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January 25, 2016

To: Bipartisan Senate Finance Committee Chronic Care Working Group
Chronic_care@finance.senate.gov

Dear Senators:

On behalf of the University of Michigan's Institute for Healthcare Policy & Innovation (IHPI), I am submitting the following comments regarding the December 2015 Policy Options Document of the Bipartisan Senate Finance Committee Chronic Care Working Group. We appreciated meeting with the Working Group staff this Fall and enthusiastically support the Working Group's goal to develop policy options based on data-driven input.

IHPI is a leading university-based institute of health services researchers who evaluate and investigate questions about effectiveness, access, value, affordability, quality, and safety in healthcare. More than 460 University of Michigan researchers from across 17 schools, centers, and institutes at the university (including public health, medicine, nursing, social work, pharmacy, dentistry, public policy, law, business, and others) collaborate at IHPI on research studies and innovations in healthcare delivery and technology to enhance the health and well-being of local, national, and global populations. Together we oversee more than $600 million in active research grants.

The following document is a compilation of comments from researchers who have a particular focus on Medicare and/or the questions posed by the Senate Working Group on these issues:

- Improving Care Management Services for Individuals with Multiple Chronic Conditions
- Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries
- Adapting Benefits to Meet Needs of Chronically Ill Medicare Advantage Enrollees
- Maintaining ACO Flexibility to Provide Supplemental Services
- Eliminating Barriers to Care Coordination under Accountable Care Organizations
- Expanding Access to Prediabetes Education

If you have questions or would like to further discuss our comments, please contact Eileen Kostanecki, the IHPI Director of Government & External Relations, at 202-554-0578 or ekostan@umich.edu. Thank you for your consideration.

Sincerely,

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Improving Care Management Services for Individuals with Multiple Chronic Conditions

Patient Criteria for a Potential New High-Severity Chronic Care Management Code

Debate continues on the more than 100 definitions used to measure and define multimorbidity, or the coexistence of multiple chronic conditions. One of the most commonly used measures is the disease count, which measures the number of chronic conditions that a patient has. While the disease count can be easily computed in medical claims data, this count alone is not sufficient for identifying patients with the most complex or severe chronic conditions.

First, ambiguity persists around which conditions should contribute toward the disease count.

Second, the disease count does not account for the diversity and severity of diseases. Both common and rare diseases can have a wide-ranging impact on health-related quality of life. Treating diseases equally, such as in a disease count, may oversimplify their full impact on patient health and associated healthcare cost and utilization.

Third, a simple count will underrate morbidity in individuals with single but devastating diseases. For example, an individual with severe multiple sclerosis in isolation would not be considered to have multimorbidity despite having several-fold worse health-related quality of life, utilization, and cost, than an individual with multiple, less severe conditions. For example, hyperlipidemia and hypertension are among the most prevalent chronic conditions, but for many individuals these conditions become stable and well controlled on medication with minimal or no symptoms or impact on health-related quality of life.

Finally, the disease count fails to recognize the important role of socioeconomic factors in delivering effective, high-quality patient care.

High quality care for patients with severe multimorbidity is comprehensive, continuous, long-term, and patient-centered. We suggest incorporating functional status, which would in part capture disability and frailty, to identify and risk-stratify severe chronic care patients. At present, functional status is not routinely measured in hospital or outpatient settings, particularly in non-geriatric settings, yet many young and middle-aged adults already show measurable declines in functioning as measured by instruments such as the Medical Outcomes Study Short Form-36 physical functioning scale.

For individuals with undocumented physical functioning, recent multimorbidity measures have been developed to incorporate physical functioning and other health-related quality of life measures. Such scales enable conditions associated with greater decrements in physical functioning to contribute greater weight to a patient's disease burden than disease count. In particular, weighting conditions by their impact on physical functioning recognizes chronic, debilitating diseases, such as the highly prevalent osteoarthritis, as having high impact on patients' health outcomes. Upon further development and validation in administrative data, these tools may be automated with billing and electronic health records to identify beneficiaries for the severe Chronic Care Management Code.

Types of Providers Who Should be Eligible to Bill the New High Severity Chronic Care Code

The primary care provider or subspecialist providing the most direct and frequent comprehensive care and care coordination for the patient should be eligible for the chronic care code. The primary care provider may evolve over time and may involve multiple providers, such as in the case of acute illness or decompensation. To reduce redundancy, there should be explicit communication on care coordination between the primary providers to reduce redundancy in effort and potential overbilling.

Methodologies to Measure Impact, Effectiveness, and Compliance in Relation to this New Payment Construct

As opposed to specific conditions such as diabetes and cancer, there is no single test to track patients with multiple chronic conditions. To measure the impact and effectiveness of the chronic care management code on patients, we suggest including a generic (not age, sex, or condition specific) patient-centered instrument such as health status or health-related quality of life. Self-assessed health status (whether an individual perceives his or her health as excellent, very good, good, fair, or poor) has been validated as an indicator of health. Health status decreases with age, so inclusion of an additional generic (as opposed to disease-centric) health-related quality of life measure would be appropriate and informative.

Should the New Code be Made Permanent, Temporarily Mandated, or Temporarily Instituted?

As methods to identify eligible patients and measure performance for complex patients with multiple chronic conditions remain in development, we recommend that the new chronic care management code be instituted on a temporary basis until further research is conducted. Utilization and cost increase and health-related quality of life decreases with severe multiple chronic conditions, but further studies are needed to assess the association and clinical and public health significance with other health outcomes. Health-related quality of life is an important patient-centered outcome that could be used to quantify the severity of individual diseases contributing to severe multiple chronic conditions.

Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries

IHPI believes the Working Group should consider organizational and financial incentives for collaborative care between primary care and behavioral health practitioners, and should also consider value-based insurance design principles for better addressing behavioral health needs of people with chronic conditions.

First, the Working Group may want to consider incentives for both organizational and financial integration of care for individuals with combined chronic physical health and behavioral health conditions. While the incorporation of depression screening requirements into the Medicare Shared Savings Program (MSSP) was an important step, there is an opportunity to expand beyond *screening* to enhanced *treatment* for beneficiaries with combined chronic physical health and behavioral health conditions. Various models of “integration” of primary care and behavioral health care exist, ranging from the partnering of a primary care practitioner with a consulting behavioral health practitioner at a different site, to a collaborative care partnership model in which behavioral health social workers serve on-site at primary care practices, to a fully co-located model where behavioral health practitioners--such as psychiatrists, social workers and other care managers with behavioral health expertise--are available on-site at primary care practices (O'Donnell AN, et al. Mental Health in ACOs: Missed Opportunities and Low Hanging Fruit. *Am J Manag Care* 2013; 19(3):180-184).

Models also vary as to the skill set required by primary care providers, with greater emphasis on behavioral health screening and treatment provided by the primary care providers where the behavioral health providers are not co-located. There is good evidence that these types of integrated models have been associated with improved quality of care and improved patient health outcomes, with costs either declining, remaining stable, or at worst increasing slightly. Please refer to the following two articles for evidence: Katon W, et al. Collaborative depression care: history, evolution and ways to enhance dissemination and sustainability. *Gen Hosp Psychiatry* 2010; 32(5):456-464, and van Steenbergen-Weijenburg KM, et al. Cost-effectiveness of collaborative care for the treatment of major depressive disorder in primary care. A systematic review. *BMC Health Services Research* 2010; 10(19).

Notably, the effectiveness of the collaborative care model has been demonstrated by over 80 randomized controlled trials. The Working Group may want to consider the following avenues for encouraging care integration.

Organizationally, primary and behavioral health integration can be incentivized within Medicare ACOs. The Working Group's current proposed recommendation of a study to assess the current status of such care integration among public and private sector ACOs is a worthwhile consideration. We suspect the prevalence of care integration will be low and that the Working Group may want to consider whether to require care integration in future Medicare ACO programs.

Financially, the Working Group may want to consider enhanced payment to both behavioral health and primary care practitioners who implement care integration via collaborative care or other models. Such changes in payment to the Physician Fee Schedule for collaborative care are currently being considered. It will also be important for the Working Group to consider how payments to non-physician providers such as licensed social workers, nurse case managers, and care coordinators may also be changed.

Second, to support access to behavioral services for people with chronic conditions and develop policies to improve the integration of care for individuals with both a chronic condition and a behavioral health disorder, the Working Group could consider leveraging consumer engagement tools with value based insurance design (V-BID) principles to improve beneficiary access to behavioral health services.

V-BID is built on the principle of lowering or removing financial barriers to essential, high-value clinical services. V-BID aligns patients' out-of-pocket costs, such as copayments, with the value of services (i.e. no or lowered copayments for high value services such as behavioral health services and services, treatment, and exams for chronic conditions). V-BID recognizes that medical services differ in the amount of improved health produced, and the clinical benefit derived from a specific service depends on the consumer using it, as well as when and where the service is provided.

Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees

IHPI researchers believe there is great promise in the proposal to give Medicare Advantage (MA) plans greater flexibility to establish a benefit structure that is tailored to the individual enrollee based on the individual's chronic conditions. Of particularly interest is incorporating the value-based insurance design concept in the Options Document to allow MA plans to offer a "reduction in cost sharing for items/services that treat the chronic condition or prevent the progression of the chronic disease." We are enthused about the recently announced CMMI demonstration to incorporate V-BID in several MA plans across the country and believe that leveraging consumer engagement tools with V-BID principles to improve beneficiary access to health services will prove to be a way to improve health and quality of life for many people living with chronic conditions. This concept goes hand in hand with the goal of better addressing behavioral health needs of people with chronic conditions, which was discussed above.

Maintaining ACO Flexibility to Provide Supplemental Services

The Options Document notes that it is considering clarifying that ACOs participating in the MSSP may furnish social services or transportation services for which payment would not traditionally be made under fee-for-service Medicare. On a broader level, IHPI researchers encourage the Working Group to look at applying value-based insurance design principles to ACOs.

Medicare ACOs, such as those under the Medicare Shared Savings Program (MSSP) and the Pioneer ACO program, currently have little ability to encourage beneficiaries to seek care within the ACO's network. Restricting an ACO from leveraging benefit design to encourage the use of high-value providers inhibits the ACO's ability to manage or encourage coordinated, high-value care. Reducing or eliminating cost sharing (or using V-BID principles) when beneficiaries see providers within the ACO provides a potential mechanism to encourage beneficiaries to stay within their network. A variation of this approach would allow nuanced reduction or elimination of cost sharing for specific services for beneficiaries with certain diseases, when delivered by ACO providers.

Eliminating Barriers to Care Coordination under Accountable Care Organizations

Policies aimed at eliminating barriers, particularly financial barriers for Medicare enrollees, to care coordination is important to achieve better care outcomes. As discussed above in *Maintaining ACO Flexibility to Provide Supplemental Services,* the Working Group may want to consider incorporating value-based insurance design principles, or allowing ACOs in two-sided risk models, the flexibility to waive beneficiary cost sharing for services that treat a chronic condition or prevent the progression of a chronic disease. ACOs may also want to furnish non-covered long-term services and supports and social services for their ACO beneficiaries.

Expanding Access to Prediabetes Education

Pre-diabetes is a highly prevalent risk factor, affecting 38% of the adult population (Menke A, Casagrande S, Geiss L, Cowie CC. Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012. *JAMA.* 2015;314(10):1021-1029. doi:10.1001/jama.2015.10029). That translates to approximately 92 million adults who could benefit from the Diabetes Prevention Program (DPP) and almost 15 million cases of diabetes that could be prevented in the next three years.

There are many factors that are causing delays in realizing the potential of the DPP but one of the barriers is the sheer volume of the patients affected. Restricting compensation to highly trained and expensive providers will dramatically limit the reach of the program and increase the costs without improving outcomes. **There is strong evidence that lay group leaders can effectively deliver the DPP curriculum in a group setting if they have proper training and support** (Ali, Mohammed K., Justin B. Echouffo-Tcheugui, and David F. Williamson. "How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program?" *Health Affairs* 31.1 (2012): 67-75).

Perhaps the most promising modality of DPP delivery is online programs. Online interventions are relatively inexpensive and rapidly scalable. A company called Omada Health has developed an online version of the DPP that has been shown to be effective in clinical trials (Moin T, Ertl K, Schneider J, Vasti E, Makki F, Richardson C, Havens K, Damschroder L. Women Veterans' Experience With a Web-Based Diabetes Prevention Program: A Qualitative Study to Inform Future Practice. *J Med Internet Res* 2015;17(5):e127, and Sepah SC, Jiang L, Peters AL. Long-Term Outcomes of a Web-Based Diabetes Prevention Program: 2-Year Results of a Single-Arm Longitudinal Study, *J Med Internet Res* 2015;17(4):e92).

In our recently completed VA Diabetes Clinical Demonstration Program (conducted from 2012 to 2015), veterans with pre-diabetes enrolled in one of three weight loss programs: 1) VA's traditional MOVE! behavioral weight loss program, 2) an in person group based implementation of the DPP or 3) the online Omada Health Prevent DPP program. Those in the Omada Health Prevent online program lost as much weight as those in the in person DPP groups and both of the DPP groups lost more weight than those in the MOVE! Program. These results have been presented at a national meeting but are not yet published.

Cardiac rehabilitation and pulmonary rehabilitation have been restricted to brick and mortar health care facilities and one of the arguments for this is that there is a risk associated with getting sick people to exercise. This restriction has dramatically limited the reach of these programs. Such a restriction makes even less sense when the population is pre-diabetic individuals who are at substantially lower risk of an adverse cardiac event.

The process of paying for services may be easier if eligible vendors only include health care providers, however, this restriction unnecessarily limits the reach of the intervention. Allowing programs such as the YMCA, Omada Health and other programs committed to delivering high quality versions of the DPP to get reimbursed for their services will greatly expand access to the program without degrading quality.

There is already an established registration process hosted by the CDC to certify DPP programs offered in the community (the following is a link to the CDC registry of recognized organizations: http://www.cdc.gov/diabetes/prevention/facts-figures/index.html). The set of criteria that programs must meet to qualify for the CDC's National DPP recognition program is a high bar and many organizations including the YMCA and Omada Health Prevent programs have already achieved this status. Some private payers have negotiated contracts in which they only pay for the program for those individuals who lose at least a 5 or 7% weight loss, thus holding program vendors accountable for quality and outcomes. Others reimburse the participant only if they attend (or complete online) at least 9 of the 16 groups sessions. While such reimbursement plans increase complexity, they also increase the probability that money spent on such programs will not be wasted.

Because of the results of our research in the VA which showed that the DPP curriculum whether delivered in an in-person group setting or online is more effective than the current MOVE! Program, the VA's National Center for Prevention recently adopted the DPP curriculum for all veterans with BMI > 30 and replaced the traditional MOVE! Curriculum with a VA version of the DPP program.

As a health care payer for 96% of Americans 65 years of age and older, Medicare stands to benefit substantially if private payers offer the DPP lifestyle intervention to people with prediabetes <65 years of age. Medicare should also consider seeking authority to offer the DPP lifestyle intervention to eligible adults 65 years of age and older. Recent health policy changes have directed Medicare to reimburse for screening tests that can identify DPP-eligible participants. Medicare should consider reimbursing all NDPP-accredited programs to deliver the DPP to Medicare beneficiaries with prediabetes.

Lastly, the Working Group solicited feedback on whether there is evidence to support coverage of services analogous to DSMT for beneficiaries who are at risk of complications from other chronic conditions. IHPI researchers believe there is strong evidence and numerous studies that indicate individuals with many chronic diseases including COPD, back pain, PAD, CVD, depression, bipolar disorder, and schizophrenia could benefit from self-management training and support. Additionally, cancer survivors generally have increased risk of CVD and are more likely than those who are not cancer survivors to be sedentary and obese.