

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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April 15, 2016

Dr. Patrick Conway
Deputy Administrator for Innovation
And Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Conway:

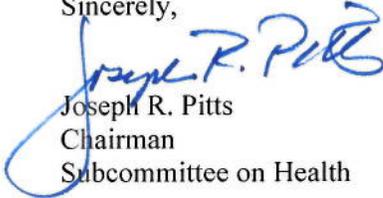
Thank you for appearing before the Subcommittee on Health on March 17, 2016, to testify at the hearing entitled "Medicare Access and CHIP Reauthorization Act of 2015: Examining Implementation of Medicare Payment Reforms."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 29, 2016. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Joseph R. Pitts

1. Can you detail the steps CMS has already taken to engage the stakeholder community notably physicians and providers, as well as their specialty associations, in the development of the MACRA rule? Specifically, MACRA explicitly requires CMS to engage directly with physician stakeholders to implement various aspects of MACRA, can you update us on this communication to date and what will be forthcoming?
2. The final rule for MACRA implementation for performance year 2017 is expected to be released later this year. Some have worried that a few months is not enough time for practices to transition to MIPS. How does CMS plan to accommodate practices during this transition period?
 - o The legislation provides CMS with instruction and funding for physician outreach in this transition and information on how to report - what type of education and support will be provided to practices?
 - o Will specific efforts be undertaken for small or rural practices?
 - o Can you outline these efforts and what we can tell our providers to expect as far as resources and engagement from CMS?
3. When does CMS plan to notify physicians whether they are qualified APM participants for the 2019 payment year?
4. Will CMS administer the 2019 APM payment update in a way that allows physicians who are qualified APM participants to forego participation in MIPS in 2017 or do you think all physicians will need to assume they must meet the 2017 MIPS reporting requirements because they will not know whether they meet the 2019 APM payment update requirements?
5. Would you be willing to speculate as to how many physicians will qualify for the APM bonus payment in the initial years of its availability? If the number is low, why?
6. Building off the efforts to align quality measures, has CMS done any modeling if commercial payers are engaged in value based products and payment arrangements?
 - o Would CMS be open to counting risk based commercial models to a providers APM threshold?
 - o Do you envision that Medicare Advantage would or could count towards a providers APM threshold?
7. The Merit Based Incentive Program (MIPS) attempted to respond to criticisms that quality measures were being applied to physicians in a one size fits all manner with practices being judged on measures complexly irrelevant or inapplicable to their practice. What is CMS

doing to further the Congressional intent of the statute and can you describe how MACRA provides flexibility for providers to be judged on quality measures relevant to their unique practice or specialty?

8. MACRA made important reforms to how quality measures can be more quickly incorporated into Medicare by allowing the Secretary to work with provider and physician groups on validating and adopting quality measures that may not yet be endorsed. Can you speak to this new flexibility and how CMS is approaching the ability for this enhanced collaborative relationship with providers on quality measurement?
9. In order to improve patient outcomes and enhance quality of care, the Merit-Based Incentive Payment System (MIPS) incorporates patient engagement features. The RFI issued in October regarding Section 101 of MACRA did not request comment on patient engagement and self-management assessment. There is a direct connection between patients taking an active role in managing their health conditions and improved outcomes especially when providers coach patients in a customized manner to encourage better self-management. National and international use of patient self-management assessment measures that are validated and extensively peer-reviewed and paired with interval level self-management intervention techniques have repeatedly resulted in enhanced health outcomes and reduction in unnecessary utilization. As CMS develops MIPS, will it direct providers to rely on an empirically validated, interval level, patient self-management assessment tool to determine a beneficiary's self-management capabilities?
10. One of the major challenges facing measure developers is getting quality measures approved by a consensus based organization. MACRA created new flexibilities to encourage measure development and create a direct line for those society developed measures to CMS. Yet, CMS' proposal in their draft Quality Measure Development Plan would require measures that are not NQF-endorsed to align with NQF requirements for its consensus review process. This action seems to undercut the flexibility provided under MACRA. Can you speak to this?
11. Section 102 of MACRA authorizes \$75 million to be used over five years, beginning with fiscal year 2015, to expand and enhance existing measures and to develop new measures to fill performance gaps. Has CMS allocated any of this funding, and if not, why not?
12. What, if any, analysis has CMS conducted as to whether or not existing quality programs (including both value based payment arrangements as well as Physician Quality Reporting System PQRS) have had a meaningful effect on quality improvement?
 - o Can you speak to any savings these efforts have generated in addition to quality improvement?
 - o Do you have any information in this regard broken down by medical specialty?
 - o If so are there certain specialties that are notable in their work to meaningfully improve quality?

13. As you know, failure to appropriately apply risk adjustment can inappropriately penalize providers who care for high risk or complicated populations which is why MACRA allowed for a professional to see their MIPS score adjusted – what are your thoughts on the successful implementation of risk adjustment given CMS’s experience with other risk adjustment methodologies?
14. We have heard from physicians and physician practices that were previously successful with PQRS but who have been marked as PQRS failures in 2016 and are receiving a penalty. Many are reporting they do not know why. Can you explain why there appears to be such a high failure rate with PQRS in 2016?
 - o Have you looked to see how many previously successful PQRS reporters were judged to have failed this year?
15. How do you envision providers will be able to document, report or attest to their participation in or completion of clinical practice improvement activities?
16. What process will CMS create for physician specialty societies to create and/or propose Clinical Practice Improvement Activities? Do you intend to require participation in certain activities?
17. Does the agency intend to evaluate the impact of the value modifier program on small practices and solo practitioners in time to inform how resource use will be applied to MIPS?
18. MACRA allows any performance category that a physician, group or specialty could not realistically succeed in to be reweighted. Will CMS consider re-weighting the resource use category until there is more consensus on the best means by which to evaluate resource use? Does CMS intend to have issues surrounding resource use application settled by implementation? How does CMS anticipate transitioning from the measures under the value based modifier to the use of episode groups?
19. As outlined in the law, the HHS Secretary can incorporate Part D drug spending as part of the resource use component of MIPS, to the extent it is feasible. The current resource use metrics only account for spending on physician administered drugs paid under Part B. Some physicians sometimes have the option to prescribe either a Part B or a Part D drug for a given condition. Since the decision usually comes down to patient choice, one provider may treat a patient with a Part B drug while another rheumatologist treating a patient with the same indications and risk factors could just as easily choose a Part D drug. Under CMS’ current resource use methodology, the patient who opted for the Part B drug would appear more costly than the patient who opted for the Part D drug, which would translate into higher resource use and potential financial penalties for the treating physician. Can you elaborate on this situation and how patient choice and the practice of medicine will not be impacted by this provision? Will the proposed rule speak to how CMS is planning to address resource use when it comes to physician-administered and self-administered medications? Has CMS come to a conclusion on how it can incorporate Part D drugs in resource use measurement under the new MACRA programs?

20. Can you update us on CMS' and more broadly the Department of Health and Human Services efforts to implement the December 18, 2018 deadline for EHR interoperability imposed by MACRA?
21. When Congress enacted the "Protecting Access to Medicare Act of 2014" (P.L. 113-93), which I am proud to say I sponsored, one of our goals was to promote evidence-based care by utilizing appropriate use criteria for certain advanced diagnostic imaging services. In so doing, we wanted to ensure these provisions did not have an unintended consequence of delaying care for patients who sought medical attention in an emergency department until after it was determined that they did not have an emergency medical condition (as defined in section 1867(e)(1)). This exception not only covers individuals with an identified emergency medical condition, but also the applicable imaging service ordered to determine whether or not the individual has an emergency medical condition.
22. What is your agency doing to make sure that the rules being promulgated in regard to this section of P.L. 113-93 are compatible with our intent? Can you assure me that the appropriate use criteria exception will cover the medical screening exam as well as patients with an emergency medical condition?

The Honorable Michael C. Burgess

1. What is CMS doing to ensure that there are alternative payment model options for physician groups looking for options that are not built on fee-for-service platform but that do not require the massive financial investment of say, an ACO?
2. A goal of MACRA, as well as a major provision of 21st Century Cures, is to deal with the inexcusable lack of interoperability between electronic health record systems. How could CMS potentially restructure the EHR-meaningful use program to ensure that this component of MIPS is more flexible, and is tailored to the needs of specialty practices?
3. We have heard concerns regarding the current set of resource use measures used under the Value-based Payment Modifier. Some have argued that they hold physicians accountable for care provided outside of their control, that the measures focus on conditions and diseases that are irrelevant to many specialists, or they are based on total Part A and Part B costs, which is more appropriate for hospital measurement. What steps is CMS taking to ensure the availability of a more relevant and accurate set of resource use measures in time for the first year of MIPS? If CMS is unable to develop additional measures on time, is there a contingency plan to ensure specialists are not inappropriately dinged?
4. MACRA created a new category within the MIPS payment system called Clinical Practice Improvement Activities. The idea behind this category was to reward physicians for quality improvement activities that they might already be undertaking but not being acknowledged for such as continuing medical education, expanded office hours and the use of clinical data registries. Does CMS plan to recognize a wide variety of clinical practice improvement activities or focus on a more narrow set?

The Honorable Leonard Lance

The spirit and intent of MACRA emphasizes working with and learning from stakeholders in the medical community who are developing alternative payment models and those participating in these new payment models. In particular, medical specialty societies can play an important role, as they lead the development of guidelines and quality metrics in their areas of medicine and increasingly are working to develop alternative payment models.

1. Can you describe for the Committee how are you planning to work with specialty organizations/societies in developing alternative payment models to ensure that MACRA implementation is flexible enough and meaningful to allow specialists from across medicine to fully participate?
2. It is my understanding that the radiation oncology specialty society has developed models related to breast cancer and palliative care, and they have several more models in the works. Likewise, other radiation therapy stakeholders are developing and testing new models. I think it's important for CMMI to work closely with medical specialties and other stakeholders. Can you describe how you plan to engage radiation oncologists and the broader physician specialty community in the development of these new models for cancer care?

The Honorable Renee Ellmers

1. Does the Department have the authority it needs to ensure that successful participation in the Meaningful Use program and use of technology certified for the Meaningful Use program will enable success in value-based payment, or does the Administration need additional authorities from Congress?
 - o If additional authorities are needed, what are they?
2. Similarly, do you interpret the MACRA statute, or HITECH for that matter, to enable CMS to manipulate the construct of the Meaningful Use Program to no longer be all-or-nothing for both doctors and hospitals? Or only doctors?
 - o If only for doctors, how do you account for challenges the potential discrepancies in the Program's construct for doctors and hospitals can pose?
 - o Do you need additional statutory authority to make any changes?
3. We hope the Department is quickly progressing in their efforts to equip physicians to be successful under the new payment models, either in MIPS or APMs, given that 2017 is the first program year for physicians under MACRA. We hope to see the proposed rules released soon to ensure the industry has the best chance of success in 2017.
 - o I'd like to hear if the Administration believes physicians are equipped with the technology they need to be successful under MACRA. Especially given the ongoing struggles of providers in the Meaningful Use Program and the lack of nationwide

- interoperability. Will EHRs certified for the Meaningful Use program enable success in the new world of value-based payment?
- Does CMS have the technical capacity to administer these new payment policies?
 - Does CMS need additional resources to successfully administer the MACRA programs?
4. As you know, the “Meaningful Use” program was part of the HITECH Act, which was enacted five years prior to MACRA and the accelerated movement to value-based-payment announced last year by the Department.
 5. Acting Administrator Slavitt said of the Meaningful Use program, “as it [Meaningful Use Program] has existed, will now be effectively over and replaced with something better.” If those changes are being considered by MACRA, can CMS make such changes for the current program year if they are good policy beginning in 2017?
 - For example: Can CMS relax the "all or nothing" nature of grading for 2016? Does in 2016 who try and still fail to be meaningful users will receive a whopping -4% reduction in Medicare revenue in 2018, just as they are trying to get used to reporting as they will need to under MIPS.
 - CMS should do everything within its regulatory power to keep providers in the program and not take this hit especially since they have the power to lower the bar in a sense.
 6. How can docs have faith in MIPS and APMs if they don't believe they can be considered meaningful users of HIT, being that 206,000 doctors were subject to Meaningful Use Penalties in 2016? What can we do to ensure physicians have the best chance possible to be successful in the Program in 2016?
 7. There's no question that delivery system reform won't be possible without an interoperable healthcare delivery system. What is the Administration doing to advance interoperability? How can the Administration leverage some of the progress that has been made in the private sector to advance interoperability?
 8. MACRA created a new category within the MIPS payment system called Clinical Practice Improvement Activities. The idea behind this category was to reward physicians for quality improvement activities that they might already be undertaking but not being acknowledged for such as continuing medical education, expanded office hours and the use of clinical data registries. Does CMS plan to recognize a wide variety of clinical practice improvement activities or focus on a more narrow set? Please elaborate on why.
 9. Will CMS be able to evaluate certified EHR technology to assure it can meet the goals of the EHR quality assessment so that physicians are not penalized for standards that EHRs cannot yet achieve?
 10. Congress envisioned MACRA as a means to provide greater flexibility for physicians and not impose new burdens. What is CMS doing to achieve these goals?

11. A recent article published in Health Affairs found that physicians are spending \$15.4 billion a year to comply with quality reporting measures that many believe do nothing to improve quality. We know CMS is working on modifying the Meaningful Use requirements, but what is CMS doing to make substantial changes to the problems in the Value Modifier (VM) and Physician Quality Reporting System programs?
12. Current timeframes for the release of feedback reports are too long, as CMS typically provides feedback reports, often fraught with errors, six to nine months after the close of the reporting period. This delay means that physicians are already well into the next reporting cycle and have no opportunity to change their behavior before they are penalized again. MACRA also calls for CMS to provide timely, valid and reliable data. What is CMS doing to provide more rapid cycle and accurate feedback to physicians so physicians can have the ability to act on the information and engage in meaningful quality improvement?
13. MACRA did include funding for technical support for small and rural practices, but practices of all sizes are already dealing with long wait times on MACRA's hotline, QualityNet, and long turnaround time on questions submitted via email. When practices do receive information back from QualityNet, sometimes unanswered questions remain, or information is difficult for clinicians to understand. What type of support systems does CMS envision having in place to help all providers and practices with the questions they have as MACRA is being implemented? How will CMS ensure that information and feedback provided to clinicians and practices is clear and actionable?

Dr. Conway, earlier this month, HHS announced that it had hit their goal of tying 30% of Medicare payments to alternative payment models. The announcement stated this included those participating in the Medicare Shared Savings Program as well as the Center for Medicare and Medicaid Innovation and listed examples of alternative payment models as Accountable Care Organizations (ACOs), advanced primary care medical homes and new bundled payment models. As of January 2016, CMS estimates that \$117 billion out of a projected \$380 billion in Medicare fee-for-service payments are tied to alternative payment models.

CMS reports that there are 477 ACOs participating in the Medicare Shared Savings program and the Pioneer ACO program. These ACOs are broken down as Track 1, Track 2 and Pioneer ACOs.

14. Dr. Conway, can you walk me through CMS's calculation of this \$117 billion? Which types of ACOs were included in reaching this \$117 billion? Track 1 ACOs? Track 2 ACOs? Pioneer ACOs?
15. If CMS included all types of ACOs into this calculation, does that mean that CMS considers them all alternative payment models that should be qualified to be considered for MACRA bonuses?

The Honorable Gene Green

One of the most important Clinical Practice Improvement Activities in which nuclear cardiologists, as well as other physician specialists, engage is consultation with imaging appropriate use criteria (AUC).

Prior to passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress passed the “Protecting Access to Medicare Act of 2014” (PAMA) which establishes that health care professionals must consult AUC prior to referring a patient for an advanced diagnostic imaging test, such as nuclear imaging, computed tomography and magnetic resonance.

1. What efforts are being made by CMS to ensure that physicians who fulfill the Medicare AUC Program requirements also receive credit for this activity under the Clinical Practice Improvement Activity component of the Merit-Based Incentive Payment System (MIPS)?
2. For many specialists, like nuclear cardiologists and radiologists, MIPS and alternative payment models will center on the performance, interpretation and quality of imaging tests. Has CMS considered how the AUC Program requirements could be fulfilled through the MIPS and APMs rather as a stand-alone program, which would allow for consultation of AUC, the goal of the AUC Program, to be measured against robust quality and resource use metrics?

The Honorable Elliot Engel

1. As you know, MACRA included language that afforded the Secretary the authority to develop measures and alternatives to reflect the way non-patient facing physicians practice medicine. These physicians, as you know, do not have regular and direct interaction with patients. How is CMS implementing that provision to enable physicians to comply with the quality programs in the MIPS program