

## POSITION STATEMENT

# Advancing Value-Based Healthcare: Laboratory Medicine's Essential Role

May 2017

## Introduction

Medicare is changing the way it pays for health services. The program is transitioning from a fee-for-service payment model that reimburses based on the volume of services to a value-based system that rewards providers for better coordination of care, improved patient outcomes, and reduced program costs. Laboratory testing is critical to the success of this new model. Clinicians routinely order tests to diagnose their patients, make treatment decisions, and monitor therapy, so it is vital that the right tests are ordered and appropriately interpreted. Without this judicious use of the laboratory, patient care suffers and healthcare costs needlessly increase. Laboratory professionals are uniquely positioned to help clinicians identify the most effective testing protocol and interpret the results accurately. Clinical laboratorians can further reduce healthcare costs by developing new, more precise tests to personalize patient care and creating computerized clinical decision support interventions to aid test selection.

## Background

In 2010, Congress passed the Affordable Care Act (ACA), which extended comprehensive health insurance coverage to millions of Americans. The legislation also included several reforms to the Medicare payment system, as Congress sought to curtail Medicare spending, which was increasing at an annual rate of nine percent. One reform was the creation of the Centers for Medicare and Medicaid Services (CMS) Innovation Center. This new bureau was authorized to develop and test new health delivery systems and payment models that would reward providers for more efficient, evidence-based care. Key elements of the CMS prototypes are: better care coordination; reduction in program costs; shared

### AACC POSITION:

AACC supports efforts to improve patient care through better test utilization and test interpretation. These objectives can be accomplished through a variety of means, such as increased use of evidence-based test protocols, the creation of clinical decision support systems, and expanded clinician education. In addition, the use of diagnostic management teams, sufficiently detailed test reports, and the development and use of laboratory quality measures can further streamline the healthcare delivery system and result in better patient outcomes.

savings between the agency and participating providers; the acceptance of bundled payments; and meeting various performance measures. The agency has extended these concepts to existing programs as well. Quality reforms are also present as CMS rolls out the Quality Measure Development Plan (MDP), required by The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The MDP is a focused framework to help CMS build and improve quality measures for clinicians.

### Greater Accountability and Cost Containment Inpatient testing facilities

Nearly one-third of Medicare funds go to hospitals. Most of this money is for in-patient services.

Once a patient is diagnosed, the case is assigned a diagnosis-related group (DRG) and the hospital is paid a single fee pre-determined for that DRG to cover all services provided to that patient. This process, which was established in the early 1980s, encourages hospitals to continually refine and upgrade their care system to reduce costs, while maintaining quality services. In recent years, Medicare has extended this concept to apply to emergency department patients who are discharged directly and not admitted as inpatients. Since 2012, the CMS has also tied a portion of hospitals' annual payment increase to meeting certain quality measures. Hospitals must more efficiently utilize their resources to survive in this payment environment.

### Outpatient Testing Facilities

Currently, laboratories are paid for outpatient testing ordered by physicians under the Clinical Laboratory Fee Schedule (CLFS), a Medicare fee-for-service program. Outpatient tests are typically provided by independent clinical laboratories, hospital outreach laboratories (which function similarly to independent laboratories), and physician office laboratories. Under the CLFS, each test is assigned a specific code by the American Medical Association and a set price by CMS. CMS is concerned that the existing Medicare payment system, which also includes the Medicare Physician Fee Schedule, incentivizes caregivers to provide more services than are medically necessary because it reimburses based on volume rather than outcomes. CMS is experimenting with several payment models that would reverse this pattern, including Accountable Care Organizations (ACOs). ACOs are provider networks comprising hospitals, physicians, clinical laboratories, and others, which join to provide coordinated patient care. The more than 500 ACOs receive a set fee per-patient and a bonus if the organization achieves cost savings and meets agreed-upon quality metrics. Another experimental model pays chronic care providers a single bundled payment for managing an individual episode of care. Greater predictability in care and cost are central to the new payment paradigm.

### Laboratory Expertise Is Critical

The recent emphasis on coordinated care, cost control and the use of quality measures represents a shift from the fee-for-service, a la carte approach to healthcare that has been the standard in the US. This changing payment paradigm creates new opportunities for health systems to improve patient

care while more efficiently and effectively utilizing their resources. The clinical laboratory provides the majority of the objective data available to clinicians. If used properly, this information can help produce the desired effects of enhancing quality and improving cost-effectiveness (1). Laboratory medicine professionals are poised to contribute their expertise to work with clinicians in devising more effective and efficient diagnostic and therapeutic protocols, and should be invited to be part of guideline development panels.

## Considerations

### Test Utilization

There are currently more than 3,500 laboratory tests that physicians can order to diagnose patients and manage their treatment (2). Each test has its own strengths and limitations, and the nomenclature can be inconsistent between laboratories. The multiplicity of test names is a source of confusion for many physicians (3). For example, a physician ordering a test for Vitamin D could have 12 different options for selecting the same, similar, or related tests (3). Due to the complexity of modern laboratory testing, such as genetic testing and other esoteric tests, it would be unrealistic to expect physicians to be experts in laboratory medicine. Nearly 15 percent of physician's report that they are uncertain about what tests to order (4). Studies indicate that nearly 21 percent of all laboratory tests ordered are either unnecessary or unwarranted based on the patient's symptoms (5). Estimates show that hospitals could reduce their costs by perhaps \$5 billion annually by eliminating redundant tests (6). Additional savings to the overall healthcare system could be realized through increased use of appropriate tests to diagnose diseases early, when treatment is more effective and less costly. Laboratory professionals have the knowledge and expertise to help improve test utilization through a variety of methods, including the design of educational materials, development of disease-specific test ordering guidelines, and creation of computerized clinical decision support interventions that identify those tests not suitable for the condition being investigated (7).

### Test Interpretation

Another challenge for clinicians is the interpretation of laboratory test results. In Hickner's study of primary physicians' test ordering patterns, he found that clinicians were "uncertain how to interpret the

diagnostic tests they ordered” in 8.3 percent of their patient encounters, translating to 13 million patients per year (2). Ensuring that physicians understand test results necessitates greater interaction among laboratorians and medical practitioners. One option is for laboratory professionals to include interpretative comments in the test report when the test or test panel cannot be understood by the numeric data alone, when the finding is unique, or when the physician poses a clinical question (8). Another alternative is utilizing a team approach, with all the patient’s caregivers—including an expert from the clinical laboratory—collaborating to interpret the results in conjunction with the clinical symptoms. Where employed, diagnostic teams have improved patient care, reduced hospital stays, and provided cost-savings to the hospital (9).

## Education

Clinicians receive limited formal education and training in laboratory medicine. Few medical schools include a separate and distinct course on laboratory medicine in their curriculum, require training in a clinical laboratory setting, or assess the competency of the resident in laboratory medicine (10). As educators, laboratory professionals can develop the program curriculum and courses needed to inform residents about testing and how best to utilize it in patient care decisions. Clinical laboratorians also can teach the residency courses and develop the tools to assess competency in laboratory medicine. Laboratory professionals can also help clinicians with patient education. The laboratory community has developed an award-winning website, [Lab Tests Online \(LTO\)](#), which educates consumers worldwide on the purpose and importance of laboratory tests. Physicians can direct their patients to this free resource to help them understand the reasons for the test and what the findings may indicate.

## Test Evaluation and Quality Assessment

Healthcare insurers are “increasingly demanding evidence that interventions positively affect health outcomes” before paying for new procedures (11). Laboratory professionals can help generate this evidence by participating in clinical studies that demonstrate the value of a test or, in other instances, illustrate that a test has little clinical value or is obsolete. Laboratorians also can advise clinicians on whether expensive tests, such as new molecular or esoteric tests, can be replaced with others that are both more effective and less expensive. The

laboratory medicine field has enjoyed great success in maximizing the effectiveness and efficiency of laboratory operations through the development and application of quality indicators (12). Laboratory professionals can translate this experience by partnering with others to develop quality measures that go beyond the laboratory and address issues in the overall healthcare system.

## Test Innovation

Healthcare providers and insurers continually seek more accurate, cost-effective tests to improve diagnosis and disease management. Laboratory professionals have worked to address this challenge by developing new technologies and adapting scientific advances to improve patient care. Over the past few decades, laboratories have automated their services to provide faster, more cost-effective testing in both the core laboratory and at the patient’s bedside. Clinical laboratorians also have adapted new technologies, such as mass spectrometry, to more efficiently and accurately perform tests for many medical conditions, e.g. newborn metabolic diseases.

Laboratorians are also developing noninvasive molecular tests to diagnose cancer, as well as screening tests that identify individuals likely to reject an organ transplant. In more recent years, laboratory professionals have been in the forefront of precision medicine, discovering the biomarkers associated with specific diseases and/or therapies, and developing analytical methods so this new knowledge can be applied to patient care. Clinicians use this information to prescribe targeted drug therapies that can more effectively attack the disease and/or reduce polypharmacy, a national financial burden. Much more could be accomplished in these areas if additional federal funding were available to facilitate the research and development needed to translate initial findings into reality.

## Positions

### Congress

- ▶ AACC urges Congress to continue to fund evidence-based studies through programs such as the Patient-Centered Outcomes Research Institute (PCORI), which can evaluate the performance of laboratory tests; these studies will provide the data necessary for developing best practice guidelines.
- ▶ AACC endorses additional federal funding

for basic and clinical research in the field of laboratory medicine, including the translation of new laboratory tests into clinical practice.

### Federal Agencies

- ▶ CMS should support the development and implementation of evidence-based quality measures that assess the utilization of laboratory services (e.g., over- or under-utilization of testing, misuse of tests, accurate interpretation of results).
- ▶ AACC recommends that CMS conduct a pilot program to evaluate whether wider adoption of collaborative caregiver group models, such as diagnostic management teams, can improve clinical decision-making, enhance patient care, and/or reduce costs, specifically through optimized test selection and the accurate interpretation of test results.
- ▶ The Agency for Healthcare Research and Quality should partner with the private sector to develop clinical decision support tools to guide clinicians in selecting laboratory tests.

### Laboratory and Clinical Community

- ▶ Laboratory directors should provide detailed interpretive comments for test values as warranted.
- ▶ Laboratory professionals need to partner with clinicians to develop test ordering protocols to help clinicians select the most appropriate test(s) for a patient presentation.
- ▶ Laboratory organizations and physician societies must work together to develop laboratory courses for inclusion in medical school curricula, and educate clinicians regarding laboratory medicine and its applications.

5. Zhi M, Ding EL, Theisen-Toupal J, Whelan J, Arnaout R (2013). [The Landscape of Inappropriate Laboratory Testing: A 15-Year Meta-Analysis](#). *PLoS ONE* 8(11): e78962. doi:10.1371/journal.pone.0078962.
6. Ashish K. Jha, et al. [Improving Safety and Eliminating Redundant Tests: Cutting costs in U.S. Hospitals](#). *Health Affairs* 28, no.5(2009):1475-1484.
7. Kahalifa M, Khalid P. [Reducing Unnecessary Laboratory Testing Using Health Informatics Applications: A Case Study on a Tertiary Care Hospital](#). *Procedia Computer Science* 2014; (37): 253-260.
8. Plebani M. [Interpretative commenting: A tool for improving the laboratory—clinical interface](#). *Clinica Chimica Acta* 2009; 404:46-51.
9. Laposata M. [How Can a Diagnostic Management Team Improve Patient Care and Save Money? Long-Standing and Rapidly Worsening Problem of Obtaining An Accurate Diagnosis Quickly](#). *CLN* June 4, 2014.
10. Smith BR, Kamoun M, Hickner J. [Laboratory Medicine Education at U.S. Medical Schools: A 2014 Status Report](#). *Academic Medicine* 2016; 91(1): 107-112.
11. Neumann PJ, Tunis SR. [Medicare and medical technology—the growing demand for relevant outcomes](#). *N Engl J Med*. 2010; 362(5):377-9.
12. Plebani M. [Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety](#). *Clinical Biochemistry* 2013; 46:1170-1174.

## References

1. Price C, St. John A, et al. [Leveraging the real value of laboratory medicine with the value proposition](#). *Clinica Chimica Acta* 2016; 462:183-186.
2. Hickner J, Thompson PJ, et al. [Primary Care Physicians' Challenges in Ordering Clinical Laboratory Tests and Interpreting Results](#). *JABFM* 2014; 27:268-274.
3. Passiment E, et al. [Decoding Laboratory Test Names: A Major Challenge to Appropriate Patient Care](#). *J Gen Intern Med* 2012; 28(3):453-458.
4. Marques MB, Hickner J, et al. [Primary Care Physicians and the Laboratory](#). *Am J Clin Pathol* 2014; 142:738-740.