



American  
Clinical Laboratory  
Association

**COMMENTS OF THE  
AMERICAN CLINICAL LABORATORY ASSOCIATION  
ON THE MEDICARE PROGRAM; MEDICARE SHARED SAVINGS PROGRAM:  
ACCOUNTABLE CARE ORGANIZATIONS  
PROPOSED RULE (CMS-1345-P)**

The American Clinical Laboratory Association (ACLA) is pleased to have this opportunity to submit our comments on the *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Proposed Rule* (the “Proposed Rule”).<sup>1</sup> ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of clinical diagnostic laboratory services to Medicare beneficiaries, ACLA member companies will be directly impacted by the Proposed Rule. However, the Proposed Rule does not appear to recognize (a) the important role that independent laboratories currently play in improving the quality and coordination of patient care and could play in accountable care organizations (ACOs), or (b) the impact of the Medicare Shared Savings Program (MSSP) on independent laboratories and their ability to serve Medicare beneficiaries. Therefore, ACLA’s comments will focus on the following:

- The value independent laboratories bring to patient care and can bring to the MSSP;
- The ambiguity around laboratories’ ability to participate in the MSSP;
- The incentive to withhold or underutilize important services under the MSSP;
- The potential that beneficiaries could be denied innovative laboratory tests and procedures as a result of the MSSP;
- The distribution of shared savings among ACO participants and ACO providers/suppliers; and
- Additional laboratory-focused quality measures that should be used in the MSSP.

**I. Independent Laboratories Enhance the Quality, Efficiency and Outcomes of Patient Care and Can Help Achieve the Goals of the MSSP**

Independent laboratories have much to offer towards achieving CMS’ “triple aim” of improving care for individuals, improving population health and reducing costs. In fact, laboratory testing already helps promote these very same goals. For example, laboratories provide health professionals with critical information about individual patients’ health status,

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<sup>1</sup> 76 *Fed. Reg.* 19528 (Apr. 7, 2011).

which allows practitioners to select the most appropriate treatments and other interventions, as well as data analysis and tracking services that allow individual patients to be monitored over time. In fact, laboratory testing has been shown to influence 70-80 percent of clinical decisions while representing only a tiny percentage of overall health care spending. Based on laboratory testing results, practitioners often change the course of care for patients, leading to better health outcomes. In addition, the growing availability of personalized testing can reduce the utilization of more costly interventions. As examples, genetic testing can be used to determine if a cancer patient is likely to have a recurrence or will benefit from the use of chemotherapy, and to predict if a heart transplant patient is likely to reject his new heart. Laboratories also screen populations to detect disease and provide population-level analysis and trending, and can monitor utilization over time, which helps providers track and adjust their use of particular tests and their spending on clinical and anatomic laboratory services. Finally, independent laboratories often have sophisticated health information technology systems that can share test results electronically, which helps coordinate care among distinct providers, improves efficiency, and reduces duplication of tests due to lost or unavailable results. All of these services help promote high quality, cost effective care that improves patient outcomes.

In light of the value independent laboratories bring to the quality, efficiency and outcomes of patient care, ACLA is concerned that CMS may have overlooked laboratories in the Proposed Rule and failed to adequately address how laboratories can participate in ACOs. At the very least, as discussed in section II below, the definitions CMS has proposed for “ACO participant” and “ACO provider/supplier” are ambiguous as to the ability of laboratories to qualify. In fact, independent laboratories’ strengths align well with the goals of ACOs and the MSSP: laboratories improve the quality of care provided to Medicare beneficiaries, and they help practitioners deliver the right care to patients at the right time, increasing efficiency and improving health outcomes. Laboratory testing plays a key role in developing evidence-based medicine and in monitoring adherence to clinical practice guidelines, which are critical elements of the concept of accountable care. Thus, to prevent (or fail to clearly define) the participation of laboratories in ACOs would be, at best, a missed opportunity for quality improvement and cost savings and, at worst, detrimental to beneficiary care and access to needed laboratory services.

## **II. CMS Should Clarify the Ability of Independent Clinical Laboratories to Participate in the Medicare Shared Savings Program**

In the Proposed Rule, CMS defines two key terms that are instrumental in determining who is allowed to participate in an ACO under the MSSP: “ACO participant” and “ACO provider/supplier.” ACLA is concerned that CMS has defined these terms in a way that makes it unclear whether or not independent laboratories are able to participate in ACOs. While it seems clear in both the preamble text and the regulatory text that a laboratory may be an ACO *participant*, CMS’ intent as to the ability of laboratories to be ACO providers/suppliers is ambiguous. In fact, as currently drafted, the term is defined in a way that could raise questions about whether or not laboratories are included. In addition, the preamble text and the regulation text are inconsistent as to which ACO participants are eligible to form ACOs on their own. ACLA requests that CMS clarify its intent with respect to each of these ambiguities.

*“ACO Provider/Supplier”*

CMS has proposed to define “ACO provider/supplier” as: “(1) A provider (as defined in § 400.202); or (2) A supplier (as defined at § 400.202) that bills for items and services it furnishes to Medicare beneficiaries *under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.*”<sup>2</sup> Under §400.202, a supplier is “a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.” Thus, independent laboratories meet the definition of “supplier.” An “ACO participant” is defined simply as “a provider (as defined in § 400.202) or a supplier (as defined at § 400.202), as identified by a TIN.”<sup>3</sup> Because independent laboratories are suppliers and have TINs, they would qualify as “ACO participants.”

However, it is unclear how the definition for ACO provider/supplier, cited above, would apply to a laboratory and, in particular, what is meant by the phrase “under a billing number assigned to the TIN of an ACO participant.” We assume that by using the term “assigned” CMS does not mean there is a formal “assignment” as that term is used when a supplier reassigns its billing rights; rather, we believe that CMS uses the term in the more general sense that there is a “link” between the billing number and the TIN of the participant. This is an important distinction, because unlike some other types of professionals, laboratories cannot usually assign their right to bill to another entity. Further, it is our understanding that the Proposed Rule is not intended to change how providers and suppliers bill Medicare for their services. That is, the current billing and reimbursement rules will continue to apply to all Medicare providers and suppliers, whether or not they participate in an ACO, which means that laboratories will continue to directly bill the Medicare program for services provided to Medicare beneficiaries (whether or not they are assigned to an ACO).

Under our interpretation that “assigned” simply means that the billing number of the entity would link back to the TIN of an ACO participant, if an individual laboratory entity had its own TIN, and was an ACO participant, then presumably the laboratory would also be considered an ACO supplier because its billing number would “link to” the TIN of the ACO participant. In this situation, the laboratory would be an ACO supplier because of its status as an ACO participant. On the other hand, if the laboratory entity had its own billing number, but was also part of a larger corporate entity that holds the TIN for all of the subsidiaries, and that larger entity was an ACO participant, then the laboratory would be considered an ACO supplier because the billing number of the individual laboratory entity would “link” or be “assigned” to the TIN of the ACO participant. However, under the language of the Proposed Rule and the current Medicare billing rules, there does not appear to be a way for an independent laboratory that bills under a Medicare billing number linked to its own TIN to be an ACO supplier without also being an ACO participant.

ACLA does not believe that CMS intended to exclude laboratories from participation as ACO providers/suppliers while allowing laboratories to be ACO participants. It would be

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<sup>2</sup> *Id.* at 19641 (proposed 42 C.F.R. §425.4) (emphasis added).

<sup>3</sup> *Id.*

counterintuitive to permit laboratories to participate in the formation and governance of an ACO as an ACO participant while precluding them from providing services on a contractual basis as an ACO supplier.

In view of the substantial ambiguity surrounding the definition of “ACO provider/supplier”, we respectfully request that CMS either amend the definition or clarify its intent in the final rule. In either case, we request that CMS make clear that independent laboratories may participate in ACOs as ACO participants and/or ACO providers/suppliers. Finally, we request that CMS clarify that Medicare billing and reimbursement processes are intended to proceed in identical fashion, whether or not a provider or supplier is participating in an ACO under the MSSP.

#### *Eligible Providers and Suppliers*

There is also ambiguity around whether laboratories would meet the definition of eligible providers and suppliers, which are those entities who can actually establish an ACO. Under proposed §425.5, Eligibility and governance requirements, CMS provides a list of the providers and suppliers eligible “separately or in combination, to form ACOs that may participate in the Shared Savings Program.” Among this list are “Providers and suppliers otherwise recognized under the Act that are not ACO professionals or hospitals.” The inclusion of this last group suggests that there is a broad list of other entities that would be eligible to form ACOs, which could include laboratories.

However, in the preamble discussion, CMS does not include this broad category. In the preamble, CMS describes at length its decision to permit only the statutorily-defined groups of ACO participants (e.g. ACO professionals in group practice arrangements, hospitals employing ACO professionals), supplemented by critical access hospitals billing under Method II, to form ACOs on their own.<sup>4</sup> Thus, while the preamble specifically listed the five entities or groups of entities eligible to form ACOs on their own, the regulatory text actually includes another category—any other non-ACO professionals and non-hospital entities recognized under the Act. We therefore request that CMS clarify its intent on this point, because this inconsistency makes it unclear whether or not laboratories can help to establish an ACO.

The final rule should make clear that, in addition to being able to participate as ACO participants and ACO providers/suppliers, laboratories could be involved in the formation of an ACO. Although laboratories cannot themselves be ACOs without the collaboration of ACO professionals and hospitals, many independent laboratories may be well positioned to bring together these groups and entities to form ACOs. Indeed, many independent laboratories have strong relationships with physician group practices, hospitals and other providers and could function as the necessary link to establish a successful ACO. CMS should encourage capable independent laboratories and other non-hospital, non-physician entities to work together with their existing business partners to determine whether establishing an ACO would be feasible. Independent laboratories have the ability to assist with data management, coordination of care

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<sup>4</sup> See generally *id.* at 19537-19539.

and ongoing monitoring of patients' health. In this way, laboratories may be able to provide the impetus for an ACO in a community that might not otherwise have one.

Furthermore, laboratories will have a key role to play in the operation of the ACO. For example, a number of the quality performance measures required for ACOs depend on laboratories, including measures of Hemoglobin A1c control and urine protein screening for patients with diabetes, measures of low-density lipoprotein for patients with coronary artery disease and other cardiovascular conditions, monthly INR for patients on warfarin, and colorectal cancer screening for patients between 50 and 75 years old. ACOs will have to perform these tests consistently in order to ensure that the ACO remains in compliance with its contractual obligations and can, as envisioned under the Proposed Rule, receive the highest possible level of shared savings. Given the importance of laboratory measures, independent laboratories should be permitted to be involved in the formation of the ACO.

For the reasons above, we request that CMS clarify its intent with respect to which suppliers and providers may form an ACO on their own. Further, CMS should clarify that, even if they are not permitted to form an ACO on their own, laboratories are permitted to collaborate with other providers, suppliers and professionals to form an ACO.

### **III. The Medicare Shared Savings Program May Incent Providers to Withhold or Underutilize Important Patient Services to Achieve Cost Savings**

In a system where shared savings are awarded on the basis of comparative costs from one year to the next, the natural incentive for ACO-participating entities and professionals will be to reduce their utilization of items and services. Certainly some degree of reduced utilization is to be expected due to better coordinated care, which reduces duplication of services. However, we believe that under CMS' proposal, providers and suppliers may be incentivized to reduce utilization to a greater degree in order to receive the highest possible level of shared savings. As drafted, there are significant structural and financial hurdles to establishing an ACO, and a relatively low level of shared savings (only up to 65 percent of the savings in the best case scenario, which will not likely apply to most ACOs). Due to the significant upfront investment and the comparatively small financial reward (assuming the ACO is successful), ACOs admitted to the MSSP will likely wish to take every opportunity to reduce the costs that will be attributed to their assigned population, including withholding higher cost items and services.

ACLA is concerned that patient access to more advanced or complex types of testing, such as personalized and genetic testing, could be compromised if additional safeguards are not put in place. Many ACOs may default to using laboratories connected to hospitals that are part of the ACO for the majority of their laboratory testing; however, such laboratories may not always offer these complex types of testing. Independent laboratories are on the cutting edge of developing new and innovative tests, including personalized and genetic tests. If ACOs refer patients by default to in-house laboratories that do not offer such tests, patient access to innovative and personalized testing could be compromised.

In light of this inherent incentive to withhold care, we encourage CMS to include stronger safeguards in the Proposed Rule. We understand that the quality performance standards are intended to provide some confidence that quality care is not being sacrificed in order to reduce costs, and we fully support the use of these measures. However, 65 individual measures, even if performed to the highest level, cannot guarantee that items and services that fall outside of the quality measures are being delivered at the proper levels. For instance, a physician who would ordinarily order 3-4 different laboratory tests to help her diagnose a patient's condition may choose to order only the 1 or 2 tests that she considers most conclusive or for which there is an applicable quality performance measure. Practitioners are likely to perform to meet the standard, even if the standard is too low in a particular situation.

To ensure that ACO providers and professionals are not unduly withholding items and services, we recommend that CMS consider adopting additional safeguards, such as the following:

- The 3-year baseline should include both costs and utilization of services for the assigned population and CMS should monitor utilization patterns during the agreement period to ensure that there is not a significant, undue decline in particular services.
  - ACOs for which a significant decline in services is discovered through monitoring should be subject to corrective action, similar to ACOs found to have avoided at-risk beneficiaries, and subject to termination if corrections are not made.
- The 3-year baseline should include morbidity and mortality measures and CMS should monitor these data throughout the agreement period to ensure that outcomes are not impacted due to reduced utilization or withholding of care.
  - ACOs for which an increase in morbidity and/or mortality is discovered through monitoring should be subject to corrective action, similar to ACOs found to have avoided at-risk beneficiaries, and subject to termination if corrections are not made.
- CMS should establish a mechanism for reporting underutilization or withholding of care by an ACO or its participating entities or professionals. For example, independent laboratories can track ordering patterns from their provider clients and can determine if providers are ordering tests that are the standard of care for a particular diagnosis. CMS should establish a notification process if there is a reasonable belief that ACO-participating entities or professionals are purposely withholding the proper care for an individual or their assigned population.

We believe that these safeguards will help to ensure that beneficiaries assigned to an ACO receive the proper level of care throughout the agreement period.

Furthermore, these are not just matters for CMS to review; it is also appropriate for the antitrust authorities to also consider these issues when determining whether to permit an ACO to

move forward. Beyond just looking at measures of market power, the antitrust authorities should also consider whether the position of the prospective ACO will allow it to take steps to reduce services, inhibit innovation and generally affect quality. Such an impact could indeed occur if there were insufficient competitors in the market to serve as a check on such improper actions.

#### **IV. Patient-Centeredness Criteria and Quality Performance Standards Should Ensure Beneficiary Access to Individualized Care**

As described above, ACOs will have the incentive to reduce costs as much as possible in order to receive shared savings, while still meeting the minimum quality performance standards that dictate the percentage of shared savings. Similar to the effects on utilization, the MSSP will have an impact on providers' choice to use the most individualized therapies or diagnostic tools, even when they are the most appropriate to meet an individual patient's needs. In addition, as discussed above, many ACOs may default to using the laboratory that is part of an ACO member, which could mean that more complex testing, such as genetic and genomic testing, may not be as readily available to a particular individual.

CMS has not proposed sufficient safeguards to protect access to individualized care, even though CMS' first patient-centeredness principle is that "care should be individualized, based on the person's unique needs, preferences, values, and priorities."<sup>5</sup> As drafted, the required patient-centeredness criteria include having "systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs."<sup>6</sup> This criterion does not adequately achieve the patient-centeredness principle of individualized care, because the criterion limits the requirement of individualized care plans to targeted populations and only requires that the *plan* be individualized, not the care itself. CMS should strengthen this criterion to require that *care* be individualized in order to ensure that beneficiaries always have access to the care that is most appropriate for their needs. In the case of laboratory services, for instance, a beneficiary who needs a genomic test should be referred to an independent laboratory that offers the test, rather than forgoing the test due to the fact that the laboratory that is part of the ACO does not offer it.

In addition, CMS should allow the quality standards to be met through use of testing and treatment that exceed the minimum level of performance. ACOs and their participating entities and professionals should not be penalized for going beyond the minimum level of performance, such as if a more individualized laboratory test is developed and is used in lieu of the minimum test required by a particular quality measure. CMS should include in the final rule and regulations an allowance for such substitutions made in an effort to improve the quality of care.

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<sup>5</sup> *Id.* at 19548.

<sup>6</sup> *Id.*

**V. CMS Should Ensure Fair Distribution of Shared Savings within ACOs**

In order to ensure that providers are not further incentivized to severely limit their utilization of services across the Medicare program, CMS should consider regulatory limitations on the manner in which shared savings may be distributed among ACO participants and ACO providers/suppliers. ACLA is concerned that individual providers may limit or reduce care in order to obtain a larger share of the potential savings. To guard against this eventuality, CMS could put a percentage cap on the amount that any one physician can earn in shared savings, such as 10 percent of his or her allowed charges. CMS should also consider requiring that savings be distributed on a per-capita basis rather than proportionally to the savings generated by a particular physician.

**VI. CMS Should Incorporate Additional Laboratory Testing-Based Quality Measures into the Performance Measurement of ACOs**

There are numerous other laboratory testing practice guidelines that CMS should consider incorporating into the performance measurement system for ACOs. In addition to the testing measures CMS has already identified, organizations such as the American Society of Clinical Oncology and the National Comprehensive Cancer Network maintain guidelines that are well established and the product of consensus, and are kept up to date to reflect evolving standards of care. As CMS considers the final set of quality measures and updates them from year to year, ACLA would be pleased to work with the agency to identify those laboratory testing guidelines that are reliable measures of high quality patient care.

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ACLA appreciates the opportunity to comment on the Proposed Rule. If you have any questions or need any further information, please do not hesitate to contact JoAnne Glisson at (202) 637-9466 or [glisson@clinical-labs.org](mailto:glisson@clinical-labs.org).