THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 17 2015

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter to OMB Director Donovan and me regarding the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (EHR Incentive Programs). I am responding on behalf of both of us.

Patients, providers, businesses, health plans, and taxpayers all have a common interest in building a health care system that delivers better care, spends health care dollars more wisely, and makes our communities healthier – all with the patient at the center of his or her care. Electronic health records are critical to this effort. We share the goal of having actionable electronic health information available when and where it matters most and for health care providers and consumers to be able to readily, safely, and securely exchange information.

Over the past several years, we have seen increasing numbers of physicians, clinicians, and hospitals using EHRs to improve patient care. More than 70 percent of eligible physicians and other clinicians, and more than 95 percent of eligible hospitals, have successfully used EHRs and received incentive payments from the federal government. That represents great progress from the days when a doctor's handwriting needed to be interpreted and paper records could be misplaced.

We recognize we have more to do. We have heard from physicians and other providers about the challenges they face making this technology work well for their individual practices and for their patients. Providers have described the challenge of planning for and reporting on numerous meaningful use requirements and expressed frustration at competing reporting requirements among programs.

On October 6, the Centers for Medicare & Medicaid Services (CMS) published a final rule with a 60-day public comment period on certain provisions. In recognition of concerns we have heard, the regulations make significant changes in current requirements. They will ease the reporting burden for providers, support interoperability, and improve patient outcomes.

With these regulations, we are aligning our current regulatory framework with recent bipartisan legislation – the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) – that requires the establishment of a Merit-based Incentive Payment System (MIPS) for physicians and providers. We view the regulations as a bridge to the new payment system for physicians and providers and look forward to receiving input about how best to continue to align the EHR

Incentive Programs into the new payment system. This rule moves us beyond the staged approach of "meaningful use" by 2018 and supports a delivery system based on the quality of care delivered, as opposed to quantity. The CMS final rule, together with the final rule for 2015 Edition Health IT Certification Criteria (2015 Edition) issued by the Office of the National Coordinator for Health IT, will promote more widespread exchange and accessibility of health information, providing for improved health outcomes for patients.

HHS is committed to working with physicians, clinicians, hospitals, consumers, and other stakeholders to make these programs as effective as possible. As part of the final rule, CMS announced a 60-day public comment period on certain provisions of the rule to facilitate additional feedback about our vision for the EHR Incentive Programs going forward. In addition, we will continue to actively listen to key stakeholders through meetings and outreach. We want to use this time to reflect on how the safe and secure exchange of actionable electronic health information can best be used to deliver better patient care, and how to create an infrastructure that supports that.

We also understand the concerns expressed in your letter related to those eligible professionals and hospitals that have received negative payment adjustments under the Medicare EHR Incentive Program. We know that some physicians are not ready to participate in meaningful use and are concerned about these adjustments. We intend to use our administrative flexibility as much as we can to help eligible professionals, hospitals, and critical access hospitals that are making efforts to adopt and demonstrate meaningful use of certified EHR technology succeed.

To that end, CMS is encouraging physicians to apply for a hardship exception from the payment adjustment for 2015 through the existing request process. In anticipation of a potential surge in hardship requests, we have made accommodations such as moving the request process to a rolling basis and increasing contractor support for the handling of such requests.

We appreciate your letter and support of our efforts to simplify and strengthen the EHR Incentive Programs. Should you have questions or concerns, please contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I will also send this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell

Sylvia M. Burwell

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC 23 2015

The Honorable Tom Price, MD
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

As a follow up to Secretary Burwell's previous response to your joint letter in support of the proposed framework in the Medicare Physician Fee Schedule (PFS) calendar year (CY 2015) proposed rule to implement an Appropriate Use Criteria (AUC) program for advanced diagnostic imaging services (as established in section 218(b) of the Protecting Access to Medicare Act of 2014), the Centers for Medicare & Medicaid Services (CMS) would like to refer you to the PFS final rule with comment period, which was issued on October 30, 2015.

In response to public comments, CMS finalized a definition of provider-led entity (PLE) that, similar to the proposed definition, includes national professional medical specialty societies and hospitals or hospital systems, and also includes alliances and collaboratives of hospitals and hospital systems (e.g. the National Comprehensive Cancer Network, High Value Healthcare Collaborative).

The CY 2015 PFS final rule with comment period is available at: http://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf, and the AUC preamble and regulation text are on pages 71102 – 71116 and 71380 – 71382 respectively.

Thank you again for your interest in this new program for Appropriate Use Criteria. An identical copy of this response will be shared with the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 0 2 2015

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the United States Preventive Services Task Force (USPSTF) recommendations on breast cancer screening. We share your strong commitment to supporting women's health and prevention, and agree that mammography is an important tool in the fight against breast cancer.

As you know, the USPSTF is an independent, volunteer panel of national experts in prevention that makes evidence-based recommendations about clinical preventive services. The Agency for Healthcare Research and Quality (AHRQ) provides ongoing administrative, research, technical, and dissemination support to the USPSTF. As an independent panel of non-federal experts, the USPSTF's recommendations are determined by the members of the panel, not AHRQ or the U.S. Department of Health and Human Services.

I have shared your letter with the USPSTF so they have it as they consider the comments they received from the public on their draft recommendation statement and as they work to develop a final recommendation.

I look forward to continuing to work with you to improve women's health. If you should have any additional comments or concerns, please do not hesitate to let me know.

Sincerely,

Sylvia M. Burwell

Sylvia M. Burwell

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 28, 2013

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your recommendations for implementing the Medicare Quality Improvement Organization (QIO) program provisions included in the Trade Adjustment Assistance Extension Act of 2011. I appreciate your longstanding interest in improving the quality of care in the Medicare program.

I agree that community involvement is essential in the QIO improvement projects and appreciate your recommendations with respect to maintaining state-based QIO contracts and continued involvement of local physicians in the peer review process. The Centers for Medicare & Medicaid Services (CMS) require certain contract functions to be carried out at the local level and by local physicians. As you may know, there is nothing in the new legislation that would preclude the continuation of this physician involvement.

The breadth and number of the QIO's responsibilities have grown significantly since the program's inception. Consistent with the Institute of Medicine's report in 2006 on the QIO program, a modified structure that takes advantage of the continuously evolving approaches to quality improvement may lead to more effective conduct of some QIO activities. We will be examining this issue in the coming months.

Regarding dividing functions among different organizations, we are committed to avoiding fragmentation in QIOs and to targeting the quality improvement efforts that will be most effective in achieving high-quality health care for beneficiaries. I also agree that QIOs should meet high standards and avoid conflicts of interest. I assure you that these will continue to be goals of the QIO program.

Thank you for your commitment to ensuring quality care for our Medicare beneficiaries. I look forward to speaking with you as we implement key provisions of the QIO program. I will also provide this response to Representative Ron Kind.

Sincerely,

Kathleen Sebelius

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 2 0 2015

The Honorable Tom Price
U. S. House of Representatives
Washington, D.C. 20515

Dear Representative Price:

Thank you for your letter sharing your concerns around the release of the recent United States Preventive Services Task Force (USPSTF) draft recommendation statement for breast cancer screening.

As you know, the USPSTF is an independent, volunteer panel of national experts in prevention that makes evidence-based recommendations about clinical preventive services. The Agency for Healthcare Research and Quality (AHRQ) provides ongoing administrative, research, technical, and dissemination support to the USPSTF. As an independent panel of non-federal experts, the USPSTF's recommendations are determined by the members of the panel, not AHRQ or the Department of Health and Human Services.

The recommendations the USPSTF released are draft and were distributed for the purpose of receiving public input, such as the input you provided in your letter. I have shared your letter with the USPSTF so they have it as they consider the comments they received from the public on their draft recommendation statement and as they work to develop a final recommendation. I understand your concerns around women's access to preventive care and know that mammography is an important tool in the fight against breast cancer. I appreciate your input on this important issue. I will also provide this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell

Sylvia M. Burwell

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 14, 2012

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the U.S. Preventive Services Task Force's (Task Force) draft recommendation on prostate–specific antigen (PSA) based screening for prostate cancer. I appreciate your taking the time to share your concerns for the men and families who have suffered with prostate cancer, as well as men who are at risk of developing prostate cancer.

As you are aware, this Task Force is an independent panel of non-federal, volunteer experts, most of whom are practicing clinicians whose focus and expertise are screening and prevention. The Task Force develops evidence-based recommendations on clinical preventive services to inform America's primary care professionals and the patients and families that they serve. The recommendations provide valuable guidance to the health care community and the American people.

The Task Force recognizes that each of its recommendations may have an impact on individual patients, primary care clinicians, and clinical practice overall. As such, the Task Force undertakes a rigorous process for gathering and reviewing evidence, developing recommendations, and engaging experts and stakeholders in the review of its work. The Task Force bases all recommendations on a systematic review of published medical evidence; cost is not a factor in the Task Force's recommendations.

In your letter, you noted that the Task Force evaluated five studies. In its recent update of the evidence on screening for prostate cancer, the Task Force reviewed more than 8,000 article abstracts discussing screening or treatment for prostate cancer including 5 clinical trials of screening, 14 cohort studies, and 2 clinical trials on treatment. The evidence review used by the Task Force was peer-reviewed by experts in the field, including urologists.

In making its draft recommendation, the Task Force weighed the potential benefits and harms of screening and concluded that scientific evidence does not support the common perception that PSA-based early detection of prostate cancer reduces deaths from prostate cancer or prolongs lives. According to the evidence, most men who are treated for PSA-detected localized prostate cancer will receive no benefit from treatment, while a few will die, and some will have serious complications of treatment including impotence and/or incontinence.

The members of the Task Force are committed to increasing the transparency of all of their processes and to engaging the public in the development of their evidence-based

recommendations. As a result, the Task Force posted its draft recommendation on screening for prostate cancer for six weeks, starting in October 2011, and invited the public to review the evidence and provide comment on whether the Task Force assessed the evidence accurately and fairly, and whether their draft recommendation could be improved. I recognize your concern that the Task Force may lack sufficient scientific evidence on African American men and other high risk groups in making its recommendation, and I have encouraged the Task Force to include a specific explanation of their decision regarding high risk groups as they finalize their recommendation in response to the public comments.

I also recognize your concern that the final recommendation on screening for prostate cancer could affect coverage of PSA tests. While the Department has discretion to modify or eliminate Medicare coverage for the PSA test based on the Task Force's recommendation, I do not intend to propose any changes to Medicare coverage of this screening test at this time. With respect to private plans, the Affordable Care Act permits plans or issuers to provide coverage for services in addition to those recommended by the Task Force. Plans and issuers can therefore opt to continue covering PSA screening.

I believe the most important lesson from the work of this Task Force is that the men and families of our nation deserve better and more effective screening tests and treatments for prostate cancer. I am pleased that the National Cancer Institute is engaged in research to improve prostate cancer screening and treatment methods. It is my hope that in the future we will discover new, more effective tests and safer treatments.

Again, thank you for sharing your concerns about recommendations related to prostate cancer screening. I appreciate your leadership on this important issue and look forward to continuing our work to improve the health of all Americans. Please do not hesitate to contact me if you have any further thoughts or concerns. I will also provide a copy of this letter to the cosigners of your letter.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AUG 2 6 2016

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your August 15th letter to President Obama regarding our shared desire to ensure that we are doing everything that we can to combat the Zika virus in Georgia and in the United States. I am responding on behalf of the President.

As of today, there have been more than 11,500 cases of Zika virus infection, 1,396 pregnant women with any laboratory evidence of Zika virus infection, and 17 babies born with Zika-related birth defects in the United States. Our fight against Zika has taken on added urgency in light of Florida Governor Rick Scott's announcement on July 29 that there is local transmission of Zika infection in Florida. Since that time, Florida has announced that there are 43 cases of local transmission. While the arrival of Zika in the continental United States is a development that we expected and planned for, it underscores the urgency that we must do everything possible to minimize the impact that Zika will have on Americans. In particular, pregnant women and their babies are at greatest risk because Zika virus can cause microcephaly and other significant birth defects.

As you know, the Department of Health and Human Services (HHS) is constrained in what it can do since Congress has not provided any funding to help HHS fight Zika. In the absence of any congressional funding, we have moved aggressively to repurpose existing resources, such as funds intended to combat Ebola virus, which remains a public health challenge. These limited resources are being used to support states, like Georgia, and territories in their efforts to prepare for and respond to Zika virus. This is in addition to a broad range of other efforts that the Department is undertaking to respond to Zika virus, including developing vaccines and better diagnostic tests, enhancing laboratory capacity, and educating the public about the health risks of Zika virus.

HHS Assistance to Georgia

In your letter, you asked about how much of the repurposed funds were being distributed to Georgia. Despite the lack of any congressional funding for Zika, the Department has worked aggressively over the course of the year to provide Georgia with support to fight Zika, including:

- The Centers for Disease Control and Prevention (CDC) has provided Georgia with more than $2.3 million in Zika-specific funding and $14.7 million in Public Health Emergency Preparedness (PHEP) funding that can be used to support Zika response efforts. By

awarding Georgia more than $2.3 million to support Zika response efforts, CDC has met Georgia's requests to date for Zika-specific assistance.

  - In July, CDC awarded $446,000 to Georgia in Public Health Preparedness and Response (PHPR) funding to support efforts to protect Americans from Zika virus infection and associated adverse health outcomes, including microcephaly and other serious birth defects.
  - In July, CDC awarded approximately $1.3 million to Georgia in funding through the Epidemiology and Laboratory Capacity (ELC) cooperative agreement to build laboratory capacity, enhance epidemiological surveillance and investigation, improve mosquito control and monitoring, and contribute data to the U.S. Zika Pregnancy Registry.
  - Earlier in August, CDC awarded an additional $560,000 in funding to Georgia to establish, enhance, and maintain information-gathering systems to rapidly detect microcephaly and other adverse outcomes caused by Zika virus infection; ensure that affected infants and their families are referred to appropriate health and social services; and monitor the health and developmental outcomes of children affected by Zika.

- CDC has helped develop Georgia's laboratory capacity by assisting the Georgia Public Health Laboratory with its ability to perform two critical Zika diagnostic tests (the CDC Trioplex rRT-PCR Assay and the Zika MAC-ELISA). Moreover, CDC provided the Georgia Public Health Laboratory with supplies for Zika diagnostic testing sufficient to allow Georgia to test about 1,400 samples. CDC will continue to provide samples and supplies as needed to the Georgia Public Health Laboratory and other Zika testing laboratories to meet testing needs.
- In April, CDC provided a forum for state and local senior officials from Georgia, and other states, to develop State plans for the Zika response at the Zika Action Plan Summit. CDC has been in regular contact with Georgia officials to follow up on Georgia's Zika response plan and Georgia public health officials were an important part of the federal-state table top exercise on our Zika response.

HHS continues to work to develop Zika vaccines and Georgia's academic institutions have been important partners in the biomedical research response to Zika virus. For example, Emory University is one of three sites conducting a Phase I trial for the NIH Vaccine Research Center (VRC) DNA vaccine candidate. In addition to CDC's direct assistance to Georgia, research studies to understand Zika virus and the development of Zika vaccines, therapeutics, and diagnostics will deliver public health benefits to the people of Georgia.

Steps Taken to Fight Zika without Congressional Funding

The Department is committed to using scarce federal dollars aggressively and prudently, especially in light of Congress's inaction to provide any additional resources and the uncertainty around whether Congress will provide resources in the future. As you know, in April, the Department repurposed $374 million from accounts primarily intended to help fight Ebola to support domestic Zika response efforts. These funds were almost entirely split between the CDC, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA).

Centers for Disease Control and Prevention

Since CDC is on the front lines of providing assistance to states, territories, and localities to fight Zika, it received $222 million. To date, CDC has obligated $168.5 million of this total. CDC plans to obligate virtually the entire remainder of these domestic funds by the end of the fiscal year on the following activities:

- Providing technical assistance and deploying additional CDC Emergency Response Teams (CERTs), where requested, to states and localities that are responding to local transmission or travel-related cases of Zika infection.
- Working with states to test Zika specimens. (Since January 1, CDC has tested over 30,000 specimens.)
- Continued funding of critical research efforts that will help us understand the adverse health effects of Zika.
- Continued funding to develop systems to track mothers and babies who are impacted by Zika.
- Continued funding to finance an additional 120 CDC staff who are supplementing the hundreds of existing CDC staff working on the Zika response in the field and at CDC offices and labs in Atlanta, Puerto Rico, and Colorado.

CDC has distributed the majority of obligated repurposed funds to provide assistance to states, cities, and territories. To date, CDC has awarded approximately $108 million to support these local jurisdictions in the fight against Zika, including:

- During the week of July 21, CDC awarded nearly $60 million in ELC grants to states, cities, and territories to strengthen lab capacity, mosquito control and surveillance efforts, and help states purchase additional equipment and supplies that can be used to fight Zika.
- On July 1, CDC awarded $25 million in PHEP grants to cities, states, and territories to help them strengthen their preparedness and response plans.
- In August, CDC awarded $16.4 million to help states establish birth registries for babies born to mothers who had Zika.
- In August, CDC announced awards of $6.8 million to national public health partners to assist state, tribal, local, and territorial jurisdictions with their Zika responses in a wide range of activities, including surveillance and epidemiology, vector control, communication and outreach to pregnant women and vulnerable populations, and planning with key stakeholders.

CDC has also used repurposed funding to support education and communications outreach, staffing, and other technical support for laboratory capacity, vector control, research, and innovation.

Without additional resources, the CDC will have a severely limited capacity to support mosquito control and surveillance efforts in the continental U.S. or other U.S. territories and to further improve diagnostic testing for Zika. In addition, CDC will be severely constrained in its ability to provide any additional funding to states and localities, and in its ability to help manage

additional local Zika outbreaks, including sending emergency teams to be on-site in cases of local transmission and testing specimens to determine the presence of Zika virus in communities.

National Institutes of Health

The NIH is leading the Department's efforts to develop safe and effective Zika vaccines. Importantly, the NIH VRC announced on August 3, 2016, that it has begun Phase I trials on a DNA-based vaccine ahead of schedule. In addition, NIH is working to support efforts to improve Zika diagnostics, to develop therapeutics, and to conduct other critical research activities that will assist the Zika response. The NIH received $47 million in repurposed Ebola dollars to conduct this work, and as I wrote to the Congressional leadership in an August 11th letter, this funding will be exhausted by the end of the month. In order to avoid a delay in the development of a Zika vaccine, I transferred an additional $34 million in funding to help provide short-term financing to NIH's Zika efforts. This funding will allow the NIH to conduct preparatory activities associated with the Phase IIb study of the VRC DNA vaccine candidate mentioned above. These additional resources that are being made available for NIH's Zika activities are coming exclusively from other NIH accounts. As you know, there has been bipartisan support for providing additional support to NIH as it is on the front lines of finding effective treatments and cures for many of our nation's most devastating illnesses, including cancer, heart disease, stroke, diabetes, Alzheimer's disease and others. Reallocating these NIH resources is not consistent with a strategy to provide maximum support to the important work that our nation's leading scientists are performing, but the lack of a bipartisan Zika funding bill left me no choice but to provide resources through this action.

Despite these efforts to provide resources to NIH to finance their immediate needs, there are no additional resources to ensure the execution and completion of the Phase IIb trial for the VRC DNA vaccine candidate, to support the development of other lead vaccine candidates that NIH is working to develop, and no resources to support its work on diagnostics and research activities. In addition, without additional resources, the NIH's Zika in Infants and Pregnancy (ZIP) study will be delayed. The ZIP study aims to improve our understanding of the health effects of Zika virus infection on pregnant women and infants by following 10,000 pregnant women for the duration of their pregnancies and their infants at several intervals for at least one year after birth. Additional funding is needed to accelerate and expand enrollment in ZIP, and continue following the infants through their first year to provide critical answers regarding the range and true risk of congenital abnormalities caused by the virus. The NIH estimates that it will need approximately $196 million in additional resources in FY 2017 to continue its vaccine, diagnostic and therapeutics development, and research work as it relates to Zika.

Biomedical Advanced Research and Development Authority

BARDA is leading our efforts to partner with the private sector to develop vaccines and innovative Zika diagnostic tests, and blood screening tests and pathogen reduction technologies to protect the blood supply. Earlier this year, the Department repurposed $85 million in Ebola funding to help BARDA begin this critical work. Earlier this month, BARDA estimated that it would exhaust these resources by the end of the month and would be forced to limit the number of vaccine candidates supported and delay critical vaccine development activities. To avoid any

delays in our critical vaccine development work, I made the decision to transfer an additional $47 million to BARDA. This additional funding will enable BARDA to move forward and enter into contracts with key private sector partners to initiate the development of Zika vaccines. Resources that are being provided to BARDA are being transferred from HHS agencies such as the Administration for Children and Families, which is on the front lines of fighting poverty, the Centers for Medicare and Medicaid Services (CMS), which is responsible for administering some of our most important health care programs, and the Substance Abuse and Mental Health Services Administration, which is leading our fight against opioid addiction and mental health issues. After these resources are exhausted, however, BARDA estimates that it will need $342 million in additional funding in FY 2017 to continue its vaccine, diagnostic development, and pathogen reduction work with these and other partners.

Need for Congressional Funding

Now that the United States is in the height of mosquito season and with the progress in developing a Zika vaccine, the need for additional resources is critical. With the actions described above, we have exhausted our ability to even provide short-term financing to help fight Zika. Our nation's ability to mount the type of Zika response that the American people deserve sits squarely with Congress. Our latest estimates are that domestic response funds that are being used by the CDC, NIH, and BARDA will be virtually exhausted by the end of the fiscal year.

When Congress returns in September, there will be less than one month to provide resources to avoid a scenario where agencies on the front lines of the Zika response have to severely curtail many of their critical efforts. For CDC, this could involve reducing the number of staff and related activities that comprise our Zika efforts in states and territories that are trying to control the spread of Zika. For NIH, this could involve delaying or possibly halting research work on vaccines. And for BARDA, this could result in companies that have partnered with the U.S. government to develop a Zika vaccine not having access to additional funding needed to continue their work. The Health Resources and Services Administration will be unable to expand maternal and child health services or place additional National Health Service Corps clinicians in Puerto Rico. Finally, without Congressional action, CMS will not have the authority to provide additional federal matching funds to Puerto Rico and other U.S. territories to support costs related to the screening and treatment of pregnant women and care of infants born with microcephaly. In short, allowing any of these scenarios to come to pass puts the American people needlessly at risk and will result in more Zika infections and potentially more babies being born with microcephaly and other birth defects.

I urge you to work to develop a bipartisan bill that will allow us to mount a comprehensive and timely response to the Zika virus. I stand ready to work with you to accomplish this goal.

Sincerely,

Sylvia M. Burwell

Sylvia M. Burwell

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 23 2016

The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter about recent guidance published by the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) concerning the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. In particular, you have raised concerns about OCR's explanation of the permissible fees that may be charged to individuals who exercise their right to direct a copy of their protected health information (PHI) to a third party. I have asked OCR to provide responses to your specific questions, and those responses are enclosed.

Since it was first promulgated, the HIPAA Privacy Rule has recognized a right for individuals to access their PHI (the "right of access").[1] Congress strengthened individuals' right of access in the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) by specifying that individuals may opt to have a copy of their PHI stored in an electronic health record sent directly to a third party of their choice.[2] Following enactment of the HITECH Act in 2009, HHS modified its HIPAA rules relating to individuals' right of access.[3]

While we recognize the effort it takes for providers to comply with this right, the right of access is critical to enabling individuals to take ownership of their health and well-being. It allows them to monitor chronic conditions, adhere to treatment plans, find and request fixes to errors in their records, track progress in wellness or disease management programs, and directly contribute their information to research.

The guidance OCR issued in February 2016 ("Access Guidance") on elements of the right of access under the HIPAA Privacy Rule, as revised, provides additional clarification on existing provisions of the HIPAA Privacy Rule, including the fees that HIPAA covered entities may charge individuals for copies of their information.[4] As noted in more detail in the enclosure, the guidance clarifies elements of the rule, such as when the limitation on fees applies (and when it does not), with an eye toward ensuring that covered entities understand how to comply with their HIPAA obligations to provide individuals access to their own health information.

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[1] See 65 Fed. Reg. 82239, 82554 (2000).
[2] Pub. L. No. 111-5 § 13405(e)(1).
[3] See 78 Fed. Reg. 5566, 5634 (2013) and 45 CFR § 164.524(c)(3).
[4] http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.

I appreciate your interest in these important issues and hope that this information is helpful. If you or your staff have any questions, please feel free to contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I will also provide this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell

Sylvia M. Burwell

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 14 2016

The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding your concerns with the Centers for Medicare & Medicaid Services' (CMS) proposal in the calendar year 2017 Medicare physician fee schedule (PFS) proposed rule for gathering data to use in valuing global procedures under the PFS from all practitioners furnishing such services. I greatly appreciate your bringing these concerns to my attention.

You urged us not to implement the proposal that would require all practitioners furnishing 10 and 90-day global packages to report data on post-operative services and instead to finalize a policy that would only require reporting by a "representative sample" of practitioners. You expressed appreciation that we did not propose to withhold 5-percent of payment until reporting occurred and encouraged us to maintain this provision in the final rule. As you are aware, we made this proposal to comply with section 1848(c)(8), which was added to the Social Security Act by section 523 of the Medicare and CHIP Reauthorization Act, and requires us to collect the data need to value global surgery services.

The comment period on this proposed rule closed on September 7, 2016. In addition to the opportunity to submit comments on the proposed rule, we held a town hall meeting at CMS headquarters. Stakeholders were given the opportunity to make presentations at this meeting, in person or virtually. We are in the process of considering the comments submitted as specified in the proposed rule and developing final regulations, which we expect to issue on or around November 1, 2016.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. If you or your staff have questions, please feel free to contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I will also provide this response to co-signers of your letter.

Sincerely,

Sylvia M. Burwell

Sylvia M. Burwell

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

The Honorable Joni K. Ernst
United States Senate
Washington, DC 20510

NOV 09 2016

Dear Senator Ernst:

Thank you for your letter regarding the Department of Health and Human Services' September 7, 2016, Notice of Proposed Rulemaking (NPRM) regarding "Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients." As is detailed in the NPRM, the primary goals of the proposed rule are to maintain uniformity of grants administration, ensure consistency of subrecipient participation across grant awards, improve the provision of services across geographic areas, and guarantee that Title X resources are allocated on the basis of fulfilling Title X goals.

The comment period for this NPRM ended on October 7. We have included your letter with the other public comments received regarding the NPRM. As is always the case with notice and comment rulemaking, we will review and consider comments received before taking any further rulemaking action.

Thank you for your letter and for your interest in this important program.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

cc: The Honorable Diane Black
The Honorable Roy Blunt
The Honorable John Boozman
The Honorable Bill Cassidy
The Honorable Mike Crapo
The Honorable Ted Cruz
The Honorable Steve Daines
The Honorable Mike Enzi
The Honorable Deb Fischer
The Honorable James Inhofe
The Honorable James Lankford
The Honorable Mike Lee

The Honorable Jerry Moran
The Honorable James Risch
The Honorable Pat Roberts
The Honorable Marco Rubio
The Honorable Ben Sasse
The Honorable Tim Scott
The Honorable David Vitter
The Honorable Robert Aderholt
The Honorable Rick Allen
The Honorable Brian Babin
The Honorable Lou Barletta
The Honorable Andy Barr
The Honorable Gus Bilirakis
The Honorable Marsha Blackburn
The Honorable Charles Boustany
The Honorable Kevin Brady
The Honorable Earl "Buddy" Carter
The Honorable Tom Cole
The Honorable Chris Collins
The Honorable Doug Collins
The Honorable Ron DeSantis
The Honorable Scott DesJarlais
The Honorable Jeff Duncan
The Honorable John Duncan
The Honorable Stephen Fincher
The Honorable John Fleming
The Honorable Bill Flores
The Honorable Jeff Fortenberry
The Honorable Virginia Foxx
The Honorable Trent Franks
The Honorable Bob Gibbs
The Honorable Louie Gohmert
The Honorable Paul Gosar
The Honorable Trey Gowdy
The Honorable Tom Graves
The Honorable Glenn Grothman
The Honorable Andy Harris
The Honorable Vicky Hartzler
The Honorable Jeb Hensarling
The Honorable Jody Hice
The Honorable Tim Huelskamp
The Honorable Bill Huizenga
The Honorable Randy Hultgren
The Honorable Lynn Jenkins
The Honorable Bill Johnson
The Honorable Sam Johnson

The Honorable Walter Jones
The Honorable Mike Kelly
The Honorable Trent Kelly
The Honorable Steve King
The Honorable Doug LaMalfa
The Honorable Doug Lamborn
The Honorable Bob Latta
The Honorable Daniel Lipinski
The Honorable Barry Loudermilk
The Honorable Mia Love
The Honorable Blaine Luetkemeyer
The Honorable Kenny Marchant
The Honorable Cathy McMorris Rodgers
The Honorable Mark Meadows
The Honorable John Moolenaar
The Honorable Markwayne Mullin
The Honorable Randy Neugebauer
The Honorable Pete Olson
The Honorable Steven Palazzo
The Honorable Gary Palmer
The Honorable Steve Pearce
The Honorable Collin Peterson
The Honorable Robert Pittenger
The Honorable Joe Pitts
The Honorable Ted Poe
The Honorable Bill Posey
The Honorable Tom Price
The Honorable John Ratcliffe
The Honorable Martha Roby
The Honorable Phil Roe
The Honorable Dana Rohrabacher
The Honorable Peter Roskam
The Honorable Keith Rothfus
The Honorable David Rouzer
The Honorable Steve Scalise
The Honorable Austin Scott
The Honorable Jim Sensenbrenner
The Honorable Pete Sessions
The Honorable John Shimkus
The Honorable Adrian Smith
The Honorable Chris Smith
The Honorable Ann Wagner
The Honorable Tim Walberg
The Honorable Randy Weber
The Honorable Brad Wenstrup
The Honorable Joe Wilson

The Honorable Kevin Yoder
The Honorable Theodore Yoho

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 10 2016

The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter about the importance of utilizing the Physician-focused Payment Model Technical Advisory Committee (PTAC) to develop new alternative payment models (APMs) and for sharing your recommendations for steps we can take to realize the promise of this provision of the Medicare Access and CHIP Reauthorization Act (MACRA).

We share your goal of increasing the variety, efficacy, and number of alternative payment models (APMs), including Advanced APMs, and APMs for specialists, rural physicians, and small practices. We also share your enthusiasm for the valuable role of the PTAC in reviewing and making recommendations on physician-focused payment models (PFPMs). We look forward to physician and medical specialty groups engaging with the PTAC to propose models as well as to receiving recommendations from the PTAC. We hope to leverage the expertise of both stakeholders and the PTAC to inform the design of future APMs.

On April 27, 2016, we issued a proposed rule to implement key provisions of MACRA. The proposed rule would implement many of these changes through a unified framework called the "Quality Payment Program." This program includes both the Merit-Based Incentive Payment System (MIPS) and Advanced APMs. Effective implementation of the Quality Payment Program is a top priority for the Department with the goal of linking clinician payments to value and quality. Delivering new opportunities for physicians and other clinicians to engage with Medicare through APMs is one of the pillars of the Quality Payment Program.

The rule proposes the PFPM criteria for the PTAC to use in making comments and recommendations on models. These criteria are available for public comment in the proposed rule, and we look forward to receiving input on these criteria from the public. We believe that the proposed criteria will encourage physician and medical specialty groups to submit robust proposals for new, innovative APMs. We also believe that this process will help physician and medical specialty groups in designing APMs that appeal to CMS as well as physicians.

The PTAC is developing concrete steps for the PFPM review process and has requested public comment on a draft proposal process. We believe these public comments will be helpful to stakeholders in planning for the process and receiving input from the PTAC during its review. The PTAC will use their expertise to help prioritize concepts and help to guide submission of proposals.

In addition to the criteria proposed in the QPP NPRM, we are taking steps to increase the transparency of CMS's process for designing and testing APMs. We have published a list of factors CMS considers in the selection of models for testing (https://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf). Furthermore, in order to facilitate and potentially expedite the consideration of models for testing by CMS following PTAC review and recommendation, we have proposed "supplemental information elements" stakeholders may include in their PFPM proposals to assist CMS review. We believe these materials will better position stakeholders to submit robust proposals to the PTAC.

We are eager to review all proposals recommended by the PTAC and believe that proposals to the PTAC could fill gaps in our current portfolio and, therefore, be a priority for testing. We are hoping to collaborate closely with the PTAC through consideration of their comments and recommendations on PFPMs and through sharing information about alternative payment model design, including the design of Advanced APMs.

Thank you for insight and for your commitment to transforming our nation's health care delivery system through expanding opportunities for providers to participate in APMs. If you or your staff have questions, please feel free to contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I will also provide this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 0 1 2016

The Honorable Tom Price
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Price:

Thank you for your letter regarding the potential for a Medicare home health services prior authorization demonstration. The Centers for Medicare & Medicaid Services (CMS) is tasked with ensuring access to quality care for Medicare beneficiaries and minimizing provider burden, while also protecting the Medicare Trust Funds from fraud and other improper payments.

On June 8, 2016, CMS announced a pre-claim review demonstration for home health services. This will be a three-year demonstration in Illinois, Florida, Texas, Michigan, and Massachusetts. The demonstration will begin in Illinois no earlier than August 1, 2016, and the remaining states will phase in during 2016 and 2017.

This announcement follows a Paperwork Reduction Act (PRA) notice published in the Federal Register on February 5, 2016, indicating that CMS was seeking to develop and implement a Medicare demonstration project for the prior authorization of home health services. The PRA notice was not an announcement of a demonstration for home health services, and as such, did not include detailed information about how such a potential demonstration would work. However, CMS received significant number of comments regarding the possibility of a prior authorization demonstration and took the comments into consideration as we developed the pre-claim review demonstration for home health services.

I share your concern about beneficiary access to home health services. The demonstration has been carefully designed and will be implemented in such a way so as to not cause a delay in care. The pre-claim review process is different from prior authorization in that the start of home health services can begin before the pre-claim review is conducted. The pre-claim review will occur after the home health agency (HHA) conducts the required intake and assessment procedures, and submits the initial Request for Anticipated Payment, after the first service has been provided, but before the final claim submission. In this way, there should be no delay for the start of services while the submitted pre-claim review is being conducted. This demonstration should not change a beneficiary's ability to receive home health services. Once a HHA submits a pre-claim review request, Medicare will review the submitted documentation to determine if all coverage requirements for home health services are met and will issue a pre-claim review decision generally within 10 days for initial submissions and 20 days for subsequent submissions following a non-affirmed decision.

Compared to current procedures, HHAs with a provisionally affirmed pre-claim review decision will know early in the process that they have the correct documentation necessary for payment as long as they continue to meet all coverage requirements.

If no pre-claim review request is submitted, when the final claim is submitted for reimbursement, it will be subjected to pre-payment review. Such claims subjected to prepayment medical review that are determined to be payable will be paid with a 25 percent reduction of the full claim amount. The payment reduction requirement will begin three months after the start of the demonstration in each state so that HHAs have an opportunity to learn the new pre-claim review process. Under the demonstration, a HHA will be able to use the standard procedures in place today to begin furnishing home health services before the pre-claim review occurs without a payment reduction. The reduction will only apply to claims that are submitted without a pre-claim review decision and undergo a pre-payment review. Those claims submitted with a non-affirmed decision will be denied and all ordinary claim appeal rights will apply. Any application of the 25 percent reduction for failure to obtain pre-claim review would not be transferable to the beneficiary.

The pre-claim review demonstration will not create any new or additional documentation requirements. This demonstration will also provide HHAs with assurances that a beneficiaries' condition meets Medicare's coverage requirements. CMS will share detailed reasons of any non-affirmed pre-claim review decisions with the HHA, and the HHA will be given unlimited resubmissions of any non-affirmed pre-claim review requests. This allows the HHA to resubmit all necessary documentation in order to obtain a provisional affirmation before the final claim is submitted. If a HHA receives a non-affirmed pre-claim review decision, it may either resubmit the pre-claim review request with additional documentation or submit the claim for payment. If the claim nevertheless is submitted for payment, the claim will be denied and all ordinary claim appeal rights will be afforded. By having a provisionally affirmed pre-claim review decision, the HHA will be afforded some assurance that its claim will be paid as long as all Medicare guidelines continue to be met. Generally, the claims that have a provisionally affirmed pre-claim review decision will not be subject to additional review, making sure there is no duplication in review and further reducing provider burden.

We will test the demonstration under section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)), which authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act." We believe the demonstration will provide a wealth of data to analyze, which will provide for new ways of identifying, investigating, and combating fraudulent behavior. Among other things, we will analyze the number of claims submitted, the referral of potential fraud cases to investigators, and the development of fraud cases, as necessary. The data will be used for the purpose of making comparisons between the demonstration and non-demonstration states. The rates of prior authorization requests that are provisionally affirmed and non-affirmed will also be collected, along with the rate and adjudication status of appealed claims. CMS will collect qualitative information to help determine whether and to what extent the prior authorization process improved upon existing methods for investigating and prosecuting fraud and reducing improper payment rates for home health services.

Based on our previous experience, Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports, Government Accountability Office (GAO) reports, and Medicare Payment Advisory Commission (MedPAC) findings, there is extensive evidence of fraud and abuse in the Medicare home health program. In particular, the OIG, GAO, and MedPAC have found significant evidence of fraud and abuse in Medicare's home health benefit in the demonstration states. Moreover, most of these states have also been identified as high-risk states that have select cities and counties under the temporary moratoria on home health provider enrollment authorized under the Affordable Care Act. Finally, the Medicare improper payment rate for home health services increased from 17.3 percent in 2013 to 51.4 percent in 2014 and the Fiscal Year 2015 HHS Agency Financial Report reported a further increase to 59 percent in 2015.

This demonstration will also help prevent fraud because it will educate HHAs about the necessary documentation prior to payment of final claims, and will make sure only medically necessary home health services are being provided to Medicare beneficiaries. In addition, by reviewing all home health, claims in the demonstration states, it will help identify patterns that may be indicative of potential fraud. Claims where potential fraud is suspected will be referred to the appropriate entity.

During the course of the demonstration, as well as when it concludes, CMS will monitor and analyze data to evaluate the impact of the demonstration on fraud and other improper payments in the demonstration states, and may consider if a more focused risk-based approach to pre-claim review is warranted in the future. In addition, the demonstration will help assist in developing improved procedures for the investigation and prosecution of Medicare fraud occurring among HHAs providing services to Medicare beneficiaries, while still making sure eligible beneficiaries receive timely care in their homes, and the Medicare Trust Funds are preserved and protected for all Medicare beneficiaries. Finally, we will closely monitor Medicare utilization in the demonstration states for any unintended consequences, such as an increase in the length of hospital stays or in the number of readmissions.

Thank you again for sharing your views on this important issue. If you or your staff have questions, please feel free to contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I will also provide this response to the co-signers of your letter.

Sincerely,

Sylvia M. Burwell

RENEE L. ELLMERS
2ND DISTRICT, NORTH CAROLINA

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

ENERGY AND COMMERCE
SUBCOMMITTEE ON
COMMUNICATIONS AND TECHNOLOGY

SUBCOMMITTEE ON
HEALTH

SUBCOMMITTEE ON
ENERGY AND POWER

Congress of the United States
House of Representatives
Washington, DC 20515–3302

September 28, 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 (NC-02)
Member of Congress

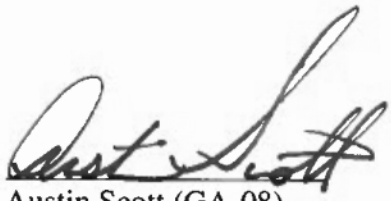
Tom Price (GA-06)
Member of Congress

David Scott (GA-13)
Member of Congress

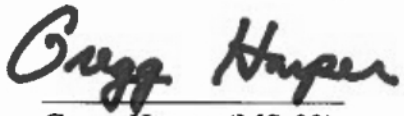
Brad Ashford (NE-02)
Member of Congress

Brian Babin (TX-36)
Member of Congress

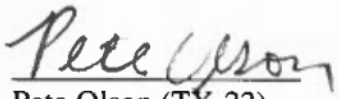
Andy Barr (KY-06)
Member of Congress



Austin Scott (GA-08)
Member of Congress

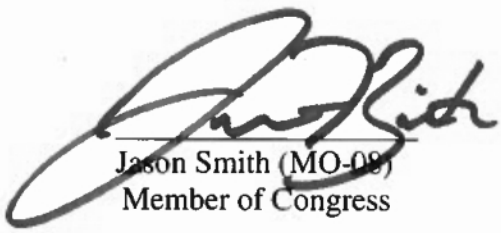


Gregg Harper (MS-03)
Member of Congress

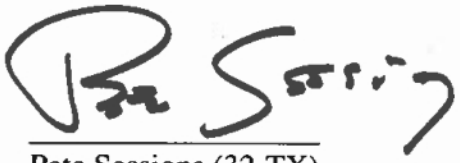


Pete Olson (TX-22)
Member of Congress

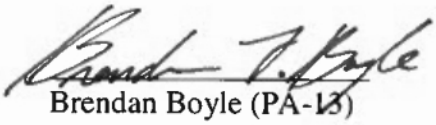
André Carson (IN-07)
Member of Congress



Jason Smith (MO-08)
Member of Congress



Pete Sessions (32-TX)
Member of Congress



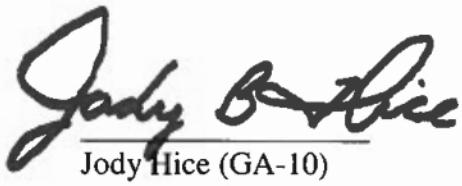
Brendan Boyle (PA-13)
Member of Congress

Chris Collins (NY-27)
Member of Congress

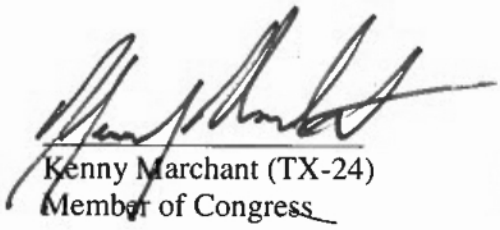
Gary Palmer (AL-06)
Member of Congress

Lynn Jenkins (KS-02)
Member of Congress

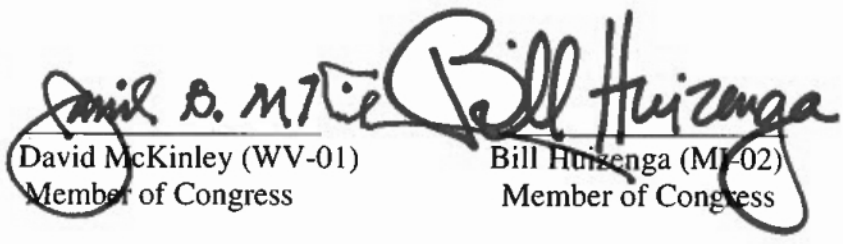
David Rouzer (NC-07)
Member of Congress



Jody Hice (GA-10)
Member of Congress

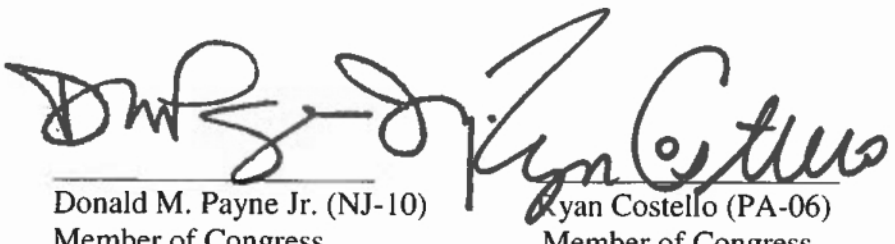


Kenny Marchant (TX-24)
Member of Congress



David McKinley (WV-01)
Member of Congress

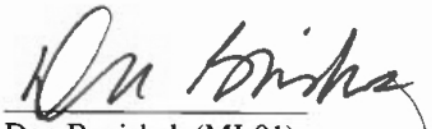
Bill Huizenga (MI-02)
Member of Congress



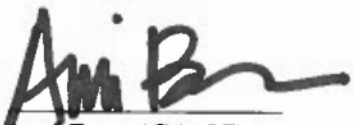
Donald M. Payne Jr. (NJ-10)
Member of Congress

Ryan Costello (PA-06)
Member of Congress

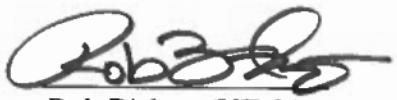
Patrick Meehan (PA-07)
Member of Congress



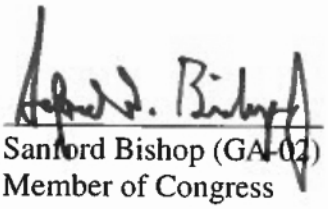
Dan Benishek (MI-01)
Member of Congress



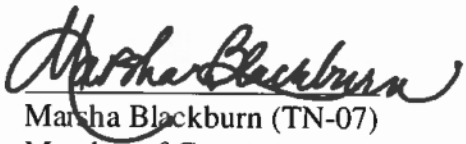
Ami Bera (CA-07)
Member of Congress



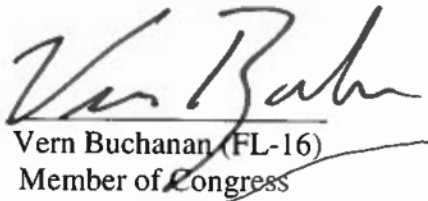
Rob Bishop (UT-01)
Member of Congress



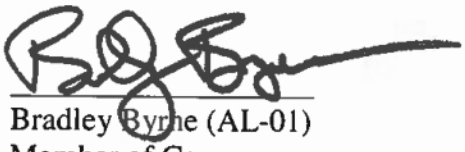
Sanford Bishop (GA-02)
Member of Congress



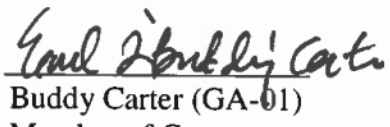
Marsha Blackburn (TN-07)
Member of Congress



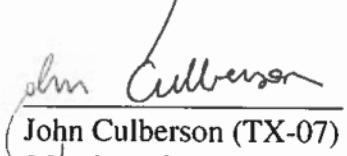
Vern Buchanan (FL-16)
Member of Congress



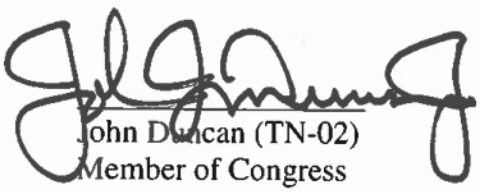
Bradley Byrne (AL-01)
Member of Congress



Buddy Carter (GA-01)
Member of Congress

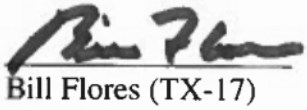


John Culberson (TX-07)
Member of Congress

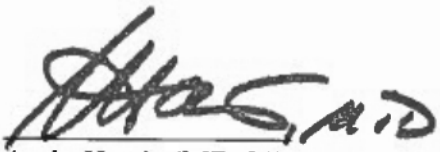


John Duncan (TN-02)
Member of Congress

Mike Fitzpatrick (PA-08)
Member of Congress

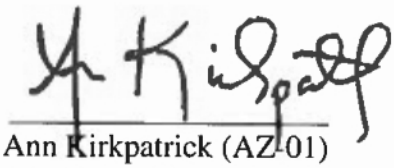


Bill Flores (TX-17)
Member of Congress

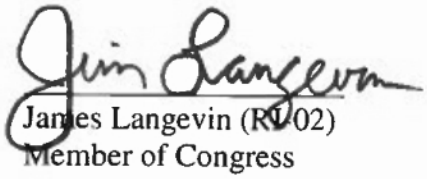


Andy Harris (MD-01)
Member of Congress

Evan Jenkins (WV-03)
Member of Congress

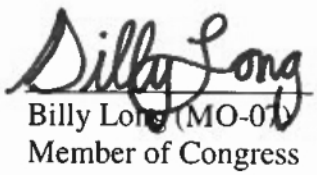


Ann Kirkpatrick (AZ-01)
Member of Congress



James Langevin (RI-02)
Member of Congress

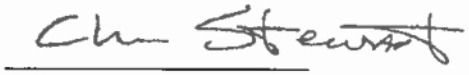
Leonard Lance (NJ-07)
Member of Congress



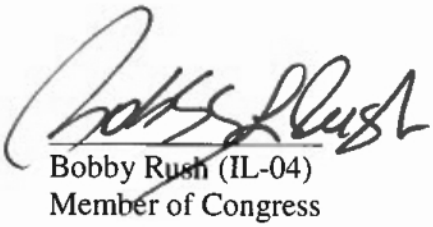
Billy Long (MO-07)
Member of Congress

Mia Love (UT-04)
Member of Congress

Phil Roe (TN-01)
Member of Congress

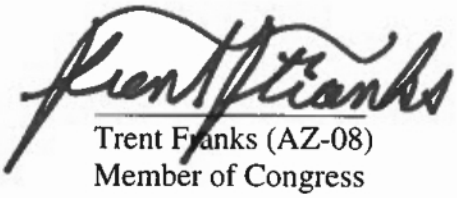


Chris Stewart (UT-02)
Member of Congress



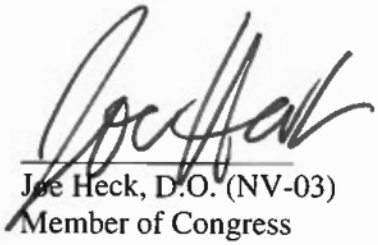
Bobby Rush (IL-04)
Member of Congress

Mike Bost (IL-02)
Member of Congress

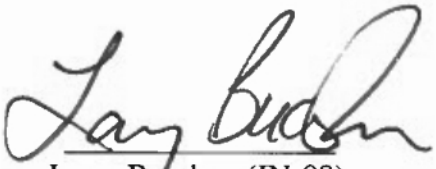


Trent Franks (AZ-08)
Member of Congress

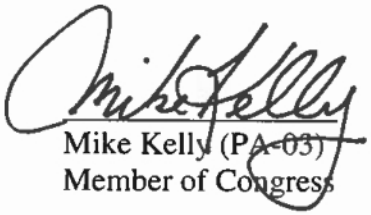
Devin Nunes (CA-22)
Member of Congress



Joe Heck, D.O. (NV-03)
Member of Congress



Larry Bucshon (IN-08)
Member of Congress

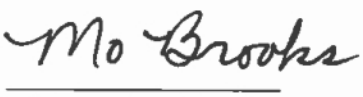


Mike Kelly (PA-03)
Member of Congress

Stephen Fincher (TN-08)
Member of Congress

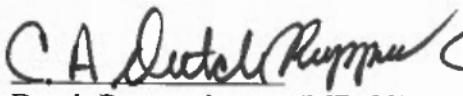
Steve Knight (CA-25)
Member of Congress

Jason Chaffetz (UT-03)
Member of Congress

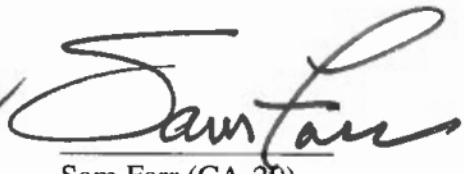


Mo Brooks (AL-05)
Member of Congress

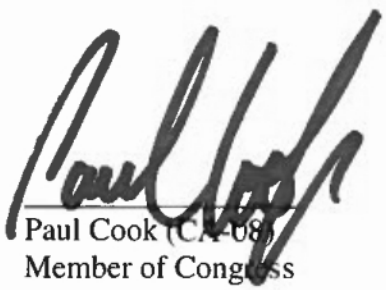
Mimi Walters (CA-45)
Member of Congress



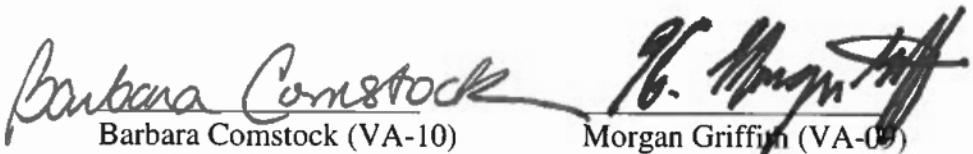
Dutch Ruppersberger (MD-02)
Member of Congress



Sam Farr (CA-20)
Member of Congress



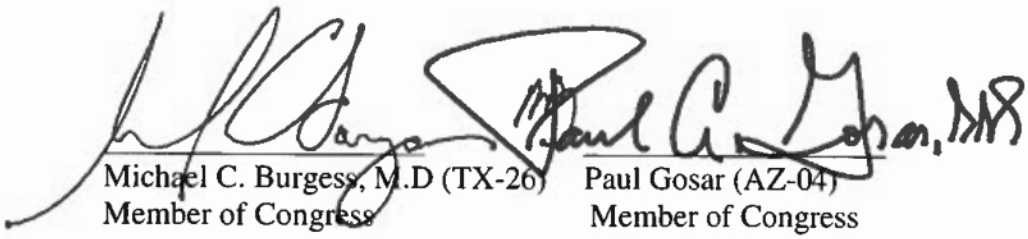
Paul Cook (CA-08)
Member of Congress



Barbara Comstock (VA-10)
Member of Congress

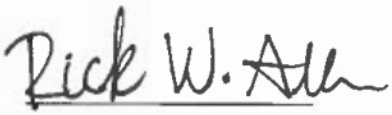
Morgan Griffith (VA-09)
Member of Congress

Rob Woodall (GA-07)
Member of Congress

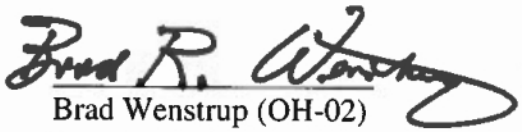


Michael C. Burgess, M.D (TX-26)
Member of Congress

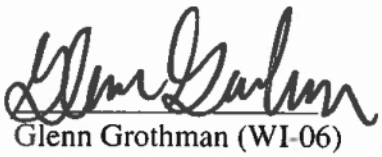
Paul Gosar (AZ-04)
Member of Congress



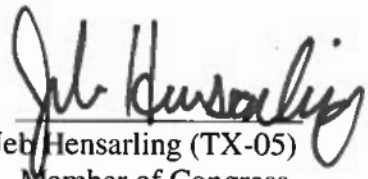
Rick Allen (GA-12)
Member of Congress



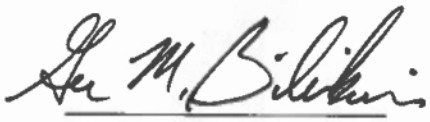
Brad Wenstrup (OH-02)
Member of Congress



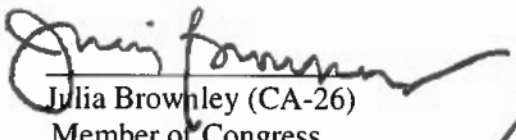
Glenn Grothman (WI-06)
Member of Congress



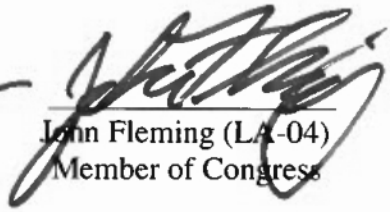
Jeb Hensarling (TX-05)
Member of Congress



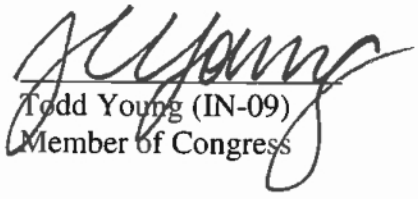
Gus Bilirakis (FL-12)
Member of Congress



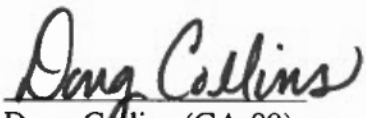
Julia Brownley (CA-26)
Member of Congress



John Fleming (LA-04)
Member of Congress

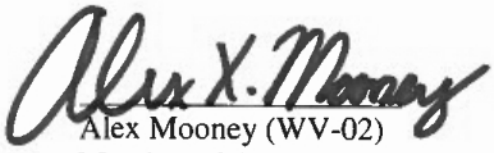


Todd Young (IN-09)
Member of Congress

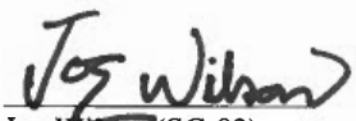


Doug Collins (GA-09)
Member of Congress

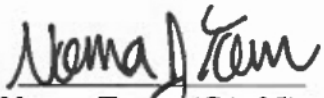
Steve Israel (NY-03)
Member of Congress



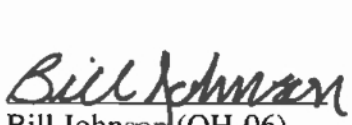
Alex Mooney (WV-02)
Member of Congress



Joe Wilson (SC-02)
Member of Congress

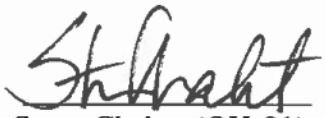


Norma Torres (CA-35)
Member of Congress

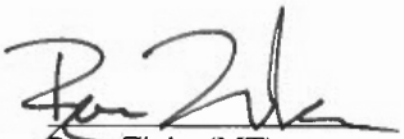


Bill Johnson (OH-06)
Member of Congress

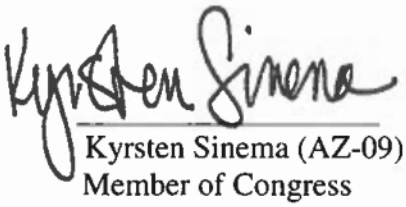
Lou Barletta (PA-11)
Member of Congress



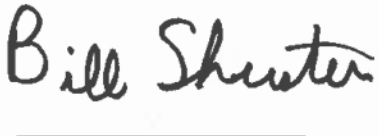
Steve Chabot (OH-01)
Member of Congress



Ryan Zinke (MT)
Member of Congress

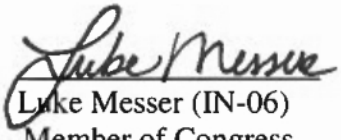


Kyrsten Sinema (AZ-09)
Member of Congress

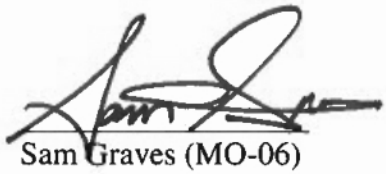


Bill Shuster (PA-09)
Member of Congress

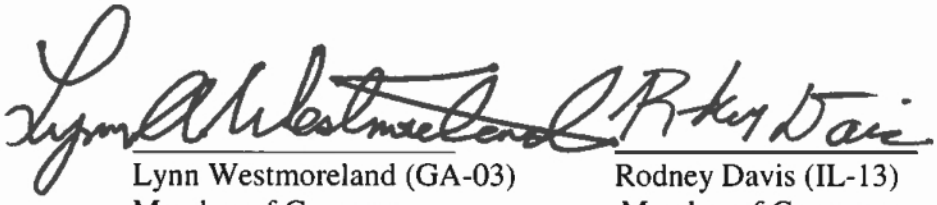
Ed Royce (CA-39)
Member of Congress



Luke Messer (IN-06)
Member of Congress



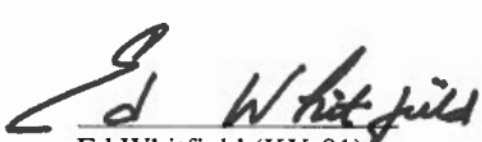
Sam Graves (MO-06)
Member of Congress



Lynn Westmoreland (GA-03)
Member of Congress

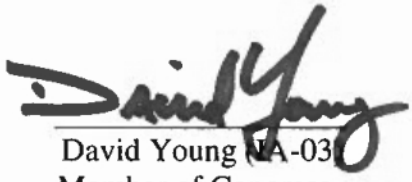
Rodney Davis (IL-13)
Member of Congress

Louie Gohmert (TX-01)
Member of Congress

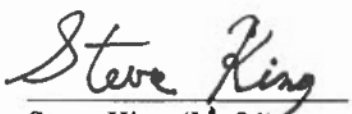


Ed Whitfield (KY-01)
Member of Congress

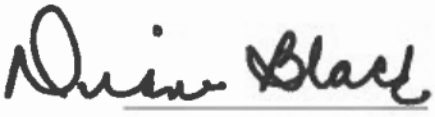
Brett Guthrie (KY-02)
Member of Congress



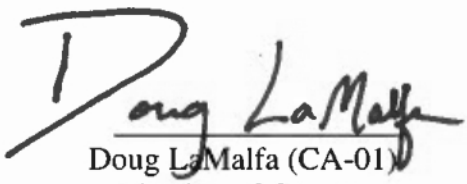
David Young (IA-03)
Member of Congress



Steve King (IA-04)
Member of Congress

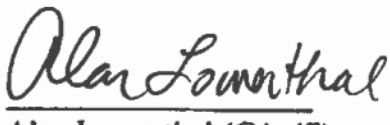


Diane Black (TN-06)
Member of Congress

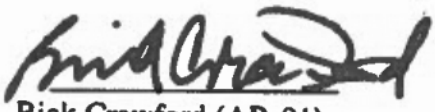


Doug LaMalfa (CA-01)
Member of Congress

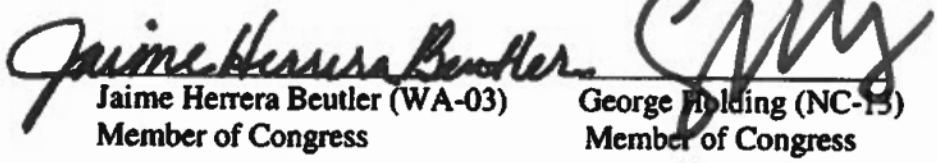
Chris Smith (NJ-04)
Member of Congress



Alan Lowenthal (CA-47)
Member of Congress

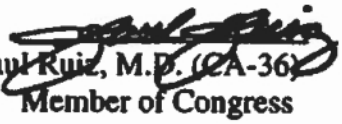


Rick Crawford (AR-01)
Member of Congress



Jaime Herrera Beutler (WA-03)
Member of Congress

George Holding (NC-13)
Member of Congress

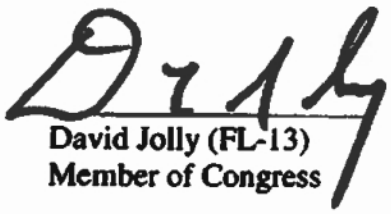


Raul Ruiz, M.D. (CA-36)
Member of Congress

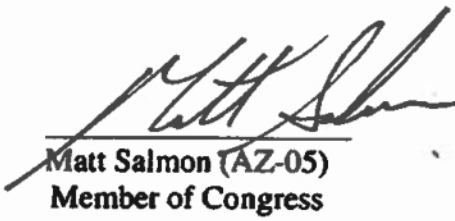
Gerald E. Connolly (VA-11)
Member of Congress

Scott Peters (CA-52)
Member of Congress

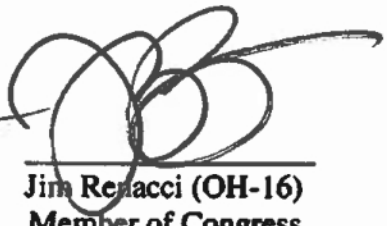
Bob Goodlatte (VA-06)
Member of Congress



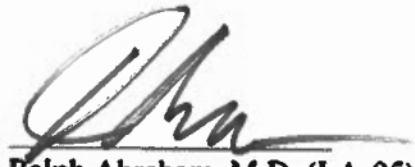
David Jolly (FL-13)
Member of Congress



Matt Salmon (AZ-05)
Member of Congress



Jim Renacci (OH-16)
Member of Congress



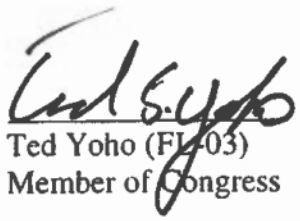
Ralph Abraham, M.D. (LA-05)
Member of Congress

Kristi Noem (SD)
Member of Congress

Bill Posey (FL-08)
Member of Congress

Charles Boustany, M.D. (LA-03)
Member of Congress

Patrick Tiberi (OH-12)
Member of Congress



Ted Yoho (FL-03)
Member of Congress

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

John Ratcliffe (TX-04)
Member of Congress

Congress of the United States
Washington, DC 20515

September 18, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Ave S.W.
Washington, DC 20001

Dear Secretary Burwell:

We write to express our support for the framework that the Centers for Medicare and Medicaid Services ("CMS") has taken in proposing a definition of "provider-led entities" for the purposes of implementation of initial features of the Appropriate Use Criteria ("AUC") requirements established under section 218 of the "Protecting Access to Medicare Act of 2014" ("PAMA").

Section 218 of PAMA requires that beginning in 2017, ordering physicians must consult with applicable AUC before referring a Medicare patient for an advanced imaging service, such as Computed Tomography ("CT") or Magnetic Resonance Imaging ("MRI"). In determining which clinical guidelines will qualify as applicable AUC, CMS is directed to identify evidence-based AUC that are developed or endorsed by "national professional medical specialty societies or other provider-led entities."

We are strongly supportive of ensuring that physicians are armed with evidence-based tools to aid in diagnostic decision making. PAMA's AUC provisions inherently and explicitly envision that AUC would be developed, maintained, and updated by clinicians and providers who care for patients on a daily basis. Unlike for-profit resource management entities, such as Radiology Benefit Managers ("RBMs"), prior authorization organizations, or even the federal government, these clinicians, providers, and national medical professional societies that develop the AUC have both the scientific and real-world health care delivery expertise concerning the diagnostic value of clinical imaging tools. Furthermore, guidelines developed by anyone other than clinicians, providers, and national medical professional societies do not rely upon the same rigorous development process and, therefore, are more reflective of consensus medical opinions rather than rooted in clinical evidence.

As a part of the Calendar Year ("CY") 2016 Medicare Physician Fee Schedule ("MPFS") proposed rule recently released in July 2015, CMS proposes to define "provider-led entities"—for the purpose of the "applicable AUC" determination—as including national professional medical specialty societies or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare. We believe that this definition aligns with the vision that Congress had for AUC when establishing this overarching policy in PAMA. We urge CMS to retain this definition of provider-led entities when it releases the CY 2016 MPFS final rule in November 2015.

We thank you for your thoughtful work on this proposal and look forward to continuing to work with you as the implementation of AUC requirements moves forward.

Sincerely,

Michael C. Burgess, M.D.
Member of Congress

Ami Bera, M.D.
Member of Congress

Tom Price, M.D.
Member of Congress

Eliot Engel
Member of Congress

Marsha Blackburn
Member of Congress

Phil Roe M.D.
Member of Congress

Andy Harris, M.D.
Member of Congress

Joe Heck, D.O.
Member of Congress

Devin Nunes
Member of Congress

Bill Flores
Member of Congress

Dan Benishek, M.D.
Member of Congress

Mike Simpson
Member of Congress

Ralph Abraham, M.D.
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Renee Ellmers
Member of Congress

Pat Tiberi
Member of Congress

Richard Neal
Member of Congress

Pete Olson
Member of Congress

Paul D. Tonko
Member of Congress

Chris Collins
Member of Congress

H. Morgan Griffith
Member of Congress

Bill Pascrell, Jr.
Member of Congress

Mike Kelly
Member of Congress

Brian Babin
Member of Congress

Peter Welch
Member of Congress

Todd Young
Member of Congress

Kenny Marchant
Member of Congress

Diane Black
Member of Congress

John Fleming, M.D.
Member of Congress

Congress of the United States

Washington, DC 20515

May 6, 2015

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

Dear Secretary Burwell:

As strong supporters of women's health, we are committed to protecting access to breast cancer screening to minimize the impact of this deadly disease. According to National Cancer Institute data, the U.S. breast cancer death rate has dropped 35 percent since mammography screening became widespread in the mid-1980s.

On April 20, 2015 the United States Preventive Services Task Force (USPSTF) released draft recommendations proposing a major change in the approach to breast cancer screening. The USPSTF essentially re-stated their 2009 recommendation by assigning a "C" grade for biennial screening mammography for women ages 40 to 49, which can be interpreted as advising against screening in this age group and limit life-saving early detection. Additionally, the USPSTF proposed a "B" grade to only biennial screening mammography for women ages 50 to 74 years.

The 2009 recommendations received widespread criticism from patient advocates and medical experts, and organizations including the American Cancer Society (ACS), the American College of Radiology, and the American College of Obstetricians and Gynecologists went as far as to advise physicians and patients to ignore the recommendation. Subsequently, a provision was signed into law that was meant to prevent the 2009 USPSTF recommendation from going into effect.

If the draft recommendations which were released on April 20th are finalized, women ages 40 to 49 who choose routine screening, and those 50 to 74 who want to be screened annually may encounter issues finding an insurance plan which provides this level of coverage, or at the very least be forced to pay more for this added benefit. The impact of impaired access to breast cancer screening would affect all U.S. women, particularly those in underserved communities who are hardest hit by the disease.

In its explanation, the USPSTF concluded that "some women in their 40s will benefit from mammography… while others will be harmed." The panel said those hurt include the effect of exposure to radiation from multiple tests and the stress of over-diagnosis on the patient. This highlights the importance of individualized assessment of risk factors, and what a woman and her physician decide is the best screening option for her. Lack of coverage for mammograms as a screening tool could take away this choice from some patients for accessing the care they need. As Members of Congress concerned about the impact of breast cancer, we believe (and many

experts agree) that delayed detection and treatment have a far worse outcome than the harm USPSTF has laid out.

While we acknowledge these are draft, not final, recommendations, years of science and medicine have shown that appropriate screening can lead to early detection and save lives. We urge the USPSTF to take into consideration the benefits of prevention, keep in mind the thousands of women who are diagnosed with breast cancer in their 40s, and not jeopardize access to these screenings.

Sincerely,

David Vitter
U.S. Senate

Heidi Heitkamp
U.S. Senate

Cathy McMorris Rodgers
U.S. House of Representatives

Debbie Wasserman Schultz
U.S. House of Representatives

Renee Ellmers
U.S. House of Representatives

Rosa L. DeLauro
U.S. House of Representatives

Kelly Ayotte
U.S. Senate

Kirsten Gillibrand
U.S. Senate

Susan Collins
U.S. Senate

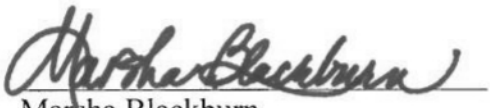
Michael Bennet
U.S. Senate

Pat Roberts
U.S. Senate

Jerry Moran
U.S. Senate

Mark Kirk
U.S. Senate

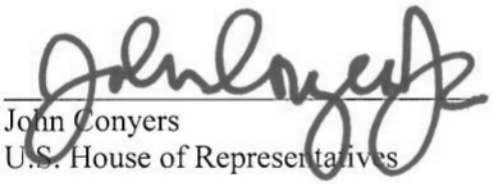
Cory Gardner
U.S. Senate



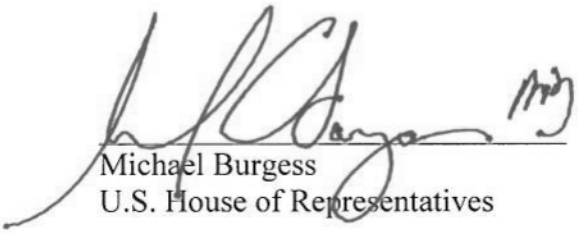
Marsha Blackburn
U.S. House of Representatives

Lois Capps
U.S. House of Representatives

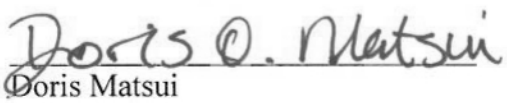
Kristi Noem
U.S. House of Representatives



John Conyers
U.S. House of Representatives



Michael Burgess
U.S. House of Representatives



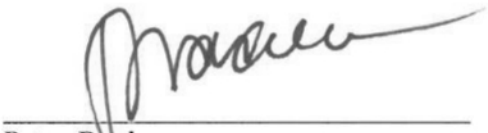
Doris Matsui
U.S. House of Representatives

Bill Flores
U.S. House of Representatives

Alcee Hastings
U.S. House of Representatives

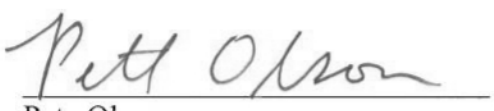
Charles Boustany
U.S House of Representatives

Alan Grayson
U.S. House of Representatives



Peter Roskam
U.S. House of Representatives

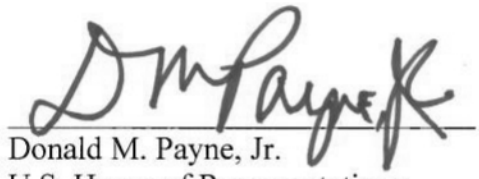
David Cicilline
U.S. House of Representatives



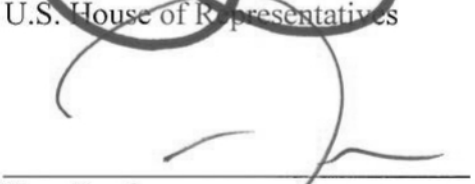
Pete Olson
U.S. House of Representatives

Lois Frankel
U.S. House of Representatives

Jim Renacci
U.S. House of Representatives

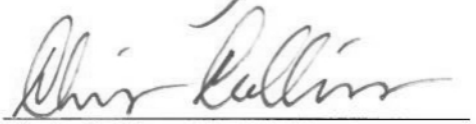


Donald M. Payne, Jr.
U.S. House of Representatives

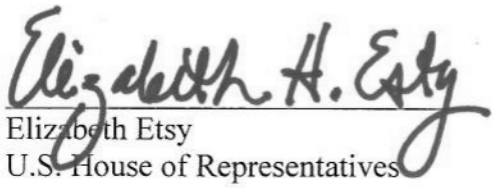


Tom Reed
U.S. House of Representatives

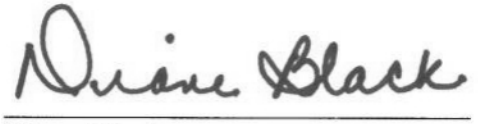
Marcia Fudge
U.S. House of Representatives



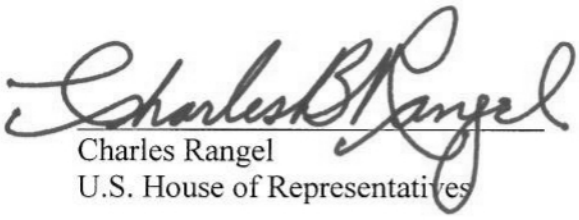
Chris Collins
U.S. House of Representatives



Elizabeth Etsy
U.S. House of Representatives

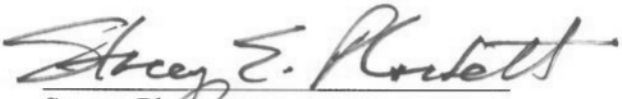


Diane Black
U.S. House of Representatives



Charles Rangel
U.S. House of Representatives

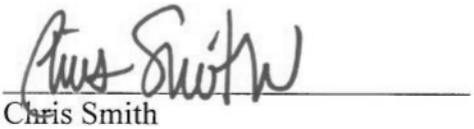
Brett Guthrie
U.S. House of Representatives



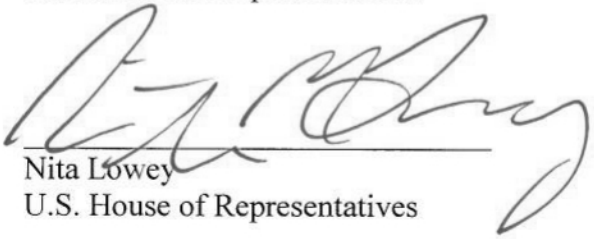
Stacey Plaskett
U.S. House of Representatives

Pat Meehan
U.S. House of Representatives

Al Green
U.S. House of Representatives

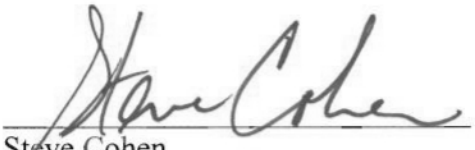


Chris Smith
U.S. House of Representatives

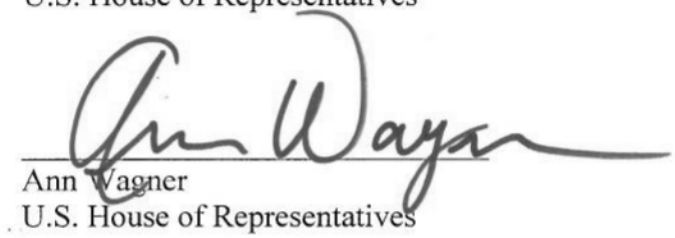


Nita Lowey
U.S. House of Representatives

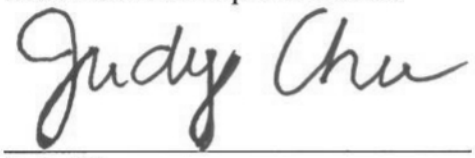
Chris Gibson
U.S. House of Representatives



Steve Cohen
U.S. House of Representatives



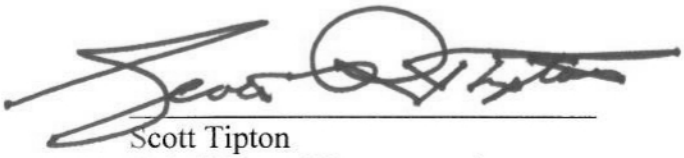
Ann Wagner
U.S. House of Representatives



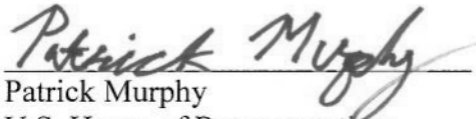
Judy Chu
U.S. House of Representatives

Susan Brooks
U.S. House of Representatives

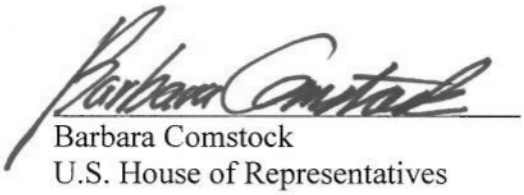
Paul Tonko
U.S. House of Representatives



Scott Tipton
U.S. House of Representatives



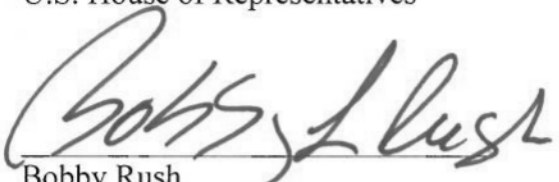
Patrick Murphy
U.S. House of Representatives



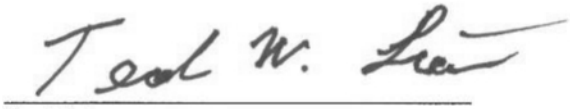
Barbara Comstock
U.S. House of Representatives

Diana DeGette
U.S. House of Representatives

Ted Deutch
U.S. House of Representatives

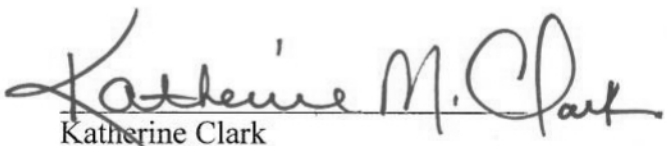


Bobby Rush
U.S. House of Representatives

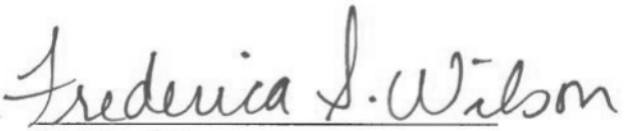


Ted Lieu
U.S. House of Representatives

Jackie Speier
U.S. House of Representatives



Katherine Clark
U.S. House of Representatives



Fredrica Wilson
U.S. House of Representatives

Mimi Walters
U.S. House of Representatives

Tom Price
U.S. House of Representatives

Leonard Lance
U.S. House of Representatives

Bob Dold
U.S. House of Representatives

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

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FAX: (202) 225-4656

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(770) 565-4990
FAX: (770) 565-7570

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(678) 493-6176

www.house.gov/tomprice

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON HUMAN RESOURCES

COMMITTEE ON THE BUDGET

REPUBLICAN POLICY COMMITTEE
CHAIRMAN

DEPUTY WHIP

Congress of the United States
House of Representatives

November 16, 2012

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington D.C. 20201

Dear Madam Secretary:

We are writing to express our concerns about the implementation of Medicare Quality Improvement Organization ("QIO") program provisions that were included in the Trade Adjustment Assistance reauthorization bill (Section 261 of H.R. 2832, or "the trade bill"). We are aware that the U.S. Department of Health and Human Services ("the Department") is moving forward with implementing H.R. 2832 and with plans for the 11th Statement of Work for the QIO program, and we wish to encourage you to apply your discretion in implementation to address key concerns we have regarding the QIO program changes.

As you may know, we are co-sponsors of the Quality Improvement Organization Program Restoration Act (H.R. 5942), which would repeal the QIO provisions in H.R. 2832 and allow for full consideration of QIO program changes by the committees of jurisdiction – an opportunity that was not afforded when H.R. 2832 passed. Our legislation would ensure that the QIO retain its current state-based structure, which has delivered proven results.

Although we will continue to pursue passage of H.R. 5942 to roll back the QIO provisions in H.R. 2832, we understand that the Department is required by law to move ahead with some aspects of implementation. As you do, we urge you to proceed cautiously and to consider our main concerns:

1) ***Maintaining the state-based scope of QIO contracts.*** The trade bill permits QIOs to be regionalized or even nationalized, which would harm the long-standing relationships of state-based QIOs with local provider communities. This structure is critical to the National Quality Strategy and major initiatives to improve quality of care (such as the national campaigns to reduce readmissions and hospital-acquired infections). Currently, providers across the nation are required to be involved in many quality improvement activities and often turn to the QIOs to help understand their responsibilities. We are concerned that disrupting the state-based nature of the QIO program not only would harm QIO program efforts, but also may impact the success of broader initiatives to improve healthcare for all Americans. Providers have come to know and trust QIOs in their states, and the QIOs serve as resources on many health care quality-related issues. Moreover, health care challenges and circumstances are different in each state, and overcoming these challenges requires a locally-focused approach. The current state-based nature of the QIO program is ideally suited to address that reality. With health care quality receiving more attention, now is not the time to upend a structure that has worked well for many years.

2) ***Maintaining integrated QIO functions within one state-based organization.*** The trade bill permits a QIO's discrete functions (*e.g.*, hospital and nursing home technical assistance, investigation of beneficiary complaints) to be broken up among different organizations instead of integrating the

functions within the one state-based QIO. Improving quality requires a comprehensive and integrated approach – not a fragmented one – and this is best carried out by a single, locally focused organization. Therefore, we do not believe that HHS should permit the QIO functions to be parceled out especially in light of the proven structure of the current program.

3) ***Involving local physicians in peer review in their states.*** Although the legislative changes allow HHS discretion in establishing requirements for peer review processes, we strongly urge the continued involvement of local physicians in the peer review process, consistent with past practice and endorsed by the American Medical Association. Peer review clearly means assessments by similarly situated professionals with full experience in the care delivery circumstance in that state. We are concerned that changes to the current structure, under which peer review is conducted by local physicians, would unnecessarily disrupt a system that works well now.

4) ***Maintaining the independence of the QIO program.*** The trade bill gives HHS the authority to determine appropriate eligibility requirements for organizations to serve as QIOs. Currently, QIOs are independent agents for positive change in their communities and must meet strict requirements regarding governance structure, avoiding conflict of interest, and maintaining independence from providers. These requirements ensure that QIOs are fair and unbiased in their quality improvement work, which is especially important as we move toward paying providers based on quality of care. It is important to maintain high standards of independence for organizations offering improvement assistance to providers. In order to maintain this high level of independence, the requirements that QIOs currently must meet should apply to all organizations that HHS allows to serve as QIOs in the future.

As you begin preparation for the 11th Scope of Work for the QIO program (scheduled to begin in August 2014), we urge you to keep in mind that the trade bill gives discretion to the Secretary with whether or not to abandon the state-based scope of QIO contracts or to parcel out the functions of each QIO to a number of different contractors. For the reasons we outlined above, we believe it would be detrimental to the QIO program if such changes were to be made in the 11th Scope of Work, or at any time in the future.

We will monitor implementation of the QIO provisions closely, and we hope that you will give serious consideration to our concerns.

Sincerely,

Tom Price
Member of Congress

Ron Kind
Member of Congress

JUL – 6 2015

Congress of the United States
Washington, DC 20515

June 29, 2015

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 416 G
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

As medical providers and elected representatives, the GOP Doctors Caucus would like to share our serious concerns with the recently proposed U.S. Preventive Services Task Force (USPSTF) breast cancer screening recommendations.

We disagree with the Affordable Care Act's policy of tying preventative service coverage requirements to USPSTF recommendations. But because it is the law, the "C" grade the USPSTF assigned to screening mammograms for women between the ages of 40 and 49 will limit access to this valuable diagnostic tool for 17 million women. These draft recommendations are not only inconsistent with current clinical practice, but could also result in thousands of additional breast cancer deaths if followed.

We believe that patients and the medical providers with whom they have an established relationship—who themselves follow clinical guidelines developed by their specialty societies—should decide which diagnostic tools are most appropriate in a given case. We would also remind the USPSTF and other stakeholders to keep in mind that patients are not study subjects, but human beings. For a woman stricken with breast cancer, the incidence of disease is 100 percent. Should the USPSTF recommendations become finalized, they will have a chilling effect on coverage for diagnostic mammograms, jeopardizing the health of American women.

We urge you do everything in your power to ensure that these draft recommendations are not finalized so that women are not confused about the role of screening, and so that access is preserved to the best screening tools available when a patient and her medical providers decide a mammogram is necessary.

Sincerely,


TN-04

Congress of the United States
Washington, DC 20515

December 9, 2011

Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Sebelius:

We are writing to express our concern with the United States Preventive Services Task Force (USPSTF) recent draft recommendation against prostate-specific antigen (PSA)-based screening.

According to the Center for Disease Control, prostate cancer is the second most common cause of cancer death in men. The American Cancer Society estimates that 33,470 men will die this year from prostate cancer.

The PSA test is a diagnostic blood test which indicates whether a man may have a cancerous tumor in his prostate. The test informs the physician and patient of whether further action is needed, such as a biopsy or treatment. Many treatment options only work if the cancer is detected early. Based on these new recommendations, more men will wait until symptoms of prostate cancer appear. According to ZERO, a leading prostate cancer patient advocacy group, the appearance of prostate cancer symptoms means the cancer has likely already spread to areas outside of the prostate, and a man's chance of survival for more than five years has dropped by more than 40 percent.

Since the PSA test came into widespread use for early detection in the mid-1990s, the rate of deaths due to cancer has fallen by 40 percent, we find it extremely troubling that the Task Force is discouraging screening. Prior to PSA screening, the 10 year survival for prostate cancer was 53%; it's now over 97%. Additionally, prior to the widespread adoption of PSA-based screening, only 35% of men with prostate cancer were diagnosed with the cancer in a curable disease state, it's now almost 90%. Decisions about when to get screened are best left to patients and their doctors- not panels of bureaucrats tinkering with algorithms at HHS.

In addition, USPSTF's recommendation appears to be based on specious and unreliable studies and scientific evidence. The USPSTF evaluated 5 studies, which, by its own admission, included three that were of poor quality and two that were of fair quality. Additionally, the two fair studies contradict each other, with the Prostate Lung Colorectal and Ovarian Screening (PLCO) not showing advantage to screening, and the European Randomized Screening for Prostate Cancer (ERSPC) showing advantage to screening.

USPTF chose not review their findings with urologists or oncologists, the doctors that treat prostate cancer.

The most recent study, a 2010 study considered to be the best designed and controlled study, from Göteburg, Sweden demonstrated a 44% reduction in disease specific mortality. Although the Task Force referenced the Göteburg subset, they use it as a justification to discount the broader ERSPC study which incorporated a subset of its data, and the Task Force chose to disregard the prostate cancer specific survival, citing overall population survival. To issue a "Grade D" rating, the USPSTF must find moderate to high certainty that there is no scientific merit to performing screening. However, the USPSTF appears to have cherry-picked information that supports a preconceived notion rather than analyze the benefits of screening, a grievous danger for high-risk populations such as African American men.

It is deeply troubling that any entity supported by your agency would issue a recommendation that had the potential to further erect barriers to this highly at-risk population receiving adequate treatment. This recommendation jeopardizes the health of countless American men, particularly those populations that are most at risk, like African American men or men with a family history of prostate cancer, who have the highest incidence of and death rates from prostate cancer.

Recognizing the unique interaction between HHS and USPSTF, we ask that you push for the withdrawal of this draft recommendation. While Medicare's coverage of PSA-based screening may not be affected in the short term, the USPSTF's recommendation has the potential to severely undermine coverage in the private market, resulting in countless men being unable to receive needed treatment. Thank you for your attention in this matter, and we look forward to your response.

Yours truly,

Rep. Tom Price

Rep. André Carson

Rep. John Fleming

Rep. Devin Nunes

Rep. Brian Bilbray

Rep. Mike Rogers

Rep. Phil Gingrey

Rep. Dan Benishek

Rep. Dan Burton

Rep. Austin Scott

Rep. Jean Schmidt

Rep. Peter King

Rep. Steve Chabot

Rep. Pat Tiberi

Rep. Larry Buschon

Rep. Charles Boustany

Rep. Phil Roe

Rep. Diane Black

Rep. Marsha Blackburn

Rep. Leonard Lance

Rep. Charlie Bass

Rep. Michael Burgess

Rep. Nan Hayworth

Rep. Pat Meehan

Rep. Pete Olson

Rep. Brett Guthrie

Rep. Cathy McMorris Rogers

Rep. Spencer Bachus

Rep. Tim Bishop

Rep. Joe Baca

Rep. Jesse Jackson

Rep. Eleanor Holmes Norton

Rep. Charles Rangel

Rep. Bob Latta

Rep. Joe Wilson

Rep. Vern Buchanan

Rep. Paul Broun

Rep. Tim Murphy

Rep. Mike Pompeo

CC: David Meyers, MD
Center for Primary Care, Prevention, and Clinical Partnerships
Agency for Healthcare Research and Quality (AHRQ)

Virginia Moyer, MD, MPH
Chairwoman
United States Preventive Services Task Force

Congress of the United States
Washington, DC 20515

August 15, 2016

The Honorable Barack Obama
President of the United States
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear President Obama,

The Zika virus is a real and present threat to our country, and we have been diligently working to secure funding to meet this challenge. We are shocked and disappointed by the misinformation that has been spread about the Zika funding compromise negotiated by the House and Senate. We strongly urge you to help stop the mis-information being spread and encourage bipartisan support and swift enactment of this legislation to properly prepare for imminent dangers posed by the spread of the Zika virus.

As families travel for summer vacations and mosquito season is in full gear, the Centers for Disease Control and Prevention (CDC) and other agencies are working around the clock to protect us and our loved ones from the spread of the Zika virus. In this public health emergency, the speed of a solution is imperative. As the number of Zika cases in the U.S. grows, so does the number of mosquitos that can transmit the virus. The Zika virus is attacking moms and babies and poses a serious national public health threat, and Georgia, along with other Southeastern states, is in the firing line for potential outbreaks.

The Administration must abandon partisan politics and act now so that health officials can track the mosquitos, improve mosquito control methods, develop an effective vaccine, improve the accuracy and speed of tests, expand laboratory capacity, and begin robust tracking of babies born to women exposed to Zika virus.

As we have seen this year with the Zika virus, international public health threats are unpredictable and have no regard for national borders. The spread of this disease throughout multiple regions and the recent cases of local transmission of Zika in Florida emphasizes the importance of these resources to ensure global disease protection and emergency preparedness and response.

There have been several mischaracterizations of the Zika conference report proposed by Congress surrounding health services for women. However, there are no provisions in the conference report that restrict women's health services, and any Medicaid provider is eligible to be paid with these funds. In fact, this structure mirrors your own request to fund primary health care through the Medicaid program.

Officials within your Administration have suggested that you would veto the conference report, which appropriates $1.1 billion to fight Zika here and abroad, although we have not seen a formal Statement of Administration Policy. However, CDC Director Frieden's written testimony

at a July 13th Senate Foreign Relations Committee hearing stated that CDC "urgently needs a surge of resources to prevent and control the spread of Zika virus in the U.S. Commonwealth of Puerto Rico and the U.S. Virgin Islands, and other U.S. territories…the emergence and reemergence of health threats, including those spread by mosquitoes and other vectors, will continue for the foreseeable future. These outbreaks cannot be expected to occur in isolation."

There is an apparent disconnect between CDC's urgency to procure this critical funding and the absence of action by your Administration to put politics aside and reach agreement. We are concerned about the mothers and babies the virus is attacking. We are concerned about the dozens of cases of Zika in Georgia and the more than ten million people in Georgia who are at risk of contracting and spreading the virus every day that passes without action.

For these reasons, we respectfully pose the following questions:

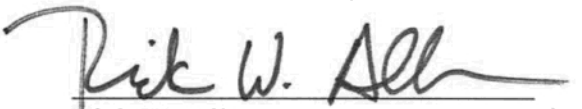
1. Your Administration's veto threat has led some to believe that if the Administration is refusing funds, this funding may not be urgent and critical. Are you able to dispel this assumption?
2. If the Senate passes the Zika conference report, will you sign it?
3. Recognizing that some members of the Senate have raised concerns with aspects of the conference report, do you believe it is more important to get Zika funding enacted now and then go back and address those concerns later, or should we wait until those concerns can be fully resolved before finalizing a Zika funding bill?
4. Please elaborate on how your Administration will fill the gap if funds are not provided before Congress returns on September 6th?
5. How much of the $589 million reprogrammed Zika funds are being distributed in Georgia? Please provide a detailed account of how these funds are being utilized in Georgia to maximize success of ongoing efforts.
6. When the current supply of transferred funds is depleted, please detail how your Administration plans to continue prevention and response measures. Will efforts in certain areas cease?

We urge you to make this public health crisis a priority and ensure CDC and other agencies working on the front line for our nation's public health have the resources they need to keep America safe. We look forward to your response by August 21, 2016. If your staff has any questions, please have them contact Jordan Bartolomeo on Senator Isakson's staff at 202-228-5441.

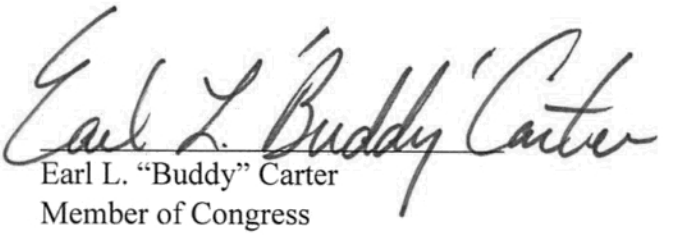
Sincerely,

Johnny Isakson
U.S. Senator

David Perdue
U.S. Senator



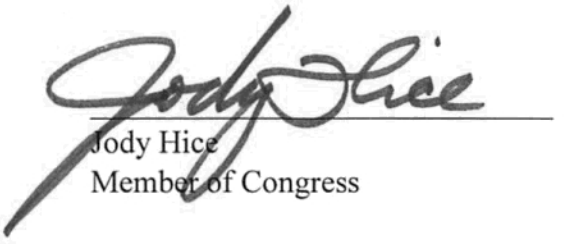
Rick W. Allen
Member of Congress



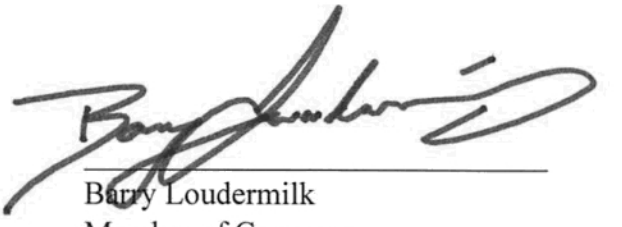
Earl L. "Buddy" Carter
Member of Congress

Doug Collins
Member of Congress

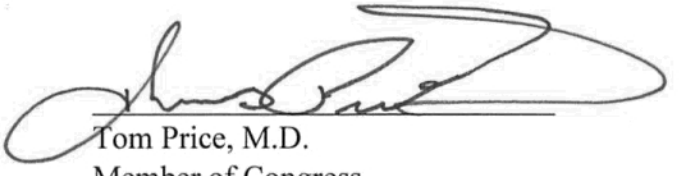
Tom Graves
Member of Congress



Jody Hice
Member of Congress



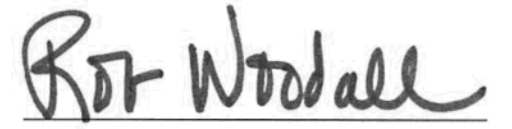
Barry Loudermilk
Member of Congress



Tom Price, M.D.
Member of Congress

Austin Scott
Member of Congress

Lynn Westmoreland
Member of Congress



Rob Woodall
Member of Congress

cc: Secretary Sylvia Burwell

JOHNNY ISAKSON
GEORGIA

http://isakson.senate.gov

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VETERANS' AFFAIRS
CHAIRMAN

SELECT COMMITTEE ON ETHICS
CHAIRMAN

FINANCE

HEALTH, EDUCATION,
LABOR, AND PENSIONS
SUBCOMMITTEE ON
EMPLOYMENT AND WORKPLACE
SAFETY, CHAIRMAN

FOREIGN RELATIONS

United States Senate

WASHINGTON, DC 20510

April 22, 2016

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Secretary Burwell:

We write to express concerns regarding the February 25, 2016 Health Insurance Portability and Accountability Act (HIPAA) guidance, which aims to regulate the production of patient records, issued by the Health and Human Services (HHS) Office for Civil Rights (OCR) and posted in the form of Frequently Asked Questions (FAQs). We believe the guidance, while well-intended, may delay and ultimately jeopardize patient access to protected health information.

OCR's guidance limits the fees health care providers can charge for access to patient records to commercial businesses operating outside the health care and medical research sectors. OCR has put forward a series of fee limits that we believe do not take into account the complexity of patient records research, production, and compliance. For example, OCR proposes that these commercial enterprises should pay no more than $6.50 for a record that can be thousands of pages long and requires production from multiple electronic databases.

Revenue from the current fee structure allows providers to keep costs low for patient records provided solely to patients and within the medical community. This model has saved providers and patients billions of dollars and is helping the health care industry to better achieve HIPAA's goals of privacy, data security, and patient access. The new OCR guidance has the potential to upend that progress. Therefore, we respectfully pose the following questions to OCR in order to provide us with information on your efforts to improve access to patient records and protect patient information:

1. Please explain why OCR issued this policy change through a non-binding guidance instead of a rule-making process with a comment period.

2. Commercial third party record requests are regulated at the state level in a system that has been in place for decades. What problem is OCR trying to solve with such a broad based application of low cost record access via the patient directives?

3. The FAQs suggest that providers should charge no more than $6.50 for electronic records of any size. The practice of price-setting by OCR is unprecedented. Does HIPAA

authorize OCR to set a specific price – in dollars and cents – for the production of these records?

4. Many states allow hospitals to charge higher rates to those with a non-clinical, commercial need for the records, such as insurance companies. These structured rates allow hospitals to minimize costs charged to patients and doctors while encouraging investment in new technologies for further improvements. By allowing patients to direct their records to these commercial enterprises for non-clinical needs and receive the benefit of the fee limits OCR is now undermining these state regulations. Did OCR take into account the impact of the guidance on future investments?

5. Did OCR consider applying its revised cost structure guidance only to Continuity of Care Document requests by individuals and not to the more complex legal electronic health records, which can be more time consuming and expensive to generate?

We look forward to your response, and appreciate your attention to this matter.

Sincerely,

Johnny Isakson
U.S. Senator

David Perdue
U.S. Senator

Rick W. Allen
Member of Congress

Sanford Bishop
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Doug Collins
Member of Congress

Tom Graves
Member of Congress

Jody Hice
Member of Congress

Barry Loudermilk
Member of Congress

Tom Price, M.D
Member of Congress

Austin Scott
Member of Congress

David Scott
Member of Congress

Lynn Westmoreland
Member of Congress

Rob Woodall
Member of Congress

cc: Director Jocelyn Samuels

Congress of the United States
Washington, DC 20515

September 16, 2016

Honorable Sylvia M. Burwell
Secretary
Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

We are writing to express our opposition to the provision in the Centers for Medicare and Medicaid Services' (CMS) Physician Fee Schedule (PFS) proposed rule for calendar year (CY) 2017 to collect all data for all 10- and 90-day global services from all practitioners who perform these services, rather than from a "representative sample" of practitioners, which was required by The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Congress was united in opposition to the policy in the CY 2015 PFS final rule that would have transitioned all 10- and 90-day global codes to 0-day global codes beginning in 2017, because of concerns that the change would compromise patient care and significantly increase administrative burdens. Instead, Congress required CMS to collect data, starting January 1, 2017, on the number and level of visits furnished during the global period. Specifically, Section 523 of MACRA explicitly calls for CMS to gather information needed to value surgical services from a "representative sample" of physicians. Beginning in 2019, CMS must use these data to facilitate accurate valuation of surgical services.

We appreciate that CMS is not proposing at this time to implement the 5% withhold for services on which the practitioner is required to report, and we encourage CMS to maintain its proposal to avoid implementing the 5% withhold in the final rule. However, the CY 2017 PFS proposed rule disregards congressional mandate and requires any practitioners who furnish a procedure that is a 10- or 90-day global code report the pre- and post- operative services furnished on a claim using proposed "G-codes." The proposal will impose an undue administrative burden on the surgical community, disproportionately directing provider resources toward compliance and away from patient care. This burden will likely be compounded by other new reporting requirements from MACRA implementation, which is the most significant physician payment change in 25 years. Taken as a whole this has the potential to negatively impact both quality and access for patients.

We ask that CMS not implement this proposal in the final rule but instead include policy that reflects the law as passed to collect data from a "representative sample" that is the least-burdensome, yet adequate sample to yield statically viable results.

Sincerely,

Larry Bucshon, M.D.
Member of Congress

Ami Bera, M.D.
Member of Congress

Kyrsten Sinema
Member of Congress

Tom Price, M.D.
Member of Congress

Andy Harris, M.D.
Member of Congress

Bill Flores
Member of Congress

Kenny Marchant
Member of Congress

David P. Roe, M.D.
Member of Congress

F. James Sensenbrenner, Jr.
Member of Congress

Mike Pompeo
Member of Congress

Dan Benishek, M.D.
Member of Congress

Ann Kirkpatrick
Member of Congress

Mo Brooks
Member of Congress

Brett Guthrie
Member of Congress

Michael C. Burgess, MD
Member of Congress

Marsha Blackburn
Member of Congress

Brian Babin
Member of Congress

Markwayne Mullin
Member of Congress

David McKinley, P.E.
Member of Congress

Brenda L. Lawrence
Member of Congress

Raul Ruiz
Member of Congress

Tom Reed
Member of Congress

Bradley Byrne
Member of Congress

Robert J. Dold
Member of Congress

Anna Eshoo
Member of Congress

Pete Olson
Member of Congress

Tom Graves
Member of Congress

Lynn Jenkins
Member of Congress

Brad Ashford
Member of Congress

Kristi Noem
Member of Congress

Gus M. Bilirakis
Member of Congress

Carlos Curbelo
Member of Congress

John J. Duncan, JR.
Member of Congress

Patrick J. Tiberi
Member of Congress

Chris Collins
Member of Congress

Joe Heck, D.O.
Member of Congress

Todd Rokita
Member of Congress

H. Morgan Griffith
Member of Congress

Julia Brownley
Member of Congress

David G. Valadao
Member of Congress

Mike Coffman
Member of Congress

Kurt Schrader
Member of Congress

Jason Smith
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

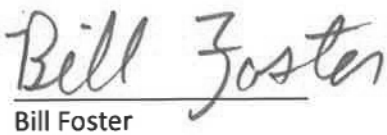
Bill Johnson
Member of Congress

John Shimkus
Member of Congress

Pete Aguilar
Member of Congress

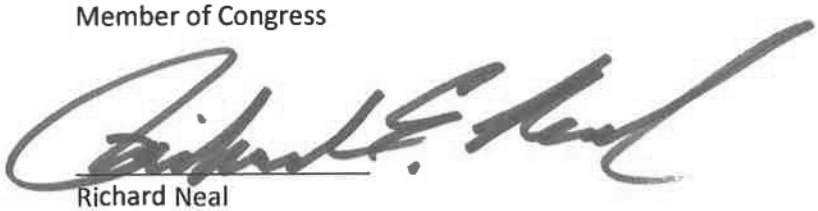
Matt Salmon
Member of Congress

Lou Barletta
Member of Congress



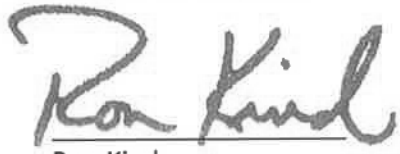
Bill Foster
Member of Congress

David Schweikert
Member of Congress



Richard Neal
Member of Congress

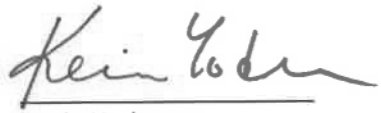
Dan Donovan
Member of Congress



Ron Kind
Member of Congress

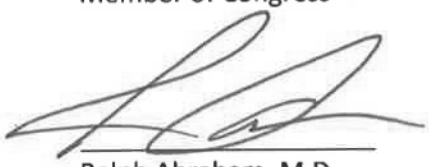
Susan Brooks
Member of Congress

Barbara Comstock
Member of Congress

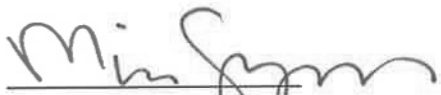


Kevin Yoder
Member of Congress

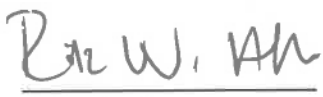
James R. Langevin
Member of Congress



Ralph Abraham, M.D.
Member of Congress



Mike Thompson
Member of Congress



Rick W. Allen
Member of Congress

Steve Israel
Member of Congress

Adrian Smith
Member of Congress

Mike Kelly
Member of Congress

Renee Ellmers
Member of Congress

Jackie Walorski
Member of Congress

Joe Wilson
Member of Congress

Robert Pittenger
Member of Congress

Steve Cohen
Member of Congress

Linda T. Sánchez
Member of Congress

John B. Larson
Member of Congress

Devin Nunes
Member of Congress

Adam Kinzinger
Member of Congress

Chris Van Hollen
Member of Congress

Todd Young
Member of Congress

Michael M. Honda
Member of Congress

Mark Walker
Member of Congress

Joe Crowley
Member of Congress

Garret Graves
Member of Congress

Peter Roskam
Member of Congress

Charles W Boustany Jr., M.D.
Member of Congress

Erik Paulsen
Member of Congress

Pete Sessions
Member of Congress

Bill Pascrell, Jr.
Member of Congress

Sanford D. Bishop, Jr.
Member of Congress

David Joyce
Member of Congress

Reid Ribble
Member of Congress

Scott Garrett
Member of Congress

Diane Black
Member of Congress

Mia Love
Member of Congress

Charles W. Dent
Member of Congress

John Culberson
Member of Congress

Bill Huizenga
Member of Congress

Cheri Bustos
Member of Congress

Robert E. Latta
Member of Congress

Joe Barton
Member of Congress

Ryan Costello
Member of Congress

Bill Posey
Member of Congress

David Scott
Member of Congress

Michelle Lujan Grisham
Member of Congress

Gregg Harper
Member of Congress

Evan Jenkins
Member of Congress

Jeff Duncan
Member of Congress

Steve King (IA)
Member of Congress

Dutch Ruppersberger
Member of Congress

Paul Gosar
Member of Congress

George Holding
Member of Congress

Leonard Lance
Member of Congress

Billy Long
Member of Congress

Andy Barr
Member of Congress

Rod Blum
Member of Congress

Brad Wenstrup, D.P.M.
Member of Congress

Congress of the United States

Washington, DC 20510

September 23, 2016

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

Dear Secretary Burwell,

We write to express our strong opposition to the Department of Health and Human Services (HHS) September 7, 2016, notice of proposed rulemaking titled "Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients." Although we appreciate the Department's intent to follow proper regulatory procedure pursuant to the Administrative Procedure Act, HHS's purpose for engaging in the rulemaking appears on its face to be an attempt to subvert the will of elected representatives.

Moreover, apart from the Department's impetus for the notice of proposed rulemaking, we also question whether the Department's stated rationale adequately supports its conclusion that providers with a reproductive health focus are more "effective" than other health providers that offer comprehensive care for women and men. Nowhere in the proposed notice of rulemaking does HHS clearly define what it means to provide Title X services in an "effective" manner. It does appear to assert that a number of factors – such as the range of contraceptive methods on-site, the number of clients in need of publicly funded family planning services served, and the availability of preconception care – distinguish providers with a reproductive health focus as more "effective" and "high quality" than other types of providers. However, that list of factors falls far short of all of the attributes and recommendations included in the Centers for Disease Control and Office of Population Affairs report entitled "Providing Quality Family Planning Services: Recommendations of CDC and the US Office of Population Affairs."[1]

To further complicate the argument about quality and effectiveness, the data cited in the notice of proposed rulemaking is not adequate for determining patient outcomes. The Department relies heavily on utilization and demographic statistics, but appears to lack hard data regarding actual patient outcomes and need, as the Department does not require grantees to track patients or verify their income. As you know, the issue of inadequate data has previously been raised by the Institute of Medicine (IOM), after the HHS Office of Family Planning in 2007 asked IOM to provide a critical review of the Title X Family Planning Program. In addition to finding "no clear, evidence-based process for establishing or revising program priorities and guidelines," IOM stated the following in its May 2009 Report Brief:

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[1] Centers for Disease Control and Prevention, Recommendations and Reports: Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (April 2014).

> "The committee concludes that the program does not collect all the data needed to monitor and evaluate its impact. Therefore, the committee proposes a comprehensive framework to evaluate the program and assess how well clinics meet the family planning needs of the program's clients. The committee concludes that additional data will be needed in the areas of client needs, structure, process, and outcomes in order to assess the program's overall progress."[2]

We welcome evidence that this recommendation has been fully adopted, but are unaware of any clear evidence confirming that to be the case. If HHS cannot clearly define an "effective" or "high quality" provider, it is unclear to us how state and local project grantees are supposed to do so in order to comply with this proposed rule. It is also therefore unclear how HHS will be able to accurately determine in every case whether state or local project recipients – who are generally closer to and more familiar with subrecipients and the patient base in their geographical region – have considered inappropriate criteria in evaluating subrecipients. Rarely do the American people benefit when the federal government attempts to substitute its judgment for that of state or local governments – particularly when the criteria used to inform that judgment are unclear, and that judgment is not supported by coherent and impartial facts.

Finally, if HHS is going to assert the authority to adapt its rules in order to address changing circumstances, we implore HHS to consider the recent general shift in health care policy toward comprehensive care. As HHS states on its website, in addition to assisting individuals and couples in planning and spacing births, part of the mission of Title X is to contribute to "improved health for women and infants."[3] HHS's suggestion that subrecipients like federally qualified health centers – which provide greater preventive and primary health care services than providers with a reproductive health focus – are per se less "effective" than providers with a reproductive health focus does not comport with that stated mission.

We urge HHS to reconsider this overreaching and ill-supported rule. We will continue to closely monitor this proposed rulemaking, and intend to submit this letter as a formal comment. We look forward to a detailed response from your Department.

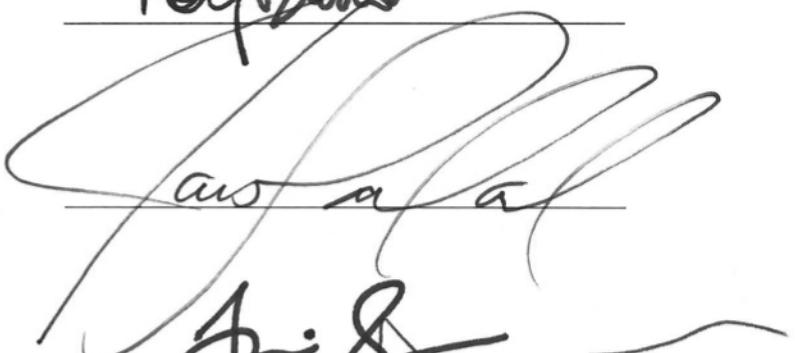
Sincerely,

Joni K. Ernst
United States Senator

Diane Black
United States Congressman

[2] Institute of Medicine, Report Brief: A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results (May 2009).
[3] U.S. Department of Health & Human Services, Office of Population Affairs, Title X Family Planning, http://www.hhs.gov/opa/title-x-family-planning/.

Ben Sasse



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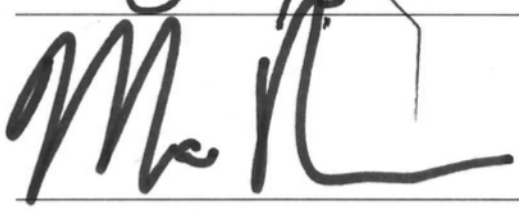

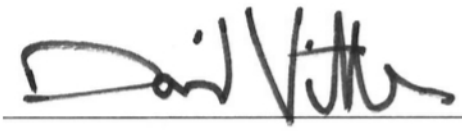

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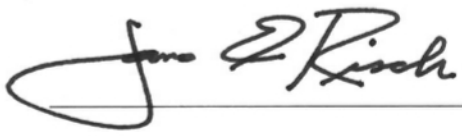
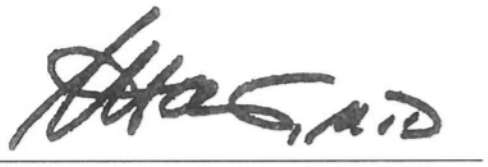
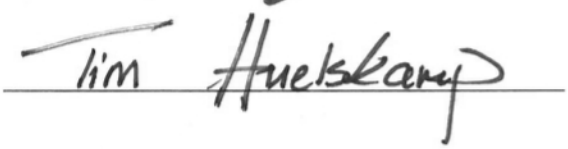
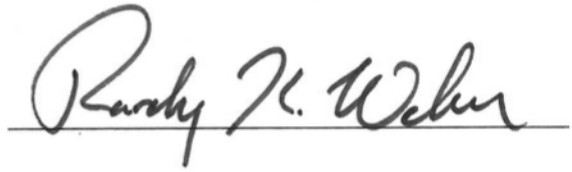
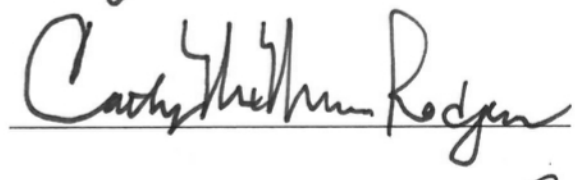
John Boozman

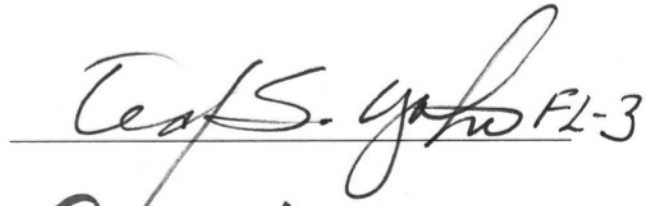


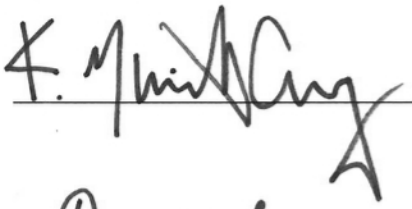












Walter B. Jones

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Doug Lamborn

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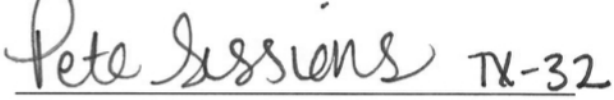

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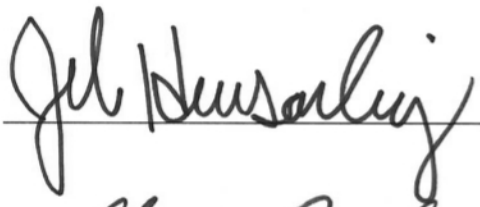

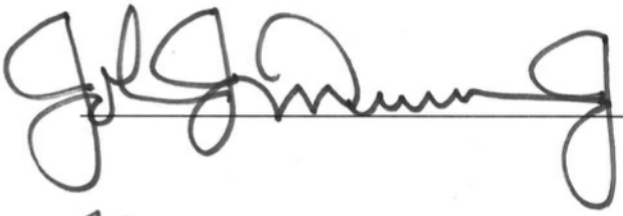

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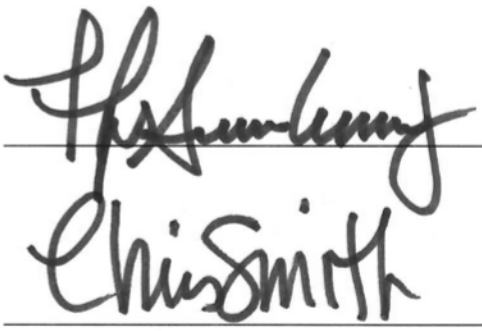

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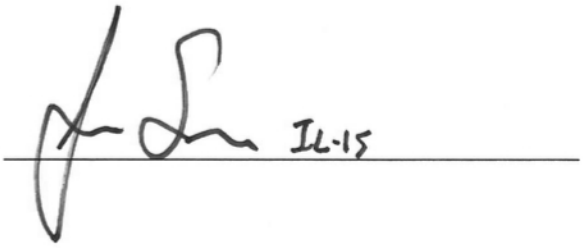


IL-15

Steve King

Joe Wilson

Adrian Smith

Marsha Blackburn

Virginia Foxx

K Michael

TX-26

Steve Pearce

Jim Walberg

Sam Graves

Austin Scott

Randy Hultgren

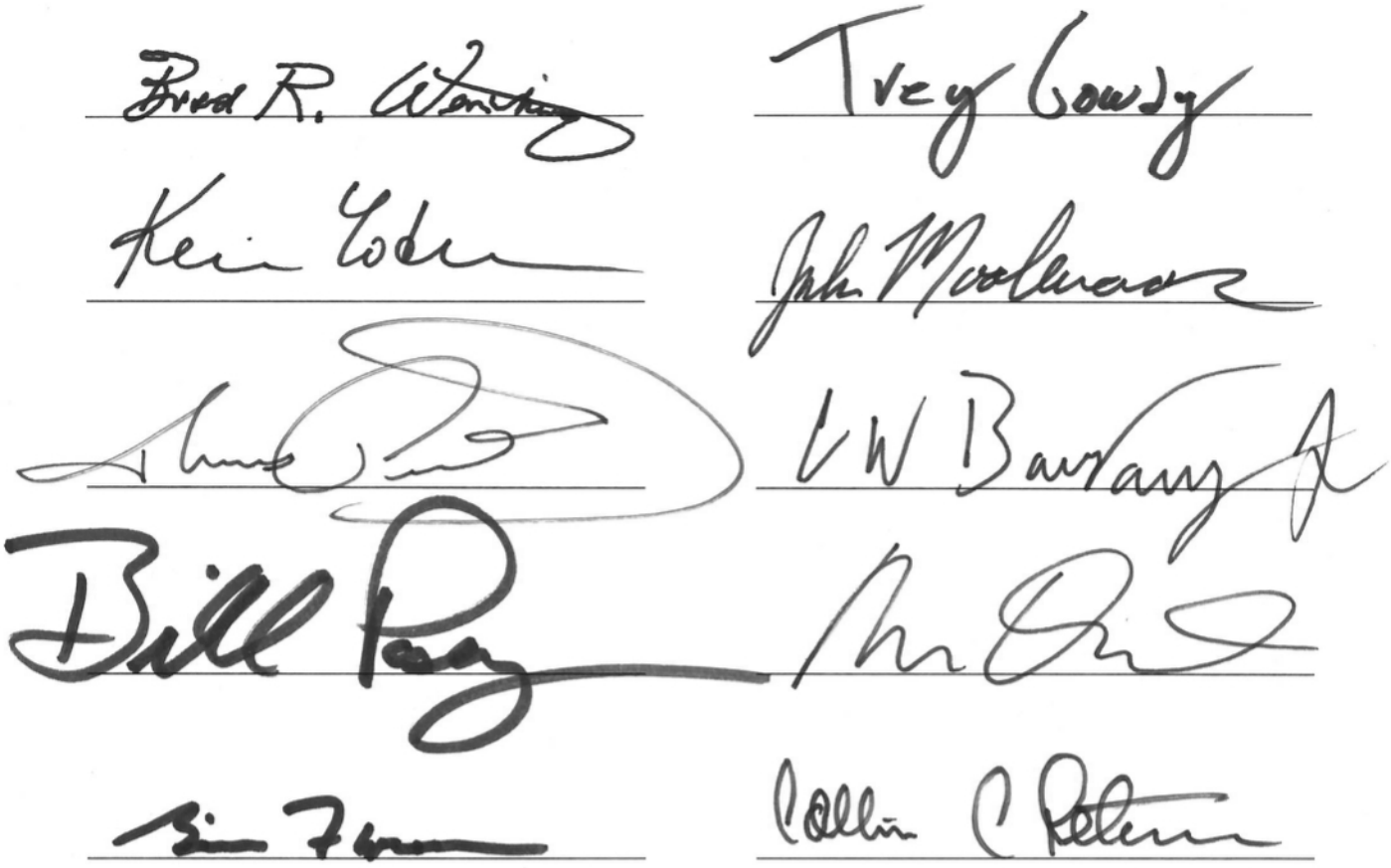
Tom Price

Bob Dold

TN-04

Earl L "Buddy" Carter

Glenn Grothman



Congress of the United States
Washington, DC 20515

April 20th, 2016

Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
Room 120F
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Andrew M. Slavitt
Administrator (Acting)
Centers for Medicare and Medicaid Services
Room 310G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

We write to urge the Department of Health and Human Services (HHS), particularly the Centers for Medicare and Medicaid Services (CMS), and the Office of the Assistant Secretary for Planning and Evaluation to ensure that the Department engages with physician and medical specialty groups in a timely and productive manner to accelerate the development of alternative payment models (APMs).

In crafting the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress put an emphasis on modernizing our health system with a particular focus on methods of payment based on the value of care. MACRA is built on the principle of encouraging provider groups to develop APMs that can ultimately be adopted by CMS and commercial payers. Specifically, MACRA encourages physician and medical specialty groups to submit APM proposals to the Physician-Focused Payment Models Technical Advisory Committee (PTAC). As you know, this process was created by MACRA to capitalize on medical expertise by actively involving stakeholders in the development of APMs and to increase the variety, efficacy, and number of qualified APMs, maximizing the number of physicians and medical specialties that would be able to participate in them.

The physician community strongly supports this provision in MACRA. Currently, many medical specialties are re-examining how their physicians are paid and investing significant time and resources in developing models that will incentivize and facilitate high quality care and improved patient outcomes. We believe that a timely and efficient implementation process at HHS will be critical to realizing the promise of this provision of MACRA.

First, we urge the Administration to review and quickly implement as many physician-focused APMs as possible. CMS has indicated that its current process for reviewing and implementing an APM requires one to two years to complete, and that the resources needed to carry out this process limit the number of APMs that can be implemented. The Secretary should eliminate unnecessary steps and requirements to establish a fast-track process for implementing APMs that are developed by medical societies and hold promise for improving patient care and/or generating savings. With the likely first performance period for payment updates in 2019 fast approaching, timely implementation is essential for all stakeholders involved.

Second, it is our hope that the APM provisions of MACRA will lead to a diverse array of APMs developed by providers, including models for small physician practices, specialists, and rural physicians. Consequently, we urge HHS and CMS to offer assistance to physicians and medical societies in the development of APM proposals by providing feedback and transparency, including access to data.

Third, we urge the agencies to give priority consideration to models recommended by the PTAC. MACRA created this provision in the hopes that it would lead to a proliferation of physician-focused payment models applicable to a wide variety of specialties.

Finally, we urge the agencies to ensure that the PTAC provides helpful feedback at an early stage on whether participation in a proposed APM is an acceptable alternative to participation in the Merit-Based Incentive Payment System. APMs must be meaningful to improve health care delivery and allow for more than nominal risk, and physician and medical specialty groups need to receive clear feedback on the strength of their proposals in order to generate successful APMs.

We share the goal of improving Medicare by empowering providers to work with us to improve patient care. Physician and medical specialty groups are uniquely positioned to help develop effective APMs that take into account the unique needs of patients with different health conditions. We ask the Secretary to move quickly to publish for public comment the criteria the PTAC will use to evaluate proposed APMs and announce a clear process for the submission, review, approval, and implementation of proposed APMs, and to provide as much technical assistance as needed to providers and their medical societies regarding APM development. We ask the Secretary to expeditiously review and implement such APMS developed by physicians and medical societies. We look forward to working with you to implement this important law.

Sincerely,

TOM PRICE, M.D.

BILL PASCRELL, JR.

LARRY BUCSHON, M.D.

DAVID LOEBSACK

Congress of the United States
Washington, DC 20515

May 25, 2016

Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
Room 120F
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Andrew M. Slavitt
Administrator (Acting)
Centers for Medicare and Medicaid Services
Room 310G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

Home health is a critical service for seniors and people with disabilities that allows them to stay in their home and remain active in the community. The Centers for Medicare and Medicaid Services (CMS) recently issued in its Paperwork Reduction Act Federal Register Notice (PRA Notice) a potential mandatory prior authorization for home health as a demonstration in five states.[1] The Medicare home health benefit allows beneficiaries to receive medically necessary services at home, in the least costly setting, and can support improved care transitions that help to prevent expensive hospital readmissions. Prior authorization has never been applied to post-acute care within fee-for-service Medicare. We encourage you to refrain from moving forward with the proposed demonstration project in order to avoid delays or a disruption in patient care and prevent restrictions on patient access to home health services.

We are concerned that a demonstration project centered on prior approval or "prior authorization" of home healthcare would interfere with the patient-doctor relationship and is in conflict with the policy goal of moving toward patient-centered care. Stated simply, prior authorization of home healthcare imposes a requirement that prevents a patient from receiving home health services after the physician orders home healthcare unless and until an intermediary has reviewed and approved the order.

Under the proposal, a home health agency would be penalized if it attempted to proceed and care for a patient without delay. Under the proposed demonstration, a home health agency that provides care without prior authorization would be penalized with a 25 percent payment reduction, even if the claim were approved as appropriate and payable.[2]

We are most concerned with the potential impact of a prior authorization demonstration on access to

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[1] The proposed demonstration is described in the Paperwork Reduction Act notice in the Federal Register from February 5, 2016. The five states captured by the demonstration include Florida, Texas, Illinois, Michigan and Massachusetts.

[2] *Supporting Statement Part A – Medicare Prior Authorization of Home Health Services Demonstration*," CMS-10599 (Feb. 5, 2016), retrieved from: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-10599.zip

care. Requiring prior approval for every home health patient across five states for critically important services that keep people in their homes rather than institutions, often when they are at their most medically vulnerable, will effectively delay and deny home health coverage for countless Medicare beneficiaries. Under this demonstration project, CMS would have to review more than 900,000 claims each year before each patient could receive care. Today, approximately 3.5 million of Medicare's most vulnerable beneficiaries depend on home healthcare services. These patients are often elderly, low income patients with serious illnesses, who are more likely to be disabled, a minority, or female than all other Medicare populations combined.[3] An unwarranted disruption and delay in patient care will put the oldest and frailest Medicare beneficiaries at greatest risk.

This demonstration project could limit access to home health services, while generating longer and costlier hospital stays and potentially increasing readmission rates. Many patients find themselves in the most clinically fragile condition during the week following a hospital discharge. It is vitally important that we continue to meet the care needs of Medicare patients during this critical transition time post-hospital discharge.[4]

We are also concerned about what a prior authorization proposal will mean to the taxpayer. CMS estimates that administrating this demonstration project would cost taxpayers more than a quarter of a billion dollars.[5] CMS aims to reduce fraud and improper payments within home health agency claims; however, it is unclear to what extent this proposal would actually prevent fraud and the submission of faulty paperwork or claims. Rather than a more focused approach targeting bad actors, this proposal will put a tremendous administrative burden on agencies with absolutely no track record of fraud. Physicians and home health agencies are already required to provide significant documentation for each patient in order to demonstrate a clinical need for home health services. A prior authorization demonstration as proposed would add an increased administrative burden on both physicians and home health agencies, while likely adding little value for identifying and preventing fraud. Further, prior authorization would be a duplicative process as CMS already reviews claims on a pre-payment basis.

Finally, we are concerned about the authority stated by CMS in pursuing prior authorization for home health services. The authority cited in the rule for implementing the program gives the Secretary authority "to develop or demonstrate improved methods for the *investigation and prosecution of fraud* in the provision of care or services under the health programs established by this chapter (emphasis added)."[6] The proposal to screen every home health service through a prior authorization process for the five identified states, however, tests a method of screening and utilization management, not a

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[3] Avalere Health, *Medicare Beneficiary Analysis: Key Differentiating Characteristics of Medicare Home Health Beneficiaries*. March 2014 http://homehealth4america.org/media-center/attach/207-1.pdf

[4] Medicare certified home health agencies are required in the conditions of participation to conduct the initial assessment visit "either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date." A prior authorization process could delay care for as long as 10 to 20 days, directly counter to CMS's regulation. Additionally, CMS created a home health performance measure for timely initiation of care that measures the "percentage of home health episodes of care in which the start or resumption of care date was either on the physician-specified date or within 2 days of the referral date or inpatient discharge date whichever is later." This National Quality Forum (NQF) endorsed measure has also been included on the Home Health Compare website. Thus, a prior authorization process for home health care would be inconsistent with CMS's measure of quality in home health care.

[5] CMS estimates that the costs associated with performing prior authorization for home health services would be approximately $223 million in Phase I and an additional $71.4 million in Phase II over the 3-year demonstration period for just five states. Future expansion of this rule to all 50 states would cause the costs to escalate dramatically.

[6] 42 U.S.C. Section 1395b-1(a)(1)(J)

method for investigation or prosecution of fraud. Apart from the question of authority, the PRA Notice is insufficient from an administrative perspective to promulgate such a wide-reaching program. A full notice and comment rulemaking process, allowing stakeholders to comment with specificity on the details of a proposed demonstration project, would be required.

This demonstration project imposes costs on patients, providers and taxpayers. Delaying patient care while waiting for CMS to approve home health services may put patient health in jeopardy and cause patients to stay in the hospital longer than necessary. We ask you to withdraw the proposed demonstration for prior authorization of home health services in order to avoid health risks to patients, delays or disruptions in patient care and unnecessary restrictions on patient access to home health services.

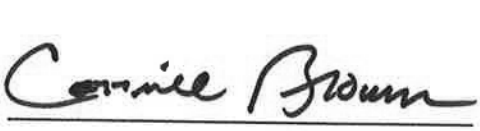
Sincerely,

Tom Price
Member of Congress

James P. McGovern
Member of Congress

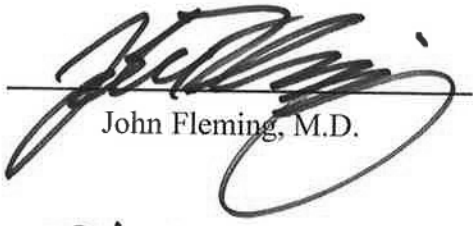
Charles W. Boustany, Jr. M.D.

Niki Tsongas

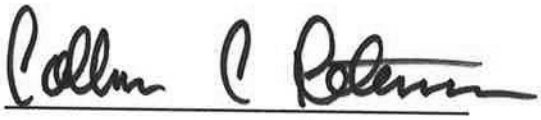


Corrine Brown

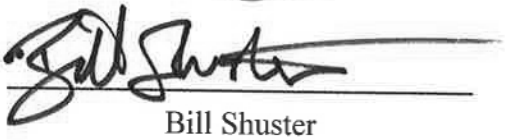
Sheila Jackson Lee



John Fleming, M.D.

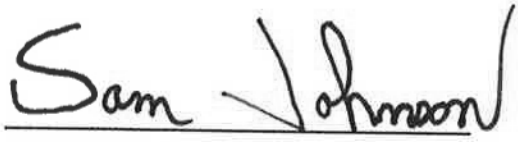


Collin C. Peterson



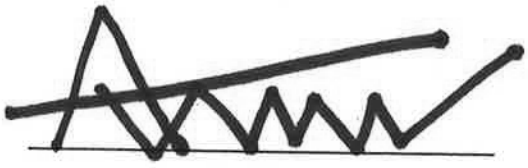
Bill Shuster

Darrell Issa



Sam Johnson

Lamar Smith



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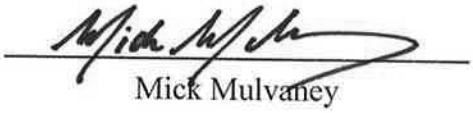

Mick Mulvaney

Mike Conaway

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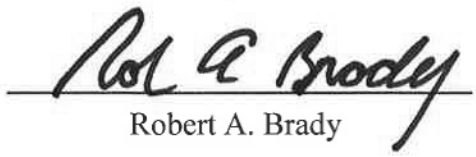
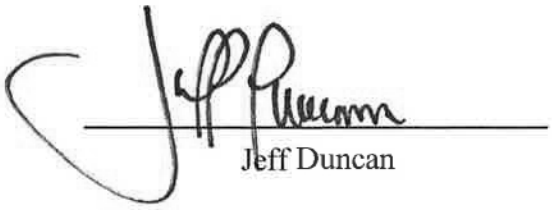


Robert A. Brady



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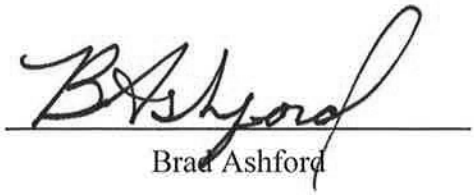
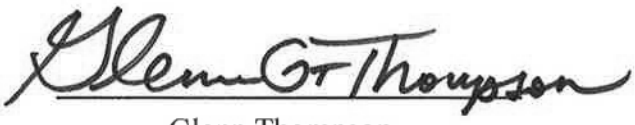


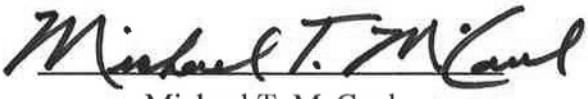
Brad Ashford

Lou Barletta



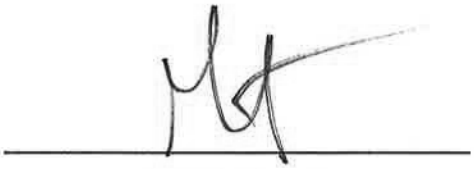
Glenn Thompson

Bruce Westerman



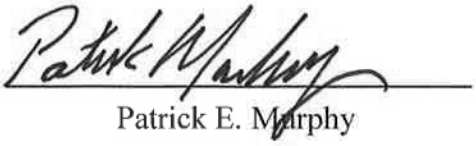
Michael T. McCaul

Ann Kirkpatrick

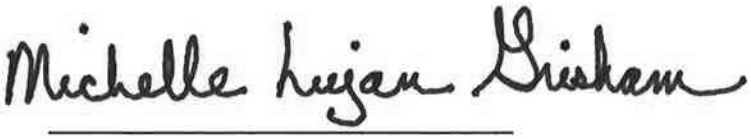


Garret Graves

Gary Palmer



Patrick E. Murphy



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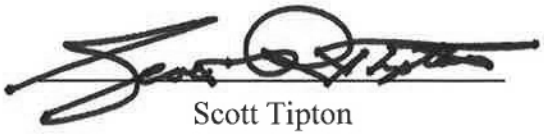
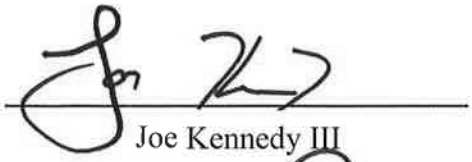


Scott Tipton

Robert B. Aderholt

Cedric Richmond



Joe Kennedy III

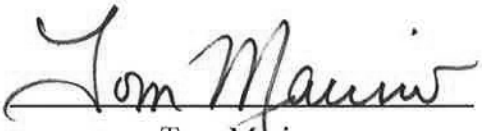
William Keating

Brian Babin

John Ratcliffe

Richard E. Neal

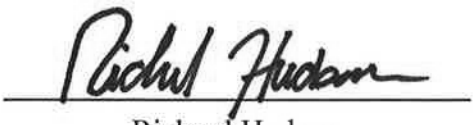
David 'Phil' Roe, M.D.



Tom Marino

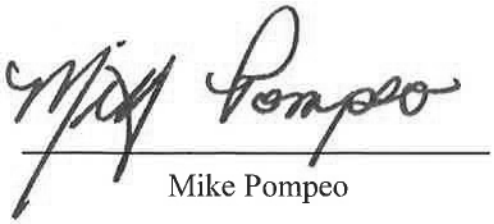
David McKinley

Ralph Abraham, M.D.

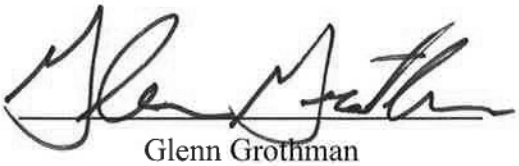


Richard Hudson

Patrick Meehan



Mike Pompeo



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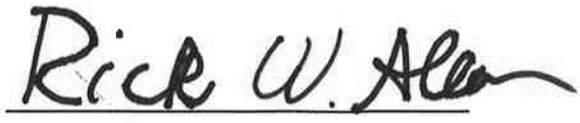

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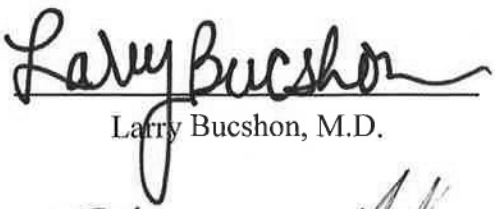
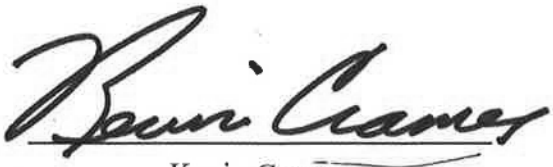
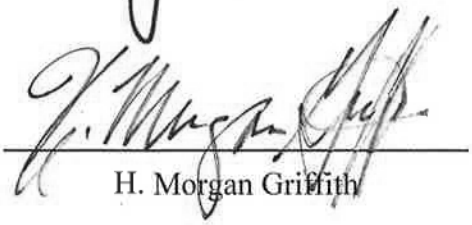


Larry Bucshon, M.D.

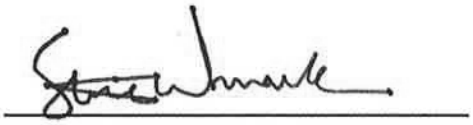


Kevin Cramer

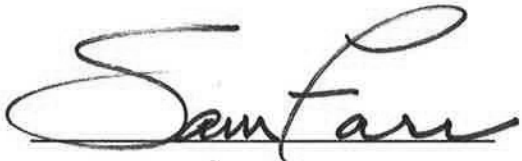


H. Morgan Griffith

Jason Smith



Steve Womack



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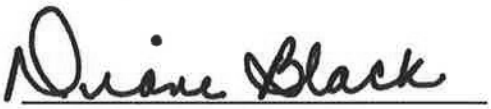
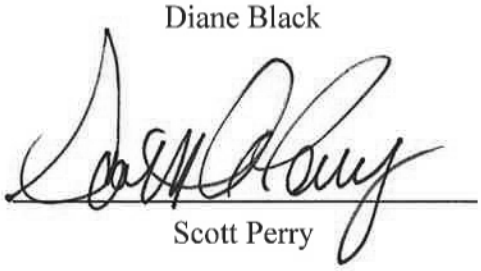


Diane Black

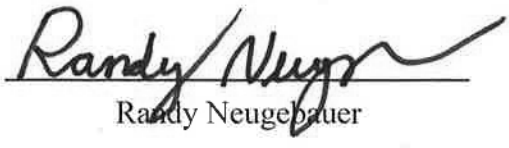
Terri A. Sewell



Scott Perry

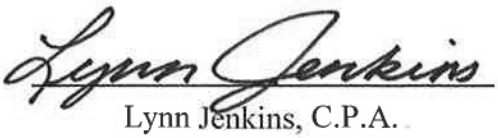
French Hill

Mo Brooks



Randy Neugebauer

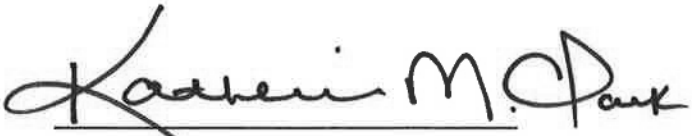
Mike Kelly



Lynn Jenkins, C.P.A.

Andy Harris, M.D.

Rick Crawford

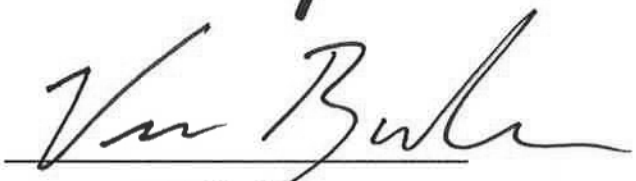


Katherine Clark

Richard Nugent

David Jolly

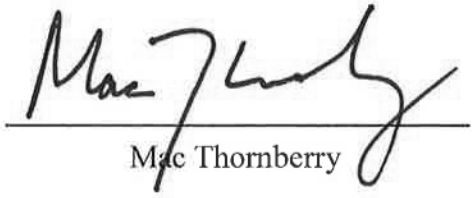
Rodney Davis



Vern Buchanan

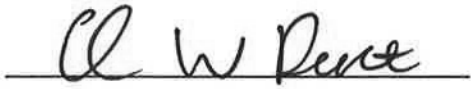
Pete Olson

Lynn Westmoreland

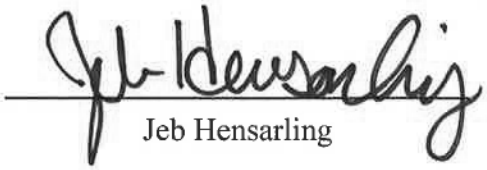


Mac Thornberry

Steve King



Charles Dent



Jeb Hensarling

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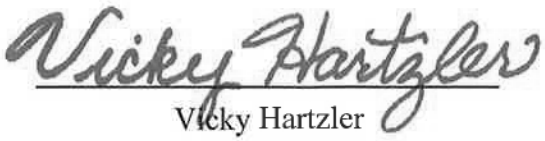
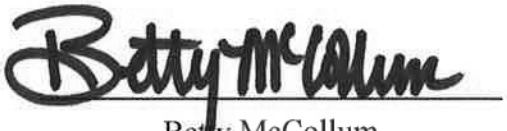


Vicky Hartzler

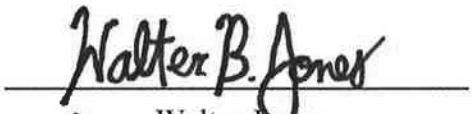
Louie Gohmert



Betty McCollum

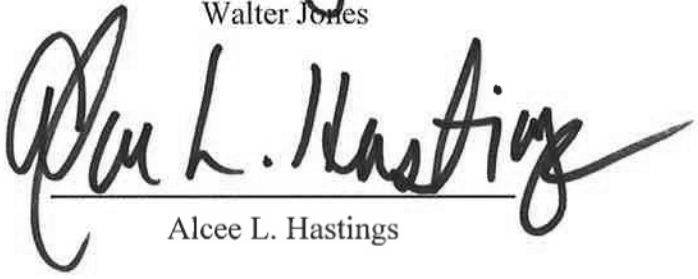
Marsha Blackburn

Kenny Marchant

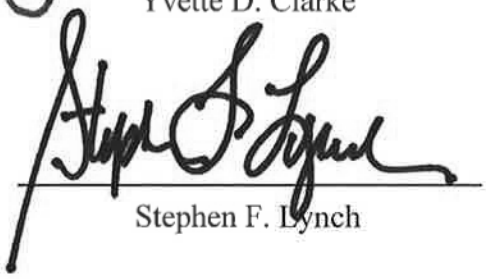


Walter Jones

Yvette D. Clarke



Alcee L. Hastings



Stephen F. Lynch

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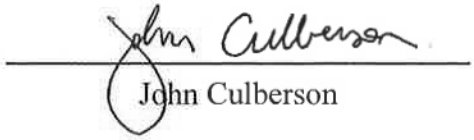

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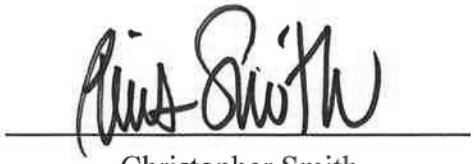

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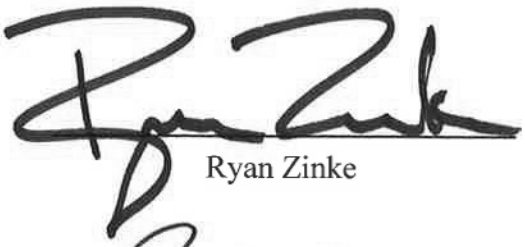
Doug Lamborn



Ryan Zinke

Robert Hurt

Rod Blum

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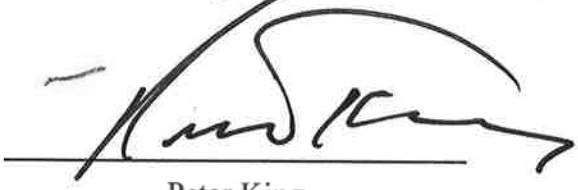

Peter King

Ryan A. Costello

Mike Bishop

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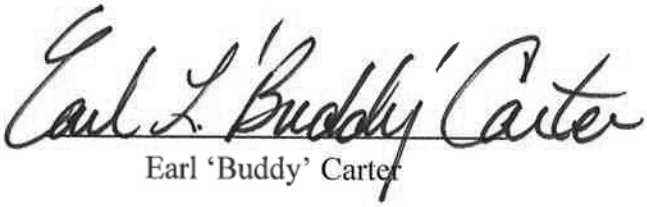

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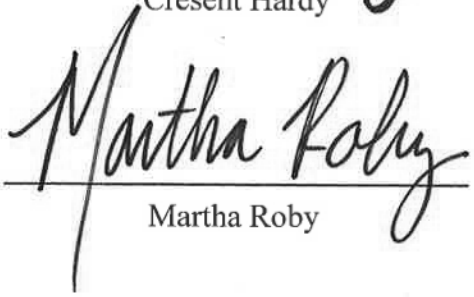
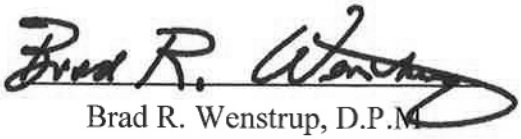


Martha Roby

Bill Huizenga



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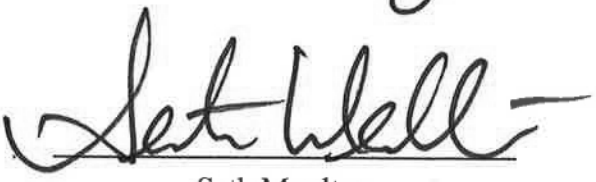

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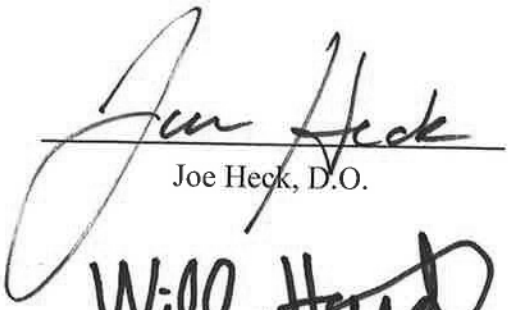
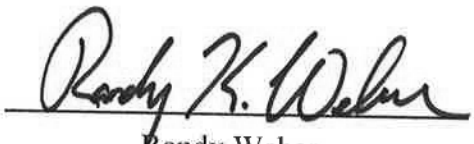


Joe Heck, D.O.

Ann McLane Kuster

Will Hurd

Evan Jenkins



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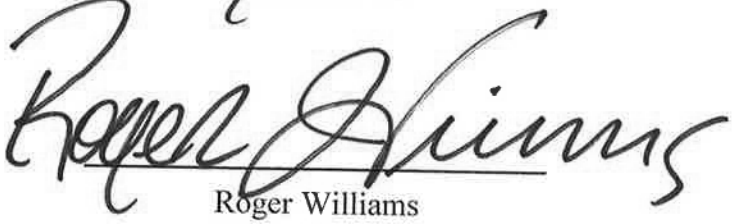

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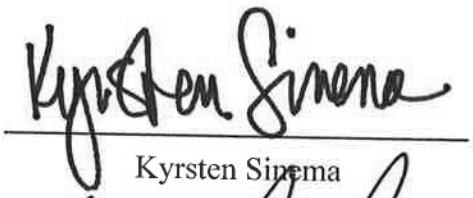

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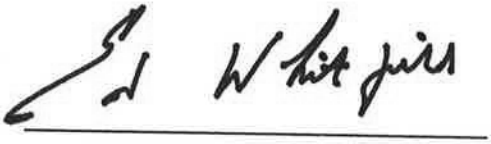

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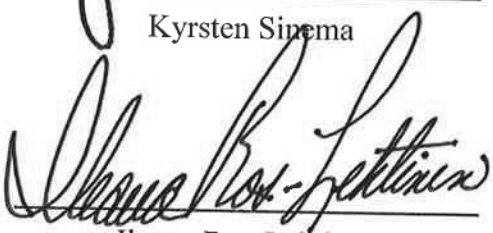
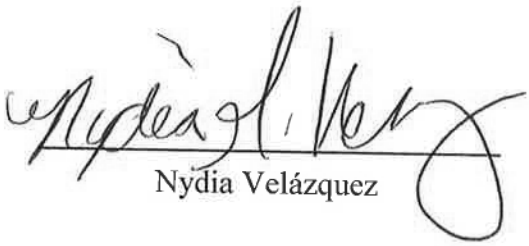
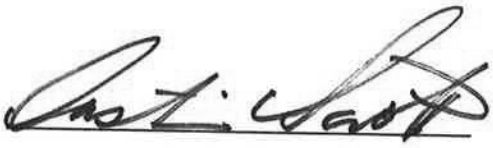


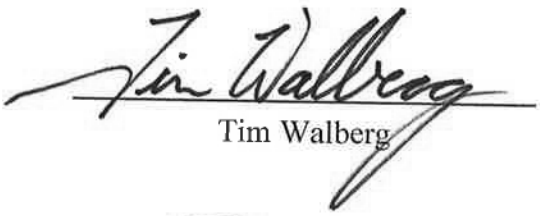
Ileana Ros-Lehtinen



Nydia Velázquez



Austin Scott



Tim Walberg

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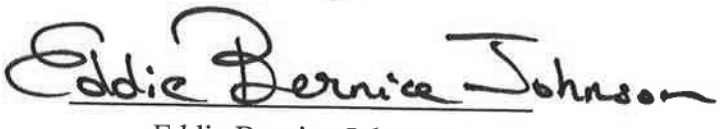

Eddie Bernice Johnson

Bradley Byrne

Tammy Duckworth

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

December 1, 2009

The Honorable Tom Price, M.D.
House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the proposals announced in the 2010 Physician Fee Schedule Proposed Rule. In your letter you express concern about the impact of proposals related to practice expense on Medicare payment for physicians' services provided by cardiologists, oncologists, and imaging services.

You also express concerns about proposals relating to the Physician Practice Expense Information Survey (PPIS). The PPIS was undertaken as a replacement for both the American Medical Association (AMA) Socioeconomic Monitoring System (SMS) Survey, which is approximately 15 years old, and the specialty-specific supplemental survey data, which we accepted beginning in 2001, in accordance with section 212 of the Balanced Budget Act of 1997, to augment the discontinued SMS survey data. The AMA and 70 individual specialties and health care professional associations contributed a minimum of $25,000 each toward the cost of the survey. The Centers for Medicare & Medicaid Services purchased PPIS data from the AMA and proposed to replace the current data sources with the new PPIS data.

While we recognize that the use of the PPIS data results in significant payment increases and decreases for several specialties, we believe that the newer data provide more accurate estimates of physician practice costs today than do older survey data that we are currently using. In response to public comments from the oncology community, we decided to use a practice expense survey done several years ago by the American Society of Clinical Oncologists (ASCO) in place of the PPIS survey. Use of this data mitigates the impact on chemotherapy administration services and is consistent with provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that require ASCO's survey to be used in the determination of payment for drug administration services. Further, although we decided to use the PPIS data in the final rule for other practice areas, we also adopted a policy to transition the changes over the next 4 years to mitigate the financial impact of the change in any single year. The physician fee schedule final rule provides a more detailed response to each of the points that were raised by commenters concerned about these proposals.

Please know that the Department of Health and Human Services is fully committed to fighting cancer and heart disease and ensuring patient access to needed services to treat these conditions. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program.

Sincerely,

Kathleen Sebelius

TOM PRICE, M.D.
6TH DISTRICT, GEORGIA

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Congress of the United States
House of Representatives

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RANKING MEMBER

REPUBLICAN STUDY COMMITTEE
CHAIRMAN

DEPUTY WHIP

October 30, 2009

Kathleen Sebelius, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

As you may know, on July 13, 2009, the Centers for Medicare and Medicaid Services (CMS) issued proposed rulemaking (CMS-1413-P) which would implement changes to the calculation of the Physician Fee Schedule used in providing reimbursement for services rendered under Medicare Part B. This proposal seeks to implement data developed under the recently completed American Medical Association (AMA) Physician Practice Information Survey (PPIS). While I applaud CMS' decision to move toward more current and accurate data to determine practice expense (PE) payments for all Medicare Part B providers, I have concerns with the detrimental cuts to cardiology, oncology and imaging reimbursements and the negative impact it will have on patient care.

It has come to my attention that the sample sizes, breadth of facilities included, and cost factors taken into account in the survey were limited in scope thus failing to capture all conditions faced by providers that lead to cost increases. Specifically, I would ask that CMS releases the data so affected stakeholders have the opportunity to fully review the entire data set before such significant policy changes are implemented. It should also be noted that the government's flawed physician payment structure will continue to harm quality and access to care unless substantial changes are made.

I would urge you to consider these additional items before implementing any significant modifications to the Medicare Physician Fee Schedule (MPFS).

Thank you in advance for your immediate help in this matter.

Yours Truly,

Tom Price, M.D.

Member of Congress

Fax Cover Sheet
Congressman Tom Price
6th District of Georgia

424 Cannon House Office Building
Washington, DC 20515
Phone: (202) 225-4501
Fax: (202) 225-4656

To: Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services

From: Congressman Tom Price

Comments: Letter to HHS regarding the Centers for Medicare and Medicaid Services (CMS) issued proposed rulemaking (CMS-1413-P)

Number of Pages including Cover Sheet: 2