



Better health through
laboratory medicine.

June 16, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

Earlier this year, Congress enacted, and the President signed into law, H.R. 4302, the Protecting Access to Medicare Act of 2014, which ‘modernizes’ the clinical laboratory fee schedule by shifting to a market-based payment approach. Under the statute, CMS will be required to calculate a “weighted median” fee based on private market pricing and volume data. This payment amount would apply to all laboratories. AACC has serious concerns about this approach.

The market- based scheme assumes that all facilities performing testing are comparable in how they bill, their costs and volume of testing, the clientele they serve, their hours of operation and the roles they serve within their communities. This is not accurate. There are significant differences between testing providers— with each assuming distinct and invaluable roles within the health care system. The result, however, is that each type of facility has a different cost structure for performing testing.

For example, many commercial laboratories have contracts with physician offices to perform testing during routine business hours, thus reducing costs. Hospitals, however, must offer more comprehensive health services 24 hours a day seven days a week, often in medical emergency situations that require immediate, costly testing. Each laboratory is meeting an important need, each is vital to the health system, but each has different built-in costs for performing testing that must be considered when setting payment rates.

AACC is concerned that under the new law, the market-based pricing structure is likely to reflect the lower prices offered by commercial laboratories that have higher economies of scale. These payment rates may force many smaller community laboratories, hospitals, and physician office

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laboratories to either scale back or discontinue their testing. If this were to occur, it could have significant ramifications for patient access to testing, particularly in rural and other underserved areas.

Before CMS implements this approach, AACC urges the agency to conduct a preliminary analysis on the impact of this new market-based approach. This study should evaluate:

- the ability of the various laboratories to provide the required information;
- the costs of upgrading provider billing systems and hiring additional personnel to provide the required data;
- how the new approach may alter the menu of testing services provide by the differing types of laboratories;
- the financial impact of the market-based payment system on the differing testing facilities; and
- most importantly, what impact the new payment method may have on patient access to testing, particularly any geographic or population-based differences.

AACC recognizes the difficulty of the task that has been assigned to CMS and is willing to work with the agency to find ways to mitigate the potentially devastating problems that may emerge.

By way of background, AACC is the principal association of professional laboratorians--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and practice in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and medicine and its applications to health care. If you have any questions, please call me at (336) 716-2639, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Steven H. Wong



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President, AACC