AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

October 19, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW.,
Washington, DC 20201

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the document, "Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System," that the Centers for Medicare & Medicaid Services (CMS) posted on September 22, 2017.

Since passage of the *Protecting Access to Medicare Act* of 2014 (PAMA), the AAFP has repeatedly expressed concern to CMS about PAMA's Section 216, which significantly revises the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). Most recently, the AAFP and others wrote CMS an October 6, 2017 letter, a September 8, 2017 letter, an August 30, 2017 letter, and a March 30, 2017 letter. Significantly amplifying these concerns, the agency posted private payor rate-based CLFS payment amounts, which beginning on January 1, 2018, Medicare will use to calculate Medicare payment rates for most laboratory tests paid under the CLFS. CMS estimates that the use of this data will considerably slash CLFS payment rates by about $670 million in 2018.

The AAFP is extremely concerned that these CLFS payment cuts:

- Will endanger Medicare patients' access to clinical testing in settings where patients receive most of their medical care. Family physician and other primary care practices already operate on slim financial margins. Upcoming cuts in 2018 CLFS payments, which approach 10% annually across the board for the next three years, threaten to shutter physician office-based laboratories (POLs), which provide essential and rapid point-of-care testing to their patients.
    - For example, a family physician in rural North Carolina expressed concern to the AAFP with the upcoming cuts to CLFS payments, *"I had a patient who came into the office on a Friday afternoon as a new patient. He appeared healthy and had very little symptoms except black stools. He had no physical findings other than being pale and slightly tachycardic. His point-of-care testing revealed his hemoglobin to be 4.1, which means he had had lost two-thirds of his blood volume. Without this point-of-care test within my POL, he would have gone through the weekend with an actively bleeding peptic ulcer and probably would have died."*
    - Another family physician, in rural Kansas, told the AAFP, *"I recently treated a 16-year-old female who presented with fatigue and used point-of-care testing in my office lab. I*

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quickly found out her hemoglobin was 7 and appropriately sent her to the emergency department. Without this testing, the patient likely would have been sent home, with potentially disastrous consequences."

- Are predominately based on flawed data, largely due to CMS issuing a final CLFS regulation on June 23, 2016, that inexplicably specified most of the data collection period (January 1 – June 30, 2016) to occur before issuance of final rule. Based on CMS's definition of "applicable laboratory," the data collected by CMS is based on large laboratory corporations, which does not accurately translate to smaller or rural POLs. To remedy this, the AAFP urges CMS to extend the PAMA data reporting period deadline to March 30, 2018, and conduct market segment surveys (reference laboratories, physician office–based laboratories, independent laboratories, and hospital community laboratories) to validate and adjust the final amount calculated.
- Are taking place while physicians are preparing to participate in the two payment pathways called for in the *Medicare Access and CHIP Reauthorization Act* of 2015.

The AAFP believes the size of the projected cuts is due to problematic implementation of the new payment methodology. The consequences of a $670 million cut in CLFS payments in 2018 for our members' patients will be pronounced. We urge CMS to implement several measures to ensure that new payment rates are accurate and consistent with Congressional intent:

- On or before December 1, 2017, issue an interim final rule to modify existing regulation and provide that CMS will conduct market segment surveys (reference laboratories, physician office–based laboratories, independent laboratories, and hospital community laboratories) to validate and adjust the final amount calculated based on the current data collection to ensure Congressional intent achieved that payments reflect private market payments.
- Allow pricing to proceed as planned on January 1, 2018, based on data collection and submission under existing rule only for:
    - Sole source clinical tests, since the data submissions are reasonably expected to be accurate given the limited test menus and since the final amount calculated can be easily validated by the sole source clinical laboratory.
    - Any additional clinical tests where factors establish high data integrity and transparency of private payer payment calculation.
- Delay pricing changes for all other clinical tests until market segment surveys are complete and final amounts calculated based on the current data collection are either validated or adjusted based on the market segment surveys.

At a time when relief from overly burdensome regulation has become a top priority of the Administration, we urge CMS to ensure that implementation of PAMA results in as little administrative burden and disruption as possible. We look forward to ongoing communication and dialogue with CMS as implementation continues to ensure that Medicare beneficiaries have access to medically necessary clinical testing.

Sincerely,

John Meigs, Jr., MD, FAAFP
Board Chair