



American
Clinical Laboratory
Association

June 22, 2015

Senator Johnny Isakson, Co-Chair
Senator Mark Warner, Co-Chair
Senate Finance Committee Chronic Care Working Group
219 Dirksen Senate Office Building
Washington, DC 20510
Via email: chronic_care@finance.senate.gov

Dear Senator Isakson and Senator Warner:

The American Clinical Laboratory Association (“ACLA”) is pleased to submit these comments in response to the call from the Senate Finance Committee Chronic Care Working Group (“Working Group”) for stakeholder input on ways to improve current law, promote alternative payment options, and develop solutions to serve Medicare beneficiaries with chronic conditions better and more efficiently. ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. ACLA members provide millions of laboratory services to Medicare beneficiaries with chronic conditions each year and are deeply invested in the Working Group’s success.

As you know, clinical laboratory services are vital to maintaining and improving the health of Medicare beneficiaries. We hope that as the Working Group considers various policy options to help improve outcomes for those with chronic conditions, it considers the importance of adequate access to and reimbursement for clinical laboratory tests, the risks of overutilization that are associated with the Medicare Physician Self-Referral Law’s In-Office Ancillary Services exception, and the value of meaningful interoperability standards for health information technology to support permissible sharing of patient health information between care providers.

A. The Vital Role of Clinical Laboratory Testing in Care for Beneficiaries with Chronic Conditions

Clinical laboratory services represent less than two percent of all Medicare spending; yet laboratory test results have a tremendous impact on diagnostic and treatment decisions made by clinicians. In 2013, approximately four-fifths (81 percent) of fee-for-service (FFS) Medicare beneficiaries received at least one clinical laboratory service. The tests provide objective, actionable information that allows patients to be diagnosed, treated, or monitored appropriately and quickly. Clinical laboratory tests save time, money, and lives by enabling health care providers and patients to identify diseases and treat symptoms earlier than ever, detect diseases before symptoms occur, and utilize preventive strategies to avoid more costly care later.

Personalized medicine – identifying the right therapy for the right patient at the right time – is a key priority for the Department of Health and Human Services and depends heavily on clinical laboratory testing. Clinical laboratory testing can reduce health care costs by helping to determine whether or not a particular drug may work for a patient and by reducing overtreatment of certain diseases that may be better suited for watchful waiting. For patients with chronic diseases, knowledge of a genetic predisposition toward a particular disease complication

oftentimes is a powerful incentive to adhere to a treatment regimen that otherwise might be ignored.

As such, clinical laboratory testing plays a critical part in the delivery of quality health care. A physician or other clinician orders a test to diagnose or monitor a patient's condition, and a sample of blood, tissue, or other biological matter is collected from the patient and sent to the lab. Some test services are conducted manually, while others are performed using sophisticated instrumentation. When testing is complete, a lab issues a report to the ordering clinician, who then can make an informed decision about the most appropriate treatment for the patient.

Medicare beneficiaries with chronic conditions receive many different types of laboratory testing services, ranging from relatively simple services to extremely complex ones. Treatment for some chronic conditions, such as diabetes, involves clinical chemistries like complete blood counts, glycosylated hemoglobin tests, and lipid panels. Other chronic conditions such as chronic myeloid leukemia ("CML"), may be detected and monitored with a highly complex molecular diagnostic test to identify the BCR-ABL fusion gene or with fluorescence in situ hybridization ("FISH") testing. These critical testing services provide hard data for health care providers and help guide clinical decisions, so that the most appropriate treatments may be rendered to beneficiaries as quickly as possible. However, despite the critical importance of clinical laboratory services for beneficiaries with chronic conditions, clinical laboratories also are unusual in that they oftentimes do not have face-to-face interaction with patients and must rely on other health care providers to coordinate care.

Looking at the Medicare population, the Centers for Medicare and Medicaid Services (CMS) found that almost half (45 percent) have high cholesterol levels, nearly a third (31 percent) experience heart disease, and close to a third (28 percent) live with diabetes, among other chronic conditions in 2010. Furthermore, more than two-thirds (68 percent) of beneficiaries experience two or more chronic conditions. As a result of the ongoing need to monitor both the disease and wellness status of Medicare beneficiaries with multiple chronic conditions, they are prescribed additional clinical laboratory services. Per capita in 2013, FFS beneficiaries having no chronic conditions received approximately two clinical laboratory tests, while those experiencing two or more chronic conditions received roughly 11 tests, those living with four or more chronic conditions received approximately 17 tests, and for those experiencing six or more chronic conditions, approximately 35 tests. The value proposition of these clinical lab services for patients and providers is significant, given the low level of corresponding program expenditures for these particular services, beginning at just \$30 annually in 2013 for those experiencing no chronic conditions, and ending at \$460 for those living with six or more chronic conditions—in contrast to the average overall total program spending per capita of \$9,738 in 2010.

The individually tailored and timely data that clinicians have access to through clinical laboratory testing, allows for highly personalized treatment for beneficiaries at a relatively low cost to the Medicare program. This rifle shot approach, facilitated by specific clinical evidence, allows beneficiaries to receive the most clinically appropriate treatment in a timely fashion, which often prevents downstream health care costs. Thus, we consider the return on investment for clinical lab testing as highly positive for both patients and the Medicare program as a whole.

For example, chronic kidney disease — experienced by 15 percent of Medicare FFS beneficiaries in 2010 — is a prime example of where early clinical laboratory tests and effective care coordination can reduce costs and improve outcomes. Many of these patients only learn of their condition when the disease has already progressed. A routine blood test, done earlier, might have led to a care plan to stop, slow, or even reverse the trajectory to kidney failure. Reducing the incidence of chronic kidney disease would help moderate Medicare expenditures, given that in 2010, 17 percent of total Medicare dollars (including Part D) or \$41 billion was spent managing just this condition.

Another example is diabetes. Close monitoring of blood glucose levels allows health care providers to work with both beneficiaries already living with diabetes to enhance their quality of life through effective management and treatment, as well as with those experiencing pre-diabetes in order to prevent progression. Consider that one of the most common blood glucose tests in Medicare, the Hemoglobin A1C, costs about \$13 (much less than the cost of a typical oil change for a car) but provides valuable information about a beneficiary. According to the Medicare Payment Advisory Commission, Medicare spent over \$100 billion dollars to manage and treat diabetes within FFS beneficiaries in 2010. According to the American Diabetes Association, health care costs for the Medicare-eligible population is expected to rise to \$171 billion by 2034. Regular lab testing for diabetes can also prevent more costly complications down the road — hospitalization, heart attack, high blood pressure, kidney failure or dialysis, to name a few.

Generally, laboratory data can also dramatically improve patient care with triggered alerts if a chronic condition has been aggravated, signaling the need for physician intervention and ultimately preventing hospitalizations and reducing Medicare spending— such as elevated blood glucose levels for those with diabetes. Moreover, laboratory claims data can be used to identify appropriate candidates for certain disease management programs that engage both the physicians and the patient in the development of a treatment plan, for instance, cardiovascular disease.

Efforts to coordinate lab reports, increase provider-to-provider communication, and streamline care are steps in the right direction for effectively caring for beneficiaries with chronic conditions. Deficiencies such as poor coverage and reimbursement of early testing and lack of coordination among multiple providers cause disconnects in care, leading to adverse patient outcomes and skyrocketing costs. Cooperatively managing chronic diseases early and often will save the Medicare program billions of dollars.

B. Medicare Reimbursement for Clinical Laboratory Tests Must be Adequate

ACLA asks the Working Group to ensure that its policy prescriptions result in Medicare reimbursement for clinical laboratory tests at levels that allow independent clinical laboratories to continue providing services to beneficiaries and investing in new life-saving technologies. Since 2009, Congress has passed three laws cutting Medicare payments for clinical laboratory services, which have resulted in up to a 23 percent cut in reimbursement from 2013 through 2022. Clinical laboratories have experienced a disproportionate level of cuts in recent years when compared to other health care providers and suppliers.

In 2014, Congress passed *the Protecting Access to Medicare Act* (“PAMA”), which includes a section that overhauls the Medicare rate-setting process for clinical laboratory tests. CMS has not yet released a proposed rule to implement the law, so laboratories are uncertain about the precise impact. However, we are certain that when the rates take effect, it will signal a profound change in Medicare reimbursement for clinical laboratory tests, as the rates will be based for the first time on private market rates. It is very likely that reimbursement for most tests will be cut below current rates, which will impose even greater economic pressure on laboratories.

As the Working Group develops policy solutions, we hope it will keep in mind the many changes occurring in the laboratory industry and the difficulties that many laboratories would experience in continuing to provide their vital services in light of additional reimbursement reductions or other federal policy changes that result in reimbursement reductions. It is critical whatever future steps are taken by Congress and the Administration to address the specific needs of Americans living with chronic illness, that disincentives not be created for the provision of medically necessary clinical laboratory testing for beneficiaries.

C. Physician Self-Referral of Clinical Laboratory Tests

We also urge the Working Group to consider the risks presented by the In-Office Ancillary Services (“IOAS”) exception to the Medicare Physician Self-Referral Law and the benefits of eliminating the exception. As we have expressed before to the Senate Finance Committee, ACLA supports narrowing the IOAS provision because of our concerns about overutilization of certain kinds of laboratory tests by self-interested physicians, the added costs to the Medicare program, and the impact on beneficiaries.

The intent of the IOAS exception was to allow clinicians to provide simple services, such as blood tests, to guide diagnosis and treatment of beneficiaries during office visits. However, there is ample evidence that physicians regularly exploit the exception to provide complex ancillary services, like anatomic pathology, that are not, and cannot be, completed during the time frame of a patient visit. Note that anatomic pathology services are highly specialized, where biopsied tissues are individually prepared and analyzed by pathologists to diagnose the presence, absence, extent and type of cancer or other disease. Given the existing IOAS exception, physicians may be motivated far more by the prospect of receiving reimbursement for services that they self-refer than by the need to choose the best provider of these services, which could be an independent clinical laboratory.

By definition, the IOAS exception serves as a disincentive for a physician to coordinate care with other health care providers caring for a Medicare beneficiary with multiple chronic conditions. When the Finance Committee held a hearing on May 14 on improving care for beneficiaries with chronic conditions, the Executive Director of the Medicare Payment Advisory Commission (“MedPAC”), Dr. Mark Miller, addressed these risks. Dr. Miller illustrated the problem of duplicative services with the story of a beneficiary who visits a physician who performs a diagnostic test on the beneficiary and is paid for the test; a second physician replicates the test and also is paid. The second physician has no incentive to coordinate with the first physician or to ask for the patient’s test results, because getting results from another physician would mean losing out on the revenue from the test. The problem demonstrated in this vignette may be

exacerbated when a Medicare beneficiary has multiple chronic conditions and many different physicians.

The IOAS exception to the Medicare self-referral statute is a barrier to the Working Group's goal of incentivizing health care providers to coordinate care for Medicare beneficiaries with multiple chronic conditions. Congress should reform the IOAS exception by excluding the provision of anatomic pathology from the exception. These tests, unlike simple blood tests, cannot be performed during a patient visit to guide a physician's treatment options. Narrowing the IOAS exception would ensure that the intent of this law would be carried out.

D. Health Information Technology Interoperability

Because clinical laboratory tests guide a significant percentage of medical decisions made by health care providers, it is critical that health information technology ("HIT") interoperability standards specifically include the transmission and incorporation of laboratory test data. ACLA believes that electronic health record ("EHR") "meaningful use" requirements should include an attestation by a user that he or she uses EHR transmission and incorporation functions. We also believe that laboratory result reporting should be as seamless as possible and that EHRs should not need special customization in order to send and receive laboratory results. These standards could help incentivize health care practitioners to request and share clinical laboratory test results with other practitioners caring for the same beneficiary more readily than they do now.

E. Conclusion

Thank you for considering ACLA's input on these important issues. We look forward to working with both the Working Group and Finance Committee overall in crafting policies designed to improve outcomes for Medicare beneficiaries with chronic conditions. If we as a nation are to improve care for those experiencing chronic diseases, we must acknowledge and highlight the role inpatient and outreach laboratory testing services play in evidence-based care and preserve appropriate access as well as opportunities for innovation. It is critical that lawmakers work together on policy that modernizes, synchronizes, and coordinates care, enabling Medicare patients with chronic conditions the best opportunity to manage their diseases in conjunction with their health care providers, armed with all the knowledge that state-of-the-art laboratory testing can provide. Please do not hesitate to contact me if you have any questions about our comments or if there is any way we can assist you.

Sincerely,

A handwritten signature in cursive script that reads "Alan Mertz".

Alan Mertz,
President