AMERICAN CLINICAL LABORATORY ASSOCIATION

August 29, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Program; Request for Information on Medicare (CMS-4203-NC)

Dear Administrator Brooks-LaSure,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the above-referenced Request for Information (RFI).[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

We appreciate the opportunity to provide feedback on ways to strengthen the Medicare Advantage (MA) program, as enrollment approaches half of the Medicare beneficiary population.[2] ACLA's comments focus on how to improve utilization management and other processes to ensure that MA plan enrollees' access to medically necessary laboratory testing is not adversely affected.

1. **Prior Authorization**

ACLA was encouraged by the recent Centers for Medicare & Medicaid Services (CMS) responses to the recommendations set forth in the U.S. Department of Health and Human Services Office of Inspector General (OIG) report on prior authorization.[3] Prior authorization oftentimes is used to discourage and delay medically necessary laboratory testing. We urge the agency to incorporate the issues below into the guidance it is developing for MA Organizations (MAOs) and into other CMS policies and communications, as appropriate.

ACLA member laboratories face the same types of challenges with MAO prior authorization that are described in the OIG report. These include denials of requests for prior authorization for services that met Medicare coverage rules, delays and denials based on unnecessary documentation requests, and delayed and denied payments for services laboratories had already delivered. ACLA developed prior authorization tenets in 2018 when several MAOs

[1] 87 Fed. Reg. 46918 (Aug. 1, 2022).
[2] *Id.* at 46921.
[3] "Some Medicare Advantage Organization Denials of Prior Authorization Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), *available at* https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

expanded their laboratory prior authorization programs. [4] The tenets focus on improving prior authorization processes and minimizing unnecessary delays in laboratory testing and results. As these barriers and delays persist, we offer the following laboratory-specific recommendations.

Laboratories' Ability to Initiate and Track Prior Authorization Requests. Laboratories should be permitted to initiate prior authorization requests for the patients they serve and to track the status of those requests. Several MAOs do not permit a laboratory to initiate prior authorization requests or even track prior authorization status from the initial request to issuance or denial. In these instances, only the provider that orders the test can initiate a prior authorization request and get status updates. This places additional burdens on ordering providers and their administrative and clinical teams, which have to spend time checking on the status of a prior authorization request and relaying that information to the laboratory.[5] In order to ensure that specimens do not degrade before testing, laboratories often perform tests while still waiting to hear about the authorization outcome from the provider, sometimes resulting in uncompensated care.

Transparency. Information about program requirements, coverage policies, medical necessity criteria, and required coding for services requiring prior authorization should be available to laboratories and ordering providers in real-time. This real-time query functionality would enable laboratories and other providers to incorporate prior authorization into their electronic workflows, a critical component of accuracy and timeliness in the prior authorization process for both providers and beneficiaries. Without the ability to run queries in real-time, laboratories and ordering providers have to request prior authorization by fax submission and/or phone calls. This often results in lengthy hold times and multiple transfers with no resolution or decision on prior authorization.

Documentation Requirements. Laboratories continue to bear a disproportionate burden with respect to medical documentation to support the reasonableness and medical necessity of laboratory testing – documentation that laboratories neither create nor have in their possession in most cases. Laboratories often receive requests for documentation that can be furnished only by the ordering provider. Through the years, ACLA has expressed significant concerns about the substantial and unnecessary burdens imposed on clinical laboratories to produce documentation they do not create or possess. ACLA members also experience denials for lack of medical documentation when documentation they provide is, in fact, sufficient to support medical necessity.

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[4] *See* https://www.acla.com/wp-content/uploads/2018/05/ACLA-Prior-Authorization-Tenets.pdf.

[5] The American Medical Association (AMA) 2021 Prior Authorization Physician Survey (*available at* https://www.ama-assn.org/system/files/prior-authorization-survey.pdf) found that physicians and their staffs spent an average of almost two full business days or 13 hours each week completing prior authorizations. Eighty-eight percent of survey respondents described the burden associated with prior authorization as high or extremely high. The AMA has conducted the annual survey five times, and the overwhelming administrative burden for ordering providers and laboratories has not abated.

Expedited Review/Appeal. It is important that MAOs provide avenues for expedited administrative review, rather than just a denial with appeal rights, and to allow laboratories to submit and secure authorization after the date-of-service but before claims submission. When a denial is administrative (*e.g.*, the laboratory was not permitted to secure prior authorization), a laboratory should be able to submit information sufficient for the MAO to assess whether an authorization should be issued and, if so, immediately grant a post-test authorization.

The OIG report's detailed descriptions of denials of medically necessary laboratory services were alarming, yet all too familiar to ACLA members. As administered by many MA plans, prior authorization often discourages medically necessary laboratory testing and poses a serious risk to patient care. Surveys have quantified the negative impact of prior authorization on patients: 93 percent of physicians surveyed in 2021 reported delays in care associated with prior authorization and 82 percent responded that prior authorization can sometimes lead to treatment abandonment.[6] More than half of physicians surveyed in 2021 reported that prior authorization has led to missed or abandoned testing or treatment, which interfered with patients' abilities to perform job responsibilities due to reduced productivity or missed work time.[7] Prior authorization inappropriately restricts access to services and, in some instances, leads to delayed or suboptimal care. The current approval processes are unnecessarily onerous, and CMS should establish reasonable parameters for MAOs' prior authorization programs.

2. MA Organization Determinations

ACLA members continue to report many instances in which MAOs' determinations are not issued in conformance with the regulations at 42 C.F.R. Part 422 and CMS guidance. The result is increased administrative burden on laboratories and ordering providers and possible delays in care and impediments to access for MA enrollees.

These instances arise under certain rules and procedures specific to Medicare Part C for notifying an individual that an item or service is not covered. The regulatory requirements are set forth at 42 C.F.R. §§ 422.566, 422.568, 422.572, and 422.574, and they are contained in a regulatory subpart concerning protections for enrollees, grievances, and appeal rights. Each MAO must have a procedure for making a timely organization determination regarding the benefits an enrollee is entitled to receive under an MA plan and regarding non-coverage of items and services. An enrollee's request for services from a contracted provider or from another provider, such as a laboratory, as a result of a referral from a contracted provider, is a request for an organization determination.

In May 2014, CMS issued a memo to MAOs, cost plans, and Health Care Prepayment Plans

[6] *Id*.
[7] *Id.*

entitled "Improper Use of Advance Notices of Non-Coverage."[8] The agency voiced its concern that MAO enrollees were being advised on non-coverage of items and services through notices based on the Advance Beneficiary Notices of Non-Coverage (ABNs) used in original Medicare, even though ABNs are not applicable to Medicare Advantage. CMS said that notice provided to an enrollee as part of the organization determination process set forth in the MA regulations "is necessary to deny coverage or payment," and "the failure to provide a compliant denial to the enrollee means that the enrollee is not liable for services provided by a contracted provider or upon referral from a contracted provider."

Effect of MA Organization Determinations for Laboratory Services

When an MAO's contracted provider makes a referral to a laboratory for a non-covered test and neither the enrollee nor the contracted provider sought or received an organization determination about coverage for the test, the MAO is prohibited from holding the enrollee financially responsible for the test. However, a laboratory should not be required to bear the cost of a non-covered item or service if no organization determination was sought.

While an enrollee clearly could not be held financially responsible in the absence of such an organization determination, it is illogical that a laboratory to whom a referral is made – and that furnished the ordered service as requested by the ordering physician – should be held financially liable. Rather, the referral is a "favorable determination made on behalf of the MAO" and a laboratory should be paid for the service.

In most cases, it is impractical for a laboratory to seek an organization determination on an MAO enrollee's behalf after receiving a test order from the enrollee's physician but before performing the test. A laboratory cannot delay testing in order to seek an organization determination on behalf of an enrollee because of specimen integrity issues and test turnaround time requirements. Moreover, an MAO has up to 14 days after receiving a request to respond to standard organization determinations,[9] and CMS's regulations permit only an MAO enrollee or physician to request an expedited organization determination.[10] It simply is not possible for a laboratory to hold a specimen for up to two weeks while awaiting a response from an MAO plan on an organization determination request.

Laboratories have been put in the untenable position in many instances of providing laboratory services to MAO enrollees without receiving any reimbursement for the services their ordering providers have determined are medically necessary and appropriate often for common and frequently performed tests in the Medicare population. In many cases, a laboratory's only interaction with a patient may be through billing, not face-to-face contact. ACLA, therefore,

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[8] *See* "Improper Use of Advance Notices of Non-coverage" (May 5, 2014), *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/improper%20abn%20use%2005%2005%2014_55.pdf.

[9] 42 C.F.R. § 422.568(b).

[10] 42 C.F.R. § 422.566(c)(2).

believes the referral for a laboratory service from a participating ordering practitioner should be considered a favorable organization determination, regardless of whether the lab is participating or non-participating, and an MAO should pay a laboratory for these services.

We urge CMS to improve and clarify the organization determination process requirements so that MAO enrollees and laboratories are protected from undue financial liability, and administrative burden and potential delays in care minimized.

Thank you for this opportunity to provide input on improving the MA program and key process issues that impact access to medically necessary laboratory services for Medicare beneficiaries. Please contact me at swest@acla.com with any questions.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs
American Clinical Laboratory Association