STATEMENT OF
THE AMERICAN CLINICAL LABORATORY ASSOCIATION
ON AUTOMATED CHEMISTRY TEST PANELS
UNDER PAMA

American Clinical Laboratory Association

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to submit a written statement to the Centers for Medicare & Medicaid Services (CMS). ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, hospital, end-stage renal disease, and nursing home laboratories.

As CMS knows, prior to implementation of the Protecting Access to Medicare Act (PAMA), Medicare recognized a discrete set of 23 AMCC tests and created specific rules for how they should be billed and paid for, based on the number of tests that are ordered and billed for, regardless of which tests they are.

In addition, there are certain "Organ and Disease Panels" recognized by CPT that consist of AMCC tests. Each panel includes a specified group of AMCC tests and only those may be included under the CPT code applicable to the panel. If other AMCC tests are ordered along with the Organ and Disease Panel, they are to be billed separately.

The previous payment system for AMCC tests is inconsistent with PAMA requirements. Since PAMA requires that prices be reported on a test-by-test basis, reporting the prices for bundles of different AMCC tests is not permitted. Recognizing this inconsistency, CMS appropriately abandoned the reimbursement formula and as required by PAMA, began paying separately for each individual AMCC test.

Questions were raised about how laboratories may be billing the Medicare program for AMCC tests since January 1, 2018, when new PAMA CLFS rates went into effect. In its November 2018 report, the Government Accountability Office (GAO) suggested that laboratories *could be* billing inappropriately for automated chemistry tests that should be billed using panel codes, by "unbundling" the claims (billing the individual tests codes instead of the panel code). The GAO stated that if *every* laboratory did so, Medicare expenditures *could increase* by a tremendous amount. Regrettably, that became the headline when the GAO's report was released. The GAO's assumption about laboratories "unbundling" organ and disease panels is <u>not</u> supported by Medicare's own publicly-available claims data, or by the results of a survey that ACLA conducted of its own members.

ACLA agrees that panel tests with billing codes should be paid at the panel code's rate. Laboratories are required to bill Medicare according to the American Medical Association (AMA) CPT guidelines, which provide clear direction on billing organ and disease panels. The guidelines instruct laboratories to bill the panel CPT code when all of its component-level tests are performed. If there are remaining tests that are not part of the panel, labs are directed to bill using the individual CPT codes for those additional tests. PAMA's implementation had no impact whatsoever on CPT coding guidelines. CMS's December 14, 2018 transmittal saying that "laboratories shall report

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the panel test where appropriate and not report separately the tests that make up the panel" merely reiterated what has been long-standing guidance from the AMA about how to bill for test panels.

ACLA reviewed publicly-available Medicare claims data to compare claims submitted in the first half of 2017 for the seven organ and disease panels and for their component tests individually, with claims submitted in the first half of 2018. The comparison of the claims submitted before and after PAMA implementation does not show a dramatic increase in claims using the individual CPT codes for the organ and disease panels' component tests and a corresponding decrease in claims using the panel codes. Rather, it shows decreases of similar amounts in claims submitted for panel codes and for the individual component test codes. This would not be the case if laboratories all of a sudden had started inappropriately unbundling the tests codes and billing them individually, rather than using panel codes.

ACLA conducted a survey of its own members under privilege, regarding claims submitted for each of the seven organ and disease panels using the panel's CPT code, and claims submitted with the individual component test codes, instead. The survey solicited information about claims submitted in the first three quarters of 2017, before PAMA was implemented, and in the first three quarters of 2018, after implementation. We found no change in member laboratories' billing patterns. In both the pre- and post-PAMA survey periods, less than .003 percent of claims were submitted with individual test codes when all tests in a panel were performed, rather than with the appropriate panel code.

The GAO identified a potential problem—not a problem that currently is widespread. We agree with CMS's continuing efforts to ensure that laboratories submit claims for organ and disease panels and their component tests appropriately and in accordance with long-standing coding guidance.

CMS hosted a session on AMCC tests at its CLFS Annual Laboratory Meeting on June 24, 2019. As part of its presentation on AMCC tests, the agency stated that spending on these tests has increased, and listed "potential options to address cost differences."

The requirements in determining reimbursement rates for laboratory tests under PAMA are clear. Under the plain language of Section 216 of PAMA, after January 1, 2018, "the payment amount…shall be equal to the weighted median that is derived from the applicable information reported for each test." Elsewhere, the statute states that CMS shall calculate a weighted median "for each laboratory test with respect to which information is reported…for a data collection period." In other words, a test is to be priced based on the weighted median of private payor rates and volumes reported for that test. That is, in fact, the whole basis for the system established under PAMA. Attempts to bypass this system for a subset of tests is unnecessary, and inconsistent with both the intent of PAMA and the plain language of the statute.

In addition, rather than experiencing an increase in spending, Medicare spending on AMCC tests will be reduced as a result of PAMA. According to publicly-available Medicare claims data, 96 percent of AMCC tests are billed under an organ and disease panel code, as compared to individual analyte codes. The organ and disease panel codes will experience some of the most severe PAMA reductions. For example, the fully implemented weighted medians for the both the comprehensive metabolic panel and the lipid panel will result in reimbursement cuts of

over 30 percent, respectively. The severity of these reductions will not only result in reduced Medicare spending on AMCC tests, the cuts also threaten Medicare beneficiary access to critical, routine testing used to diagnose, treat and monitor disease.

Thank you for this opportunity to share our views. ACLA looks forward to continuing to work with CMS on the Protecting Access to Medicare Act.