningful penalties for payers that fail to provide the notice within the applicable timeframe and to communicate publicly the agency's intent to enforce them.

---

[3] *Id*. at 76293.

[4] This is consistent with CMS's descriptions of plan-directed care in the Medicare Managed Care Manual and in resources for beneficiaries. *See, e.g.*, Medicare Plans Cover All Medicare Services, *available at* https://www.medicare.gov/what-medicare-covers/what-medicare-health-plans-cover/medicare-advantage-plans-cover-all-medicare-services.

[5] 87 Fed. Reg. 76296.

[6] We acknowledge that other requirements applicable to some payers, such as those pertaining to MA organization determinations, may impose a penalty on a payer for failure to provide a timely response to a pre-service request from a provider for coverage information.

3. Public Reporting of Prior Authorization Metrics

ACLA appreciates that CMS's proposal that would require impacted payers to publicly report on their website or via a publicly accessible hyperlink certain organization-level aggregated metrics about prior authorization, yet the association recommends more specificity in what is reported be required to make the information more meaningful. In the proposal rule, CMS writes it is "not proposing that payers report on categories of items and services, but rather aggregate the information as totals or percentages of total items and services" because "[a]ggregate data could allow each organization to examine trends and obtain insight into their own performance."[7] The proposed metrics are:

- A list of all items and services that require prior authorization,
- The percentage of standard prior authorization requests that were approved, denied, and approved after appeal,
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved,
- The percentage of expedited prior authorization requests that were approved and denied, and
- The average and median time that elapsed between a submission of a request and a determination by the payer, plan, or issuer, for standard and for expedited prior authorization requests.[8]

While ACLA supports transparency about prior authorization requirements and performance, the association does not consider the proposal list to be particularly useful to CMS or to providers, and it is not clear that payers would have any incentive to "obtain insight into their own performance" from the metrics. Metrics that are aggregated at the organization level have little practical value. For example, a specialist who wants to determine whether to contract with a particular payer may want information about whether the payer routinely denies initial prior authorization requests for services the specialist routinely performs and then approves them after appeal, thereby increasing the administrative burden on the specialist's office and staff. Metrics that are aggregated at the organization level would not yield helpful information in this type of situation.

ACLA recommends that, to be meaningful, prior authorization metrics should be broken down by the provider type of the requestor. CMS should require applicable payers to report the metrics broken down at the Health Care Provider Taxonomy code set Level II, Classification, which is a code set used in HIPAA standard transactions.[9] This would produce at least some useful information to CMS and to providers about different payer's tendencies to approve or deny certain types of services. CMS also should add to the required reporting metrics "percentage of prior authorization requests denied for each denial reason," as those standardized reasons are finalized, as well as "percentage and number of prior authorization requests for which determinations were

[7] 87 Fed. Reg. 76304.
[8] *Id*. at 76305.
[9] *See* National Uniform Claim Committee code set list, v. 23.0 (Jan. 2023), *available at* https://taxonomy.nucc.org/.

not made by the payer, plan, or issuer within the applicable timeframe" and "a list of all items and services requiring prior authorization that are covered under an applicable Local Coverage Determination or National Coverage Determination" (for MA plans only).

Further, ACLA recommends that in the future, as prior authorization standards and systems develop, payers should be required to report on even more granular metrics (*e.g.*, "the percentage of prior authorization requests for genetic testing approved or denied for Medicaid managed care recipients in [State] because of insufficient documentation").

4. "Gold Carding" Programs for Prior Authorization

CMS discusses payers that have implemented "gold carding" programs to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance.[10] ACLA recommends CMS establish a "gold-carding measure" as a factor in quality ratings of MA organization and QHPs as a way to decrease the burden of prior authorization on all stakeholders. An element of the "gold-carding" measure must be that it is available to all those that may submit prior authorization requests to the MA plans and QHPs—in other words, it should be available to ordering healthcare practitioners and to those providers and suppliers furnishing items and services as a result of referrals.

B. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

CMS requests input on several aspects of data collection relevant to social risk factors.[11] As CMS develops plans for data standardization, collection, and sharing, ACLA asks that the agency keep in mind that laboratories often do not have face-to-face interactions with patients and generally only have patient medical and demographic data relevant to the laboratory testing they perform. During the COVID-19 pandemic, laboratories were faced with a myriad of public health reporting requirements that varied by state, territory, and locality, with which it was unreasonable for laboratories to be expected to comply as these requests sought data well beyond the scope of data elements held by laboratories. Laboratories have limited data and little or no resources to obtain it from the "source of truth"—the patient or the healthcare practitioner treating the patient. While laboratories may request this information from ordering practitioners that have direct access to patient demographic data, these practitioners have no incentive to provide it to laboratories with a test order, and even if such demographic data is provided to a laboratory there often are no standards for storage or transmission of the data. Whether or not social risk factor data may be valuable for public health purposes, it is unreasonable to expect clinical laboratories to supply it. In summary, ACLA urges CMS to ensure that clinical laboratories are not required to report data that they do not have, that is not needed to perform a test, for which there are no adopted standards, or that another type of healthcare provider is better positioned to collect and report.

C. Request for Information: Improving the Exchange of Information in Medicare Fee-for-Service

CMS seeks stakeholder input on ways to improve the exchange of medical information

[10] 87 Fed. Reg. 76307.
[11] *Id*. at 76321.

between and among providers and suppliers or patients in the Medicare fee-for-service context. ACLA appreciates that CMS acknowledges that the healthcare practitioner who orders an item or service often is different from the provider or supplier that furnishes the item or service to a Medicare beneficiary and that the burden of obtaining medical documentation from the ordering practitioner for prior authorization or to respond to an audit request is substantial. ACLA believes there is significant need for improvement in the exchange of information.

Problems associated with getting medical documentation from ordering health care practitioners have been around as long as the medical documentation requirements for laboratory tests themselves. As you may know, pursuant to the Balanced Budget Act of 1997, CMS engaged in a negotiated rulemaking on laboratory services payable under Medicare Part B. In the 2001 final rule that established national coverage and administrative policies for clinical laboratory tests, CMS addressed the burdens on laboratories struggling to collect medical documentation:

> We acknowledge the burden that accompanies the task of collecting diagnostic information to support medical necessity. However, the [Social Security] Act requires that Medicare only pay for services that are reasonable and necessary. Medicare cannot pay for services that do not meet this standard simply because the laboratory has expended a specified amount of effort to obtain documentation. We have, however, identified a process for requesting documentation that we believe reduces the burden on laboratories for collecting and submitting information to us…[T]he laboratory is responsible for maintaining information it receives from the ordering practitioner, and the practitioner is responsible for maintaining the information in the medical record. Our initial request for information is made to the entity submitting the claim. That entity should submit whatever documentation it has in support of the claim. If the documentation submitted by the entity submitting the claim does not demonstrate that the service is reasonable and necessary, we will take the following action: (1) provide the ordering physician information sufficient to identify the claim being reviewed; (2) request from the ordering physician those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed; and (3) if the ordering physician does not supply the documentation requested, inform the entity submitting the claim(s) that the documentation has not been supplied and deny the claim.[12]

CMS also acknowledged that the entity submitting the claim is the one that may experience a payment denial and that laboratories are not precluded from seeking additional documentation from an ordering provider.

Since the 2001 final rule, ACLA members now have more than two decades of experience with the burden reduction effort as set forth in the negotiated rulemaking and cannot discern any reduction in burden to date. As CMS acknowledged more than twenty years ago, the *ordering health care practitioner* creates and maintains the documentation showing intent to order and supporting the medical necessity of a test, yet the *performing laboratory's* payment is at stake

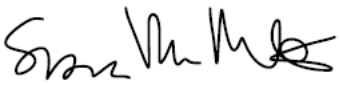
[12] 66 Fed. Reg. 58788, 58800 (Nov. 23, 2001).

when the documentation is not produced or is insufficient. No incentives are in place that would lead health care practitioners to spend extra time and resources responding to requests from CMS, contractors, or laboratories for medical documentation. CMS should start by tracking and measuring health care practitioners' response rate to requests for medical documentation from the agency and from its contractors (*e.g.*, Medicare Administrative Contractors and Comprehensive Error Rate Testing (CERT) contractors) and communicating with practitioners about how their response rate compares to similarly-situated practitioners. CMS also should consider whether financial incentives for responding to documentation requests – or financial penalties for failure to do so – would improve the likelihood and timeliness of practitioners' responses. In keeping with the spirit of burden reduction, ACLA requests that CMS revisit and update policy to establish such incentives, adding rationality to information sharing while also working with the Office of the National Coordinator to ensure appropriate information exchange.

* * *

ACLA appreciates the opportunity to provide these comments and the association would be pleased to provide additional information to the Agency.

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association