

COURT OF APPEALS RULES THAT PAMA RULE IS ARBITRARY AND CAPRICIOUS

In 2014, Congress passed the *Protecting Access to Medicare Act* (PAMA). Section 216 of the law reformed the Clinical Laboratory Fee Schedule (CLFS) to establish market-based CLFS rates derived from private payor rates reported to the Centers for Medicare & Medicaid Services (CMS) by independent labs, hospital labs, and physician office labs. CMS's implementation failed to capture sufficient data from all major laboratory segments. As a result, CLFS rates declined far more than projected when PAMA was enacted – ultimately threatening access to timely, accurate, and reliable lab services, the nation's laboratory infrastructure, and investment in the next generation of diagnostics.

The seriousness of ACLA's concerns with PAMA is underscored by its multi-year legal challenge to the law, recently resolved in ACLA's favor with a ruling by the Court of Appeals for the D.C. Circuit. ACLA challenged CMS's definition of "applicable laboratory" (an entity that is required to report private payor rates to CMS) because the definition did not comport with the statutory language, and it had the effect of excluding almost all hospital laboratories from reporting their private payor rates to CMS, thereby decreasing Medicare CLFS rates below true market-based rates. The Court of Appeals ruled that CMS's 2016 final rule is arbitrary and capricious. It also ruled in ACLA's favor on procedural grounds, finding that laboratories have been harmed by PAMA's implementation.

The Court of Appeals decision addressed one of PAMA's most vexing problems, however further legislative action is needed to put Medicare payment for clinical laboratory services on a sustainable pathway forward. Congress has acted three times to delay the second round of data reporting under PAMA. It is time for passage of H.R. 2377/S. 1000, the *Saving Access to Laboratory Services Act* (SALSA) to address critical shortcomings of PAMA:

- **Statistical sampling.** To improve overall quality, SALSA would allow representative data to be used in CLFS rate-setting and to alleviate the overall reporting burden, SALSA would require statistical sampling of private payor data from independent labs, hospital labs, and physician office labs for "widely available" tests. Use of statistically valid sampling would eliminate bias in favor or against private payor rates paid to a particular type of lab or from a single market segment. Just 21 of the 1,942 laboratories that reported data in the 2017 reporting period were hospital laboratories. Independent laboratories accounted for 90 percent of data reported to CMS in 2017, yet they accounted for only 50 percent of Medicare CLFS volume at that time.
- **Guardrails.** SALSA would set a limit of five percent on how much a CLFS rate could be increased or decreased from year to year. This would create stability for both laboratories and the Medicare program by mitigating the shock of rapid rate fluctuations up or down. Under current law, a CLFS rate may not be decreased by more than 15 percent annually in 2025 and 2026, after which there are no limits on annual decreases to CLFS rates, and there are no limits on rate increases.
- **Data quality.** SALSA would make improvements to the types of private payor data used to set CLFS rates. First, it would exclude Medicaid managed care rates from reportable data, because by law, the Medicaid rates may not exceed Medicare CLFS rates. Inclusion of Medicaid managed care rates skews CLFS rates downward artificially. Second, it would greatly reduce the overall reporting burden by permitting laboratories to exclude manual (paper) remittances from their reporting, as long as they do not comprise more than 10 percent of the data the laboratory is required to report.
- **Burden.** Data reporting would occur every four years under SALSA. Under current law, data reporting is to occur every three years. Increasing the length of time between reporting periods would bring stability to CLFS rates and reduce reporting burdens across the laboratory industry.

ACLA urges Congress to enact SALSA to reform PAMA, establish sustainable reimbursement rates, ensure Medicare beneficiary access to vital laboratory testing, and support the nation's laboratory infrastructure and investment to advance laboratory testing to improve and save lives.