

**Congress of the United States**  
**Washington, DC 20515**

November 7, 2016

The Honorable Sylvia Matthews Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell:

We are writing to reiterate the importance of successful implementation of the Protecting Access to Medicare Act of 2014 (PAMA), which requires the Centers for Medicare and Medicaid Services (CMS) to establish a market-based payment system for the Clinical Laboratory Fee Schedule (CLFS). We are concerned that under the process outlined in final regulations issued on June 17, 2016, many laboratories, especially small community and regional laboratories, may not have the necessary reporting capabilities in place. These laboratories could struggle to properly report data and comply with the regulations, which could result in significant problems for CMS' implementation efforts, as highlighted in a recent report issued by the Office of the Inspector General (OIG). In addition, the impact of these regulations could ultimately threaten the ability of small laboratories to provide needed services to Medicare beneficiaries.

The laboratory payment reform mandated by PAMA relies on an assessment of private market rates for laboratory services, which are reported by applicable laboratories. Updating the CLFS is a highly complex task with significant implications for all stakeholders. The reforms to the CLFS must be accomplished in a deliberate and measured manner, providing the necessary time for stakeholders to comply with guidance that has only recently been issued.

We understand the Agency also has concerns about its ability to obtain accurate payment rate information through the PAMA reporting process. During a recent PAMA Advisory Panel hearing, the Agency stated that it does not know how it will collect data for Automated Test Panels and related chemistry tests. These tests are primarily used by physicians to manage patient care. It is critically important for CMS to work with laboratory stakeholders to develop a manageable reporting solution to capture the data in order to set payment rates for these tests.

The OIG has also indicated that CMS does not plan to verify the accuracy of the data it receives. The importance of accurate data cannot be overemphasized. Given that CMS must use these data to establish new payment rates, the Agency must ensure that data can be captured correctly for all tests.

CMS recently allowed for flexibility in reporting for clinicians during the implementation of the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA), understanding the potential for issues faced by small group and individual clinicians. We request that the Agency consider a similar approach in implementing the laboratory reporting provisions in PAMA. Flexibility would enable more laboratories to accurately report the necessary data to support the transition to the new payment system.

Laboratories will be subject to significant civil monetary penalties if they are unable to report data in accordance with the Agency's timelines. We want to ensure all laboratories have the opportunity to be successful in complying with the PAMA regulations to support payment reform. We urge CMS to consider flexibilities in implementation, particularly for small laboratories, to ensure that the data that serve as the basis of the new payment system are sound. Unduly rushed and incomplete data collection risks inaccurate rate setting which would negatively impact small community and regional laboratories and the patients they serve.

We are committed to the successful implementation of laboratory payment reform. We look forward to continuing to work with CMS to ensure a smooth transition throughout implementation.

Sincerely,

  
Greg Walden

  
Patrick Meehan

  
Steve Chabot

  
Nydia M. Velázquez

Joseph R. Pitts  
Joseph R. Pitts

Bobby L. Rush  
Bobby L. Rush

Bill Pascrell, Jr.  
Bill Pascrell, Jr.

Patrick J. Tiberi  
Patrick J. Tiberi

Michael C. Burgess, M.D.  
Michael C. Burgess, M.D.

Kurt Schrader  
Kurt Schrader

Richard E. Neal  
Richard E. Neal

Tom Price, M.D.  
Tom Price, M.D.

Marsha Blackburn  
Marsha Blackburn

Eliot L. Engel  
Eliot L. Engel

Ann Kirkpatrick  
Ann Kirkpatrick

Charles W. Boustany, Jr., M.D.  
Charles W. Boustany, Jr., M.D.

Chris Collins  
Chris Collins

Tim Ryan  
Tim Ryan

Lynn Jenkins, C.P.A.  
Lynn Jenkins, C.P.A.

Donald M. Payne, Jr.  
Donald M. Payne, Jr.

*Joe Barton*

Joe Barton

*Yvette D. Clarke*

Yvette D. Clarke

*Tony Cardenas*

Tony Cardenas

*Leonard Lance*

Leonard Lance

*Kenny Marchant*

Kenny Marchant

*Ron Kind*

Ron Kind

*Brenda L. Lawrence*

Brenda L. Lawrence

*Mike Kelly*

Mike Kelly

*Gus M. Bilirakis*

Gus M. Bilirakis

*Kathleen M. Rice*

Kathleen M. Rice

*Peter A. DeFazio*

Peter A. DeFazio

*Larry Bucshon*

Larry Bucshon, M.D.

*Kevin Cramer*

Kevin Cramer

*Grace Meng*

Grace Meng

*Andre Carson*

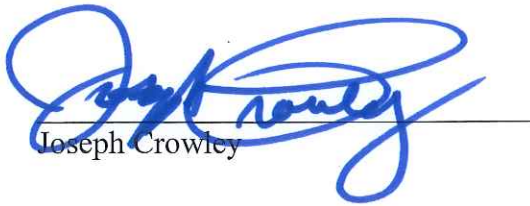
Andre Carson

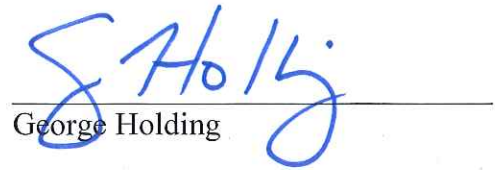
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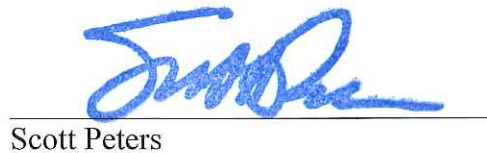
  
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Mike Thompson

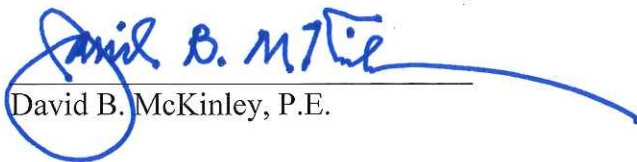
  
Pete Olson

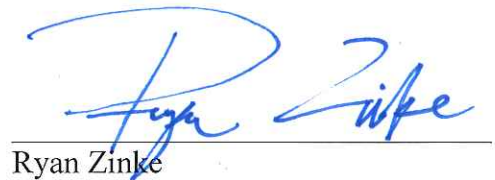
  
Erik Paulsen

  
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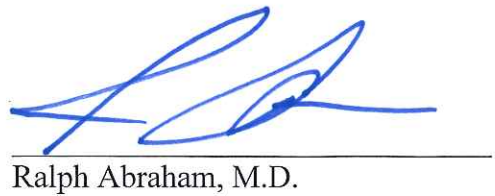
  
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David G. Reichert

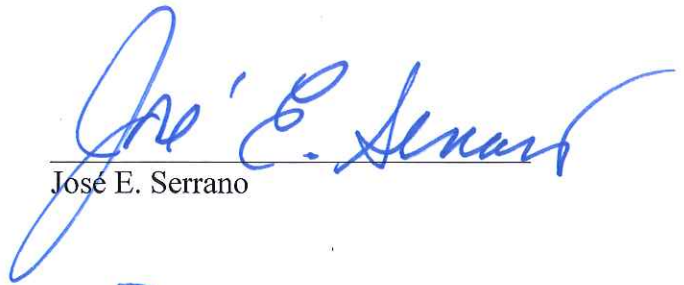
  
David B. McKinley, P.E.

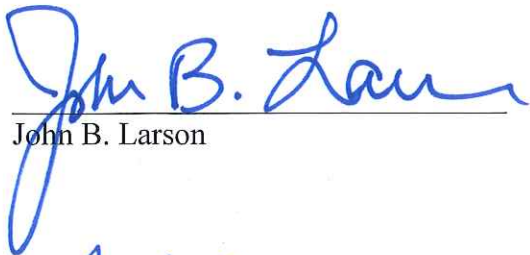
  
Ryan Zinke

  
Jody Hice

  
Ralph Abraham, M.D.

  
Gregg Harper

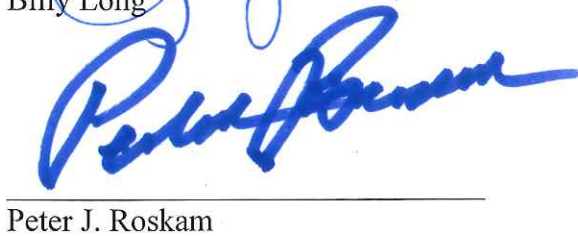
  
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Peter T. King

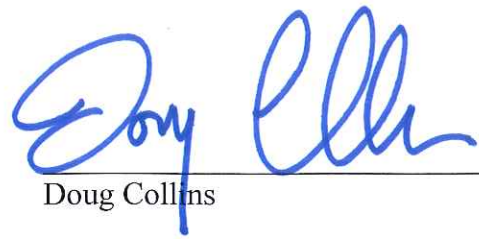
  
Mike Pompeo

  
H. Morgan Griffith

  
Tom McClintock



Brian Babin



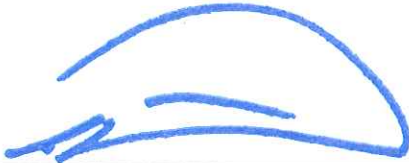
Doug Collins



Ryan A. Costello



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Chuck Fleischmann



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Randy Hultgren



Andy Harris, M.D.



Evan Jenkins



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Scott R. Tipton



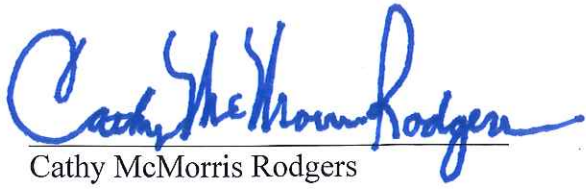
Chris Stewart



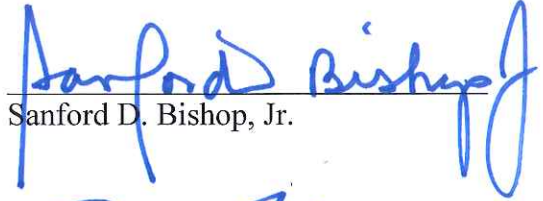
Richard Hudson



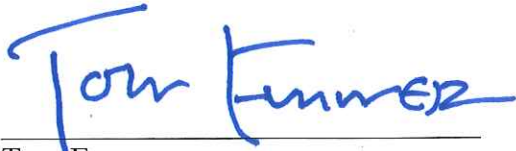
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Cathy McMorris Rodgers



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Tom Emmer



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