OMB/OIRA MEANINGFUL USE MEETING
September 25, 2015
2:00 pm Meeting
(gather in OMB cafeteria in the basement at 1:00pm)

1800 G Street, NW
9th Floor, Conference Room 1
(Mabel Echols is the contact person)
Bring government-issued photo ID (we do not need to provide security info in advance)

Expected Attendance

Julie Brown, CAHIMS
Health IT Policy
American College of Cardiology
2400 N St. N.W., Wash, DC 20037
jbrown@acc.org
Tel (202) 375-6351

Sonya Clay
Government Relations Representative
American Academy of Family Physicians
1133 Connecticut Avenue, NW, Suite 1100
Washington, DC 20036
Tel (202) 232-9033
Cell (202) 285-9966
sclay@aafp.org

Rebecca Hancock
Manager, Quality & HIT Policy
American Academy of Ophthalmology
20 F Street, NW, Suite 400
Washington, DC 20001
Tel (202) 737-6662
rhancock@aaodc.org

Leslie Krigsten
Vice President of Congressional Affairs
College of Healthcare Information Management Executives (CHIME)
20 F Street, NW, Suite 700
Washington, DC 20001
Tel (202) 507-6158
lkrigstein@chimecentral.org

Kristen O'Brien
Washington Counsel
Division of Legislative Counsel
American Medical Association
25 Massachusetts Avenue, NW, Suite 600
Washington, DC 20001
Tel (202) 789-7428
Kristen.o'brien@ama-assn.org

Michael Repka, MD
Medical Director for Governmental Affairs
American Academy of Ophthalmology
20 F Street, NW, Suite 400
Washington, DC 20001
Tel (202) 737-6662

→

Mari Savickis
Vice President of Regulatory Affairs
College of Healthcare Information Management Executives (CHIME)
20 F Street, NW, Suite 700
Washington, DC 20001
Cell (202) 294-3828
msavickis@chimecentral.org

Karen Sealander, Esq.
Washington Counsel, Intermountain Healthcare
McDermott Will & Emery LLP
500 N. Capitol Street, NW
Washington, DC 20001
Tel (202) 756-8024
ksealander@mwe.com

Robert M. Tennant, MA
Director, Health Information Technology Policy
Medical Group management Association
1717 Pennsylvania Avenue, NW, Suite 600
Washington, DC 2006
Tel (202) 293-3450, ext. 1373
Toll free at (877) 275-6462, ext. 1373
Fax (202) 293-2787
rtennant@mgma.org

Steve Waldren, MD, MS [on the phone]
Senior Health Care Information Technology Strategist
American Academy of Family Physicians
11400 Tomahawk Creek Parkway
Leawood, KS 66211

Chantal Worzala, PhD
Director, Policy
American Hospital Association
800 10th Street, NW
Two City Center, Suite 400
Washington, DC 20001
cworzala@aha.org
Tel (202) 626-2313

Shahid Zaman, Esq.
Policy Analyst
America's Essential Hospitals
1301 Pennsylvania Ave, NW, Suite 950
Washington DC 20004
Tel (202)585-0124
Fax (202)585-0101
szaman@essentialhospitals.org

NB: This letter is not yet final.

September 17, 2015

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 Ellmers
Member of Congress

Dr. Tom Price
Member of Congress

David Scott
Member of Congress

Additional signatories as of 9-24-15

Allen
Ashford
Babin
Barr
Benishek
Bera
Bilirakis
Bishop, Rob
Bishop, Sanford
Blackburn
Bost
Brooks, Mo
Brownley
Buchanan
Bucshon
Burgess
Byrne
Carter, Buddy
Chaffetz
Collins, Doug
Comstock
Cook, Paul
Culberson
Duncan, John
Ellmers*
Farr
Fincher
Fitzpatrick
Fleming
Flores
Franks
Gosar
Griffith
Grothman
Harris, Andy
Heck
Hensarling
Israel
Jenkins, Evan
Kelly, Mike
Kirkpatrick
Knight
Lance
Langevin
Long
Love
Nunes
Price, Tom*
Roe
Ruppersberger
Rush
*Scott, David**
Stewart, Chris
Torres
Walters
Wenstrup
Wilson, Joe
Woodall

September 17, 2015

Shaun Donovan
Director
Department of Management and Budget
725 17th 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

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
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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

Shaun Donovan
September 17, 2015

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

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

testing and refinement of standards, as well as time to work through implementation issues, before a standard becomes a regulatory requirement.

Indeed, we still have many lessons to learn from Stage 2, given that 2015 is the first year that most providers will be meeting the Stage 2 requirements. According to the latest data from CMS, only 38 percent of hospitals and 11 percent of physicians registered for the EHR incentive programs met Stage 2 in 2014 (presentation to HIT policy committee, March 2015). In the spirit of a learning regulatory system, we believe that Stage 3 requirements, including the higher thresholds and more robust requirements for technology should be built on evaluation of experience in Stage 2 by all providers, and not just those that are among the first adopters.

Furthermore, as you know, recent legislation calls for changes to meaningful use for physicians in the coming years. Specifically, the Medicare Access and CHIP Reauthorization Act of 2015 directs HHS to create a Merit-based Incentive Payment System (MIPS) that combines meaningful use with the existing value-based modifier and physician quality reporting system programs. To ensure coordination across programs and avoid duplicative or contradictory policies, we urge you ensure that Stage 3 rules are consistent with your development of the MIPS program. While MIPS only will apply to eligible professionals, it is important to keep the meaningful use requirements for hospital and physicians aligned.

Our commitment to the successful use of electronic health records and electronic exchange of health information remains strong. We believe that providing additional time for maturation of implemented technology and optimization to support meaningful use and other regulatory requirements is the right policy to keep all stakeholders focused on the activities that will support the better quality care for patients and for populations.

Sincerely,

America's Essential Hospitals
American Hospital Association
Association of American Medical Colleges
Catholic Health Association of the United States
Children's Hospital Association
Premier healthcare alliance
VHA Inc.

Cc: Andrew M. Slavitt, Acting Admistrator, CMS
Karen DeSalvo, Acting Assistant Secretary for Health and National Coordinator for Health Information Technology

September 17, 2015

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

Dear Secretary Burwell:

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 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.

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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

Reasons Why OMB/OIRA Should Release the Meaningful Use Modifications Final Rule ASAP and Return the Stage 3/2015 CEHRT Final Rules to HHS So That the Stage 3/2015 CEHRT Rules Can be Reoriented to More Effectively Move the Nation to Interoperability (reasons not in order of importance):

1. It is deeply concerning to hospitals and physicians that the much needed relief contained in the Meaningful Use Modifications Final Rule is now apparently coupled with the Stage 3 Final Rule. In the Modifications Proposed Rule, CMS stated that its purpose was "to make changes to the requirements for Stage 1 and Stage 2 of meaningful use for 2015 through 2017 to align with the approach for Stage 3 of meaningful use in 2017 and subsequent years." In reality, however, many of the changes in the modifications rule are actually fixes to Stage 2 to make it achievable for the large number of providers that have struggled to meet Stage 2's extremely burdensome requirements. For example, the creation of a 90 day reporting period for 2015 is a welcome policy proposal but has nothing to do with aligning Stage 2 with Stage 3. **It is arguably arbitrary and capricious that the much needed regulatory changes to Stage 2 are now apparently tied to the final Stage 3 rule and final 2015 Certified Electronic Health Record Technology (CEHRT) rule that dozens of provider organizations, the Senate Health, Education, Labor and Pensions Committee Chair, and more than 40 members of the House of Representatives have called upon the administration to pull back from OMB/OIRA review and return to HHS for revision.**

2. Meaningful Use currently certifies specific, prescriptive functionalities in Electronic Health Record (EHR) technology. This means that **providers have been mandated to purchase costly certified EHRs that do not always support them in meeting the federal Meaningful Use requirements and that are largely unable to assist them in achieving their larger goals for improving patient care. The certification process is broken; providers are finding that their 2014 CEHRT does not work as expected and requires significant and expensive patches or work-arounds. Certified technology cannot easily generate accurate electronic clinical quality measures and CMS is having trouble accepting the data. As CMS is increasingly mandating that successful participation in programs other than Meaningful Use requires the use of CEHRT, it is critical that HHS utilize the certification lever to ensure higher performing and interoperable systems. Promising efforts are underway in the private sector to drive interoperability but vendors and providers are far too distracted by Meaningful Use to maximize those efforts.** Meaningful Use has required vendors to develop product that helps providers count how many times they've performed a function rather than assist providers in managing population health, coordinating care and succeeding in alternative payment models. **Certified technology does not share data easily, either within a hospital or across care settings. Vendors are being forced to develop technology whose primary purpose is to meet CMS requirements, not provider or patient needs. CEHRT is, generally speaking, not interoperable. Stage 3 and 2015 CEHRT do nothing to change that.** Unless the Stage 3/2015 CEHRT final rules are re-oriented to focus on certifying against standards, maximizing clinician usability, and optimizing patient outcomes, the nation will not make needed advances to interoperability or achieve goals relating to precision medicine and value-based payment.

3. **Interoperability's benefits will only be fully realized if ALL providers are effectively utilizing EHR technology. One of every two physicians is receiving a Meaningful Use penalty in 2015. More than 60% of hospitals and about 90% of physicians have yet to attest to Stage 2.** The pending Stage 2 modifications rule should be finalized swiftly, which hopefully will enable providers to find success in the revised Stage 2. Because the proposed rules for Stage 3 build on the onerous aspects of the current Stage 2 rules, it could well cause providers to leave the program and stumble on their journey to effective use of EHR technology. The Meaningful Use program needs a significant course correction in order to maximize provider success in the program. That course correction can only be achieved by pulling back the Centers for Medicare and Medicaid Services (CMS) Stage 3 final rule and the companion HHS Office of the National Coordinator (ONC) 2015 certification final rule and re-orienting the program.

4. **Stage 3 in many instances builds on Stage 2 and ratchets up unrealistic Stage 2 requirements** (e.g., the Stage 2 measure requiring 5% of patients to view, download or transmit to a third party their health information increases to 25% in the proposed Stage 3 rule – this and other Meaningful Use requirements hold providers responsible for the actions or preferences of people over whom they have no control. **Particularly in an "all or nothing" program where missing one single measure by even a minuscule amount means failing the entire program for the year, this is fundamentally unfair.** Stage 3, as currently structured, will be more onerous for providers than Stage 2, underscoring the need to push pause on Stage 3 so that the CMS and ONC rules can be re-oriented to focus on optimizing patient outcomes, enhancing the workability of EHR technology, ensuring the certification system certifies against interoperability and NOT against numerous functionalities, and truly advancing the needle on interoperability.

→

5. **Stage 2 is a huge pain point, but some relief is likely in sight in the 2015-2017 CMS modifications final rule**. The modifications rule was proposed April 15, 2015. The comment period closed June 15. We await the final rule, which is expected to change the 2015 reporting period from 365 days to 90 days and to change hospitals' program year from the fiscal year to the calendar year, among other changes. **Given that we are now in the final days of the current 365-day reporting period for hospitals and in the 9th month of the current 365-day reporting period for physicians, the government should focus on expediting the modifications rule and then assess providers' experience with the program, as modified, before moving on to Stage 3.** This would not allow "time off" from Meaningful Use because eligible providers still have to meet Meaningful Use requirements each and every year. But, it would make the Meaningful Use program better reflect a learning health system so that actual experience with Stage 2 can appropriately inform Stage 3.

6. There is no data of which we are aware that demonstrates Meaningful Use Stage 2 has improved care delivery or interoperability. EHR implementation needs time to settle in. The continued disruption of workflow and lack of time to focus on usability given the consuming imperative to meet Meaningful Use requirements leads the nation down the wrong path. **A delay in Stage 3 would allow hospitals and physician practices to focus on usability and workflow, which will inherently lead to better patient information in the system, a prerequisite to realizing the benefits of interoperability. Sharing junk information does not help anyone.**

7. **There is nothing in the proposed rules for Stage 3 that helps with usability, workflow enhancement or interoperability.** The rules need to be withdrawn and re-written.

8. **Success in the precision medicine initiative and in alternative payment models, including bundled payment and Accountable Care Organizations (ACOs), demand the availability of comprehensive and accurate patient data wherever it is needed for decision making. Stage 3 would, in many cases, perpetuate substandard data, the sharing of data that is NOT computable, and quality measures that produce unreliable data.** The Stage 3 and 2015 CEHRT rules need to be re-written.

9. CMS has indicated that **Stage 3 is the final stage of the Meaningful Use program**. While changes could conceivably be made to Stage 3 after it is finalized, **it would be far better to get Stage 3 right the first time.**

10. The proposed Stage 3 rules would require all providers to be at Stage 3 using 2015 Edition CEHRT January 1, 2018, with January 1, 2017 an option for providers. **There should be NO optional early start in ANY final rule; this places undue pressure on vendors** to develop and have technology available to roll-out just in case clients want it early. A repeat of the 2014 CEHRT development and rollout delays could well occur.

11. With Meaningful Use-certified software required for all physicians under the new Medicare physician payment regime (for physicians in the Merit-based Incentive Payment System (MIPS), MU is one of the four MIPS performance categories so these physicians must meet all MU requirements using EHR technology certified for MU; for physicians participating in Alternative Payment Models (APMs) instead of MIPS, they must also use CEHRT), and with virtually all hospitals participating in the Meaningful Use program, certification is a powerful tool available to compel vendors to develop the technology needed to truly transform health care. Today's certification program falls far short of that bar, as do the 2015 CEHRT requirements in the proposed ONC rule. Indeed, **ONC** has recognized this and **is holding "Technical Expert Panel" meetings in September/October 2015 to assess HIT capabilities and rank potential certification criteria that would allow success in APMs. Accordingly, pushing pause on the Stage 3 rules is imperative in order to ensure that vendors have time to innovate and develop the product that will transform health care.** Developing to Meaningful Use specifications has consumed vendors' time, attention and resources, leaving very little room for innovation. Further, **HHS should refrain from finalizing the Stage 3/2015 CEHRT rules for Meaningful Use until HHS issues a final rule implementing the MIPS, given that Meaningful Use and/or CEHRT are incorporated into both paths (MIPS and APMs) available to physicians**.

12. Some have said that providers should not be "let off the hook" for Meaningful Use after they have received incentives. **In no way would providers be "let off the hook" if Stage 3 and 2015 CEHRT were returned to HHS** and re-issued when those rules can provide product that will enable providers to be successful in APMs and assist providers in optimizing patient health. **Providers MUST meet whatever Meaningful Use requirements are in effect each and every year. Pushing pause on Stage 3 would simply elongate a modified Stage 2.** With respect to incentive dollars, providers greatly appreciate the federal assistance. However, the approximately $18 billion in incentives to hospitals and $12 billion to physicians is far less that the $47 billion hospitals spent on HIT each and every year between 2010 and 2013.

FACTSHEET

Getting Meaningful Use Right

THE ISSUE:

The American Recovery and Reinvestment Act (ARRA) of 2009 incentivized the adoption and meaningful use of certified electronic health records (EHRs) by providing the possibility of short-term positive incentives for hospitals, physicians and other eligible professionals (EPs), followed by long-term financial penalties that began in 2015 and do not sunset. The program has led to greater adoption of EHRs over the past five years, particularly among hospitals. However, the administration's implementation of the Medicare and Medicaid EHR Incentive Programs has proved challenging and unwieldy – particularly its creation and implementation of a three stage system with tiered requirements that would trigger incentives or penalties for providers. The timeline for the program has been overly aggressive, moving too quickly from Stage 1 of "meaningful use," to Stage 2, and now a proposed Stage 3. The requirements for Stage 2 are, in some cases, too prescriptive and hold providers accountable for events outside their control. Furthermore, providers have been mandated to purchase costly certified EHRs that do not always support them in meeting the federal requirements or achieving their larger goals for improving patient care. Due to these regulatory choices, the current program is overly complex and burdensome, which means patients will not realize the benefits of a wired health care system.

AHA POSITION:

America's hospitals are strongly committed to the adoption of EHRs. The transition to an EHR-enabled health system is well underway, but we need to fix the meaningful use program to realize the benefit for patients. That is why the AHA has asked the Department of Health and Human Services (HHS) to provide more flexibility in the Stage 2 meaningful use requirements and refrain from finalizing Stage 3 rules.

WHY?

- **The meaningful use program started in 2011 and most hospitals have attested to Stage 1, although critical access hospitals (CAHs) have faced greater challenges and are less likely to have met the federal requirements.** Hospitals are committed to EHR adoption and want the meaningful use program to work.

- **However, more than 60 percent of hospitals and about 90 percent of physicians have yet to attest to Stage 2.** Hospitals face tremendous challenges meeting Stage 2 for a number of reasons:
  - **The certification process is broken.** Vendor delays and implementation issues have limited hospitals' ability to meet Stage 2 requirements. Hospitals are finding that 2014 Edition Certified EHRs do not work as expected and require significant and expensive patches or work-arounds. The biggest problems have been with the "transitions of care" and "patient portal" requirements.
  - **2014 Edition Certified EHRs do not share data easily, either within the hospital or across care settings. They are not, generally speaking, interoperable.** In addition, many areas of the country do not have efficient and affordable information exchange networks in place.
  - **The program holds hospitals accountable for events outside their control.** For example, to meet the transitions of care requirement, a hospital must find other providers ready to receive information in the manner required by the government. However, post-acute care providers are not part of the meaningful use program, and many physicians have yet to implement their 2014 Edition certified EHRs.

- **The Centers for Medicare & Medicaid Services (CMS) has yet to finalize a proposed modifications' rule that it released in April 2015 that would address some stakeholder concerns by shortening the reporting period in 2015 and offering limited flexibilities in the Stage 2 requirements.** Hospitals greatly appreciated the proposed flexibilities, but need the certainty of a final rule now to begin the process of reviewing performance and ensuring they have met all of the revised requirements.

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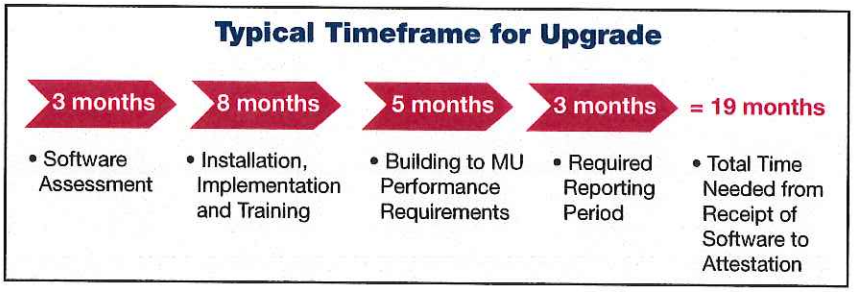
- **The modifications final rule is past due,** given that it will affect the current program year for meaningful use. Indeed, under current rules, meaningful use applies to fiscal year performance for hospitals. Fiscal year 2015 ends Sept. 30. Failure to release a final rule soon could lead to widespread failure of hospitals to meet meaningful use, resulting in significant undeserved financial penalties and lost incentive payments.

- **Despite the limited experience with Stage 2 and the need to make modifications to it, CMS already has proposed a higher bar for Stage 3 requirements. CMS should wait until a sufficient number of hospitals have met Stage 2 before setting the start date or requirements for Stage 3.** This is a matter of common sense when so few have met Stage 2. Once 75 percent of hospitals and EPs have met Stage 2 then Stage 3 rules can be considered. HHS has had to fix both the Stage 1 and Stage 2 rules after they were first finalized because experience on the ground proved some of the requirements unworkable. Stage 3 should not follow that same pattern.

- **The move to Stage 3 will require costly upgrades to a new version of certified EHRs.** Hospitals estimate that it takes 19 months, on average, to properly and safely implement an upgrade to their EHR system. Changing a system disrupts both clinical care and operations, consumes capital and delays other important initiatives, such as building out new models of care. CMS should have solid proof that the benefits of Stage 3 will outweigh the costs before imposing this mandate.

KEY FACTS:

- **The meaningful use program has spurred remarkable growth in EHR adoption by hospitals.** The most recent AHA survey data show by 2014, 75 percent of hospitals had at least a basic EHR in place – almost five times the share in 2010. However, having a basic EHR does not mean it meets requirements for meaningful use.



- **CMS has paid about $18 billion in incentives to hospitals, and $12 billion to physicians.** Hospitals greatly appreciate this federal assistance.

- **However, the AHA estimates that, collectively, America's hospitals spent $47 billion on information technology IT each and every year between 2010 and 2013.**

- **Medicare penalties began in 2015.** CMS has reported one of every two EPs will receive a 1 percent Medicare payment penalty this year because they could not meet meaningful use in a prior year. About 200 hospitals paid under the inpatient prospective payment system also received payment penalties this year. The share of CAHs receiving penalties will not be known until after the end of the fiscal year.

- **Meaningful use is an all-or-nothing program.** If a hospital fails to meet a meaningful use objective, such as use of computerized provider order entry, by a single percentage point, the hospital will fail to meet meaningful use and be exposed to significant payment penalties. CMS should increase flexibility in the program requirements so that a small mistake does not have a large impact. The current "all-or-nothing" approach of having to meet each and every metric, or fail altogether, is solely a regulatory design and is unfair.

- **The rules of the program expose hospitals to financial penalties if they choose to switch vendors, and cannot meet meaningful use while they are changing systems.** While Congress gave CMS the authority to grant hardship exceptions from the penalties, the agency has refused to grant an exemption for providers that are switching vendors. This policy is unfair to providers and reduces competition among EHR vendors.

- **Certified EHRs cannot easily generate accurate electronic clinical quality measures (eCQMs).** We strongly support the long-term goal of using EHRs to streamline and reduce the burden of quality reporting, but eCQMs and EHRs require additional improvements before they can feasibly and reliably generate valid performance data. Additional time is needed for development, independent testing and rigorous review.

PRESS RELEASES

Alexander Calls for Delay of Making Final Rules for Stage Three of Electronic Health Records Program (http://www.alexander.senate.gov/public/index.cfm/pressrelID=23db6882-737e-4f2a-b0f3-cddf8f676381)

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"

Posted on September 16, 2015

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

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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 immediately adopt its proposed modifications to the stage two requirements—so physicians and hospitals have time to adapt to these huge changes," he said.

"Our senate health committee has held five hearings on this electronic health records program," Alexander said. "Many of those who testified have urged us to delay making final these stage three requirements in order to really help patients. I look forward to working with Senator Murray, Secretary Burwell and other members of the administration on finding the best ways to modify this program and these requirements."

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For access to this release and the senator's other statements, click here. (http://www.alexander.senate.gov/public/index.cfm/pressreleases)

To stay up-to-date on the senator's latest actions, follow him on Twitter (https://twitter.com/SenAlexander) and YouTube. (https://www.youtube.com/user/lamaralexander)

Click play to view the video or follow this link https://www.youtube.com/watch?v=m9HVkrzkPyk (https://www.youtube.com/watch?v=m9HVkrzkPyk)

Permalink:
http://www.alexander.senate.gov/public/index.cfm/2015/9/alexander-calls-for-delay-of-making-final-rules-for-stage-three-of-electronic-health-records-program (http://www.alexander.senate.gov/public/index.cfm/2015/9/alexander-calls-for-delay-of-making-final-rules-for-stage-three-of-electronic-health-records-program)

H.R. 3309 - Further Flexibility in HIT Reporting and Advancing Interoperability Act - Flex-IT 2 Act
Talking Points

Challenge #1: Align MU Rulemaking

- CMS has proposed modifications to the 2015 - 2017 MU program; however, these rules have not been finalized, leaving physicians and hospitals with uncertainty about the current program's structure.
- In addition, the Merit Based Incentive Payment System (MIPS), which sets the new formula for physician Medicare reimbursement, includes MU in its calculations but the MIPS regulations have not been written.
- There is confusion about how CMS will evaluate the MU program changes and how the MIPS program and the MU program will be reconciled.

Recommendation: Press pause on Stage 3 of MU and the new certification requirements until the vast majority of participants are successful in the current program or the final regulations implementing the MIPS program are issued by CMS to ensure the programs work seamlessly together.

Challenge #2: Pass/Fail Approach, Need for Proportionality

- MU is designed so that anything less than 100% will result in a financial penalty.
- This all-or-nothing approach fails to recognize differences across specialties and patient populations, and is contrary to other quality reporting programs (such as e-prescribing) that set different thresholds for success and failure.
- Participation remains low partially because there is no incentive to try if physicians and hospitals believe they cannot meet a single threshold or measure.

Recommendation: Incentivize participation by creating a fairer system—the program should be designed to reflect that all hospitals and physicians are not identical and need different accommodations to provide high quality patient care.

Challenge #3: Streamline Quality Reporting

- Hospitals and physicians are being forced to duplicate quality reporting requirements, wasting important resources that should be devoted to patient care.
- The MU quality reporting requirements are less robust than many existing quality reporting programs.

Recommendation: Deem participants who have successfully met more robust physician and hospital quality reporting requirements to satisfy the MU quality requirements.

Challenge #4: Insufficient hardship exemptions

- HITECH authorizes the Secretary to grant hardships, yet the program has not included explicit exemptions for technology problems or when providers want to switch EHR vendors (which can take several months to complete).
- The rigid MU program also fails to take into account cyber-attacks and technology delays that can cause physicians and hospitals to fail MU measures despite their good faith efforts to comply.

Recommendation: Expand the "unforeseen circumstances" hardship to:

1. Provide an exemption for providers who switch certified EHR products;
2. Provide an exemption for providers who experience a cyber-attack or other disruptive technology problems; and
3. Provide an exemption for certain physicians based on their specialty or if close to retirement.

Challenge #5: Remove barriers to innovation

- A key barrier to interoperability is the fact that certification does not ensure data is sent, received, and seamlessly incorporated across EHR systems.
- The MU full year reporting period also limits innovation as vendors and physicians have no down-time to tweak products, improve usability, and test innovative solutions.
- ONC and CMS have also frequently changed the program requirements mid-year, creating confusion and disrupting workflows, which prevent providers from reporting for a full calendar year.

Recommendation: 1) Prioritize interoperability by ensuring EHRs are capable of sending, receiving, and incorporating data through repeated testing and evaluation by end-users. 2) Implement a 90-day reporting period for 2015 and beyond to facilitate innovation, remove barriers to interoperability, and promote usability.