SOLICITATION OF PUBLIC COMMENTS ON INITIAL DATA COLLECTION AND REPORTING PERIODS FOR CLINICAL LAB FEE SCHEDULE (CLFS)

In the proposed rule, CMS requests comments about the experience that certain "applicable laboratories" had in collecting and reporting private payer laboratory test payment data, as required by the June 23, 2016 final rule implementing a new "market-based" payment system for clinical diagnostic laboratory tests paid under the CLFS. This new payment methodology, enacted under a provision of the PAMA, is intended to ensure that the Medicare CLFS rates are based on the rates paid by private payers for laboratory tests. Under the CLFS final rule, certain applicable laboratories were required to collect, and then report to CMS, certain private payer laboratory test payment information. In general, the payment amount for a test on the CLFS furnished on or after Jan. 1, 2018, will be equal to the weighted median of private payer rates determined for each test collected during a data collection period and reported during a data reporting period. CMS established the first data collection period as Jan. 1, 2016 through June 30, 2016. The first data reporting period was Jan. 1, 2017 through May 31, 2017.

The AHA has serious concerns that the data that CMS collected from laboratories is inaccurate, incomplete and unable to be validated, and, therefore, will result in payment rates that do not accurately reflect the broad spectrum of private payer payment rates as Congress intended. This is of great import to hospitals that offer testing through community outreach laboratories and to the patients they serve. While most hospital laboratory services are packaged and paid through the inpatient and outpatient prospective payment systems, hospital outreach laboratories are currently paid through the CLFS, and these laboratories furnish critical laboratory testing for patients in physician offices and nursing homes. **The significant payment reductions expected to result from the flawed PAMA process will place hospital outreach laboratories in an untenable situation and could have serious consequences for patient access to care.**

We have learned from our members and other laboratory stakeholders about difficulties encountered during the data reporting period, including problems with laboratories accurately and completely reporting their private payer data and in CMS accepting the data. Notwithstanding CMS's final regulation and other PAMA-related resources, we understand that applicable laboratories used a range of approaches in determining which private payer rates and volumes to report. These data reporting problems largely resulted from CMS's decision to impose a retrospective data collection period for applicable laboratories. For instance, there are reports that some laboratories erroneously reported partial payments due to the inability to accurately match primary insurer payments with related patient copayments and third-party insurer payments. **As a result, we are concerned that the data CMS will use to calculate 2018 CLFS payment rates are unreliable and incomplete.**

Further, CMS has not clearly described how it will aggregate reported payment data for each clinical test or a way that it, or its stakeholders, can validate the accuracy of the final payment rates. **This lack of transparency and inability to validate the payment rates calls into question the integrity of the rates that CMS will publish for CY 2018**.

Addressing these concerns will certainly require a delay in implementing the new CLFS rates; however, we urge the agency to take such steps immediately. As a first step, the agency should publish preliminary information to improve transparency for impacted laboratories. We recommend that CMS release, as soon as possible, the number of clinical laboratories that reported private payer data, based on market segment and geographic locations. This should allow the agency as well as stakeholders to better understand whether reporting was truly representative of the wide spectrum of laboratories providing services under the CLFS. In addition, we urge CMS to publish its preliminary CLFS rates for CY 2018 to allow laboratories time to prepare for any potential disruptions to care delivery resulting from potential significant reductions in payments.

Second, given the serious concerns that the AHA and many other laboratory stakeholders have regarding the integrity and validity of the data that is to be used to set payment rates, we urge CMS to consider ways that it can address these shortfalls. For instance, one option would be to issue an interim final rule that modifies its existing regulations so as to allow for the agency to conduct a limited market segment survey of the full range of laboratories. Doing so would allow CMS to validate and adjust, as necessary, the PAMA-derived CLFS rates using the survey data in order to ensure that the final CLFS rates meet congressional intent that payments reflect private market payments.

Finally, we believe that one part of the PAMA-derived CLFS rates can move forward on Jan. 1, 2018, as planned. That is, the rates that CMS calculates for clinical laboratory tests that are only offered by one laboratory can be presumed to be accurate since these laboratories typically offer only a limited test menu and the final payment amounts calculated for these laboratories should be easily validated by the performing laboratory itself.