## United States Senate

WASHINGTON, DC 20510

September 28, 2015

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

Dear Secretary Burwell,

We write to request that the department delay until no sooner than January 1, 2017, making final rules for stage three of the meaningful use program, and then phase in stage three requirements at a rate that reflects how successfully the program is being implemented. In addition, we ask that the modified rule proposed for stage two of the program be adopted immediately. These actions will help most doctors and hospitals to comply with the government's requirements.

Patients need an interoperable system that enables doctors and hospitals to share their electronic health records, but the government, doctors, and hospitals need time to do it right. To date, taxpayers have invested \$30 billion to encourage electronic health records adoption. While all hospitals and most physicians met the requirements of the first stage of the meaningful use program, stage two requirements are so complex that only about 12 percent of eligible physicians and 40 percent of eligible hospitals have been able to comply. This year alone, 257,000 physicians have seen a 1 percent reduction in their Medicare reimbursements and 200 hospitals stand to see an even greater reduction. The modified stage two rule will enable more providers to comply with the government's requirements. It should be adopted immediately to give physicians and hospitals time to adapt to these huge changes.

If the department does not delay making final the stage three rules and instead proceeds before it can measure the impact of the modified stage two rule, it will be a missed opportunity to build support among providers. Pausing the stage three rules will also enable the department to ensure its final rules align with the new payment models created by the Medicare Access and CHIP Reauthorization Act, which created the Merit-Based Incentive Payment System.

For many years, our constituents have contacted us about their frustrations with the implementation of the meaningful use program. We respectfully request that you delay making final the stage three rules and immediately adopt the modifications to the stage two rule. We look forward to your response.

Sincerely,

JOHN THUNE

Vnited States Senator

LAMAR ALEXANDER
United States Senator

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RENEE L. ELLMERS

2ND DISTRICT, NORTH CAROLINA

1210 LONGWORTH HOUSE OFFICE BUILDING WASHINGTON, DC 20515 (202) 225-4531

### Congress of the United States House of Representatives

Washington, **BC** 20515-3302

September 28, 2015

ENERGY AND COMMERCE
SUBCOMMITTEE ON
COMMUNICATIONS AND TECHNOLOGY

SUBCOMMITTEE ON

SUBCOMMITTEE ON ENERGY AND POWER

The Honorable Shaun Donovan Director Office of Management and Budget 725 17th Street, N.W. Washington, DC 20503 The Honorable Sylvia Mathews Burwell Secretary Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

Re: Medicare and Medicaid Electronic Health Record Incentive Program

Dear Director Donovan and Secretary Burwell,

We are writing to ask that you refrain from finalizing Meaningful Use Stage 3 at this time and work to refocus the program to better serve patients and the providers who care for them. We have an interest in being active partners in successfully enabling health information technology to serve as the digital infrastructure necessary to achieve delivery system reform and meet the needs of a modern healthcare system. To that end, we urge you to refrain from finalizing Meaningful Use Stage 3 and 2015 Edition Certification at this time.

Six years after passage of Health Information Technology for Economic and Clinical Health Act (HITECH), there exists an opportunity to make policy decisions apart from the arbitrary deadlines of the EHR Incentives Program. We believe that additional time is necessary for the proper evaluation and optimization of implemented technology to ensure the technology can ensure better quality care for all patients.

We believe that the Stage 3 rule should be paused as it should rely on proven technology – designed outside the limitations of current federal requirements – that can support a shift to outcomes and interoperability rather than measures and objectives. Unfortunately, the proposed Stage 3 rule, currently under review at the Office of Management and Budget (OMB), exacerbates current problematic policies of Stage 2. We should incentivize technology that enables interoperability and improved health outcomes rather than incentivizing technology that counts how many times a provider performs an activity. The additional time would also give policymakers a chance to understand how the private sector performs relative to modifications proposed for program years 2015 through 2017. Taking the time to get it right now will surely pay dividends in the future.

Further, pausing Stage 3 at this time will provide the opportunity to evaluate the environment after these regulatory changes and consider the implementation issues surrounding the Merit-Based Payment System (MIPS) and Alternative Payment Models (APMs). Since the Stage 3

regulation was developed in a world prior to the Medicare Access and CHIP Reauthorization Act (MACRA), CMS should take the opportunity to reevaluate Stage 3 in light of MIPS and APMs.

While healthcare providers are committed to implementing EHRs, many are becoming disenchanted by the seemingly unrealistic expectations dictated by the Meaningful Use Program. Unfortunately, the frustrations voiced by providers and policymakers regarding the systems deployed in over 80 percent of hospitals and physician offices are real. According to the Centers for Medicare & Medicaid Services (CMS), an estimated 257,000 providers are currently subject to payment adjustments in the 2015 program year for failing to meet the Meaningful Use Program's requirements. We believe this signals a failure that is indicative of issues outside the hands of health care providers. We believe the solutions to address the provider community's concerns are well within the Department's reach and action must be taken now, as we have arrived at a pivotal time in the Program.

We appreciate the opportunity to share our constituents' perspectives on the need to reevaluate how we can foster an interoperable health information infrastructure that does not disrupt patient care. We reiterate the importance of refraining from issuing the Meaningful Use Stage 3 and the accompanying certification rule until a rigorous evaluation of provider participation in Stage 2 has been completed. Frankly, we were surprised and disappointed to see that the Stage 2 modifications rule was transmitted to OMB simultaneous to the transmission of the Stage 3 final rule and the new EHR certification rule. A learning health system should incorporate the lessons learned from Stage 2 into Stage 3. This is not possible at present because a minority of providers have achieved Stage 2 and because the Stage 2 modifications rule has yet to be implemented.

In order to ultimately reach our shared goals of better health care, smarter health care spending and healthier patients, the administration needs to take time to reevaluate the program. We ask that you refrain from finalizing Meaningful Use Stage 3 at this time and work to refocus the program to better serve patients and the providers who care for them. We respectfully ask for a response no later than 30 days from the receipt of this letter.

Yours truly.

Renee Elimers (NC-02)

Member of Congress

Member of Congress

David Scott (GA-13)

Member of Congress

Brad Ashford (NE-02

Member of Congress

Brian Babin (TX-36)

Member of Congress

Member M Congress

Austin Scott (GA-08) Member of Congress	Gregg Harper (MS-03) Member of Congress	Pete Olson (TX-22) Member of Congress
André Carson (IN-07) Member of Congress	Jason Smith (MO-08) Member of Congress	Pete Sessions (32-TX) Member of Congress
Brendan Boyle (PA-18) Member of Congress	Chris Collins (NY-27) Member of Congress	Palmer (AL-06) Member of Congress
Lynn Jenkins (KS-02) Member of Congress	David Rouzer (Ne 07) Member of Congress	Jody Hice (GA-10) Member of Congress
Kenny Marchant (TX-24) Member of Congress	David McKinley (WV-01) Member of Congress	Bill Huisenga (MJ-02) Member of Congress
Donald M. Payne Jr. (NJ-10) Member of Congress	Ayan Costello (PA-06) Member of Congress	Patrick Meehan (PA-07) Member of Congress

Dan Benishek (MI-01)

Dan Benishek (MI-01) Member of Congress Ami Bera (CA-07) Member of Congress

Rob Bishop (UT-01) Member of Congress

Santord Bishop (GA-02) Member of Congress

Marsha Blackburn (TN-07) Member of Congress

Vern Buchanan (FL-16) Member of Congress

Bradley Byrne (AL-01) Member of Congress Buddy Carter (GA-01)
Member of Congress

John Culberson (TX-07) Member of Congress

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ohn Duncan (TN-02) Member of Congress

Mike Fitzpatrick (PA-08) Member of Congress Bill Flores (TX-17) Member of Congress

Andy Harris (MD-01) Member of Congress Evan Jenkins (WV-03) Member of Congress

Ann Kirkpatrick (AZ 01) Member of Congress

James Langevin (RV02) Wember of Congress

Leonard Lance (NJ-07) Member of Congress Billy Long (MO-07) Member of Congress

Phil Roe (TN-01) Chris Stewart (UT-02) Member of Congress Member of Congress Member of Congress Bobby Rush (IL-04) Mike Bost (IL-02) Trent Franks (AZ-08) Member of Congress Member of Congress Member of Congress Jee Heck, D.O. (NV-03) Vevin Nunes (CA-22) Larry Bucshon (IN-08) Member of Congress Member of Congress Member of Congress Steve Knight (CA-25) Member of Congress Mike Kelly (PA-03) Stephen Fincher (TN-08) Member of Congres Member of Congress Mo Brooks Jason Chaffetz (UT-03) Mo Brooks (AL-05) Mimi Walters (CA-45) Member of Congress Member of Congress Member of Congress

> Sam Farr (CA-20) Member of Congress

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Dutch Ruppersberger (MD-02)

Member of Congress

Barbara Comstock (VA-10) Morgan Griffim (V Rob Woodall (GA-07) Member of Congress Member of Congress Member of Congress Michael C. Burgess, M.D (TX-26) Paul Gosar (AZ-04) Rick Allen (GA-12) Member of Congress Member of Congress Member of Congress Brad Wenstrup (OH-02) Glenn Grothman (WI-06) Jeb Hensarling (TX-05) Member of Congress Member of Congress Member of Congress Gus Bilirakis (FL-12) in Fleming (LA-04) Julia Brownley (CA-26) Member of Congres Member of Congress Member of Congress Doug Collins (GA-09) Member of Congress Todd Young (IN-09) Steve Israel (NY-03) Member of Congress Member of Congress

Alex Mooney (WV-02)
Member of Congress

Joe Wilson (SC-02) Member of Congress

Norma Torres (CA-35) Member of Congress Bill Johnson (OH-06)
Member of Congress

Lou Barletta (PA-11)
Member of Congress

Steve Chabot (OH-01) Member of Congress

Ryan Zinke (MT)
Member of Congress

Kyrsten Sinema (AZ-09) Member of Congress

Bill Shuster (PA-09) Member of Congress

Bill Sheuter

Ed Royce (CA-39) Member of Congress Lyke Messer (IN-06) Member of Congress

Sam Graves (MO-06) Member of Congress

Lynn Westmoreland (GA-03) Member of Congress

Rodney Davis (IL-13) Member of Congress Louie Gohmert (TX-01) Member of Congress

Ed Whitfield (KY-01) Member of Congress Brett Guthrie (KY-02) Member of Congress David Young A-03
Member of Congress

Steve King (IA-04)
Member of Congress

Diane Black (TN-06) Member of Congress Doug LMalfa (CA-01) Member of Congress



Clar Lownthal Alan Lowenthal (CA-47)

Member of Congress

Rick Crawford (AR-01)

Member of Congress

Jaime Herrera Beutler (WA-03) Member of Congress

George Molding (NC-Member of Congress

Member of Congress

Gerald E. Connolly (VA Member of Congress

Scott Peters (CA-52) Member of Congress

Bob Goodlatte (VA-06) **Member of Congress** 

David Jolly (FL-13) Member of Congress

Matt Salmon (AZ-05) Member of Congress

Jim Renacci (OH-16) Member of Congress

Ralph Abraham, M.D. (LA-05) Member of Congress

Kristi Noem (SD) Member of Congress

Bill Posey (FL-08) Member of Congress

Member of Congress

Patrick Tiberi (OH-12) Member of Congress

Ted Yoho (F) Member of Congress Charles W. Dent (PA-15)
Member of Congress

ohn Ratcliffe (TX-04) Member of Congress Shaun Donovan Director Department of Management and Budget 725 17<sup>th</sup> Street, NW Washington, DC 20503

#### Dear Shaun Donovan:

The undersigned medical societies agree that interoperable, useable, and clinically relevant Electronic Health Records (EHRs) are the essential foundation for the implementation of Merit-Based Payment System (MIPS) and Alternative Payment Models (APMs). The physician community, however, is extremely concerned with the current direction of the Meaningful Use (MU) program. To date, 80 percent of physicians are utilizing EHRs, but less than 10 percent of physicians have successfully participated in MU Stage 2. Furthermore, due to the inflexible MU regulations and certification requirements, vendors have created software products that are frequently unusable, administratively burdensome, and in many instances do not promote clinically relevant patient care.

The physician community is extremely dismayed by recent press reports that the Final Modifications Rule and the Final MU Stage 3 Rule have been combined and this rule is now under review at the Office of Management and Budget (OMB). If the administration finalizes the proposed MU Stage 3 regulation now, vendors will create software that will lock-in problematic technology, which physicians and patients will be living with for years to come. The proposed MU Stage 3 regulation exacerbates problematic policies of MU Stage 2 by continuing to "count" physicians' compliance with one-size-fits-all objectives rather than focusing on the clinical activities that should support differences in medical practices and patient care. We believe Stage 3 takes a drastic step backwards from the proposed improvements of the Modifications Rule.

Moreover, the proposed MU Stage 3 regulation was developed prior to and without consideration of the changes enacted by the Medicare Access and Chip Reauthorization Act (MACRA). Yet, the MU program will play a vital role in both the new MIPS payment system and the development of APMs. The administration should therefore pause MU Stage 3 and reevaluate the program in light of these pivotal changes to Medicare.

Importantly, pausing Stage 3 will not stop or delay progress with EHRs. Rather, we believe it will help move the program forward and drive innovation and adoption. To continue to advance EHRs, we urge the administration to proceed with finalizing the Modifications Rule as well as with integral pieces of the proposed 2015 Edition Certification Rule as soon as possible. For example, the administration should release a revised 2014 Edition and move forward with proposals to: provide updates to the testing and use of clinical and quality

Shaun Donovan September 17, 2015

document standards; adopt more stringent safety enhanced design requirements; standardize Application Programing Interfaces; conduct "in-the field" health IT surveillance; and provide transparency and disclosure requirements. Physicians and patients should not have to wait until 2018 to see improvements to current technology. Yet, the administration has waited too long and left physicians with uncertainty about the program requirements. Due to the extremely late date in publishing the Modifications Rule, we strongly believe that the agency should establish an additional hardship exemption category for physicians who could not anticipate new program mandates so late into the year.

There seems to be a view among some policymakers that by requiring more certified EHRs to populate the landscape the systems will achieve interoperability. The physician community strongly disagrees, and we are concerned that spreading poor performing systems may exacerbate the problem. Instead, we believe key interoperability challenges need to be addressed first so that the systems entities adopt will be capable of facilitating the seamless exchange of data. We believe that pausing Stage 3 at this time will provide the opportunity to evaluate the environment as we work with the administration to implement the needed changes found in the Modifications Rule. There are so many questions surrounding creation of MIPS and APMs that it is premature to proceed with MU Stage 3, especially since EHRs and MU will serve as a foundation for the success of these programs.

The physician community is committed to working with the administration on the implementation of MACRA. We, however, strongly believe that moving forward with MU Stage 3 at this time will severely undermine the ability of the health system to support the implementation of this critical legislation.

Sincerely,

American Medical Association Advocacy Council of the ACAAI AMDA - The Society for Post-Acute and Long-Term Care Medicine American Academy of Allergy, Asthma & Immunology American Academy of Dermatology Association American Academy of Facial Plastic & Reconstructive Surgery American Academy of Family Physicians American Academy of Neurology American Academy of Ophthalmology American Academy of Otolaryngic Allergy American Academy of Otolaryngology—Head and Neck Surgery American Academy of Pediatrics American Academy of Physical Medicine & Rehabilitation American Association of Clinical Endocrinologists American Association of Neurological Surgeons American Association of Orthopaedic Surgeons American College of Cardiology

American College of Gastroenterology American College of Mohs Surgery American College of Osteopathic Internists American College of Physicians American College of Radiology American College of Rheumatology American College of Surgeons American Gastroenterological Association American Medical Group Association American Osteopathic Association American Psychiatric Association American Society for Clinical Pathology American Society for Dermatologic Surgery Association American Society for Gastrointestinal Endoscopy American Society for Radiation Oncology American Society of Cataract and Refractive Surgery American Society of Hematology American Society of Plastic Surgeons American Urological Association College of American Pathologists Congress of Neurological Surgeons Medical Group Management Association North American Spine Society Society for Vascular Surgery The Society of Thoracic Surgeons

The Honorable Sylvia Burwell Secretary Department of Health and Human Services 200 Independence Avenue, SW Room 445-G Washington, DC 20201

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#### AMERICA'S HOSPITALS AND HEALTH SYSTEMS

May 28, 2015

Ms. Sylvia Burwell Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

#### Dear Secretary Burwell:

As organizations representing hospitals and health systems across the country, we are writing to express our concern about the readiness of health information technology (HIT) infrastructure to support the successful attainment of proposed Stage 3 requirements for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program in 2018. We believe the creation of an efficient and effective infrastructure for health information exchange is essential to support the delivery of high-quality, patient-centered care and is a precursor to many of the proposed advances for Stage 3. Therefore, we recommend that the Department of Health and Human Services (HHS) prioritize the activities of public and private stakeholders to accelerate the availability of the necessary infrastructure for health information exchange and refrain from finalizing a Stage 3 meaningful use rule at this time.

Our collective memberships are actively engaged in building their information infrastructures and view information exchange as vital to care improvement, as well as to successful implementation of new models of care. And, important progress is underway to facilitate easier information exchange. For example, HHS is in the midst of refining its interoperability roadmap in consultation with stakeholders, and will help the nation prioritize activities to ensure that health information can flow to support both regulatory requirements and the advancement of new models of care. In the private sector, the Argonaut project holds the promise of a new standard to support information exchange across technology platforms, but its work is in an early stage of development relative to the current scale of information exchange that is expected among clinicians and consumers. Public health departments continue to develop their platforms to accept electronically reported data using the federally adopted standards. Clinical data registries must develop that capability. And, we need to make progress on solving the challenge of correctly identifying and authenticating patients so that we have confidence that accurate information is being shared. HHS can be instrumental to this effort by supporting and coordinating across these activities to ensure that federal policy prioritizes progress on sharing data efficiently and effectively.

Success in achieving interoperability that is based on open-source, consensus-based standards is a precursor to proposed Stage 3 requirements such as providing patients with access to their data via third-party applications, expanded public health reporting options and many others. We have learned from early experience in Stage 2 that it is unwise to finalize requirements based on untested standards, such as the Direct protocol for sending summary of care documents. We need

As written, the Stage 3 Meaningful Use rule is salvageable for the future. It needs to be scoped more tightly and the thresholds have to be decreased, since many are not achievable today. After 20 years of engaging patients, Beth Israel Deaconess has regular secure electronic communications with 25% of patients. The other 75% have chosen other means. Requiring 35% in regulation is not reasonable.

The Stage 3 certification rule needs to be rewritten from scratch. It is decoupled from the Meaningful Use program and includes lists of standards that are not used anywhere in production in the world. I support offering a standards advisory document outside of regulation - highlighting emerging standards that are likely to be fit for purpose in the future. Requiring them in regulation will not help anyone. Including them as optional standards in regulation outside of the Meaningful Use program will just cause market confusion.

In summary, let's delay Stage 3 entirely, and reassess our position in 2018, after the private sector has enhanced products to meet the business demands of stakeholders.

#### Videos



Decision Support
NFL Drafts eClinicalWorks to Tackle On-Field Injuries



Health Info Exchange More Conversations Around Health Care Payments



Integrated Data Means a New Path for Care Management

#### Slide Shows

For Immediate Release

Lamar Alexander of Tennessee - Chairman

Contact:

Margaret Atkinson / Jim Jeffries (Alexander): 202-224-0387

# Alexander Calls for Delay of Making Final Rules for Stage Three of Electronic Health Records Program

Chairman says "patients need an interoperable system that enables doctors and hospitals to share their electronic health records, but the government, doctors, and hospitals need time to do it right"

"Some hospitals have told me they are 'terrified' by stage three. It does not help patients to make these massive changes fast and wrong. It does help patients to do this deliberately and correctly so that doctors and hospitals embrace the changes instead of dread them." – Lamar Alexander

WASHINGTON, D.C., Sept. 16 – Senate health committee Chairman Lamar Alexander (R-Tenn.) today called for a delay until January 1, 2017, of making final rules for stage three of the federal government's program to require doctors and hospitals to create electronic health records systems.

He said that stage three requirements should then be phased in at a rate that reflects how successfully the program is being implemented. He also said that the modified rules proposed for stage two of the program should be adopted immediately because it will help most doctors and hospitals to comply with the government's requirements.

"Patients need an interoperable system that enables doctors and hospitals to share their electronic health records, but the government, doctors and hospitals need time to do it right," Alexander told a senate hearing. "Some hospitals have told me they are 'terrified' by the prospect of stage three. It does not help patients to makes these massive changes fast and wrong. It does help patients to do this deliberately and correctly so that hospitals and doctors embrace the changes instead of dread them."

Since 2009, the federal government has spent more than \$30 billion to encourage the nearly 500,000 physicians and more than 5,000 hospitals who serve Medicare and Medicaid recipients to establish electronic health records systems. About half of these doctors and most hospitals have established such systems. Beginning this year, the government is assessing penalties on those who have not. About 257,000 physicians have begun losing 1 percent of their Medicare reimbursements and 200 hospitals may be losing more than that, the senator said.

Alexander said that all hospitals and most physicians met the requirements of the first stage of the so-called "meaningful use" program but that stage two requirements are so complex that only about 12 percent of eligible physicians and 40 percent of eligible hospitals have been able to comply. "That is why the government should