AMERICAN CLINICAL LABORATORY ASSOCIATION

May 29, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4207–NC
P.O. Box 8013
Baltimore, MD 21244–8013

RE: CMS-4207-NC Medicare Program; Request for Information on Medicare Advantage Data

Dear Administrator Brooks-LaSure,

The American Clinical Laboratory Association (ACLA) is pleased to submit our response to the CMS–4207–NC Health and Human Services (HHS) request for information.[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

Our comments below include background information along with recommendations for data collection on Medicare Advantage (MA) plans to better assess the impact of (1) utilization management techniques employed by MA plans, (2) third-party organizations contracted by MA organizations, (3) the organization determination system, and (4) the MA appeal process. In addition to our recommendations for data collection, we have also provided select policy recommendations on these topics.

I. Impact of Utilization Management Techniques Employed by MA Plans

ACLA appreciates the Centers for Medicare & Medicaid Services' (CMS's) recent reforms that are aimed at improving prior authorization. The 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F) aims to ensure that MA beneficiaries receive access to the same medically necessary care they would receive in traditional Medicare.[2] And the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) requires impacted payers to follow certain guidelines when using prior authorization.[3] We are optimistic that the transparency requirements in the CMS Interoperability and Prior Authorization final rule will help ordering providers better understand and navigate the prior authorization system, having a net positive impact on downstream laboratory processes. However, ACLA believes further reforms to prior authorization and utilization management are necessary to ensure patient access to covered laboratory services and appropriate reimbursement for laboratories for covered services that they provide.

Additionally, "prior authorization" is only one of many utilization management techniques that payers, including those with MA plans, employ to reduce and deny payments. Navigating the complex web of

[1] Medicare Program; Request for Information on Medicare Advantage Data, 89 Fed. Reg. 5907 (Jan. 30, 2024).
[2] 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F), 88 Fed. Reg. 22120 (Apr. 12, 2023).
[3] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-F), 89 Fed. Reg. 8758 (Feb. 8, 2024).

utilization management techniques results in added burden on medical providers, laboratories, and payers themselves, as all parties work through high numbers of unnecessary denials, extensive and repetitive medical documentation requirements, and long appeal processes. Concerningly, ACLA members report that utilization management techniques result in the denial of testing that meets the coverage criteria under Medicare Fee-For-Service.

Many of the utilization management techniques applied by payers hinge on ensuring medical necessity of the test in question through extensive documentation requirements. Unfortunately, many payers do not accept the types of documentation submitted with a test order to support medical necessity, such as a test requisition form (TRF) or a physician attestation to support medical necessity of the test. A TRF includes valuable information, including current diagnosis codes. Some payers' refusal to accept TRFs as medical documentation creates additional administrative burdens on the ordering provider and laboratory, as they are forced to identify and submit additional paperwork at the request of the payer throughout the claim process to establish the information previously submitted with the test order.

An ACLA member provided the following process of an MA plan claim submission for a genetic cancer test with a positive coverage determination under Medicare Fee-for-Service through an applicable Local Coverage Determination (LCD):

1. *Prior authorization:* Submission and approval is overseen by the MA plan's "prior authorization team". Throughout this process, the payer can request extensive medical documentation from the ordering physician.
2. *Pre-payment audits or medical documentation requests during claim processing*: During claim processing, the MA plan's "clinical necessity team" and/or "provider payment integrity team" oftentimes reach out to the laboratory to request medical documentation to ensure that the test was medically necessary. Our members note that the MA plan's internal teams that handle this process are sometimes not in communication with the MA plan's prior authorization team that already handled the claim. Many of the same documents are requested and must be resubmitted by the ordering provider to the MA plan.
3. *Post-payment audits:* Once the claim has been settled and paid, laboratories can be contacted for post-payment audits by the MA plan's "post-payment audit team". The stated goal of the post-payment audit process is to ensure that the claim was properly billed to the payer, as opposed to ensuring medical necessity, but this process requires high engagement from the laboratory to ensure that a payment is not clawed back. Concerningly, the MA plan's "post-payment audit teams" seem to know only that the test was performed and do not have access to the other supporting documents that were submitted throughout the claim process and do not have insight into the previous reviews. For example, a "post-payment audit team" can request the same information regardless of if the test received prior authorization or if the clinical necessity team had already approved the test for the patient.

Members report that the multiple reviews described above happen frequently, leading to overall higher rates of denials for tests that fully meet the LCD coverage criteria for MA plans compared to traditional Medicare. One ACLA member reported that on average, MA plans deny claims for tests covered under an LCD 14 to 34 times as often as the Medicare Administrative Contractor (MAC). Other members reported that on average, MA plans deny claims for their covered tests 5 to 7 times as often as the MAC.

Recommendation #1:

As CMS seeks to identify data elements that can be used to understand the impact of MA plans on beneficiary access, **we encourage the Agency to require MA plans to publish annual utilization management use and performance statistics to include:**

- **The number of claims for MA beneficiary requests received by type (laboratory test, surgery, etc.);**
- **The number of claims paid, denied, and unresolved over the previous 12 months;**
- **For denied claims, the percentage of claims denied at each level of payer review (prior authorization or pre-payment audits/medical documentation requests);**
- **For unresolved claims, the amount of time that has elapsed since the initial claim submission along with the current status of the claim (for example, awaiting additional medical documentation to be submitted by the provider, under additional review by the payer, etc.);**
- **The number of claims initially paid and then clawed back through post-payments audits;**
- **The number of denied claims appealed and their results (overturned or upheld, along with information on ultimate denial reason);**
- **A public summary by test description and Healthcare Common Procedure Coding System (HCPCS) code of the number of claims received and paid, denied or unresolved for covered laboratory tests under National Coverage Determinations (NCDs) and relevant LCDs.**

To ensure the data above is meaningful, these metrics should be broken down by ordering provider specialty.

In addition to our data collection recommendation above, ACLA also offers the following two policy recommendations:

Recommendation #2:

We suggest that CMS clarify that Test Requisition Forms are a valid form of medical documentation and provide suggested text below:

> ***Test Requisition Forms (TRFs) that are filled out by the ordering provider and submitted to the clinical laboratory along with the test order are a valid form of medical documentation. Impacted payers must consider the TRF and any additional information submitted with the laboratory test order (such as a physician attestation) as part of the medical record. Impacted payers may request additional medical documentation only when the TRF does not include the necessary clinical information to determine medical necessity.***

The need for agency-wide consensus on the topic of TRF acceptance was recently elevated, when the MolDX program utilized by multiple Medicare Administrative Contractors (MAC) released a new Local Coverage Article (LCA) that specifically states: "*When requisition forms include complete information validating medical necessity, such as qualifying clinical information that demonstrate test coverage criteria are met, the requisition form may be sufficient to determine if the service is reasonable and*

necessary without other medical information from the ordering provider." [4] While we appreciate this clarification that MACs which utilize the MolDX program will accept the TRF as part of the medical record, MA plans in these states are not bound to the requirements in this stand-alone coding article. We urge the Agency to quickly incorporate similar language to ensure parity across MACs and the MA plans.

Recommendation #3:

To ensure that MA utilization management processes are not preventing beneficiaries from accessing clinically necessary testing and resulting in denials of reimbursement for appropriate services, it is crucial that CMS is prepared to receive and handle reports of MA plans that routinely employ aggressive utilization management techniques. **We recommend that the Agency proactively establish a "hotline" or other well-publicized reporting process through which beneficiaries and other stakeholders can identify MA plans with utilization management processes that limit access to services covered under NCDs and LCDs inappropriately.** We envision the proposed "hotline" being similar to the newly launched CMS option for individuals to report potential violations of the Emergency Medical Treatment and Labor Act.[5]

II. Impact of Third-Party Organizations Contracted by MA Organizations

The growth of extensive utilization management processes for laboratory services is coupled with an increase in MA plans and other payers engaging third-party organizations to oversee various aspects of payments for laboratory services. ACLA members have identified two types of organizations with the most direct impact on coverage and payment of clinical laboratory services: laboratory benefit managers (LBMs) and "cost-lowering" third-party organizations. We are greatly concerned that HHS and CMS lack a clear line of sight into how these organizations function and impact coverage and payment of services, as they are outside the scope of the current oversight framework. We provide an overview of these categories of organizations below, along with some overarching recommendations for data collection to understand their impact on beneficiary access.

Laboratory Benefit Managers (LBMs)

Many payers rely on entities called Laboratory Benefit Managers (LBMs), which are similar to Pharmacy Benefit Managers (PBMs), to facilitate their prior authorization processes, regulate access to laboratory services, and control payment for these services. While LBMs are in many cases responsible for developing the coverage criteria and/or overseeing the utilization management processes for MA plans, it can be difficult for impacted stakeholders to engage directly with LBMs. Laboratories also report instances of LBMs' electronic portals not running as they should and many LBMs' processes necessitate labor-intensive appeals that present tremendous challenges and create inefficiencies in the

[4] A59741 MolDx: Clarification of Order Requirements for Laboratory and Molecular Diagnostic services. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59741&ver=2&contractorName=all&contractorNumber=all&updatePeriod=1093&sortBy=updated&bc=13.

[5] U.S. Department of Health and Human Services News Release "Biden-Harris Administration Launches New Option to Report Potential Violations of Federal Law and Continue to Promote Patient Access to Stabilizing Emergency Care." Released May 21, 2024 and accessible here: https://www.hhs.gov/about/news/2024/05/21/biden-harris-administration-launches-new-option-report-potential-violations-federal-law-continue-promote-patient-access-stabilizing-emergency-care.html

healthcare system.

Additionally, the involvement of an LBM can decrease transparency into coverage policies and requirements, as some LBMs consider these policies to be trade secrets that the payers that have engaged them are not allowed to share publicly. Often even when a medical policy is shared publicly, unlike LCDs and National Coverage Determinations (NCDs), LBM's medical policies withhold diagnosis codes associated with procedure codes, limiting the transparency into the coverage policy. Additionally, it is difficult for CMS, laboratories, or other stakeholders to understand the impact of an individual LBM as many payers do not disclose which LBM(s) they are working with and which service each LBM is performing. A laboratory might find out that an MA plan has engaged an LBM only if it receives an updated coverage or coding article from the payer with a disclaimer naming the LBM somewhere in the document, however, not all payers routinely include these disclaimers.

"Cost-lowering" Third-Party Organizations

Payers also have begun to engage healthcare data and technology businesses specifically to lower costs through payment policy management and prepayment coding validation. ACLA members note that one "cost-lowering" third-party organization that has become increasingly popular with state Medicaid and Medicaid Managed Care Organization (MCO) plans leverages specific proprietary coding rules, resulting in purely administrative denials for appropriate testing with positive coverage determinations.

Recommendation #4:

We recommend that CMS assess annually the reach of third-party organizations and the role they play in determining if a beneficiary's claim is paid or denied. **Along with Recommendation #1 above, we encourage the Agency to require MA plans to publish annual utilization management use and performance statistics to include:**

- **The percentage of claims denied due to a coverage policy or a utilization management process developed or overseen by a third-party organization that is contracted by the MA plan.**

To ensure the data above is meaningful, these metrics should be broken down by ordering provider specialty.

In addition to our data collection recommendation above, ACLA also offers the following policy recommendation:

Recommendation #5:

We recommend that CMS require MA plans to clearly mark on all published material regarding coverage policies and utilization management policies if these policies and/or criteria are developed or overseen by a laboratory benefit manager or other third-party organization under contract with the payer. This information should be clearly marked to provide full transparency and accountability when patients and medical providers have questions about a given coverage policy. **Additionally, like NCDs and LCDs, coverage policies used by MA plans should include ICD-10 diagnosis and associated procedural codes to ensure transparency in coverage.**

III. Impact of Organization Determination System

MA organizations (MAOs) are required to adhere to 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 a beneficiary is entitled to receive under an MA plan and regarding non-coverage of items and services. A beneficiary'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. (When an item or service, such as cosmetic surgery, is universally excluded and an MA plan can show that it has provided that information to an MA plan beneficiary in an Evidence of Coverage (EOC) prior to receipt of the item or service, an MA plan is not required to hold the beneficiary harmless from the cost of such item or service.)

Very few items and services are universally excluded in an EOC, so an MAO typically must use the organization determination process to notify a beneficiary, or a contracted provider on behalf of a beneficiary, that an item or service is non-covered. When an MAO's contracted provider makes a referral to a laboratory for a non-covered test and neither the beneficiary nor the contracted provider sought or received an organization determination about coverage for the test, the MAO is prohibited from holding the beneficiary financially responsible for the test. However, neither a laboratory nor an MAO should be required to bear the cost of a non-covered item or service if no organization determination was sought.

In most cases, it is impractical for a laboratory to seek an organization determination on an MA beneficiary's behalf, after receiving a test order from the beneficiary's physician but before performing the test. The ordering physician or the beneficiary is in the best position to request the organization determination. A laboratory cannot delay testing in order to seek an organization determination on behalf of a beneficiary because of specimen integrity issues and test turn-around-time expectations. Moreover, an MAO has up to 14 days after receiving a request to respond to standard organization determinations,[6] and CMS's regulations permit only an MAO beneficiary or a physician to request an expedited organization determination.[7] It simply is not possible for a laboratory to hold a specimen for up to two weeks while awaiting a response from an MAO on an organization determination request. Thus, while it may be permissible in theory for a laboratory to request an organization determination on a beneficiary's behalf after receipt of the specimen, most of the time it is not a real option.

The organization determination process affords the MA beneficiaries protections and related notice and appeal rights, however ACLA members find that the process results in payments for a wide variety of laboratory services being denied by MAOs when no organization determination is obtained. ACLA members report that this is not a problem that is limited to a handful of small regional plans. Rather, it is a widespread problem that our members have with the largest organizations (as well as smaller plans). Furthermore, the problems persist both for laboratories that are contracted with the MA plans and for those that are not contracted with particular MA plans. By and large, ACLA members have reported that the tests most commonly denied for lack of an organization determination are not esoteric tests, but rather "bread and butter" tests that are commonly performed in the Medicare population. This

[6] 42 C.F.R. § 422.568 (b).
[7] 42 C.F.R. § 422.566(c)(2).

underscores the fact that laboratories deal with this issue constantly and for very high-volume tests.

Recommendation #6:

To understand the extent to which the MA organization determination process impacts MA beneficiary access to care and payment for services furnished in good faith, **we recommend that CMS collect data annually from MA plans regarding the number and percentage of claims denied due lack of an organization determination.** To ensure that this data is meaningful, we recommend that this data is broken down by test description and HCPCS code.

Recommendation #7:

Currently, there is no denial/remark code for claims denied due to lack of an organization determination, which impedes data collection by the agency to gather data on this item. **We recommend that CMS develop a denial/remark code for lack of an organization determination and require MA plans to utilize this code.**

IV. Impact of MA Appeal Process

Medicare Fee-for-Service includes a 120-day deadline for stakeholders to file a redetermination request, while Medicare Advantage only has a 60-day deadline for the first level appeal. While this condensed timeline affects all denied claims, it disproportionately affects stakeholders trying to appeal denials due to burdensome medical documentation requests. Obtaining required, frequently duplicative, medical documentation can involve extensive back-and-forth between the laboratory and the ordering provider to assemble and submit the documentation to the payer's specification. This collaborative process frequently takes longer than 60 days, and the short timeframe blocks providers and beneficiaries from being able to continue through the appeal process if this first deadline is missed.

The agency recently stated in a response to comments that it "believes most enrollees who wish to appeal a denial do so immediately"[8], however ACLA and other stakeholders are concerned that CMS currently underestimates the level of dismissals at the plan level due to untimely filing for clinical laboratory tests. While an individual beneficiary might begin the appeal within this timeline, due to the technical nature of the testing, appeals for laboratory tests are frequently performed by the laboratories themselves on behalf of the beneficiary and take longer due to volume. Additionally, as the laboratories generally have already reported out the test result to the patient and ordering provider by the time the denial is received by the laboratory, the beneficiary is frequently not aware that the denial was issued and will not proceed with an appeal on their own.

Recommendation #8:

Along with Recommendation #1 above, we encourage the Agency to require MA plans to publish annual utilization management use and performance statistics to include:

- **The number of appealed denials that are upheld due to timely filling requirements/missing various deadlines throughout appeal process.**

To ensure the data above is meaningful, these metrics should be broken down by ordering

[8] 2025 Medicare Advantage and Part D Final Rule (CMS-4205-F)

provider specialty.

In addition to our data collection recommendation above, ACLA also offers the following policy recommendation:

Recommendation #9:

To prevent inappropriate denials due to this short appeal timeline, **ACLA recommends that CMS require Medicare Advantage plans to accept appeals filed within 120 days, in alignment with Medicare fee-for-service rules.**

* * *

Thank you for your consideration of ACLA's response to the Request for Information on Medicare Advantage Data. ACLA and ACLA member laboratories are committed to serving MA beneficiaries and providers and we look forward to engaging collaboratively with the Agency as it incorporates this feedback into new action.

Please reach out to me at sthibaultsennett@acla.com with any additional questions or to set up a call with our member laboratories to discuss these important issues further.

Sincerely,

Sarah Thibault-Sennett, PhD
Senior Director, Reimbursement Policy
American Clinical Laboratory Association (ACLA)