



January 26, 2016

The Honorable Orrin Hatch  
Chairman  
Senate Finance Committee

The Honorable Ron Wyden  
Ranking Member  
Senate Finance Committee

The Honorable Johnny Isakson  
United States Senator  
Co-chair, Chronic Care Working Group

The Honorable Mark Warner  
United States Senator  
Co-chair, Chronic Care Working Group

Re: A Pathway to Improving Care For Medicare Patients with Chronic Conditions

Dear Senators:

On behalf of the American Gastroenterological Association (AGA), representing 17,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology, we thank you and your colleagues for your leadership in seeking policy solutions to improve care for Medicare patients with chronic diseases. AGA appreciates the opportunity to provide feedback on your Bipartisan Chronic Care Working Group Policy Options Document and shares your commitment to improving the value, quality and delivery of health care in managing patients with chronic diseases.

The AGA has recognized the need to effectively manage chronic digestive diseases such as gastroesophageal reflux disease (GERD), viral hepatitis B+C, hepatic steatosis, inflammatory bowel disease, esophageal, colorectal, and pancreatic cancers, and malnutrition and obesity since the downstream volume impact is significant for surgery, imaging and oncology as well as primary care. The AGA believes that the effective management of digestive diseases is critical to the success of healthcare organizations. Through the AGA's Roadmap to the Future of GI Practice, we have made considerable investments in the development of clinical guidelines, quality outcome measures, and patient registries in order to provide gastroenterologists (GIs) with the tools necessary to improve patient outcomes and to prepare them for a changing health-care marketplace. We are pleased to provide you with the following comments and will focus on the following sections to your policy options document:

**Improving Care Management for Individuals with Multiple Chronic Conditions**  
**Developing Quality Measures for Chronic Conditions**  
**Expanding Access to Digital Coaching**  
**Increasing Transparency at CMMI**  
**Study on Obesity Drugs**

**Improving Care Management for Individuals with Multiple Chronic Conditions**

The AGA supports the Working Group's recommendation to establish a new high-severity chronic care management code as part of the Medicare Physician Fee Schedule (PFS) for coordinating care outside of a face-to-face encounter for Medicare's most complex beneficiaries living with multiple chronic conditions. The AMA's CPT Editorial Panel will be considering proposals for several new care management CPT codes at its meeting in February 2016, including chronic care management performed by the physician for patients with multiple chronic diseases, and a new code for non-face-to-face physician management of patients with multiple chronic conditions. We believe that these CPT code proposals meet the Working Group's needs.

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The patient criteria for the new code is proposed to include patients with two or more illnesses that are expected to last twelve months or for the life of the patient and put the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, but whose clinical situation is sufficiently complex such that the physician must perform the chronic care coordination personally.

It is important to note that the new code for high-severity chronic care management should not be restricted to certain specialties. It should be made permanent, but with authority from the Secretary of the Department of Health and Human Services to continue, discontinue, or modify the code based on effectiveness, clinician and patient feedback, utilization of the code, and other factors with input from the public. Establishing permanent codes will allow Medicaid, Tricare, and private payors to recognize such, as we anticipate they will support a methodology to measure the impact, effectiveness, and compliance once such a code is put into place.

### **Developing Quality Measures for Chronic Conditions**

The AGA owns and serves as the measure steward for Hepatitis C (HCV) and Inflammatory Bowel Disease (IBD) measures, and is developing measures to support care quality for Gastroesophageal Reflux Disease (GERD). Although developing outcome measures has proven to be more difficult than developing process and efficiency measures, the AGA shares the Bipartisan Chronic Care Working Groups' suggestion that a focus on health care outcomes for individuals with chronic conditions is desirable. The AGA's Quality Measures Committee (QMC) continues to work toward increasing the number of available outcome measures. For example, the AGA's "Hepatitis C Virus - Sustained Virological Response (SVR)" measure is included on the CMS "List of Measures Under Consideration for December 1, 2015." Achieving a sustained virological response to treatment is the first step toward reducing future HCV morbidity and mortality, and the AGA is committed to working closely with CMS and other stakeholders to prepare this measure for future implementation. Identification of potential outcome measure topics is given ongoing, priority consideration by the AGA as new clinical topics and measures are considered.

### **Expanding Access to Digital Coaching**

AGA agrees that Medicare.gov is an appropriate site to provide medically-related information and education tools to health beneficiaries. Tools and information on this site can educate patients about their health conditions and help them in self-managing their health. While there are other venues with credible, reliable information, having it together on one site better ensures beneficiaries can find and trust the information, rather than having them sort it out on their own. With that, those external credible, reliable sources can be used to gather appropriate information and tools. Medicare.gov is also a vehicle to aggregate patient education resources from trusted outside entities, like medical associations, that create information based on up-to-date clinical guidelines and current practice. AGA is in the process of creating patient specific information guides for a number of chronic GI conditions, such as inflammatory bowel disease, celiac disease, irritable bowel syndrome, cirrhosis, obesity and Barrett's esophagus, amongst others. Pertaining to the type of information to provide, AGA has found the following modules to cover many necessary topics per condition:

- What is the condition (a brief, general overview)?
- Common symptoms of the condition
- Risk factors for the condition
- Common tests for the condition
- Newly diagnosed with the condition (resources, life adjustments, medical team, etc.)
- Treatment options for the condition
- Possible complications/comorbidities or alarm symptoms
- Additional resources (external sites with trusted, reliable information on the condition or opportunities for social support)

We are available to discuss AGA's patient engagement program and materials being developed, which can be made available on Medicare.gov.

### **Increasing Transparency at CMMI**

Over the last several years, the AGA has worked with Congress and stakeholders in the provider community to advocate for enhanced transparency at CMS. Our goal has been to improve existing processes at CMS by increasing the amount of the stakeholder input and expanding the base of public comments to ensure that the regulatory process reflects the real-world experience of patients and physicians. We believe that these principles continue to be applicable to all programs that work to refine payment structures to improve care and reduce costs. This is particularly true for CMMI, which inherently depends on stakeholder involvement.

When it was created, CMMI was tasked with working alongside stakeholders to develop innovative new care and payment models that will improve quality while shifting the direction of our health care system to reward value instead of volume. The AGA is supportive of these goals and believes that CMMI has the potential to play a substantial role in improving care in a resource-efficient manner. Since its creation, CMMI has already made great strides, but we welcome the opportunity to provide comments on issues related to transparency because the statutory authority that allows for delivery models to be expanded and implemented without rigorous oversight could pose long-term threats to the success and sustainability of CMMI initiatives. The authority to adopt models without going through formal rulemaking applied to other payment and quality initiatives put forth by CMS fails to take into account the views of many patients and physicians that did not have the opportunity to participate in the early stages of creating the model.

Physician input plays an essential role in developing care and payment models that will result in meaningful change to the way that patients receive care. While the current structure at CMMI provides directly affected groups the ability to participate in model development at an early stage, we believe that opportunities for participation should be expanded. Allowing a wider base of public comment on CMMI proposals before broad expansion will ensure that input of stakeholders beyond the specific practice area or geographic setting initially studied is incorporated. Patients and providers that were not initially included in the model development may nonetheless have important suggestions that are relevant to broader audiences but weren't addressed early on. Expanded opportunities for participation will also help CMMI to prioritize projects based on additional input and provide greater oversight before models are finalized. We are concerned that CMMI is primarily focused on models around reducing hospital admissions that fail to recognize opportunities to develop episode / bundled payments for conditions that are primarily treated only in the outpatient setting, such as colorectal cancer screening, GERD and obesity. We further believe that enhancing transparency at CMMI will help to better maximize the model design factors adopted at CMS by providing valuable insight into factors such as the extent of clinical transformation involved, the scale and clinical diversity of proposed changes, feasibility and scalability of models, as well as whether the care experience sees significant improvement.

In addition to contributing to the development of better payment models, enhanced transparency at CMMI is important to ensuring that the process of developing new models is fair and accountable. Physicians throughout the country have seen payment and practice structures shift significantly over the last several years and face additional changes as the provisions of the Affordable Care Act continue to materialize and the changes included in MACRA are implemented. The major changes facing physicians necessitate the opportunity to participate in the rulemaking process and place a critical importance on whether physicians can accurately predict the requirements that they will face in the coming years. New payment models and care delivery mechanisms have the ability to result in major shifts after being deployed and the public should have the ability to provide comment before these models are finalized. Stakeholder input will also enhance the legitimacy of CMMI's efforts in the eyes of the public, which will be helpful when soliciting new participants.

The AGA believes that steps can be taken to increase public participation in CMMI processes while also respecting the importance of fostering the timely development of innovative payment models. For specific models that will be rolled out on a large scale, we believe that a public notice and comment period is appropriate. While we do not believe that minor changes to existing models always necessitate a full rulemaking process, we do believe that the public should be made aware of significant changes before they take effect and have the ability to provide input. We also suggest that the public

input requirement is of even greater importance for major initiatives such as the CCJR Model, which should trigger a formal rulemaking process that allows for stakeholder input throughout the development process.

### **Study on Obesity Drugs**

The AGA supports the Working Group's policy of requiring a study to determine the utilization and efficacy of obesity drugs on the Medicare and non-Medicare populations. With the approval of new medications to combat obesity, the AGA believes that determining the effectiveness in the Medicare population is critical to treating this epidemic. The AGA also supports S. 1509/H.R. 2404, the Treat and Reduce Obesity Act, which would cover behavioral therapy as well as medications to treat obesity under Medicare. This legislation and the proposed study are aligned with a multi-society initiative that the AGA has developed to improve interdisciplinary obesity care management and payment policy.

The AGA also recommends that the Committee consider requiring a study to determine the utilization and efficacy of endoscopic bariatric treatments since they are an equally important tool in fighting obesity which, like obesity drugs, are not always covered and reimbursed and often require out of pocket costs to the patient. In 2015, two endoscopically placed bariatric devices were approved by the FDA, and it is our understanding that several additional devices will be reviewed by the FDA during this year. These devices are successful, however, only within the context of a multidisciplinary coordinated care approach which incorporate pharmaceuticals, low-calorie diets, and behavioral, nutritional, and exercise modifications to support and sustain weight loss even after these devices are removed. These devices, which are safe and effective and not anatomy altering, are poised to be potentially important interventions to augment obesity treatment and potentially save the Medicare program by replacing costly anatomy altering surgical procedures which have significant side effects.

The AGA has created an Obesity Workgroup which incorporates experts on obesity including advanced practice professionals, endocrinology and metabolism, bariatric surgeons, interventional endoscopists, community gastroenterologists, pharmacologists and a psychologist specializing in behavioral interventions for GI disorders. Given the complexity of obesity as a chronic disease of multi-faceted origin, it requires an interdisciplinary approach to management including behavior modification, nutrition counseling, exercise, pharmaceuticals, and potentially minimally invasive endoscopic bariatric therapy. Incorporating drugs and new technologies to fight obesity will require comprehensive weight-management programs to support patients and monitor their safety before and after any treatment intervention. The AGA is developing guidance on how gastroenterologists can safely and effectively implement these new advances for bariatric therapy into their practices to advance care for people with obesity. The AGA recognizes the burden of obesity-related diseases on our health care system via direct and indirect costs. We are in the process of developing an obesity episode payment model that has the potential to improve the value of care for patients covered by Medicare, Medicaid, and private payors.

In conclusion, the AGA appreciates the opportunity to provide input on how we can improve the quality, value, and cost of care for patients with chronic conditions. We share your ambition for implementing payment and care models that demonstrate these goals in both the Medicare and commercial patient population. We look forward to working with you on this critical initiative to our health care system. Should you have any additional questions regarding AGA's projects, please do not hesitate to contact Kathleen Teixeira, Senior Director of Government Affairs at [kteixeira@gastro.org](mailto:kteixeira@gastro.org) or 240.482.3222.

Sincerely,



John I. Allen, MD, MBA, AGAF  
Chair