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October 23, 2017

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The Honorable Seema Verma
Administrator
U.S. Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Preliminary Determinations of the 2018 Clinical Laboratory Fee Schedule

Dear Administrator Verma:

On behalf of the many Medicare beneficiaries who benefit from access to clinical laboratory testing within their physician's practice, I appreciate the opportunity to share my serious concerns with the implementation of the new payment methodology established under the Protecting Access to Medicare Act (PAMA) of 2014. I can imagine you would agree that CMS has an enormous responsibility to ensure the integrity and accuracy of the data collected as a basis for setting rates under this new payment methodology. Given the serious questions that have been raised by most stakeholders about the accuracy of the data, I urge you to issue an interim final rule to hold the CY 17 rates in place while you conduct targeted market segment surveys to validate and ensure that the final rates accurately reflect private market payments as intended by Congress.

Importantly, ninety-two (92) percent of physicians report that they highly agree/agree that elderly patients achieve better outcomes because they provide near patient (in-office) testing.¹ Similarly, ninety (90) percent of physicians report that they highly agree/agree that elderly patients would be exposed to greater healthcare risks without near patient testing.² Unfortunately, the magnitude of the cuts will result in a number of physician practices ceasing in-office testing. It is also projected that many local independent, regional laboratories will close their doors or be acquired. These regional laboratories provide an invaluable service to nursing homes/skilled nursing facilities in local communities nationwide. The simultaneous closure of both small, independent community and office laboratories would be a disastrous outcome of PAMA and it would deal a

¹ COLA. (2017). What it's Worth: The Value of Near Patient Testing. Near Patient Testing Matters Portal. Pg. 4. Retrieved from: <http://www.nearpatienttestingmatters.org/>. 10/19/17.

² Ibid, Pg. 5. Retrieved from: <http://www.nearpatienttestingmatters.org/>. 10/19/17.

devastating blow to our comprehensive network of clinical laboratories needed to respond to infectious disease outbreaks.

It is well known that seventy (70) percent of medical decisions are based on laboratory information.³ To illustrate, access to immediate test results to indicate anemia, white blood cell counts for patients undergoing chemotherapy and A1C levels for diabetic patients is invaluable information to physicians caring for their patients. To put it directly, having real-time access to laboratory information in the physician's practice can be seen as a *modern approach to caring for the elderly in the 21st Century*, an approach which can reduce downstream costs in our total healthcare system. Regrettably, moving forward with the cuts as shown in the preliminary fee schedule will reduce access to near patient (in-office) testing where real-time diagnosis and treatment of the major health concerns facing the elderly today, such as diabetes, hypertension and heart disease, really matters.⁴

Near patient testing is actually patient-centered

In early 2017, we began to gather data from clinicians nationwide on the importance of laboratory services within the clinical care setting. We spoke with an oncologist in the Upper Peninsula of Michigan who told us that a patient's condition "can change over days or hours. To have testing on the day of treatment, before we start, is very important."⁵ Near patient testing at the time of the cancer patient's treatment visit is vital in determining prescription dosages and assessing side effects resulting from chemotherapy or other medications.

Patients get better results when chemotherapy treatments are provided on a routine schedule. Interruptions in a patient's treatment will increase patient risk. Furthermore, asking cancer patients, especially those living in rural areas like the Upper Peninsula of Michigan, to travel to a reference laboratory to run a routine blood test the day before or even the day of their chemotherapy treatment and, then again, the next day, is not in the best interests of the patient, and certainly not in the interests of the Medicare program. Instead, it makes much greater sense to provide a responsible reimbursement to physicians for providing testing in their oncology practice so they can do the tests efficiently (within 10 to 20 minutes). Patients benefit from the convenience and can focus on getting healthy rather than dealing with unnecessary logistics, transportation costs, administration and further coordination of providers.

Furthermore, our preliminary data and literature review show that near patient (in-office) testing can enhance patient-centered care. In-office testing can improve patient continuity and optimize effective communication with patients. A number of studies have demonstrated a correlation between effective physician-patient communication and improved health outcomes.⁶ Very practically, laboratory information can be shared real-time with patients and their families and in meaningful ways (face-to-face) with their doctor so patients are empowered to make decisions and to take new actions.

³ Badrick T. Evidence-Based Laboratory Medicine. *The Clinical Biochemist Reviews*. 2013;34(2):43-46.

⁴ COLA. (2017). What it's Worth: The Value of Near Patient Testing. Near Patient Testing Matters Portal. Pg. 8 Retrieved from: <http://www.nearpatienttestingmatters.org/>.

⁵ COLA. (2017). Lab Testing Matters: The Value of Near Patient Testing. Michigan. Retrieved from: <http://www.nearpatienttestingmatters.org/>.

⁶ Stewart MA. Effective physician-patient communication and health outcomes: a review. *CMAJ: Canadian Medical Association Journal*. 1995;152(9):1423-1433.

Harming access in rural communities

We also spoke with a clinician in a rural community where the nearest hospital or reference lab is 80 and 100 miles from the clinic.⁷ Elderly patients are reluctant to give up their car keys and put their safety at risk this clinician shared. “One of my elderly patients fell asleep while driving her car and drove off the road,” the clinician shared. Difficulties in traveling are compounded in this rural community during the winter months. “Our weather here has been unreal. We have had record snowfall.” Record snowfall this winter season caused 10 to 15 different local road closures due to avalanches. This creates highly unfavorable situations for any traveling patients, including elderly patients. During the winter months, travel for patients is “like taking a chance on life,” the clinician added.

By performing a variety of tests in the office laboratory, including a cardiac troponin test, it can be determined whether the patient is having a heart attack. “Troponins, CBCs, and comprehensive metabolic panels are the most commonly ordered tests. I don’t know how I would practice ER medicine (in my practice) without those tests results,” the clinician elaborated.

According to this, clinician patients could possibly be transported by helicopter or ambulance to a neighboring community hospital, but at what cost? The clinician added if we can do the screening testing here it’s not necessary for elderly patients “to take ambulances and helicopter rides.” Access to needed clinical laboratory testing at the clinic also supports timely access to test results. “It simply allows us to treat the conditions promptly,” the clinician explained.

In a recent case, an elderly patient complaining of fatigue got a CBC test done showing this physician that the “hemoglobin level was 6.” The patient needed a transfusion immediately. The clinician shared if the results were received the next day or 36 hours later, in this patient’s case, the results would be too late, “the patient would have died without it.”

Delays in diagnosis were seen as the most adverse impact on patients when referring tests out. In response to our National Practice Survey, 32.8 % of the respondents reported that it takes 3 days to get test results back from a reference laboratory. Another 12.3% reported that it takes 4 days or more to get the results back.⁸ In addition, specimen transport, specimen integrity and lost specimens were all noted as challenges in rural communities when referring testing out.

The effectiveness of near patient testing

From a systems perspective, we know that if patients don’t have access to primary care, they will seek care in an emergency room for health concerns that could have been addressed in a lower cost clinical setting. Likewise, if reimbursement policies are such that near patient testing is lost, we forfeit the benefits of early diagnosis and real-time continuous monitoring of treatment plans.

Today, near patient testing is efficient, and effective in diagnosing and treating patients at the time of their office visit. A diagnosis based solely on clinical symptoms can lead to the wrong

⁷ COLA. (2017). Lab Testing Matters: The Value of Near Patient Testing. Wyoming. Retrieved from: <http://www.nearpatienttestingmatters.org/>.

⁸ COLA. (2017). National Practice Survey: The Value of Near Patient Testing.

diagnosis.⁹ Furthermore, in our new delivery models, there is a growing appreciation that laboratory testing is indeed an integral service giving rise to optimal patient health outcomes and improvement in the overall health status of our communities.¹⁰

Some research suggests that point of care testing (near patient testing) may be a better approach for providers to direct rural patient treatment and health outcomes overall.¹¹ It also allows for laboratory testing to have its place in patient-physician interactions at the time of the patient visit.¹² There is a growing body of evidence related to the multiple benefits of near patient (in-office) laboratory testing. Patients can receive optimal healthcare and better outcomes when physicians combine their knowledge with laboratory information during diagnosis and treatment.¹³

Having lab results while the patient is still in the office supports the provider in forming a more complete clinical picture.¹⁴ In addition, any uncertainty as to the quality of the laboratory result can be resolved by running the same test with special attention to areas in the lab testing process and analysis that may have caused concern.¹⁵ It enables direct feedback loops between the physician and laboratory personnel and an appreciation all around for the history and broader lifestyle of the patient. Near patient testing allows for practices to better identify and have a greater sense of responsibility for the test results they receive.¹⁶

Finally, a recent study found that when used within established guidelines, clinical laboratory testing can reduce direct and indirect healthcare costs while generating better outcomes.¹⁷ The study showed that, when used properly, near patient testing is an indispensable tool for physicians practicing in the 21st Century where innovations in science and technology allow us to diagnose acute care and treat chronic conditions rapidly and effectively.

The silent implications

COLA believes that these drastic cuts to the CLFS will hurt the public health system in the United States. As you are aware, physicians practicing in communities across the country see diseases when they first emerge. When people are feeling ill they often see their primary care doctor first or go to the local hospital. Physicians who are able to rely upon rapid, accurate testing when the patient is in their office can quickly recognize when a patient may be at risk of having an exotic disease based on their symptoms, initial laboratory results and recent travel.

When an individual needs further evaluation after initial test results, physicians promptly send the ill patient's specimen to a reference laboratory or public health laboratory. The quicker

⁹ Jordan, B., Mitchell, C., Anderson, A., Farkas, N., & Batrla, R. (2015). The clinical and health economic value of clinical laboratory diagnostics. *EJIFCC*, 26(1), 47.

¹⁰ Futrell, K. (2013). *The Value of the Laboratory in the Healthcare Model*. Orchard Software.

¹¹ Drain, P. K., Hyle, E. P., Noubary, F., Freedberg, K. A., Wilson, D., Bishai, W. R., ... & Bassett, I. V. (2014). Diagnostic point-of-care tests in resource-limited settings. *The Lancet infectious diseases*, 14(3), 239-249.

¹² Futrell, K. (2015). *Laboratory Point of Care Testing: A Future Outlook*. Orchard Software.

¹³ Plebani, M. (1999). The clinical importance of laboratory reasoning. *Clinica chimica acta*, 280(1), 35-45.

¹⁴ Drain, P. K., Hyle, E. P., Noubary, F., Freedberg, K. A., Wilson, D., Bishai, W. R., ... & Bassett, I. V. (2014). Diagnostic point-of-care tests in resource-limited settings. *The Lancet infectious diseases*, 14(3), 239-249.

¹⁵ Lippi, G., Mattiuzzi, C., & Favaloro, E. J. (2015). Pre-analytical variability and quality of diagnostic testing. *Looking at the moon and gazing beyond the finger*. *New Zealand Journal of Medical Laboratory Science*, 69(1), 4.

¹⁶ Futrell, K. (2015). *Laboratory Point of Care Testing: A Future Outlook*. Orchard Software.

¹⁷ Rohr, U. P., Binder, C., Dieterle, T., Giusti, F., Messina, C. G. M., Toerien, E., ... & Schäfer, H. H. (2016). The value of in vitro diagnostic testing in medical practice: a status report. *PLoS one*, 11(3), e0149856.

these diseases are identified, the faster the patient can be treated. Importantly, early identification prevents further spread of contagion.

Severe cuts to the CLFS will create an undue burden on physicians who offer testing in their office which will hurt the nation's public health response. For example, if a Medicare patient goes into their primary care provider's office for an influenza test and that test comes back abnormal, that could indicate something that should be referred to the local health department, a very similar situation that happened with H1N1. If the CLFS is cutting influenza tests on the average of 15%, physicians will stop testing and refer tests out, with a same, day, 1 day, 2 days, 3 days or more wait for the return of the test result depending on where the patient lives.

Another example would be if a patient presents at a physician office complaining of a fever and fatigue with a jaundice appearance, the physician will order a comprehensive metabolic panel to establish a diagnosis, a test that will be cut over 37% under the proposed CLFS. An abnormal test could trigger a further testing for Hepatitis. As you know, Hepatitis A needs to be reported immediately to the local public health officials because it is a highly contagious disease and needs to be dealt with immediately.

If providers do not have access to near patient laboratory testing because of these severe cuts to the CLFS, it could have a significant impact on the public health system in this country.

Inaccurate data collection

Finally, we have serious concerns with the data used to calculate the 2018 CLFS and we believe that it would be a tragedy to shift the risk and burden of a problematic implementation of a new payment mechanism to the elderly members of our society – our own parents and grandparents.

Physician organizations strongly urged CMS to establish the PAMA data collection period at least six months after the final rule was issued. This request was based on extensive experience implementing major changes to Medicare programs by physician organizations and physician practices. CMS instead mandated a complicated, detailed, confusing, and voluminous data collection requirement for a mostly retrospective data collection period that began approximately six months before the final rule was issued. This constituted an impossibility for a number, if not all, laboratories to report accurately and completely. Many clinical laboratories, including the largest reference laboratories that have sophisticated payments systems and that hired additional staff, struggled to collect accurate data within the retrospective data collection timeframe in a timely manner. All of the foregoing underscore that clinical laboratories were required to comply with a regulation that constituted an impossibility.

The way forward

In conclusion, COLA believes that the proposed 2018 CLFS does not properly reflect Congressional intent, which is to create a system to obtain accurate data in order to establish the correct weighted median for each test on the Medicare Clinical Laboratory Fee Schedule. Therefore, COLA urges CMS to modify the existing PAMA regulations through issuance of an interim final rule effective December 1, 2017, that holds the current 2017 CLFS rates in place until CMS has conducted targeted market segment surveys (including reference

laboratories, physician office-base laboratories, independent laboratories, and hospital outreach laboratories) to validate and adjust the final fee schedule calculated payments based on the data collection.

In my view, this is the right step to take. In doing so, we can be more assured that the payment rates accurately reflect private market payments across all market segments.

If you have any further questions, feel free to contact Brian Reuwer the Senior Healthcare Policy Analyst at breuwer@cola.org or 410-381-6581 ex 3783.

Sincerely,

A handwritten signature in black ink, appearing to read "D. A. Beigel". The signature is fluid and cursive, with a prominent initial "D" and a long, sweeping underline.

Douglas A. Beigel
Chief Executive Officer