August 11, 2017

Karen Nakano, M.D.
Panel Chair, CMS Medical Officer
Advisory Panel on Clinical Diagnostic Laboratory Tests
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Chairwoman Nakano,

The National Independent Laboratory Association (NILA) is pleased to submit a written statement to the Centers for Medicare and Medicaid Services (CMS) and the Advisory Panel on Clinical Diagnostic Laboratory Tests (Panel), in follow up to our presentation at the August 1, 2017, Panel meeting addressing Automated Test Panel (ATP) pricing. NILA represents a broad spectrum of laboratories, from small community laboratories to large multi-state regional laboratories, which work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients to provide emergency and chronic care testing. For the majority of NILA's members, 30-50 percent of their testing services are provided to Medicare beneficiaries.

Background – PAMA Reporting and Chemistry Test Panels

NILA welcomes the opportunity to have a continued dialogue with CMS and the Panel on ATPs, particularly following the first mandatory PAMA test rate reporting process. For our member laboratories, collecting and assessing pricing information about individual test components within a test panel was an extremely difficult undertaking. The reason for this is that most times, though not always, payors pay for chemistry test codes on a bundled basis, rather than on an individual test basis. Sometimes, payors do this even when physicians order the tests as individual tests. Laboratories bill for the tests in the manner they were ordered, unless the physician ordered a set of tests that should be billed as a recognized panel in accordance with CPT guidelines.

Regardless of how laboratories bill a given payor, a payor will remit payment in several different ways. Frequently, laboratories will receive payment that does not identify a specific payment rate for individual tests. NILA members also found, in going through the PAMA data collection process, that payors are inconsistent with each other and often times with themselves in how they issue such payments. Some payors offer remittance that does not assign specific prices for individual tests or panel tests billed, rather they pay a single amount that covers all tests billed. When this happens, it is not possible for a laboratory to break out what is payed for each test because the payment as issued and received is not attributed to the CPT codes billed. It is also inaccurate for a lab to apportion the amount paid between the CPT codes in the absence of any additional data from the payor. Other payors provide payments on individual chemistry tests that were billed, but the amount varies by how many tests are billed rather than which specific tests are billed. Therefore, it is not fair or accurate to attribute the bundled payment across tests as final payment rates as the payment rate is reflective of a bundle, not

individual test rates. Then there are circumstances where a payor has a set payment rate for each chemistry test. In this situation, the lab is provided a payment on the specific test.

A lab's challenge in sifting through all of the different scenarios and collecting and certifying the accuracy of payment data was made worse by CMS's decision to require a retrospective data collection period under the PAMA reporting regulation. CMS released regulatory guidance outlining the codes laboratories were to report in September 2016. This provided laboratories with less than three and a half months to reconstruct six months of billing data, certify, and report data for a PAMA reporting process that began on January 1, 2017. Three and a half months to prepare and assess the accuracy of the data imposed an extreme and unnecessary regulatory burden on laboratories. Many laboratories spent many thousands of dollars scrambling to prepare. Some of these laboratories had to pull their small administrative staff – sometimes a staff of one or two – to only focus on PAMA, disrupting day-to-day business operations. For small community laboratories, in particular, this was extremely burdensome, and for many, an impossible undertaking. The complexity and inconsistency of how payors pay for chemistry tests coupled with CMS' decision to impose a retrospective reporting process that laboratory billing systems could not comply with, raises significant concerns about the integrity of the data CMS received.

NILA is very concerned about the significant errors in the data that CMS plans to utilize to calculate new CLFS payment rates. Many laboratories reported prorated data or bundled payment amounts as final payment rates because it was impossible for them to extrapolate that data from their billing systems as they worked to manage a retrospective reporting process. CMS's final rule implementing PAMA excluded bundled payments from the definition of "applicable information". Yet, in the face of drastic financial penalties for non-compliance with reporting, laboratories reported the data they had recorded in their billing systems – data that would often not constitute final payment rates as envisioned under the regulation.

Advisory Panel Recommendations and Response

During the September 12, 2016, Panel meeting, the Panel made two separate recommendations for how the automated chemistry panels or their associated tests might be reported by laboratories and reimbursed under the CLFS. Under the first recommendation, laboratories would report prices for an automated chemistry test only when a payor paid for the test separately. CMS would then use the reported rates to set a weighted median for each test based on the data reported. Organ and Disease Panel rates would continue to be reported by laboratories under PAMA and priced as panels. Under the second recommendation, CMS would create new HCPCS codes to represent panels of chemistry tests. These codes would then be crosswalked or gapfilled. CMS officials stated at the meeting that under this scenario, it was unlikely rates would be crosswalked to current ATP rates. The Panel stated that under this option, Organ and Disease Panels would continue to be reported as panels.

As CMS and the Panel deliberate on this issue in 2017, NILA recommends that the agency reflect on what the PAMA statute allows and what it does not permit. The PAMA statute addressing CLFS payment reform requires that a test payment amount be equal to the weighted median that is derived from the applicable information reported for each test during a data collection period. Given this fact, the only appropriate recommendation for the pricing of ATPs that are without existing CPT codes is to base these test rates on the weighted median as calculated based on reported data under PAMA.

Under the second recommendation proposed by the Panel, CMS would develop bundled payment rates for ATPs and those prices would not reflect the weighted median as required under statute. Furthermore, under the recommendation as proposed, CMS would create an even bigger billing nightmare for laboratories as CMS would be creating codes that vary significantly from those used by private payors today. With everything the laboratories just endured to address PAMA reporting, and the thousands of dollars and lost staff time, to do so would be burden on top of burden, further threatening laboratory businesses.

NILA advises that the only viable recommendation permitted under statute is the first recommendation proposed by the Panel to pay for each chemistry test in an ATP and the CPT codes for Organ and Disease Panels based on the weighted median for the given CPT codes.

Additional Recommendations

Rather than focus on establishing alternative payment processes that NILA believes are outside of the agency's statutory authority, NILA advises that CMS, under the Panel's guidance, seek to address the significant concerns regarding the integrity of the PAMA data reported as a result of the retrospective reporting process. NILA also strongly advises that before moving forward to revise the CLFS, CMS and the panel address the substantial exclusion of data from a large segment of the laboratory market – independent hospital outreach laboratories. Due to the construction of the regulation, we believe only a small number of hospitals provided PAMA data through the first reporting process. As a result, the data CMS uses to calculate weighted median rates under PAMA will be incomplete and skewed - not reflective of the laboratory market, whether that be for the tests included under ATPs or any other test on the CLFS.

NILA offers the following recommendations to address data integrity and quantity to support the PAMA review and calculation of CLFS rates: 1) CMS issue an interim final rule that adjusts the PAMA timeline and postpones any calculation and publication of revised payment rates for existing tests on the CLFS; and 2) CMS amend the definition of applicable laboratory or identifies for public comment a statistically valid approach to ensure PAMA-reported data reflects the full laboratory market – physician, hospital and independent laboratories; and 3) CMS further amends the PAMA regulation to allow for a transparent validation process for the data collected and to appropriately address data integrity concerns.

Conclusion

NILA looks forward to continuing this important dialogue and working with the Panel and CMS to address concerns with implementation of Section 216 of PAMA. If you have questions concerning these comments, please contact Julie Allen, NILA's Washington Representative, at 202-230-5126, Julie.allen@dbr.com.

Sincerely yours,

Mark Birenbaum, Ph.D.
Administrator