



January 26, 2016

VIA ELECTRONIC MAIL

The Honorable Orrin Hatch
U.S. Senate
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Mark Warner
U.S. Senate
475 Russell Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
U.S. Senate
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
U.S. Senate
131 Russell Senate Office Building
Washington, DC 205

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson and Senator Warner,

On behalf of Adventist Health System (AHS), the nation's largest not-for-profit Protestant health care provider, we appreciate the opportunity to provide comments on the Chronic Care Working Group Policy Options document. Our organization includes 44 hospital campuses located across 10 states and comprises more than 8,000 licensed beds. AHS provides inpatient, outpatient and emergency room care for four million patient visits each year.

AHS commends you and the other members of the Senate Finance Committee Chronic Care working group for recognizing the need to tackle this challenging issue. AHS welcomes the opportunity to further discuss policies that may improve the delivery of care for chronically-ill Medicare beneficiaries.

Our comments address the following policy options highlighted in your letter:

- Expand Access to Home Hemodialysis Therapy
- Establish A High-Severity Chronic Care Management (CCM) Code
- Waive The Beneficiary Co-Payment for CCM Codes
- Establish A One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness
- Allow Beneficiaries with End Stage Renal Disease (ESRD) Choose a Medicare Advantage (MA) Plan
- Improve the Integration of Care for Individuals With Chronic Diseases and Behavioral Health Disorders
- Expand Access to Digital Coaching
- Develop Quality Measures for Chronic Conditions
- Increase Transparency at the Center for Medicare and Medicaid Innovation (CMMI)

Expand Access to Home Hemodialysis Therapy

The working group is considering allowing the use of telehealth for Medicare beneficiaries receiving home dialysis. This would be accomplished by expanding Medicare's originating site definition to include a patient's home or a free-standing renal dialysis facility located in any geographic area.

According to Medicare, beneficiaries receiving home dialysis treatment may receive a clinical assessment via telehealth only if this visit occurs in 1) an authorized originating site (including a physician office and hospital-based dialysis facility) and 2) the site is located in a rural Health Professional Shortage Area (HPSA) or area county outside a Metropolitan Statistical Area (MSA).

The working group seeks feedback on whether expanded telehealth availability should include mandatory periodic in-person clinical visits (e.g., once every three to six months) and whether a patient's home is an appropriate originating site for a telehealth visit.

AHS supports the proposal to expand Medicare's originating site definition to allow dialysis patients to receive their clinical assessment at home via telehealth. Typically, patients with chronic conditions receiving hemodialysis therapy will require this three times per week. By eliminating existing limitations on what qualifies as an originating site, patients with mobility challenges will be able to have more flexibility and improved access to care. Moreover, studies have demonstrated that hemodialysis, when delivered in the home, results in faster recovery time after treatment, with fewer side effects, improved cardiac status and survival rates.¹

If the availability of telehealth is expanded, AHS recommends that at least one in-person visit take place periodically and that the patient be assessed, via telehealth, at least once per month. The visit could be conducted by a qualified nurse, preferably an Advanced Registered Nurse Practitioner (ARNP). The frequency of the in-person visit should be determined by the condition of the patient. Initially, the in-person visit could be required once every three months and then be extended to every six months, based upon empirical data supporting adequate management of the patient's condition.

Establish a New High-Severity Chronic Care Management (CCM) Code

The working group is considering establishing a new high-severity CCM code that clinicians could bill under the Physician Fee Schedule (PFS). The code would reimburse clinicians for coordinating care outside of a face-to-face encounter for Medicare's most complex beneficiaries living with multiple chronic conditions.

The working group specifically seeks feedback on:

- The patient criteria for the new high-severity code.
- The types of providers that should be eligible to use the code.
- Whether the code should be made permanent or temporary based on the Centers for Medicare and Medicaid Services (CMS) analysis of data and the effectiveness of the code.

¹ Heidenheim AP, Muirhead N, Moist L, et al. "Patient Quality of Life on Quotidian Hemodialysis." Am J Kidney Dis. 2003 Jul; 42(1 Suppl):36-41.

AHS supports the creation of a new high-severity code to account for the care delivered to beneficiaries with multiple chronic conditions. We agree that the current CCM code, which only accounts for 20 minutes of non-face-to-face care within a month, does not capture the time needed to manage a complex patient's care. There will be patients who may require more than 20 minutes of care within a month to appropriately manage their chronic conditions. Also, the care needed to treat a patient may vary considerably from month to month, resulting in additional resources that are currently not reimbursed under the existing CCM code.

AHS believes that the patient criteria for this new code should reflect the degree of severity of the chronic condition and not just the number of conditions. Depending on which chronic care conditions are present, this may result in a more complex condition and higher cost. For example, according to the Department of Health and Human Services (HHS), stroke and Chronic Kidney Disease (CKD) are the costliest dyad of chronic conditions.² The costliest triads included stroke, CKD and asthma or Coronary Obstructive Pulmonary Disease (COPD) with per capita costs that are seven times higher than the average spending for Medicare beneficiaries.³ When developing the criteria for this high-severity CCM code, the working group should consider including these top costly combinations of chronic conditions.

We recommend that the working group develop a criteria that includes:

- A patient with five or more chronic conditions.
- A patient with a high cost combination of chronic conditions, based on HHS data.
- A patient with one chronic condition and two limited Activities of Daily Livings (ADLs).
- A patient with Alzheimer's disease or related Dementia.

For dual eligible patients, the criteria needs to be modified to account for the higher prevalence of depression in this group and the impact of developmental disorders that would make certain patients classify as high-severity cases. According to CMS' data, dual eligible beneficiaries are more than twice as likely to have depression or Alzheimer's disease and 1.7 times more likely to have COPD.⁴

AHS recommends that the billing of the new CCM code be made exclusive to Primary Care Physicians (PCPs) and patient medical homes. PCPs maintain a continued relationship with their patients and coordinate the majority of their health care services. Therefore, limiting the billing of this code to PCPs will help ensure that patients receive consistent CCM services, while also avoiding any gaming of the Medicare system.

AHS also recommends that the new code be made permanent. We believe that this is necessary to ensure that physicians make extensive use of the code. If physicians believe that the code is temporary, they may be discouraged to learn its billing requirements and put it into place. Moreover, some codes may require the acquisition of additional software and adjustments to a provider's Electronic Health Records

² "HHS Education and Training Curriculum on MCC" Retrieved from:

<http://www.hhs.gov/ash/initiatives/mcc/education-and-training/framework-curriculum/introduction-module.pdf>

³ "Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chart book: 2012 Edition" Retrieved from: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>

⁴ "Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chart book: 2012 Edition" Retrieved from: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>

(EHRs). This involves time and resources that may not be worth spending if the code is only made temporary. For example, the current CCM code requires a provider's EHR to have a clock that captures the exact number of minutes spent with each patient. Many providers lack such a feature, making the \$42 a month per beneficiary reimbursement not worth the technology investments or additional work needed to start billing for the CCM code.

When determining the reimbursement for this high-severity code, AHS recommends that the working group consider a reimbursement greater than what is currently available under the existing CCM code. The time and cost of setting up systems to meet code requirements make it not worth the relatively small amount that Medicare pays for the existing code.

We also believe that the reimbursement of CCM services should be reevaluated to be better aligned with the reimbursement for other comparable services, such as Advance Care Planning (ACP).⁵ Currently, Medicare pays \$42 under the CCM code for 20 minutes of non-face-to-face care. These CCM services include communication with the patient and other providers for care coordination (both electronically and by phone), medication management and 24 hour accessibility to patients and other providers. In contrast, Medicare pays \$80 for 30 minutes of ACP services under code 99497 and an additional \$75 under code 99498 for each additional 30 minutes of ACP services. The ACP services include the explanation and discussion of advance directives with patients. We do not understand why CCM services are paid significantly lower than ACP services. **We recommend that the working group reevaluates the reimbursement of CCM services to reflect the work that is done to properly manage the care of the chronic care population.**

Waive the Beneficiary Co-Payment for CCM Codes

The working group is considering waiving the co-payment associated with the current CCM code and the proposed high-severity CCM code. It is soliciting input on the extent that waiving cost sharing would incentivize beneficiaries to receive these services, especially considering that many Medicare beneficiaries have supplemental Medigap policies or elect employer retiree coverage that provides supplemental coverage.

AHS supports waiving the co-payment associated with the CCM codes when there is not a Medigap policy or other coverage available to the patient. This will provide patients with an incentive to seek care and follow up. Co-payments for CCM codes may discourage patients from seeking these services, especially if the patients believe that they should already be receiving the CCM services. Moreover, waiving the co-payment may also encourage the use of these CCM codes by providers. Currently, Medicare pays 80 percent of the \$42 billable under the existing CCM code. Paperwork must be generated to bill the patient for the remaining cost, which may be difficult to collect. Furthermore, the administrative effort to collect the co-payment may not commensurate with the reimbursement of \$42. We recommend that the working group consider these issues when determining the billing requirements of the new high-severity code and the payment associated with it.

⁵ Codes 99497 and 99498 were created in the Physician Fee Schedule (PFS) Calendar Year (CY) 2016 Final Rule.

Establish a One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia and other Serious or Life-Threatening Illnesses

The chronic care working group is considering requiring CMS to implement a one-time payment to clinicians for discussing the progression of a serious or life-threatening disease and its treatment options. This is designed to recognize the additional time needed to have conversations with beneficiaries diagnosed with a serious or life-threatening illness, such as Alzheimer's disease or Dementia.

The working group is soliciting feedback on the scope of diseases that would be considered a serious or life-threatening illness and thus be eligible for a Medicare-covered planning visit.

AHS supports the creation of a one-time visit code post-initial diagnosis of a serious or life-threatening illness. As recognized by the working group, Medicare currently covers a patient's diagnostic evaluation but fails to provide any support on how to manage the treatment of the illness after the diagnosis is made.

We recommend that the working group consider the inclusion of illnesses known to be a common cause of death in the United States, within the scope of diseases covered by this code. This may include heart disease, cancer, CKD, chronic lower respiratory diseases, stroke, Alzheimer's disease and Dementia, diabetes, pneumonia, nephritis and nephrotic syndrome.⁶ We believe that patients diagnosed with these illnesses would benefit from receiving an initial patient consultation following their diagnosis.

To distinguish this code from other Medicare codes and avoid duplicate payments, AHS recommends that the one-time visit code be used as an initial consultation post-diagnosis, rather than as a CCM service. A modifier could be used with this code, which would only be used once a year per patient. The treatment plan may change over the course of a year and a planning code should be made available to reflect the difference of the time spent with the patient and their caregiver compared to just the ongoing management of the chronic condition. Additionally, this payment code must receive higher reimbursement than current Evaluation and Management (E&M) codes. When a patient initially receives the news that he or she has Alzheimer's or any other serious illness, the patient (as well as their families) often need time to digest the diagnosis and require a second visit to discuss this with their health care provider.

Allow Beneficiaries with End Stage Renal Disease (ESRD) Choose a Medicare Advantage (MA) Plan

The working group is considering allowing beneficiaries diagnosed with End Stage Renal Disease (ESRD) to enroll in a Medicare Advantage (MA) plan after being diagnosed with such illness. Beneficiaries with ESRD are currently excluded from joining an MA plan unless they developed ESRD while already enrolled in a MA plan. The group also solicits feedback on what quality measures are available to ensure that ESRD patients have the information needed to make an informed choice when deciding whether to enroll in a MA plan.

⁶ Centers for Disease Control and Prevention. "Leading Causes of Death." Retrieved from: <http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

AHS supports allowing ESRD patients to enroll in MA plans. It is our belief that the current exclusion leaves beneficiaries who have ESRD with few coverage options. In 2000, the Medicare Payment Advisory Commission (MedPAC) recommended removing the prohibition of MA as a choice for ESRD patients.⁷ An ESRD Managed Care demonstration conducted by CMS also showed that patients diagnosed with ESRD could benefit from being enrolled in a MA plan. The demonstration sought to evaluate the efficacy and cost of MA participation for Medicare beneficiaries with ESRD. Although the demonstration did not generate any savings to the Medicare program, the results suggest that ESRD patients in MA plans can fare as well as, or better, from a clinical perspective, than they would under traditional Medicare. ESRD patients enrolled in MA plans also experienced some improvement in quality of life, particularly in mental wellbeing.⁸

To assist Medicare beneficiaries in choosing a MA plan, the working group should consider requiring MA plans to provide information on the following issues:

- **Training and Education**
 - The MA plan's coverage of training and education on how to manage ESRD (e.g. nutrition, diabetes care, weight management, blood pressure monitoring, etc.).
- **Case Management Services**
 - The MA plan's coverage of the following services:
 - Designated Case Manager and/or field nurse available for in-home visits.
 - A 24/7 information line to answer questions or provide patients with recommendations if assistance is needed.
 - Coordination of appointments.
 - Transportation services.
- **Access to Dialysis Treatment**
 - The number of dialysis centers the MA plan is contracted with. This will allow beneficiaries to assess their access to dialysis treatment.
- **Coverage of Home Dialysis and Self-Dialysis Treatment**
- **Coverage of Telehealth Services**
- **Authorization Process for Dialysis Treatment**
 - A description of the MA plan's process to authorize dialysis treatment. If a patient needs dialysis treatment and the MA plan does not have a streamlined authorization process, the patient may have to wait for this treatment, which could be life-threatening to an ESRD patient and result in hospitalization.
- **Access to Preventive Care**
 - The MA plan's coverage of the following services:
 - Blood pressure readings
 - Anemia management
 - Nutrition and weight management services
 - Diabetes and hypertension clinics
 - Eye care and foot care for diabetics

⁷ Medicare Payment Advisory Commission, Report to Congress: March 2000, page 143

⁸ "Quality of Life and Patient Satisfaction: ESRD Managed Care Demonstration." Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/03summerpg45.pdf>

- **Hyper Calcium Levels of Patients**
- **Hemoglobin Levels of Patients**
- **Vaccination Status of Patients**
- **Hospitalization Rates of Patients**

Integrate Care for Individuals with Chronic Diseases and Behavioral Health Disorders

The working group is seeking policy proposals to improve the integration of care for individuals with a chronic disease combined with a behavioral health disorder.

AHS commends the working group for its effort to improve care for patients with chronic and behavioral health conditions. As recognized by the working group, there is a significant relationship between behavioral health and chronic diseases. For example, depression is found to co-occur in 17 percent of cardiovascular cases, 23 percent of cerebrovascular cases, 27 percent of diabetes patients and more than 40 percent of individuals with cancer.⁹

To accomplish the goals of the working group, AHS recommends the adoption of the following policies:

- **Increase access to behavioral health services.** The significant shortage of behavioral health providers is a major obstacle to improving care coordination. Many clinicians may find it difficult to improve care coordination for patients with chronic care and behavioral health disorders because they cannot find a provider to refer the patient. According to the Health Resources and Services Administration (HRSA), 96.5 million Americans were living in areas with shortages of mental-health providers as of September 2014.¹⁰ There has also been no increase in federally funded Graduate Medical Education (GME) slots to train physicians, which contributes to the shortage. We believe that improved funding for behavioral health services, as well as coverage of technology such as telehealth, will help increase access to behavioral health services.
- **Integrate behavioral health and primary care.** Specifically, we recommend allowing the billing of behavioral and primary care services on the same day. It is our experience that a “warm hand-off” between physical and behavioral health providers can improve a patient’s coordination of care. This “warm hand-off” in the PCP consists of introducing the patient to the behavioral health provider at the time of the medical appointment. The goal of this approach is to establish an initial face-to-face contact between the patient and the behavioral health provider to help ensure treatment compliance. As the federal regulations currently stand, a physician’s office will need to make the patient return on a different day for the behavioral care. This leads to lack of follow up as patients with chronic conditions may have several ADLs that make transportation to the physician’s office very difficult. Moreover, the potential stigma associated with behavioral health care may dissuade the patient from seeking those services.

⁹Centers for Disease Control and Prevention (CDC). “Mental Health and Chronic Disease Issues Brief” Retrieved from: <http://www.cdc.gov/nationalhealthyworksites/docs/Issue-Brief-No-2-Mental-Health-and-Chronic-Disease.pdf>

¹⁰ Wall Street Journal. “Where are the Mental Health Providers?” Retrieved at <http://www.wsj.com/articles/where-are-the-mental-health-providers-1424145646>

- **Develop evidenced-based behavioral health tools designed for primary care.** We believe that this will help improve the screening and treatment of behavioral health conditions within a primary care setting. This is particularly important as most chronic conditions are treated by PCPs. We recommend that the working group seek guidance from the National Institute of Mental Health (NIMH) when developing these evidenced-based behavioral health tools.

Expand Access to Digital Coaching

The working group is considering requiring CMS to provide medically-related information and educational tools on www.Medicare.gov to help beneficiaries learn more about their health conditions. The working group seeks comments on the type of information that would be most helpful for beneficiaries.

AHS recommends that CMS certify existing websites containing this educational information, rather than using Medicare's website for that purpose. In our opinion, using Medicare's website for digital coaching would duplicate existing resources that are available on other websites. We believe that certifying other websites based on the quality of their content and listing their links on the Medicare website would be more appropriate.

AHS believes that beneficiaries may benefit from information such as: the description of chronic care conditions and their symptoms, common treatment protocols, self-management options, information on what has shown to be ineffective, and education on when to call a doctor versus when to go to the Emergency Department (ED). This information should be clear and simple. A feedback loop that allows for patient suggestions on what is helpful, as well as a customer rating system for these websites, would be beneficial to beneficiaries seeking more information regarding their health care.

Develop Quality Measures for Chronic Conditions

The chronic care working group is considering requiring that CMS include in its quality measures plan, the development of measures that focus on the health care outcomes for individuals with chronic disease. Specifically, this includes the following topic areas:

- Patient and family engagement
- Shared decision-making
- Care coordination
- Hospice and end-of-life care
- Alzheimer's and Dementia
- Community-level measures

AHS believes that it is critically important to utilize meaningful quality measures for chronic conditions. There is already an abundance of quality measures in existence. Therefore, rather than create additional measures, AHS believes that we should utilize existing measures and adapt them for the population at hand. We recommend that patient populations be stratified by age and socioeconomic status. Moreover, quality measures have been developed for the general population and therefore may not always apply to the chronic care population. For example, appropriate glucose levels for a 98 year old patient may vary from the appropriate glucose levels of a 68 year old.

Increase Transparency at the Center for Medicare and Medicaid Innovation (CMMI)

The chronic care working group is considering modifications that would require CMMI to either:

- Issue notice and comment rulemaking for all models that affect a significant amount of Medicare spending, providers or beneficiaries; or
- Issue notice and comment rulemaking for all mandatory models and at least a 30 day public comment period for all other innovation models.


AHS recommends that rulemaking be required for all models being proposed by CMMI. We also believe that the public comment period should be no less than 60 days. In our experience, a 30 day comment period is too short to get meaningful input from clinical areas that have the expertise to evaluate the proposal. After the public comment opportunity, any modifications or model terminations should be handled by public notification through the Federal Register. The changes would be considered interim final rules.

As we seek solutions to more effectively manage the care of our chronic care population, health care delivery models will need to adapt. As recognized by the working group, beneficiaries with chronic conditions contribute significantly to the rise of Medicare spending. Therefore, health care delivery and payment models must be designed to encourage better health care coordination and reduced costs. To do this, health care providers must achieve clinical and financial integration.

As we continue to move away from a largely Fee-For-Service (FFS) payment system and towards one based on value, it is critical for health care providers to embrace alternative delivery models that meet the needs of our chronic care population. However, the regulatory environment, which was born out of the FFS payment system, limits the ability of providers to integrate clinically and financially. The Stark and the Anti-Kickback statutes exemplify this issue. Under these statutes, hospitals attempting to work with physicians and other health care professionals across different health care settings, to achieve care coordination, face significant legal barriers. These statutes need to be modified to reflect changes in the delivery of care. CMS has recognized this need by allowing other delivery and payment models, such as Accountable Care Organizations (ACOs), waivers to these regulatory barriers. As we work to develop sound policies to guide the development of alternative payment and delivery options in order to improve the care of our chronic care populations, we believe this needs to be considered.

We commend the working group for its efforts to address chronic health care issues and improve patient care. I appreciate the opportunity to provide input as you develop legislation addressing chronic care. We look forward to further discussions on this issue.

Sincerely,



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