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SUBJ: Proposed CMS Revisions to Payment Policies Published in 7/15/2015 Federal Register:
Comments on Collaborative Care Models for
Beneficiaries with Common Behavioral Health Conditions

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Thank you for this opportunity to offer our comments and recommendations on the questions raised by CMS in the July 15, 2015, *Federal Register* in regard to the following *Register* sections:

E. Improving Payment Accuracy for Primary Care and Care Management Services
1. Improved Payment for the Professional Work of Care Management Services
2. Establishing Separate Payment for Collaborative Care
a. Collaborative Care Models for Beneficiaries With Common Behavioral Health Conditions

The Collaborative Care Model (CoCM) that CMS refers to in the *Register* has compelling scientific data supporting its effectiveness. Over 80 randomized controlled trials have shown that Collaborative Care is more effective than care as usual. Several studies have also demonstrated that the CoCM is more cost-effective than care as usual, a finding that has tremendous importance given the high costs associated with mental health and substance use disorders.

In addition to this rigorous research evidence, there is also substantial practice experience with Collaborative Care from the Mental Health Integration Program in Washington State, serving Medicaid Expansion populations and other safety net patients; the commercially funded DIAMOND program in the State of Minnesota; and similar programs in several other states.

The need for more effective treatment of individuals with behavioral conditions in primary care settings is a significant health policy issue. The lack of reimbursement for key components of Collaborative Care has been the principal barrier to widespread implementation. Data shows that while depression and other common mental disorders are associated with high health care costs, only about 25% of the patients who experience these disorders receive effective care. The majority of adult patients with mental health disorders receive their health care in primary care, but only a minority will receive effective behavioral health care in usual primary care practices.

The Collaborative Care Model for which we have the strongest evidence base is team-based care in which primary care providers who are treating patients with common behavioral health problems are supported by a behavioral health care manager and a psychiatric consultant. The widespread implementation of the CoCM under both fee-for-service payment and value-based purchasing could dramatically improve access to effective behavioral health care while at the same time reducing high health care costs associated with common mental health and substance use disorders (*Milliman-Report-Economic-Impact-Integrated-Implications-Psychiatry*).

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These considerations will only grow in importance as the health insurance expansion programs under the Affordable Care Act take hold. It is also important to note that coverage for Collaborative Care has important positive implications for ongoing CMS care-delivery and payment initiatives. For example, one of the most successful pioneer Accountable Care Organizations (ACOs), the Montefiore Medical Center, utilizes a Collaborative Care approach as part of its overall delivery strategy (*www.montefiore.org).* While previous reviews suggested that relatively few ACOs were pursuing innovative models such as the CoCM, the AIMS Center is currently working with more and more ACOs to adopt CoCM as a part of their model of care in order to address the medical and behavioral health needs of complex patient populations.

The Collaborative Care Model includes three basic elements: 1.) care coordination and care management; 2.) regular, proactive outcome monitoring and treatment to target using validated clinical rating scales; and 3.) regular, systematic psychiatric caseload reviews and consultation for patients who do not show clinical improvement (*CMS IRC-Collaborative Care Model May 2013*). Based on the overwhelming evidence base for this model, CMS should adopt a payment methodology that enables covering Collaborative Care on a national basis. We have developed our comments based on the questions raised by CMS in the *Federal Register* about the implementation of the CoCM.

We would like to point out that there are numerous variations on the treatment of behavioral conditions in primary care settings that are often referred to as "collaborative care" or "collaborative integrated care." However, these variations are not included in our comments because they do not incorporate all the essential features of the CoCM. Moreover, they often do not have the same evidence base supporting their effectiveness (see Attachment A, *Other Approaches to Integrating Behavioral Health into Primary Care*).

In our comments below, we are referring specifically to the care provided in the CoCM. The Kennedy Forum's recent issue brief, *Fixing Mental Health Care in America: A National Call for Integrating and Coordinating Specialty Behavioral Health Care with the Medical System,* provides an excellent overview of the model. We also submit that brief for CMS reference.

How could coding under the Physician Fee Schedule (PFS) facilitate appropriate valuation of the services furnished under the collaborative care model?

We recommend the development of codes and requirements for their use that are specific to the Collaborative Care Model (CoCM) for behavioral health conditions. Coding could facilitate appropriate valuation of the services furnished under CoCM if it accomplishes the following:

1. Explicitly incorporates the clinical approach and processes required for an effective implementation of evidence-based Collaborative Care; and
2. Accurately describes the work entailed in each of the explicit functions for each of the key members / providers on a Collaborative Care team.

There are three key providers required for the model: a primary care provider (PCP), a behavioral health care manager with adequate clinical supervision, and a psychiatric consultant. Two of these roles, the care manager and psychiatric consultant, are new for routine Medicare or Medicaid reimbursement in the treatment of behavioral health conditions in primary care (outside of research and practice demonstration studies including Medicare and Medicaid patients, several CMMI demonstrations, and select implementations by commercial and Managed Medicaid plans). The functions and responsibilities of these two new team members have standard descriptions, which have been developed for the model and validated in research and real world implementations of Collaborative Care. Evidence- and

experience-based summaries of these requirements are available from the University of Washington's AIMS Center in the form of sample job descriptions and job requirements for the care manager (*Care Manager Job Description*) and for the psychiatric consultant (*Psychiatric Consultant Job Description*).

Under the CoCM, the role of the PCP in treating patients with common behavioral health disorders includes the use of standardized outcome measures such as the PHQ-9 for depression, involvement of the behavioral health care manager in the care of the patient, and consultation with the psychiatric consultant for patients who are not improving.

Should separate codes be developed for the psychiatric consultant and the care management components of collaborative care services?

Our review of current CPT and other HCPCS codes did not yield any that accurately describe the functions and services of a care manager and the services provided by the psychiatric consultant for the Collaborative Care Model (CoCM). Moreover, their functions and services in a CoCM far exceed the level of service imbedded in most of the current care coordination codes such as CPT code 99490.

Consequently, fitting the CoCM and its functions into this code would carry a substantial risk that the effective care and treatment elements and algorithms of the CoCM would be lost. We envision codes developed for the CoCM as being specific to the CoCM and, in key respects, distinct from the CCM code. We view the CCM code as an essential code with a more generalized set of functions.

Therefore, we think that new codes need to be developed to properly value CoCM services provided. This could be structured as one bundled payment code that covers the primary care practice costs for both care management functions and psychiatric consultation. Alternatively, CMS could create two separate CoCM codes: one for care management functions in the primary care practice and one for the psychiatric consultation to the primary care team.

Under either coding structure, the care management functions covered will include duties of the behavioral health care manager such as patient education, outcomes tracking, coordination of care with primary care providers and psychiatric consultants, support of medication management, and evidence-based psychosocial interventions such as brief counseling or psychotherapy, facilitation of specialty referrals as needed, adequate clinical supervision of the care manager, routine use of patient outcomes using validated outcome measures such as the PHQ-9 for depression, and use of information technology such as a case registry to track clinical outcomes for all patients in care. Psychiatric consultation services will include regular (usually weekly) review of all patients enrolled in CoCM and treated in primary care who are not improving, diagnostic and/ or treatment recommendations to the primary care team, and availability for curbside consultation to primary care providers during work hours.

Should a code similar to the chronic care management (CCM) code be used to describe collaborative care services as well as other inter-professional services, or should the care be reported using the CCM codes and other E/M service codes?

We think a code or codes similar to the CCM code should be used to describe both the essential processes and essential services entailed in CoCM. The work of the behavioral healthcare manager and psychiatric consultant in an evidence-based CoCM is distinct from the work captured by the existing CCM code and substantially exceeds the level of service of that provided by the CCM care manager. The work entailed in the CoCM functions has been clearly detailed and tested over time, and the work is

described in a manner that allows it to be valued in the context of the RBRVS. Also, the essential role of the psychiatric consultant is not captured in the CCM codes or in extant E/M codes. The services for the CoCM are not adequately captured or valued in existing CCM or other E/M service codes and should not be reported using such codes.

Are there requirements similar to those for the CCM services that would be appropriate for a specific collaborative care code?

There are a number of issues that require review and specifications for new codes for CoCM that are similar to those for the CCM services. These would include the following:

- Provider eligibility to bill the codes
- Level of supervision under the *incident to* rules
- Patient eligibility
- Patient agreement requirements
- HIT requirements
- Other billing requirements

While we think there is similarity at a general level between the requirements of the CCM codes and codes for the CoCM, the actual details and resource requirements vary, especially given the fact that the new codes would be directed at evidence-based treatment for behavioral health conditions.

What resource inputs could CMS use to value the collaborative care services under the PFS (e.g., work RVUs, time, and direct practice expenses)?

We think the standardized valuation inputs of work and direct practice expenses under the RBRVS paradigm would be appropriate to use in valuing new codes for the CoCM. Based on currently operating models, which supply a rich experiential base to draw from, we project that the new CoCM codes would have defined time elements, available reference codes for valuing the work components of the care manager and psychiatric consultant, and actual data to define direct practice expenses. Fortunately, there is a substantial base of operating experience with the CoCM in diverse practice settings and with diverse patient populations for CMS to draw on in defining both the work and pricing components.

How could the resources involved in furnishing collaborative care services be incorporated into the current PFS codes without overlap?

We do not think there are any significant code overlap issues. Our view is conditioned by the fact that and actual code or codes has not yet been developed, and coding would be subject to the established vetting protocols of the AMA/Specialty Society RVS (RUC) and CMS. All face-to-face patient care encounters performed by the PCP or psychiatrist are currently covered by existing E/M codes but, while essential, these codes do not cover key components of the CoCM that involve care management functions and regular psychiatric case reviews of defined patient populations and development of diagnostic and treatment recommendations that do not involve face-to-face patient contact. The work performed by the psychiatric consultant is not captured by the pre- and post-service times or work times included in the E/M codes. The CoCM psychiatric consultant work is new, different and specific to the CoCM.

How do collaborative care services overlap with quality reporting requirements?

Collaborative Care Models (CoCM) are designed to deliver measurement-based treatment to target. To this end, such models track clinical process and outcomes, i.e., population-based screening and assessment using standardized instruments; initiation of evidence-based treatment for people who screen positive for behavioral health disorders; systematic clinical outcomes assessment at defined intervals; inter-professional consultation and treatment adjustment for patients who are not improving; and population-based measurement of remission/recovery. Such measurement is central to care coordination for patients receiving care under the CoCM; and it can also be used to monitor performance at the provider, clinical, and/or system level.

For patients with depression (the predominant behavioral health diagnosis in primary care), the performance of CoCM programs should be monitored via at least two quality measures: (1) a measure showing that PCPs are identifying people with depression, via regular/universal screening, and clinical assessment of people who screen positive, using a standardized/validated instrument; and (2) a measure showing that people with depression are remitting/recovering. As of 2015, CMS already requires both types of measures for depression as part of its Quality Measures and Performance Standards for the Accountable Care Organization Shared Savings Program (*Medicare Shared Savings Program Quality Measures*).

It is important that primary care practices use both of these measures, rather than just one or the other. Prior research indicates that screening and case identification are not sufficient to improve patient outcomes. If a practice adopts the outcome measure but not the screening/assessment measure, then they may tend to avoid identifying people with depression and focus mainly on patients with good prognosis or many patients will not receive sufficient treatment to target to achieve a remission of symptoms. Research on patients who have been identified with depression in primary care shows that as few as 19 % of patients have substantial improvement in symptoms after a course of usual care treatment.

For other behavioral disorders treated via the CoCM, analogous measures should be used to ensure population-based identification of patients with a given condition, and to track rates of remission and recovery. Standardized and validated screening and outcome instruments exist for most common behavioral disorders, including the Generalized Anxiety Disorder (*GAD7*) scale, the PC-PTSD for post-traumatic stress disorder (*pc-ptsd*), the AUDIT for alcohol use/abuse (*Audit*) and the adult self-report scales for ADHD (*ASRS)*. To the maximum extent possible, quality and outcome measures should be based on standardized instruments that can be used both for screening and assessment and for tracking or remission or symptoms and recovery.

We also recommend that pay-for-performance mechanisms be put in place for all Collaborative Care programs. Incentives should hold providers accountable for assisting their patients to achieve measurable clinical improvements or remission in common mental health disorders.
For some complex populations, including many of those who are dually eligible for Medicaid and Medicare and those who have more severe mental illnesses along with co-morbid medical conditions, achieving remission may be difficult and may take longer than for other populations. In these circumstances, we recommend that pay-for-performance strategies be tied to evidence of fidelity to the CoCM. For example, a measure might reflect evidence of treatment intensification toward a measurable clinical target or goal.

Are there appropriate care delivery requirements for billing CoCM services?

In our view, this question partially overlaps with the question on requirements addressed above. Regardless, there are a series of care delivery requirements dictated by the model that would also be appropriate requirements for billing. For example, screening with appropriate validated clinical rating scales would be an essential billing requirement. The use of a registry or a registry function embedded into an electronic medical record should be required for effectively and efficiently tracking the care manager's caseload and patient outcomes and for systematically identifying patients who should be reviewed by the psychiatric consultant, documenting weekly caseload reviews with the psychiatric consultant, and documenting diagnostic and treatment recommendations by the psychiatric consultant.

Are there necessary qualifications for psychiatric consultants and are there particular conditions for which payment would be more appropriate than for others?

There are necessary qualifications for both the psychiatric consultant and the care manager. Evidence- and experience-based summaries of these requirements are available from the University of Washington's AIMS Center in the form of sample job descriptions and job requirements for the care manager (*Care Manager Job Description*) and for the psychiatric consultant (*Psychiatric Consultant Job Description*).

We do not think there are particular diagnostic conditions that would be more appropriate for payment as long as the new codes track the clinical approach and processes defined by the CoCM. Research evidence and extensive experience with the CoCM model in a Managed Medicaid environment in Washington State suggests that with appropriate psychiatric support, a wide range of mental health and substance use disorders can be effectively treated in a primary care setting. We expect, however, that most primary care practices would use CoCM programs to treat patients with the most common behavioral health disorders managed in primary care including depression, anxiety disorders, attention deficit disorder, and substance use disorders such as alcohol or opiate misuse.

Are the CCM technology requirements or other technology requirements appropriate for these services?

Technology requirements associated with the evidence-based CoCM are derived from the scope of service and care delivery requirements. Essential to effective Collaborative Care are the routine use and tracking of patient outcome using validated rating scales such as the PHQ-9 for depression, tracking of treatments used such as pharmacological or psychosocial treatments, and clinical outcomes in entered into a registry to avoid patients falling through the cracks or patients remaining on ineffective treatments for too long. Such registry functionality can be incorporated in electronic health record systems or provided through a separate registry tool. Clinical information such as diagnostic recommendations and interventions, treatment recommendations and treatments used, and relevant clinical outcome measures should be recorded in the patient's medical record where they will be easily available to all team members including the PCP, the care manager, and the psychiatric consultant.

Should written consent for the non-face-to-face parts of collaborative care be required before such collaboration occurs, and, if so, how should this be done?

Primary care providers routinely treat patients with behavioral health problems and the evidence for the CoCM in primary care is so substantial that we do not believe that a specific consent for behavioral

health collaborative care is indicated or necessary for implementation of the CoCM. Requiring special informed consent for participating in the CoCM in primary care would single out patients treated for a behavioral health problem and, given the stigma associated with behavioral health problems, might reduce access to this essential and effective service.

As with other medical or mental health conditions, we believe that general consent to confer with relevant specialists including a psychiatric consultant should be obtained prior to enrolling patients into treatment in primary care, and this should include participation in collaborative care management in practices where such a program is offered.

How could CMS assess the application of the collaborative care model for other diagnoses and treatment modalities? Are there particular conditions for which payment would be appropriate?

The Collaborative Care Model (CoCM) is appropriate for patients with any behavioral health diagnosis (e.g. ICD-9 codes 290-318) that is being treated by the PCP. In the Collaborative Care literature of randomized controlled trials reviewed by the Cochrane Collaboration and others, there is strong evidence of effectiveness and cost-effectiveness for a wide range of behavioral disorders, including depression and other mood and anxiety disorders. There is also extensive practice evidence that more severe mental health disorders such as bipolar disorder can be treated effectively in primary care with a CoCM as long as there is sufficient involvement and support from a psychiatric consultant. Many substance use disorders can be effectively treated in a primary care clinic that has a CoCM in place that includes evidence-based treatment approaches such as screening, brief intervention, and referral to treatment (SBIRT) or medication assisted management of disorders such as alcohol or opioid dependence.

Based on the experience with mature CoCM programs, we assume that patients with more severe mental health disorders and substance use disorder will be referred to specialty behavioral programs after thorough assessment and psychiatric consultation. The care manager will be able to assist in the referral process in order to have a successful connection.

We would be concerned that covering only some behavioral health diagnoses but not others is likely to lead to modification of diagnoses to suit the coverage rules (especially in light of substantial symptom overlap, and co morbidity, between various psychiatric and substance use disorders). Also, the reality is that many patients may not have access to specialty care or may chose for other reasons to remain in primary care. Several studies have shown that over half of all counties in the US have no behavioral health professional so the only available care is through a primary care practice.

Experience from both research-based and ongoing implementations of Collaborative Care, such as in Washington State's Mental Health Integration Program (MHIP), suggests that a wide range of mental health and substance use disorders can be effectively treated in a primary care setting, with appropriate psychiatric support and care coordination. We expect, however, that most primary care practices would use the CoCM to treat patients with the most common behavioral health disorders managed in primary care, including depression, anxiety disorders, attention deficit disorder, and substance use disorders such as alcohol or opiate misuse.

Should the collaborative care model be implemented through a CMMI demonstration that would allow Medicare to further test its effectiveness with a waiver of beneficiary financial liability and/or through a variation of payment methodology and amounts for the psychiatric consultant and the primary care staff?

Based on more than 80 randomized controlled trials and large-scale practice experience that have included all major payer types (Medicare , Medicaid, and commercial insurance), we do not believe that there is a need to further study variations in payment methodology or in establishing payment amounts for the CoCM. Extensive research and practice experience with the CoCM exists to enable the development of specific codes and appropriately value these codes. We strongly encourage CMS to proceed to establishing payment for evidence-based the CoCM without additional demonstrations.

Our review with CoCM experts indicates that patient co-payments can be an impediment to the use of care management services and psychiatric consultation, both of which are key components of evidence-based CoCM. For example,some practice sites in Minnesota's DIAMOND program did require patient cost-sharing (ICSI Diamond for Depression), and it was found that cost-sharing for CoCM services and associated requirements for explicit patient consent were barriers to care. We suggest moving ahead with establishing payment methods that do not require patient co-payments.
Most research-based and ongoing implementations of the CoCM have not required patient cost-sharing. Importantly, the consistent finding that Collaborative Care is cost-effective, and cost-saving is based on programs without cost-sharing. This body of evidence represents a very strong basis for covering the CoCM in Medicare – without patient cost-sharing for care management or for psychiatric consultation.

ATTACHMENT A:
Other Approaches to Integrating Behavioral Health into Primary Care

This appendix provides a high level overview of the evidence base regarding other approaches used to integrate behavioral healthcare into primary care settings. These approaches include screening for common mental health disorders, co-location of mental health providers in primary care clinics, provider education and training, facilitated referral to mental health specialty care, and telephonic disease management programs. These approaches, if applied in isolation from other delivery strategies, have not been found to improve patient outcomes or reduce costs when compared to usual care.

Screening for Common Mental Health Disorders

Although some studies have shown that screening through the use of brief structured rating scales that measure the severity of psychiatric symptoms is helpful in detecting mental health disorders in primary care, the research clearly indicates that screening alone is not sufficient to improve outcomes for patients*.* A Cochrane review found that patients with depression randomized to depression screening did not have better outcomes than patients randomized to usual care.[i]

Co-Location of Mental Health Specialists

Another approach to improve care for patients with behavioral health problems is to simply co-locate mental health specialists within primary care clinics. The research literature on co-location is limited; several studies demonstrate that co-located behavioral health specialists can deliver effective interventions in the primary care setting[ii,iii,iv] , but a large randomized controlled trial (RCT) comparing co-located care to referral found no differences in outcomes and somewhat worse outcomes for patients with more severe symptoms.[v,vi] Co-located care improves access and provider satisfaction, but without tracking at the population level or measurement-based treatment change when patients are not improving, it doesn't work much better than usual care

Co-location does increase the opportunity for the behavioral health specialist and primary care provider to consult on patients, either informally or formally.[vii] Co-location, however, does not ensure that providers collaborate effectively in the treatment of shared patients. Overall, simply co-locating a mental health provider into primary care without effective collaboration between mental health and primary care providers and without the use of evidence-based treatments has not been shown to improve health or mental health outcomes at a population level.

Primary Care Provider Education and Training

Primary care practices are the *de facto* location of care for common mental health disorders and numerous education and training programs have been developed to improve primary care providers' ability to treat psychiatric disorders. Approaches range from structured training programs that teach providers how to detect and treat psychiatric disorders, to training in the use of evidence-based treatment guidelines to be followed when treating psychiatric disorders. However, even the most comprehensive of these programs resulted in only minimal or short-lived changes in providers' practices and patient outcomes.[viii,ix,x]

Facilitated Referral to Specialty Mental Health Providers

Patients who are referred to specialty mental health providers, similar to being referred to a cardiologist or a pulmonologist, often fail to follow through with their referral, especially those in ethnic minority groups.[xi,xii,xiii] Those who do follow through often don't stick with care long enough to get effective treatment.[xiv,xv] To address this problem, researchers developed the enhanced, or facilitated, referral model, where supports such as free transportation and follow-up reminders were used to increase the likelihood of follow-through. Research on facilitated referral suggests that enhanced referral is less effective than co-locating mental health specialists in primary care settings with regard to promoting the use of specialty mental health services.[xvi,xvii]

Even if facilitated referral was effective, there are not enough specialty mental health providers available to refer all patients in the first place. Primary care providers experience specialty mental health providers as being far less available than other specialists.[xviii,xix,xx] Referral to specialty mental health services is helpful and necessary for some individuals, and we recommend primary care practices make every effort to facilitate referrals as this will improve outcomes for those people who do connect with the specialty mental health system and engage in treatment. There is little evidence that enhanced referral assistance alone can improve patient outcomes at the population level.

Telephonic Disease Management Programs

In telephonic disease management programs, nurses from a centralized call center operated by the health plan or a disease management firm are usually working off-site and in relative isolation from the primary care providers who are treating the patient while they attempt to support treatment provided in primary care. There have now been several large studies of such disease management programs, and they have generally not been shown to improve disease outcomes such as depression or other behavioral health conditions or to reduce health care costs when these programs are separated from the treating providers.[xxi,xxii]

A critical element missing from the disease management model is that nurses do not communicate directly with the primary care providers and they do not provide evidence-based treatments for depression. Rather, they attempt to educate and activate patients to improve communication with their provider. In effective Collaborative Care programs, care managers who are closely supported by psychiatric consultants work directly with patients, provide evidence-based treatment such as brief evidence-based psychotherapies, and are in close and direct contact with the patients' primary care providers who remain in charge of the patient's overall care.

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