AMERICAN CLINICAL LABORATORY ASSOCIATION

January 27, 2025

Acting Administrator Jeff Wu
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4208-P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-P)

Dear Acting Administrator Wu,

The American Clinical Laboratory Association (ACLA) is pleased to submit our comments in response to the "Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" proposed rule (Proposed Rule).[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 on the Proposed Rule are focused on the following policy areas:

- Transparency around use of utilization management policies and procedures
- Rules on internal coverage criteria
- Guardrails for use of artificial intelligence (AI)
- Improving experiences for dually eligible enrollees
- Impact of "plan-directed care" and the MA Organization Determination system and
- Issues with the MA appeal process

I. Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures

A. Proposed Required Metrics

The Centers for Medicare & Medicaid Services (CMS) proposes to revise the required metrics for the annual health equity analysis of the use of prior authorization (which must be posted on the Medicare Advantage (MA) plan's publicly available website) to require metrics to be reported for each item or

[1] 89 Fed. Reg. 99340 (December 10, 2024).

service, rather than aggregated for all items and services.[2] CMS proposes to require MA plans to make publicly available metrics on:

- The percentage of standard prior authorization requests that were approved, reported by each covered item and service.
- The percentage of standard prior authorization requests that were denied, reported by each covered item and service
- The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.
- The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.
- The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

ACLA long has advocated for more transparency around the use of prior authorization and other utilization management techniques by MA plans and other payers and we strongly support CMS's proposal that MA plans must disaggregate utilization management metrics and report such metrics by item or service. CMS seeks comment on alternative ways to group items and services for the purpose of reporting on these metrics, while still allowing for meaningful disaggregation to increase transparency, identify trends, and address the impact of prior authorization on enrollees with the specified social risk factors.[3] We do not support grouping items and services, and we reiterate our support for granularity of MA prior authorization data and each of the proposed metrics, which would be most easily accomplished by requiring reporting by each Healthcare Common Procedure Coding System (HCPCS) code. For this information to be meaningful and to yield the "true accountability" that stakeholders told CMS they wanted, MA plans should not be permitted to hide disparities in aggregated data. ACLA agrees with CMS and other stakeholders that aggregated data is not useful to understand the effect of prior authorization on enrollees with one or more risk factors. The aforementioned categories are a good start to better understand the impacts of prior authorization.

CMS should analyze the valuable reported data and release publicly available summaries so that the public and the agency can better understand how MA plans are using prior authorization requirements across the board. In particular, we encourage the agency to review this data to understand the evolution from payers originally imposing prior authorization requirements primarily on high-reimbursement/low-volume diagnostic tests to increasingly requiring prior authorization for low-reimbursement/high-volume

[2] *Id.* at 99422.
[3] *Id.* at 99423.

tests, such as tests reimbursed at less than $100. This shift in how MA plans utilize prior authorization is particularly concerning and should be investigated by the agency, as the administrative costs to providers to comply with the requirements are higher than they would be reimbursed for the services rendered.

ACLA also supports CMS's proposal that the results of a health equity analysis would include an executive summary and must include the following elements: additional context that may be necessary or helpful for understanding the results of the analysis; clarifying information that is relevant to the results of the analysis, or that could help the public understand the analysis more fully; and an overview of the information produced by the analysis, including key statistics and results.[4] The executive summary should be factual and truly help CMS, stakeholders, and enrollees understand how MA plans' utilization management techniques affect different enrollees.

B. MA Prior Authorization Policies Harm Clinical Laboratories

In general, the concept of "prior authorization" oftentimes is not compatible with how lab tests are used to guide patient care. In practice, a physician or other clinician orders a laboratory service, sending a patient sample, such as blood or tissue, to a clinical laboratory, along with an order for specific testing. It should be the responsibility of the ordering provider to engage proactively with the patient's payer to determine if prior authorization is required for the test and submit the necessary documents prior to ordering a test. However, frequently, an order and a sample arrive at the lab without already-secured prior authorization and without documentation sufficient for the laboratory to seek prior authorization on behalf of a patient. When a laboratory discovers that prior authorization is missing, it may not be authorized to start the process itself, as many payers, including MA plans, do not allow a laboratory to secure prior authorization. Even though the ordering provider is asked to secure prior authorization for the tests they order, laboratories and ordering providers must have the option to submit prior authorization requests to payers to prevent reimbursement denials for tests already ordered.

Beyond the inefficiencies generated by this system, the regulation at § 422.566(c)(1) supports that other individuals and laboratories should be able to initiate requests as it states that an enrollee, enrollee's representative, or any provider that furnishes, or intends to furnish, services to the enrollee can request a determination. The regulation at 42 C.F.R. § 422.566(c)(1)(ii) says that an organization determination may be requested by 'Any provider that furnishes, or intends to furnish, services to the enrollee'." A laboratory is a "provider" for purposes of MA rules because it is an 'entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services'.[5] Additionally, laboratories are Medicare providers with National Provider Identification numbers and bill their laboratory testing claims to Medicare Administrative Contractors (MACs) and third-party private payers. Still, the lack of compliance by MA organizations indicates that clarification is warranted. CMS should clarify and enforce the rule that plans cannot restrict prior authorization to ordering providers or primary care providers (PCPs); they must allow enrollees, an enrollee's representative, and any provider, *including laboratory professionals,* to request prior authorization.

Invoking the "date of service" rule is another way that some MA plans leverage prior authorization processes to deny payment to laboratories. MA plans often adopt the Medicare Part B "date of service rule" at 42 CFR § 414.510(a), such that the date of service is generally the date of specimen collection. For example, OmniSeq is a biomarker test performed after a positive diagnosis of cancer. The patient is referred to an oncologist, where a treatment plan is developed with the patient that often includes further testing to determine therapies that will create the best possible outcome for the patient. Since biomarker testing is performed on the same specimen that that was used for the original pathology service, the date of service for the additional testing remains the specimen collection date – a date prior to the date the OmniSeq test was even ordered. Payers, including MA plans, that will not allow retroactive prior

[4] *Id.* at 99424.
[5] 42 C.F.R. § 422.2.

authorization for a date of service that occurred in the past are denying coverage for biomarker testing based on a technicality unrelated to the clinical rationale for the testing. This creates a barrier to cancer care for patients.

Since the date of service usually is defined as the date of specimen collection rather than the date on which the test is performed, the "date of service" often has long passed by the time the laboratory even receives the specimen for testing. If a health care practitioner does not get prior authorization before ordering or before the sample is collected—which is often the case—the laboratory will attempt to get prior authorization once it receives the order. However, this frequently results in a denial due to the date of service issue. Because patients and their physicians urgently need testing results, labs often perform testing and provide results at a time when "prior authorization" is not obtainable and are not paid for the covered services they provided. Further compounding this problem, when the prior authorization is denied after the laboratory has submitted the claim, as will often be the case when the laboratory performs the testing in a timely manner to ensure the patient receives the care they need, then the submitted claim also will be denied due to lack of prior authorization, leading to issues with the appeal process. To alleviate the many issues outlined above, ACLA recommends that the Agency require MA plans to accept submission of prior authorization requests for laboratory services at any time after the date of service.

C. MA Utilization Management Goes Far Beyond Prior Authorization

It is important for CMS to acknowledge that prior authorization is just one type of utilization management technique and that MA plans and other payers also use other types of utilization management techniques to delay or deny payment (*e.g.*, pre-pay medical documentation requests and post-pay audits). Navigating the complex web of 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. Sometimes these reviews are unnecessary and impose undue administrative burden during a patient's established course of treatment. For example, when a transplant patient has periodic laboratory testing to determine if the transplanted organ is at risk of being rejected, an MA plan should not repeatedly ask a laboratory for medical documentation as evidence that the patient has had a transplant. In another example, multiple MA plans are instituting medical records review for the vast majority of claims for a colorectal cancer screening test for average risk patients. For such a test, medical necessity can be determined via basic information (*e.g.*, age) and provided International Classification of Diseases, Tenth Revision (ICD-10) coding, rendering these burdensome documentation requests unnecessary.

Concerningly, ACLA members report that use of utilization management techniques beyond prior authorization often results in the denial of payment for testing that meets Medicare coverage criteria under Parts A and B. Many of the utilization management techniques applied by payers require extensive documentation requirements, purportedly to ensure medical necessity of the test(s) in question. To understand the impact that broader MA utilization management techniques have on beneficiary access to covered services, ACLA recommends that the agency develop similar metrics for utilization management techniques and levels of denials or delays in reimbursement broadly in future rules, such as:

- The number of claims for MA beneficiary requests, reported by each covered item and service;
- The number of claims paid, denied, and unresolved over the previous 12 months, reported by each covered item and service;
- For denied claims, the percentage of claims denied at each level of payer review (prior authorization or pre-payment audits/medical documentation requests), reported by each

covered item and service;

- 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.), reported by each covered item and service;

- The number of claims initially paid and then clawed back through post-payments audits, reported by each covered item and service;

- The number of denied claims appealed and their results (overturned or upheld, along with information on ultimate denial reason), reported by each covered item and service;

- The number of denied claims ineligible for appeal, reported by each covered item and service;

- For denied claims, the percentage of claims for which a prior authorization was approved, reported by each covered item and service; and

- A public summary by test description and 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.

D. Need for Agency Guidance with Excessive MA Plan Medical Documentation Requests

Laboratories oftentimes are required to provide extensive medical documentation to support the medical necessity of the service they perform. One issue laboratories face is that many payers and MA plans do not accept the types of documentation submitted with a test order, such as a test requisition form (TRF) or a physician attestation, to support medical necessity of a 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 to reiterate the information previously submitted with the test order. In line with this, a recent Office of Inspector General (OIG) report found that in some cases, despite MA organizations' requests for additional documentation, the provided information was already sufficient to demonstrate medical necessity.[6] It is important to note that the documentation requested by payers to substantiate a laboratory claim audit is the proprietary medical records of the ordering provider. In order to comply with the payer's request for additional medical documentation, laboratories request the chart notes from the ordering physicians, often with no response. The laboratory is penalized for not complying with the audit request and reimbursement is denied.

The need for agency-wide consensus on the topic of TRF acceptance was elevated recently when the MolDX program, which is utilized by multiple Medicare Administrative Contractors (MAC) to determine coverage and payment for molecular diagnostic tests, released a 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*

[6] U.S. Department of Health and Human Services Office of Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," *available at* https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

information from the ordering provider."[7] We urge the Agency to adopt this criteria broadly and require MA plans to accept patient background and medical information included on a laboratory requisition form filled out by the ordering clinician, along with physician attestations, as medical documentation sufficient for assessing whether items or services satisfy the coverage criteria established by an NCD or LCD, provided that the TRF includes the required information.

II. Enhancing Rules on Internal Coverage Criteria

A. Using Internal Coverage Criteria to Interpret or Supplement General Provisions

In the CY 2024 MA/Part D final rule, CMS codified at § 422.101(b)(6)(i) that MA organizations may apply internal coverage criteria when coverage criteria under "Traditional Medicare" are not fully established in three specific circumstances. One circumstance is when additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. CMS states it needs to revise the regulatory text to state its intent more clearly, which was to allow MA organizations to interpret or supplement the plain language of existing and applicable Medicare coverage and benefit criteria (as stated in applicable Medicare statutes, regulations, National Coverage Determinations (NCDs), or applicable Local Coverage Determinations (LCDs)) when needed. CMS states that "it is only in the rare instance when an NCD or LCD is lacking in specificity or clarity that we would consider [internal coverage criteria] to be permissible to interpret or supplement general provisions…".[8]

Actually, there are many laboratory LCDs and NCDs whose coverage policies are neither specific nor clear, so such internal coverage criteria are not "rare instances". ACLA and other clinical laboratory stakeholders are greatly concerned that the language in the proposed rule would create an opportunity for MA plans to deny payment for covered services due to a misunderstanding regarding how coverage information is conveyed through coverage determinations and their associated transmittals and articles.

The proposed revision would create confusion when considering other stated agency policies for coverage determinations. Coverage for clinical laboratory tests oftentimes is determined at the code level — a CPT® code, a Proprietary Laboratory Analysis (PLA) code, and/or a "Z-code" issued by the MolDX program.[9] CMS policy is that such codes may not be included in an LCD:

> *It is no longer appropriate to include Current Procedure Terminology (CPT) codes or International Classification of Diseases-Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All CPT and ICD-10-CM codes shall be removed from LCDs and placed in billing & coding articles or Policy Articles that are to be published to the MCD and related to the LCD.*[10]

Based on the wording of the proposed rule, an MA plan could deny coverage for any and all tests listed in the coding article of an LCD, using the justification that the test was not singled out by name in the LCD itself and going against the logic of how these polices are intended to be utilized. While this was not the agency's intention, it is crucial that the language in the proposed rule is addressed to ensure that the rule does not create loopholes for MA plans to skirt coverage requirements.

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[7] MolDX: Clarification of Order Requirements for Laboratory and Molecular Diagnostic Services. Articles A59792, A59743, A59744 and A59741. Accessible here: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59741.
[8] 89 Fed. Reg. 99456.
[9] *See* DEX General Facts, *available at* https://www.dexzcodes.com/palmetto/providers.nsf/files/DEX_General_FAQs.pdf/$FILE/DEX_General_FAQs.pdf.
[10] Medicare Program Integrity Manual, Pub. No. 100-08, Ch. 13, Sec. 13.5.1.

Additionally, it is important for CMS to acknowledge and account for the unique process for coverage of molecular diagnostic tests that is used by states in MAC jurisdictions that are part of the MolDX® program (administered by Palmetto GBA®). Currently, four MACs participate in the MolDX program (Palmetto GBA, Noridian Healthcare Solutions, Wisconsin Physician Services Corp (WPS), and CGS Administrators, LLC), accounting for over half of the states in the U.S. MACs that participate in the MolDX program issue and administer similar (oftentimes identical) "foundational" LCDs for molecular diagnostic tests[11], for which laboratories are required to obtain unique Z-Code identifiers in the DEX® Diagnostics Exchange database. The foundational LCDs issued by the MolDX program by their nature are "lacking in specificity or clarity" because they include only high-level information about the process and criteria that the MolDX program will use to determine whether or not a test is covered.[12] Foundational LCDs themselves do not specify which laboratory tests are covered: that information is contained either in billing articles associated with an LCD or in the MolDX proprietary database, after a "technical assessment" is conducted by the MolDX program.[13] ACLA members have shared that MA plans already struggle to understand and implement equivalent coverage of tests that are covered under the MolDX foundational LCDs because of the complexity of this system and inability to search the DEX database by tests covered under a specific LCD, and we are concerned that the proposed language would exacerbate this confusion and lead to further issues with coverage.

To make good on the promise that MA plans cover "all items and services…for which benefits are available under Parts A and B of Medicare,"[14] CMS should make clear in the final rule that coverage and benefit criteria may be found not only in statutes, regulations, NCDs, and LCDs, but also in NCD Coding Policy Manual and Change Report (CRs), LCD billing articles, and in proprietary contractor resources (such as the DEX database for molecular diagnostics under the MolDX system), and that MA plans must look to **all** such sources for evidence of Traditional Medicare coverage of laboratory test or other item or service prior to developing internal coverage criteria.

B. Definition of Internal Coverage Criteria

At § 422.101(b)(6)(iii), CMS proposes to define internal coverage criteria as any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization to make a medical necessity determination at § 422.101(c)(1).[15] The agency explains that this includes any coverage criteria that restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care. CMS clarifies that the application of additional measures or policies or more specific parameters that further define Medicare coverage policies are the application of internal coverage criteria and, therefore, must meet all regulatory requirements at § 422.101(b)(6).

We support CMS's efforts to provide greater clarity in the definition of internal coverage criteria and to assert that there are only rare instances when this should be permissible for NCD and LCD covered services. CMS states that this proposed rule is meant to build upon and enhance the regulations

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[11] MolDX has defined "Molecular Diagnostic Tests (MDT)" that fall under its purview as: "*Any test that involves the detection or identification of nucleic acid(s) deoxyribonucleic acid/ribonucleic acid (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolite(s). The test may or may not include multiple components. A MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.*" LCD MolDX: Molecular Diagnostics Tests (MDT) (L35025), accessible here: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35025.
[12] *See*, *e.g.*, MolDX: Molecular Diagnostic Tests (L35025); MolDX: Next-Generation Sequencing for Solid Tumors (L38045).
[13] DEX Diagnostics Exchange Registry, *available at* https://app.dexzcodes.com/login.
[14] 42 C.F.R. § 422.100(c)(1).
[15] 89 Fed. Reg. 99457.

and guidance outlined in the CY 2024 Policy and Technical Changes to the Medicare Advantage Program final rule released in April 2023 and subsequent FAQ released in February 2024 "Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)".

While we appreciate the additional clarity provided by this proposed rule, we also feel that CMS can have the greatest impact on its "intended goal of ensuring access to medically necessary care for MA enrollees" by enhancing its enforcement efforts related to existing regulation that requires MA plans comply with NCD, LCD, and general coverage and benefit conditions included in Traditional Medicare laws and regulations. The standard appeals process works reasonably well for low frequency discrepancies, but there is no clear mechanism to report violations when there is a systemic MA interpretation issue that causes the denial rate to be significantly higher in the Part C population than in the Part B population. It is not reasonable to expect a provider to appeal the majority of Medicare Advantage claims in order to gain a similar rate of coverage as Traditional Medicare. When attempting to escalate issues to CMS in the past, our members have been directed to contact MA account liaisons at CMS, but this outreach has not resulted in meaningful engagement. As just one example of why a clear escalation process is needed, as described above, MA plans continue to deny prior authorization requests submitted by laboratories despite regulation stating that this is permissible.

ACLA urges CMS to educate MA organizations and their associated third-party intermediaries about the regulatory requirements relevant to the definition, clearly communicate the intent of CMS to enforce the requirements, and actually enforce them. ACLA members have observed that MA organizations and their third-party intermediaries increasingly are adopting and implementing internal coverage criteria that do not meet the regulatory requirements at § 422.101(b)(6). Specifically, MA organizations, or laboratory benefit managers on behalf of or at the behest of MA organizations, are adopting and implementing internal coverage criteria that are not "publicly accessible" and are not based on "current evidence" in "widely used" treatment guidelines or clinical literature as required by § 422.101(b)(6). If the proposed definition of "internal coverage criteria" is to have any meaning, these practices must stop. For example, internal coverage criteria should include a publicly accessible list of payable diagnosis codes to increase transparency and efficiency in the system.

Additionally, we join other stakeholders in calling for CMS to establish a streamlined mechanism for providers to report systemic issues with MA plans. Specifically, we recommend that CMS create a provider-specific electronic form for reporting systemic MA violations to CMS. Further, CMS should establish a clear process to allow providers to escalate patterns of suspected violations and to resolve disputes between providers and MA organizations. 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 internal coverage criteria and associated utilization management tactics.

C. Prohibitions

ACLA appreciates CMS's proposal to remove the "clinical benefits that are highly likely to outweigh any clinical harms" requirement in both § 422.101(b)(6)(i)(A) and (ii)(C) and to replace it with two important policy guardrails in new proposed paragraph (iv) that will apply to all internal coverage criteria: that using an internal coverage criterion is prohibited when the criterion does not have any clinical benefit or when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination. CMS should amend the regulation at § 422.101(b)(6)(iv) by replacing the period at the end of clause (A) and replacing it with "; or", in order to clarify that an internal coverage criterion is prohibited <u>either</u> when there is no clinical benefit or when it is used to deny coverage automatically, not when both conditions are present.

D. Public Availability

CMS proposes to revise the public accessibility requirements to ensure that MA organizations are making internal coverage criteria available in a manner that is routinized and easy to follow.[16] First, CMS proposes to update § 422.101(b)(6) and § 422.101(b)(6)(ii) by replacing the word "accessible" with "available." The agency is proposing to update the requirements in paragraphs (b)(6)(ii)(A)-(C) to be more specific about the information that must be publicly accessible. The agency proposes that each internal coverage criterion used by the MA organization in making medical necessity decisions on Part A and Part B benefits must be clearly identified and marked as internal coverage criterion of the MA plan within coverage policies. CMS is also proposing to add to the list of evidence that supports the coverage criterion by requiring that the evidence be connected to the internal coverage criterion. CMS is proposing that by January 1, 2026, MA organizations must publicly display on the MA organization's website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions. CMS is also considering an annual reporting to CMS of the information in § 422.101(b)(6)(ii)(A)-(D). The agency solicits comment on whether CMS should require a specific format or standard template for the information posted on the MA organization website.

ACLA supports CMS's proposals to revise the public accessibility requirements to ensure that MA organizations are making information available in a manner that is routinized and easy to follow. It should be clear to all enrollees and stakeholders the items and services for which an MA plan has internal coverage criteria that supplement LCDs or NCDs, and it should be easy to find those criteria. We urge CMS to finalize policies to ensure that any stakeholder can easily access this information (*e.g.*, no password protections, no requirements to accept terms, etc.). The website that contains such information also should be user friendly.

ACLA also supports annual reporting by MA plans to CMS of the internal coverage criteria information that must be made publicly available on a website. CMS should be monitoring MA plans' compliance with internal coverage criteria requirements, and receiving this information directly from MA plans, rather than having to hunt for it, will make CMS's job easier. Further, MA plans may be more motivated to comply with the requirements, knowing that they need to report the information directly to CMS.

Beyond the requirements outlined in the proposed rule, ACLA encourages the agency to require MA plans to include publicly accessible information on the role of any third-party organization in developing, implementing, and/or overseeing the internal coverage criterion on behalf of an MA plan. In particular, we recommend that the agency require MA plans, along with the internal criteria on their websites, to disclose which, if any, third-party organizations were involved in the development or implementation of the individual coverage criteria. 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. This publicly accessible information is crucial for providers to gain sorely needed transparency into these internal policies and will help the agency better understand the roles that third-party organizations play in developing and implementing internal coverage criteria.

III. Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence

CMS proposes to revise § 422.112(a)(8) to specify that Artificial Intelligence (AI) or automated

[16] *Id.* at 99460.

systems, if utilized, must be used in a manner that preserves equitable access to MA services. Further, CMS clarifies that if an MA plan uses AI or automated systems, the plan must comply with Sec. 1852(b) of the Act,[17] § 422.110(a),[18] and other applicable regulations and requirements, provide equitable access to services, and not discriminate based on any factor that is related to the enrollee's health status.

While ACLA recognizes the important role AI can play for laboratories and the healthcare field in general, AI and automated systems used in coverage decisions should provide transparency that enables users to understand the validity, reliability, and potential biases of the system. ACLA is concerned with the application of AI and other automation that already negatively impacts enrollees, such as the application of front-end edits leading to automatic denials by third-party organizations that MA plans contract with due to proprietary coding rules before the MA plans have the opportunity to review the claim for coverage based on medical necessity. Front-end edits result in a significant number of inappropriate claim denials and are a tremendous administrative burden on the laboratory and the ordering provider to re-submit the claims despite each of the laboratory testing services being medically necessary based on medical policy. AI and automated systems should not be used to deny or impede enrollee access to services automatically. For example, AI should not entirely replace prior authorization evaluations – there must be a human evaluation to ensure enrollee are not being denied care that is necessary to address their health conditions.

IV. Improving Experiences for Dually Eligible Enrollees

CMS is proposing to add a requirement at §§ 422.2267(e)(30) and 423.2267(e)(32) that integrated plans (AIPs) must provide dually eligible enrollees one integrated member ID card to serve as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled. ACLA supports a combined ID card for dually eligible enrollees. Separate ID cards are administratively confusing, as providers may not always know which insurance to charge for which services. It is also confusing for enrollees, who may not always be aware of when to present which ID card. A combined ID card for dually eligible enrollees will decrease burden for providers and limit confusion among enrollees.

V. Impact of "Plan-Directed Care" and Organization Determination System

Clinical laboratories face significant challenges related to "plan-directed care," which occurs when a contracted provider furnishes a service or refers an enrollee for a service that an enrollee reasonably believes is a plan-covered service. Plan-directed care occurs not only when a contracted provider (*i.e.*, ordering physician) refers an enrollee to a non-contracted provider, but also when a contracted provider refers an enrollee for a service without securing an Organization Determination (OD) on behalf of the enrollee in advance of rendering the service.

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 OD 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 OD. (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

[17] 42 U.S.C. 1395w-22, Benefits and beneficiary protections.
[18] General prohibition on beneficiary discrimination.

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 OD 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 OD 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 OD was sought.

In most cases, it is impractical for a laboratory to seek an OD on an MA beneficiary's behalf, after receiving a test order from the beneficiary's physician but before performing the test. As discussed earlier, oftentimes, the laboratory does not receive an order until either after the date of service or at the time of service; a laboratory cannot delay testing to seek an OD on behalf of an enrollee due to specimen degradation issues and testing turnaround time requirements. Moreover, an MAO has up to 14 days after receiving a request to respond to standard organization determinations,[19] and CMS's regulations permit only an MAO beneficiary or a physician to request an expedited organization determination.[20] 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.

Laboratories have been put in the untenable position of providing laboratory services to MAO enrollees without receiving reimbursement for the services their ordering providers have determined are medically necessary. While the PR attempts to clarify appeal rights and makes it clear that regulatory appeal rights do not apply to the denial of a claim when there is no further financial liability, and thus an enrollee cannot be held financially responsible, it does not clarify the plan's responsibility to pay for plan-directed care. For laboratories, as contracted providers with MAOs, notice and appeal rights do not apply, and laboratories' sole recourse is contractual and to follow the MAO's process for reconsideration. Participating providers have not explicitly agreed to assume the cost of non-covered services and should be granted the same rights as non-participating providers with respect to the appeal process. In addition, we believe the referral for the laboratory service from a participating ordering practitioner should be considered a favorable organization determination, regardless of whether the lab is participating, and an MAO should pay a laboratory for these services.

ACLA members report that this is not a problem that they have only with a handful of small regional plans – it is a widespread problem that our members have with the largest organizations, as well. 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 underscores the fact that laboratories deal with this issue constantly and for very high-volume tests.

Given the unique circumstances of laboratories, who oftentimes have no face-to-face contact with patients and who realistically cannot obtain an organization determination on an enrollee's behalf, it would be appropriate for the agency to remind MA plans of their obligation to pay for a service that is referred by a participating practitioner. Additionally, we urge CMS to improve and clarify the OD process requirements so that laboratories are also protected from undue financial liability as MAO enrollees are

[19] 42 C.F.R. § 422.568 (b).
[20] 42 C.F.R. § 422.566(c)(2).

in the PR. We are aware that certain contractual issues are outside of CMS's scope of authority with respect to MA plans; nevertheless, we believe that explicit guidance from the agency would be a tremendous help to ACLA members seeking payment from MA plans.

VI. Impact of MA Appeal Process

Traditional Medicare includes a 120-day deadline for stakeholders to file a redetermination request, while Medicare Advantage only has a 65-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 as highlighted earlier. Obtaining 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 65 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";[21] 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.

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 Traditional Medicare rules.

* * *

Thank you for your consideration of ACLA's comments to the Proposed Rule. We would be pleased to answer any questions or discuss any of the information in this letter with you.

Sincerely,

Sarah Thibault-Sennett
Senior Director, Rimbursement Policy

[21] 2025 Medicare Advantage and Part D Final Rule (CMS-4205-F)