HEALTHCARE
LEADERSHIP
COUNCIL

January 28, 2016

The Honorable Johnny Isakson
United States Senator
131 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Mark Warner
United States Senator
475 Russell Senate Office Building
Washington, D.C. 20510

Dear Senators Isakson and Warner:

The Healthcare Leadership Council (HLC) applauds the Senate Finance Committee's tremendous progress toward improving care for Medicare patients with chronic conditions. The formation of the bipartisan Finance Committee Chronic Care Working group and the completion of its policy options document represent an important step forward toward improved care for patients with chronic disease both inside and outside the Medicare program, since Medicare's size greatly impacts other parts of the system. As noted by nearly all of the entities and individuals who submitted comments throughout this process, treatment of chronic illness accounts for almost 93 percent of Medicare spending, and more than two-thirds of beneficiaries have multiple chronic conditions. These costs are unsustainable and will worsen with the rapidly aging and growing Medicare population.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC--hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies--advocate measures to increase the quality and efficiency of healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to enhance value.

We were pleased to see many of the recommendations we made in our first comment letter, and during our follow-up meeting with your staff, included in the policy options document. We believe the options put forth are an opportunity to make a meaningful difference for beneficiaries while also improving the long-term financial viability of the Medicare program.

HLC Engagement on Issues Affecting Chronic Care
HLC's membership is at the forefront of improving care for patients with chronic conditions. Based on decades of experience in implementing and developing policies designed to improve disease management, streamline care coordination, improve

quality, and reduce Medicare costs, we strongly believe in the results. Our signature compendium, *The Future Is Here* (www.hlc.org/compendium) outlines several important examples of ways that HLC members--as health providers, community leaders, and large employers--are demonstrating quantifiable health improvements and cost savings.

Last year, HLC hosted a summit of the National Dialogue for Healthcare Innovation (NDHI). The initiative brought together leaders from industry, government, academia, patient organizations, and all sectors of healthcare to discuss and develop consensus approaches to challenges affecting the course of healthcare innovation. Following the summit, HLC formed three workgroups (comprised of HLC member companies, other key stakeholders, as well as academic and patient advocacy organizations) to more deeply engage in the issues that underpin a health system based in value: (1) Patient Engagement and Adherence, (2) Data Strategy and Interoperability, and (3) Outdated and Ineffective Laws and Regulations.

The efforts of the three workgroups underscores the deep and multifaceted commitment HLC and its allies have to innovative, quality care that is accessible to patients, since each of the workgroups' recommendations will ultimately help promote better care coordination for those with chronic disease.

The workgroup examining outdated and ineffective laws and regulations has recommended that legislative and regulatory reforms to the physician self-referral (Stark law) and federal antikickback statutes are needed to remove impediments to collaborations between healthcare stakeholders that can result in better integration of services, care coordination, and higher quality care. For example, in traditional payment models, a hospital that is discharging a patient with a serious chronic disease is barred from making recommendations on what type of skilled nursing facility (SNF) would provide the best care for the patient. The patient, left to their own devices, may choose a SNF that provides less optimal care. The workgroup also found that some Food and Drug Administration (FDA) regulations, in their current form, are unnecessary, redundant, or overly burdensome and impede the ability of innovative companies to bring new medicines and technologies to patients. Patients with chronic conditions can receive the most innovative care more quickly than if their treatments are mired in red tape.

The workgroup examining data strategy and interoperability has recommended accelerating progress on health information interoperability by investing the primary responsibility to drive progress with the private sector and setting an industrywide consensus date of December 31, 2018, to achieve full interoperability. Full interoperability will enable providers caring for patients to better coordinate care. Also, the harmonization of federal and state privacy laws to remove harmful and unnecessary barriers to the flow of healthcare data and the use of a unique identifier to ensure that patients are always matched with the correct medical records will further enable providers to better manage patient care across different systems and settings.

The workgroup examining patient engagement and adherence produced a set of comprehensive Care Planning Principles that lay out detailed strategies to better address chronic disease, strengthen care coordination, and improve patient engagement. The Principles (see attached) use diabetes as a case study, but can be applied to various chronic conditions. This workgroup also finalized a set of recommendations (see attached) to improve the Centers for Medicare and Medicaid Services' (CMS) approach to medication therapy management (MTM), with an eye toward speeding system improvements and encouraging collaboration between health plans and pharmaceutical manufacturers.

We urge you to consider us a partner as the working group moves forward to further develop and define these policy options.

I. Receiving High Quality Care in the Home

HLC strongly supports a move toward providing increased, high-quality care in the home setting if it is appropriate for the patient. An increasingly multidisciplinary and multi-site approach to the care of these patients may be one answer for improving patient clinical outcomes and healthcare resource utilization.

- *Expanding the Independence at Home Model of Care*

HLC supports expanding the Independence at Home demonstration into a permanent, nationwide program. We agree that hierarchical condition category (HCC) risk scores would be an improved means of identifying the patients that would most benefit from such a model. However, the HCC should be paired with additional metrics such as physician referrals, hospitalizations, or a combination of Health Risk Assessments and HCCs to best identify patients with Activities of Daily Living (ADL) deficits.

- *Expanding Access to Home Hemodialysis Therapy*

HLC supports expanding telehealth beyond the current "1834(m) restrictions" that limit reimbursement to certain services a beneficiary receives while receiving care at an "originating site" located in a rural Health Professional Shortage Area (HPSA) or a county outside a Metropolitan Statistical Area (MSA). We believe that expanding Medicare's qualified originating site definition to include free-standing renal dialysis facilities located in any geographic area would be a step toward the broader goal of making telehealth more accessible to patients and health professionals in a winder variety of circumstances. We support the Working Group proposal for patients to retain the choice to receive an in-person visit or opt for the service via telehealth. We believe that expanding the hemodialysis benefit in this way would not require at least one in-person visit every three to six months, since HLC members believe that telehealth provides a comparable service to an in-person visit.

II. Advancing Team-Based Care

HLC strongly supports greater use of a team-based care model. The Care Planning Principles developed by NDHI specifically note the need for and benefits of an interdisciplinary health team model that incorporates a wide variety of health professionals to ensure the best care for the patient. Certainly it is cost-effective for a variety of health professionals to treat a patient, often at a lower rate than a physician, but a strong team-based care platform also enables better care transitions and unified care across the continuum of disease and a variety of settings.

In addition, HLC is pleased by the consistent support of the Working Group regarding Medicare Advantage (MA) plans. Peer-reviewed research has demonstrated that MA plans are more effective than traditional fee-for-service (FFS) Medicare at addressing chronic conditions. But MA plans need stability and predictability in order to offer beneficiaries coordinated, evidence-based care. HLC urges the Working Group to continue promoting and advancing high-quality, value-based healthcare by working with CMS to sustain the MA program at current reimbursement levels in order to maintain choice and high value care.

- *Allowing End Stage Renal Disease (ESRD) Beneficiaries to Choose a Medicare Advantage Plan*

HLC members strongly support the MA program as the forerunner to a healthcare system of the future centered on consumer choice and value, and are pleased that the Working Group recognizes that after a decade of MA program experience we can be confident that a patient with ESRD would receive quality care in a MA plan. We support allowing beneficiaries who are in FFS to enroll in a MA program once they have been diagnosed with ESRD. In order to assist individuals in choosing the most appropriate health plan for their needs, we recommend sharing a few key quality measures with beneficiaries, including a plan's 5-star Rating, kidney transplant rate, US Renal Disease System (USRDS) quality measures, and overall member satisfaction.

While we do not have specific suggestions concerning quality measures that should be used for plan assessment, we believe that any methods should be developed with the consensus of relevant stakeholders and communicated well in advance of the plan year in which a plan will be rated on the measures. Further, all quality measures should be developed in a way that reduces administrative burdens while also providing utility to beneficiaries in making informed healthcare decisions.

- *Providing Continued Access to Medicare Advantage Special Needs Plans for Vulnerable Populations*

One of the themes of HLC's original comment letter to the Working Group is the need for continued flexibility to most effectively treat the sickest, costliest Medicare beneficiaries. We are pleased that the Working Group is considering expanding (either long term or on a permanent basis) authorization of MA special needs plans (SNPs). As the Working Group notes, this will allow for greater planning and investment in successful or innovative care models. SNPs allow beneficiaries access to care plans and provider networks designated especially for their health conditions. And beneficiary choice is preserved because enrollees are free to enroll in or change plans year round as chronic conditions develop or worsen. Furthermore, making the program permanent would encourage broader replication of best practices and innovation in care delivery.

We also think that requiring SNPs that enroll beneficiaries eligible for both Medicare and Medicaid (D-SNPs) to offer fully integrated Medicare and Medicaid services to their enrollees would provide greater continuation of care. While we support this proposal, it is important to recognize that limitations and barriers exist within some states. Requiring D-SNPs to offer fully integrated Medicare and Medicaid services to their enrollees in a short time frame and without adequate support or resources could inadvertently restrict beneficiary access to D-SNP products in some states. Therefore, we support a phased-in approach in order to help states and health plans transition from the D-SNP model to a fully-integrated dual eligible special needs plan model without impacting beneficiary access.

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

As mentioned above, flexibility to appropriately manage the most vulnerable patients is essential to improving care for beneficiaries with chronic conditions. HLC supports the establishment of a new high severity chronic care management code that clinicians could bill under the Physician Fee Schedule. Though adding new payment codes to the existing fee-for-service system does not resolve the fundamental structural problem that limits quality improvement and savings generation, they are a good first step to encouraging team-based chronic care management as we seek to transition to new models that encourage greater coordination of care and align incentives accordingly. In determining both whether to add a new code and its duration, we urge consideration of how that decision affects the desired transition away from FFS in the long term.

- *Addressing the Need for Behavioral Health Among Chronically Ill Beneficiaries*

HLC members strongly support the development of policies that improve the integration of care for individuals with a chronic disease combined with a behavioral health disorder. We believe that a Government Accountability Office (GAO) (or other entity) study on the current status of the integration of behavioral health and primary care among private and public sector accountable care organizations (ACOs) and medical homes could help point toward appropriate policy solutions that would be effective in a world of advanced payment models (APMs). The study should incorporate information already available from the Centers for Disease Control and Prevention (CDC), the SAMHSA-HRSA Integrated Center for Integrated Health Solutions, National Council for Behavioral Health, and others. HLC believes it would be important for the study also to examine barriers and potential solutions. Barriers include: the availability of behavioral health resources and expertise in the primary care setting; insufficient access to high quality clinicians; and data sharing and privacy rules related to mental health visits preclude coordination. We also recommend that the study examine the possibility of providing coverage of transportation, group psychotherapy, and telehealth services and incentives or models of care that co-locate physical and behavioral health.

Finally, we suggest working with CMS to further encourage and solicit integrated, high-quality community mental health resources, particularly in underserved communities.

III. Expanding Innovation and Technology

HLC strongly supports innovation in benefit design and technology to increase beneficiary access to services that are critical to improve chronic disease management. The proposals below support one of the major themes of HLC's original letter, which is the importance of providing more flexibility to providers to provide care and be reimbursed for care coordination to meet specific patient needs. Especially within larger risk pools, it's essential to encourage and tailor care coordination to meet individual patient needs. It will also be important for providers to have sufficient data to provide care—and this data must follow patients through the entire care continuum.

Regarding telehealth, we support any efforts that would expand reimbursement of telehealth in FFS until the Merit-Based Incentive Payment System (MIPS) program begins and allow for reimbursement of remote patient monitoring in FFS.

Benefit Flexibility in MA and ACOs

- *Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees*
- *Expanding Supplemental Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees*
- *Maintaining ACO Flexibility to Provide Supplemental Services*

As mentioned above, HLC strongly supports creating more flexibility within the Medicare program to meet the needs of chronically ill individuals, and we agree with the list of options currently being considered by the Working Group (including (1) supplemental benefits not currently allowed; (2) reducing cost sharing for items/services that treat or prevent progression; (3) adjusting provider networks to allow inclusion of providers and non-clinical professionals to treat disease or prevent progression; and (4) covering care improvement and/or wellness programs tailored for the chronic condition).

We urge the Working Group to promote policies that provide MA plans with additional flexibility to create and deploy tailored, innovative benefit designs and provide additional supplemental benefits for those with chronic illness. HLC is supportive of value-based insurance design (VBID) benefit structures that incentivize beneficiaries to use high-value services, and supports the ability of MA and MA prescription drug (MA-PD) plans to offer incentives (e.g., lower cost sharing) that drive increased utilization of health care improvement programs. These flexible incentives help generate patient engagement, leading to higher levels of compliance with evidence-based medicine standards.

In our original letter to the Working Group, we asked for additional flexibility so that plans could modify their benefit structure to permit more benefit variation. The Medicare Payment Advisory Commission (MedPAC) has also recommended this. Examples of this flexibility include waiving or eliminating copays on certain medications for one population, providing additional transportation to individuals with more frequent medical appointments or waiving the copay for a specialist visit based on an individual's health needs. The ability to further tailor benefits to the specific needs of the individual will result in both increased access to care and higher adherence rates. Currently, the only way health plans have to offer flexibility to the individual are medical management tools. Some services plans want to provide do not fall within medical necessity. Examples of such services are: homemaker services, home-delivered meals, personal care services (assistance with bathing and dressing), transportation escort services, inpatient custodial level care, in-home caregiver relief, adult day care services, and non-Medicare-covered medical and safety equipment (e.g., the purchase of a refrigerator to store insulin, an air conditioner in geographies with severe summer temperatures or railings to help prevent falls). The ability for MA plans to offer incentives to encourage engagement in wellness or care improvement activities focused on specific chronic conditions would also be helpful. Finally, MA plans should have the ability to offer remote access and telehealth services as part of the basic benefit package and should not be limited to the amount of supplemental benefit funds available.

Similarly, HLC would appreciate clarification that ACOs participating in the Medicare Shared Savings Program (MSSP) may furnish a social service, transportation service, or remote patient monitoring service for which payment is not made under FFS.

In each case, a key component is that the MA plan or ACO should be permitted to tailor the supplemental benefit to the individual. The plan or ACO should have the discretion to provide benefits where the benefits are most appropriate and have the most value—there should not be a mandate to provide the supplemental benefit to all beneficiaries suffering from the same chronic condition.

In addition to adding flexibility to the benefits package, care to patients would improve if health plans could structure the provider network based on a population's diagnosis to ensure the network can adequately meet the specific and unique needs of each population. Permitting health plans flexibility with respect to benefits offered can allow plans to assist low-income, high need beneficiaries with chronic diseases who are at risk of institutionalization remain in the community. Such additional benefits may also prevent a decline in health status and can reduce the quantity and cost of healthcare services that these beneficiaries receive.

All MA plans should be permitted flexibility in these areas, since all MA plans cover individuals with serious illnesses. A competitive disadvantage would be created if there is not a level playing field for all MA plans with regard to flexibility in these areas. Furthermore, patients should have access to services that provide higher quality care regardless of which MA plan they are enrolled in.

We note that the concepts described in these sections of the Policy Options document are similar to recommendations HLC made last summer. To that end, we encourage the Working Group to incorporate H.R. 3244, the "Providing Innovative Care for Complex Cases Demonstration Act," into its final product. This bipartisan legislation, introduced in the House last summer, establishes a pilot program that would test a new and innovative approach to improving care for Medicare's sickest and most chronically ill beneficiaries. The pilot would improve quality by allowing only the most highly qualified MA plans and ACOs to deliver integrated, coordinated care to the costliest 10 percent of Medicare beneficiaries (who account for nearly 60 percent of FFS spending) at a lower cost to the federal government than the current FFS system. Testing the model outlined in this legislation would allow CMS to accelerate efforts to improve care for Medicare's most chronically ill patients by adopting many of the policies proposed by the Working Group, including the ability to provide beneficiaries with more benefits, reduced cost sharing, and a dedicated health professional to help them navigate the health care system so they get the right care at the right time. The pilot would also establish high-quality provider networks that ensure patients are receiving integrated, coordinated care.

Additionally, the aim of these provisions mirror the goals of the "Community Based Independence for Seniors Act" (S. 704), which unanimously passed the Finance Committee last June. We suggest that the Working Group include an updated version of the legislation in any final product. The House recently introduced a new version of the bill (H.R. 4212), which limits payment for the additional home and community based services covered by S. 704. This change was made in order to mitigate cost concerns as well as to ensure that health plans still have adequate resources to implement the demonstration.

Expanded Use of Telehealth

- *Increasing Convenience for Medicare Advantage Enrollees through Telehealth*
- *Providing ACOs the Ability to Expand Use of Telehealth*
- *Expanding the Use of Telehealth for Individuals with Stroke*

As noted above, HLC is a strong supporter of increased use of telehealth, both in FFS and in the MA program, so we applaud the Working Group for considering permitting MA plans to include certain telehealth services in its annual bid amount. We wholeheartedly agree with the Working Group's statement that "telehealth technology is not necessarily an additional benefit, but rather an alternative mode of care delivery of mandatory benefits to an enrollee." Because of that, and the potential for telehealth to dramatically improve access to care, we agree that it would be appropriate to factor this into network adequacy requirements.

Similarly, HLC supports providing ACOs the ability to expand use of telehealth. While we would eventually desire that such benefits would be open for the entire Medicare program, limiting initial expansion to ACOs participating in two-sided risk would be a first step toward eventual wider adoption that would also provide CMS with the ability to monitor best practices and innovations among the nations' most innovative, advanced providers.

Finally, while HLC also supports expanding the use of telehealth for individuals with stroke, we feel that this indication is too narrow. Limiting the proposal to only stroke diagnoses deprives other beneficiaries with similarly high severity, time-sensitive conditions from the same technology benefits. Instead, we strongly support expanding the use of telehealth services without regard to geography or potential diagnosis to ensure that all Medicare beneficiaries are able to access quality, efficient and convenient telehealth services as appropriate. As the Working Group has noted, "prompt, accurate diagnosis leads to timely treatment and can dramatically improve patient outcomes." In general, HLC supports telehealth policy frameworks that are site-agnostic and not overly prescriptive. Providers should be able to determine if a patient can appropriately receive care via telehealth in a way that enhances care delivery and quality.

IV. Identifying the Chronically Ill Population and Ways to Improve Quality

- *Ensuring Accurate Payment for Chronically Ill Individuals*

HLC supports closely reexamining the current risk-adjustment models to more accurately identify patients with high risk and appropriately reimburse providers for the increased resources used to provide care to those patients. It is vital that the risk adjustment model be an accurate predictor of cost. The model has over-predicted the cost of the least costly beneficiaries and under-predicted the cost of the most costly beneficiaries, including those who are chronically ill. Recent actions have intended to correct this disparity and make the model more accurate and predictive of costs (e.g., implementation of the 2014 CMS-HCC risk model). However, these actions have resulted in significant and disproportionate payment cuts to plans serving the most vulnerable and chronically ill Medicare beneficiaries, placing these plans' ability to continue to offer best-in-class chronic care management at risk.

The risk adjustment model must support clinically-accurate and appropriate payment. In areas where Medicare adjusts performance metrics and associated payment based upon clinical factors, it is necessary to evaluate the adjustments so that no healthcare provider is penalized for accepting responsibility for the care of the sickest and most clinically complex patients.

We support the proposed changes to the MA HCC Risk Adjustment Model that take into account the total number of chronic conditions, the interaction between behavioral/mental health conditions and physical health conditions, dual eligibility status, and the use of more than one year's data to establish a risk score. We also urge the Working Group to consider factoring in socioeconomic status (SES) of a population. HLC believes that payment and performance metrics should also incorporate sociodemographic factors such as income, education, language proficiency, social support, living conditions, and available community resources. These variables can have a profound effect upon the patient's adherence to the treatment plan recommended by a medical professional. The current system, which does not account for these factors, creates an uneven playing field for performance measurement and subsequent performance-based payment. Furthermore, adjusted performance measures are critical for patients, payers, and others to make fair comparative evaluations about quality and value.

While the proposals identified are specifically aimed at the MA program, we encourage the Working Group to apply changes in risk models similarly across various CMS payment models (MA, ACOs, and other APMs). To the extent possible, CMS should ensure that payments, waivers, benchmarks, and other mechanisms are aligned between MSSP and the MA program – while acknowledging important differences between the programs (such as beneficiary lock-in under MA). The success of a program should depend on beneficiary choice and the value provided, not differences in regulatory requirements. Furthermore, having a common set of population metrics and data would help both programs better identify and be reimbursed appropriately for risk within their own populations, as well as help CMS compare populations and outcomes within and between various programs.

Regarding ACOs, we urge the Working Group to remember that providers taking on two-sided risk and dealing with a large population of individuals with low SES may find it to be an unsustainable business model if once they address care transitions, “hot spots,” and patient adherence and self-management, they see a plateau in savings generated. It is important that Congress and CMS work together to develop incentives to encourage providers to continue to take on two-sided risk.

Regarding the proposed study to examine whether the use of functional status (measured by activities of daily living or other means) would improve the accuracy of risk-adjusted payments, we think this would add important information to future conversations regarding appropriate risk adjustment.

- *Providing Flexibility for Beneficiaries to be Part of an Accountable Care Organization*

HLC supports giving ACOs in MSSP Track One the choice as to whether their beneficiaries are assigned prospectively or retrospectively. This would allow each ACO to choose what works best given their population. Prospective assignment – and timely, detailed claims data on assigned patients – promotes patient engagement, care coordination, and performance improvement. Furthermore, HLC believes the entire primary care physician and practitioner team (including nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNS) working in clinical teams in collaboration with or under the supervision of physicians) should be considered for purposes of determining where a beneficiary received the plurality of primary care services under step 1 of the assignment methodology (after satisfying criterion that assignment is based on primary care provider (PCP) services). By providing greater flexibility in the use of the entire primary care physician and practitioner team, ACOs will be able to allocate resources more effectively for beneficiaries.

HLC also supports the Working Group’s consideration of a recommendation that FFS beneficiaries have the ability to voluntarily elect to be assigned to the ACO in which their main provider is participating. We have urged CMS to offer a beneficiary attestation process for all MSSP ACOs, regardless of track. This process would allow beneficiaries to attest that they consider a particular provider responsible for coordinating their overall care. An attesting beneficiary would be attributed to the ACO with whom that provider is affiliated. Although CMS would retain its current stepwise attribution process, beneficiary attestation would take precedence over that process. Further, the beneficiary would remain attributed to that ACO until the beneficiary enrolled in MA, moved out of the ACO's service area, or attested to a provider affiliated with another ACO. Providing beneficiaries with the opportunity to align voluntarily with an ACO would balance the important considerations of beneficiaries' freedom to choose their providers with ACOs' interest in reducing churn, which would help provide a more defined and stable beneficiary population at the outset. This, in turn, would allow ACOs to better target their efforts to manage and coordinate care for beneficiaries for whose care they will ultimately be held accountable. In addition, allowing beneficiaries to attest to the provider they want to manage their care may help increase beneficiary engagement in that care. However, care coordination and stability are somewhat contingent on the beneficiary not receiving services from outside providers. In order to promote the effective treatment and management of patients with chronic conditions in ACOs, HLC supports polices that permit beneficiaries in an ACO to receive services from outside providers as long as they are approved by the ACO.

CMS is currently in the process of testing beneficiary attestation under the Pioneer ACO model, and plans to do additional testing of this in the future. We support this process and recommend that Congress and CMS build upon lessons learned from the Pioneer ACO model when applying this approach to all MSSP ACOs.

- *Developing Quality Measures for Chronic Conditions*

HLC supports requiring CMS to include quality measures that focus on the health outcomes of individuals with chronic disease (including patient/family engagement, shared decision-making, care coordination, hospice, and end-of-life care, Alzheimer's and dementia (including a focus on caregivers), and community-level measures). These measures, part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), in conjunction with the proposed report from GAO on community-level measures as they relate to chronic care management, would provide Congress and the Administration more data that can be used as a benchmark to measure future progress and identify promising policy levers. HLC is especially supportive of measures that are outcomes focused, and we are also pleased that several of the areas under consideration have a strong community-based focus. HLC has long been a supporter of linking community and clinical health services in order to reinforce the strengths of each setting. We suggest the GAO report also look at barriers to the provision of care in a community-based setting as well as barriers to measurement of various quality indicators and suggest possible solutions. We also suggest that the study focus on the development of outcomes-based quality measures for patients with multiple chronic conditions.

V. Empowering Individuals and Caregivers in Care Delivery

As mentioned above, one result of HLC's NDHI initiative was the establishment of a workgroup on patient engagement and adherence. As the title suggests, members were very supportive of efforts to empower and engage individuals and caregivers in care delivery.

- *Encouraging Beneficiary Use of Chronic Care Management Services*

HLC supports waiving the beneficiary copayment associated with the current FFS chronic care management code as well as the proposed high severity chronic care code described above. As noted in our original letter, current use of preventive or wellness visits is woefully low, so efforts to encourage adoption should be seriously considered. In addition to waiving the copays, HLC recommends that Congress explore ways to educate patients and providers about the benefit. Further education would also help alleviate concern about chronic care management services that appear on a summary of benefit notices even though they do not involve a face-to-face encounter. Finally, since it is not clear whether beneficiaries with chronic conditions seek to have chromic care management, providing opportunities for such services is more important than the use or elimination of a cost-sharing mechanism.

- *Eliminating Barriers to Care Coordination under Accountable Care Organizations*

HLC supports allowing ACOs in two-sided risk models to waive beneficiary cost sharing, such as copayments, for items/services that treat a chronic condition or prevent the progression of a chronic disease. HLC has long been a supporter of these types of services as essential to preventing escalating treatment and costs associated with disease progression. For patients for whom cost is a barrier to treatment, we believe that ACOs should have the option to waive copays for certain treatments, in recognition of the risk they have taken to treat such patients. Given that ACOs have already taken on a substantial amount of risk, we request that the Working Group consider a wide range of latitude in this area: we believe that the items/services eligible for reduction should be left to the discretion of the ACO, and may affect copays, coinsurance, or deductibles. Despite the prevalence of supplemental coverage among Medicare beneficiaries, the patients who this will most affect are likely the ones who do not have such additional coverage. Finally, we agree with the Working Group that “providing this option under a two-sided risk model will allow ACOs to best determine whether waiving cost sharing will lead to higher-quality care and achieve increased savings for both the ACO and the Medicare program.”

- *Expanding Access to Prediabetes Education*

Since progression from prediabetes to Type 2 diabetes (and its costly complications, including cardiovascular disease, stroke, blindness, lower-limb amputation, and kidney disease) can be delayed or halted by completion of an evidence-based lifestyle intervention such as the National Diabetes Prevention Program (National DPP) delivered in a community-based or virtual setting, it is essential that National DPP be provided to Medicare beneficiaries. HLC strongly supports the Working Group’s consideration of requiring Medicare Part B payment for evidence-based lifestyle interventions for those with prediabetes because such a change could greatly alter the trajectory of the diabetes epidemic in this country. Furthermore, a study commissioned by the American Diabetes Association, the American Medical Association (AMA), and the YMCA of the USA from Avalere Health found that enacting the “Medicare Diabetes

Prevention Act" (H.R. 2102/S. 1131) will reduce federal spending by an estimated $1.3 billion over ten years (and savings from preventing diabetes would likely increase beyond 10 years, suggesting an even more significant impact on long-term federal spending). Other studies have validated this data, and the Center for Medicare and Medicaid Innovation (CMMI) award to Y-USA to provide coverage for National DPP to Medicare beneficiaries is showing promising early results and its actuarial analysis is being fast-tracked as a result.

Regarding the Working Group's request for feedback on whether an evidence-based lifestyle program can be delivered by an entity not recognized as a provider under the Medicare statute, HLC strongly urges the Working Group to allow such entities that have been recognized by the CDC as qualified to deliver National DPP. Currently, the CDC evaluates and then recognizes applicants that demonstrate clinical results, data reporting capability, and program delivery capability. Many of the current evidence-based National DPP providers are non-Medicare providers, including community-based organizations like the Y-USA, companies—such as Weight Watchers—that offer the program virtually as well as in communities, and certified diabetes educators (CDEs). The "Medicare Diabetes Prevention Act" includes a specific definition for "diabetes prevention program provider" ("a diabetes prevention program provider may be, as determined appropriate by the Secretary, a supplier …, a health insurance or services company, a community-based organization, or any other appropriate entity.") This definition is inclusive of private sector organizations, community-based organizations, CDEs, departments of health and federally qualified health centers. Currently, the Y-USA and the American Association of Diabetes Educators are the largest in-person delivery networks for National DPP. Additionally, Omada Health and Weight Watchers International, Inc. offer virtual delivery or virtual plus in-person delivery and meet the criteria required by the CDC.

The CDC's National DPP has a set of standards in place that entities are required to meet in order to deliver the program and be recognized as an eligible provider of the National DPP. The CDC ensures that prevention program providers are trained and delivering an intervention that is faithful to the one used in the original clinical trial, and also requires program providers to submit aggregate patient outcomes data before program recognition is officially granted. The CDC requires clinical trial evidence and tracks clinical outcomes of patients for all recognized programs. In fact, the CDC recognition program is a model for outcomes based care delivery.

The NDHI Care Planning Principles used diabetes as a case study to examine how best to manage chronic disease through the continuum of care. The workgroup determined that services provided as part of DSMT (diabetes self management training, which teaches individuals with diabetes how to control their diabetes and eliminate or mitigate the consequences of unchecked diabetes through techniques for self-monitoring blood glucose levels, medication management and insulin injection administration, nutrition geared to diabetes control, appropriate exercise, and diabetes problem solving) are crucial to diabetes care.[1] These types of skills are critical to the treatment of diabetes as well as other chronic conditions. We encourage the Working Group to study whether analogous services would lessen the complications related to other chronic diseases. As stated in our original letter, allowing referrals and reimbursement for evidence-based self-management services would empower and enable Medicare beneficiaries to manage their own health.

- *Expanding Digital Coaching*

As a way to expand Medicare beneficiary access to digital health coaching, the Policy Options Document indicates that the Working Group is considering a requirement for CMS to "provide medically-related information and educational tools on its website to help beneficiaries learn more about their health conditions and help them in the self-management of their own health." This policy option contemplates relying on the Medicare.gov website as a source for reliable information about chronic diseases and ways to manage these diseases.

HLC is very concerned that this particular strategy for providing access to online information about chronic diseases and their management, while potentially very helpful, will fall short of the potential for digital health coaching. Digital health coaching programs combine expertise from the fields of human behavior, medicine, and digital content development. These programs are individually tailored to recommend concrete, customized steps patients can take to improve their health based on their personal health and wellness goals. The personalized feedback the patient gets may then be easily transmitted electronically to his or her treating physician or non-physician practitioner, thus facilitating care coordination.

This type of interactive and individually tailored coaching is similar to the digital health coaching programs currently being offered to tens of millions of commercially insured people, including MA enrollees, through insurers such as Kaiser Permanente, a number of BlueCross BlueShield plans, and Aetna. A published review of digital health coaching programs found average year-over-year cost savings of $382 in actual medical expenses per participant.[2] These savings came primarily from a reduction in hospital admissions.

We recommend that the Working Group consider providing CMS authority to contract directly for digital health coaching programs according to the specification below. We recommend that these digital health coaching programs would be made available to

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[1] Unfortunately, DSMT services (including those provided via telehealth)—while currently covered by Medicare, are not able to be provided by Certified Diabetes Educators (CDEs), the main group of health care professionals who provide most of the essential training and education for this service. A bill currently before Congress—the "Access to Quality Diabetes Education Act" (H.R. 1726/S.1345)—would recognize state-licensed or state-registered certified diabetes educators as Medicare providers. When previously scored, CBO estimated the legislation would have an unscorable, de minimis impact on the federal budget.

[2] Steven M. Schwartz, Brian Day, Kevin Wildenhaus, Anna Silberman, Chun Wang, and Jordan Silberman (2010) The Impact of an Online Disease Management Program on Medical Costs Among Health Plan Members. American Journal of Health Promotion: November/December 2010, Vol. 25, No. 2, pp. 126-133.

FFS beneficiaries as well as those covered under alternative payment models at no cost to the beneficiaries.

- The Secretary would be authorized to enter into agreements with one or more eligible entities with demonstrated experience in the design, implementation, and operation of digital health coaching programs that reduce health care expenditures and improve health outcomes in patients with chronic conditions;
- The Secretary would provide relevant CMS Internet websites and other HHS websites links to the Internet website of the digital health coaching.
- The Secretary would be required to include information on the availability of digital health coaching programs as part of the information and services furnished to beneficiaries.
- The Secretary would negotiate an annual payment amount for the provision of digital health coaching programs to beneficiaries. Such payment amount would not vary by the number of times beneficiaries access and use such programs, but may be determined on a per-beneficiary basis that takes into account an estimate of the number of beneficiaries involved.
- In no case could the aggregate payment amounts under a 5-year agreement exceed $25,000,000 for the provision of digital health coaching programs to beneficiaries during the period.
- The Secretary could renew an agreement if the Chief Actuary of CMS certifies that a new or renewed agreement for such programs would reduce program spending.

VI. Other Policies to Improve Care for the Chronically Ill

- *Increasing Transparency at CMMI*

HLC supports the work of CMMI and is looking forward to the innovative models it has developed being scaled nationally. We strongly support initiatives to increase transparency at CMMI, particularly regarding demonstrations and models where expansion would be compulsory or models that affect a significant amount of Medicare spending, providers, or beneficiaries.

Given the deep expertise of stakeholders from the private sector as well as academic and patient communities, the ability to offer input will be valuable for the success of models as well as the ability of the private sector to encourage and promote such activities. Given the nature of CMMI and the need for timely development, testing, and evaluation of new models, we suggest that public comment periods be relatively short.

Additionally, we believe that greater transparency would encourage voluntary early adoption of models that appear promising. Finally, the input of more stakeholders will help assure that future models meet the needs of the Medicare populations being served.

- *Study on Medication Synchronization*

HLC members have been engaged on the issue of medication adherence and are pleased to see that the Working Group has identified adherence as an important area of inquiry. Poor adherence (with regard to medication as well as other physician instructions on behavior change or other patient activities) limits effective management and control of chronic illnesses by increasing the likelihood of preventable disease progression. We particularly urge the Working Group to incorporate findings from the Congressional Budget Office November 2012 report that found a link between increases in prescription drug use and reductions in the use of and spending for medical services.

Medication synchronization has great promise as one lever to assist patients in taking medication as their doctor directed. However, HLC urges the Working Group to go further than a study. Representatives Kristi Noem (R-SD) and Bill Pascrell (D-NJ) have drafted legislation (the “Synchronization & Nonadherence Correction (SYNC) Act,” H.R. 4292) to test three variations of medication synchronization in Medicare Part D, so perhaps the Working Group should focus on improving and supporting an “on the ground” test of synchronization rather than a theoretical study. Regardless, we encourage the Working Group to seek more input regarding financial barriers that may prevent a beneficiary from being able to pay for all their medications at one visit per month, current barriers to coordination, best practices used by commercial drug plans and retail pharmacies, and an assessment of the feasibility of such a program in Medicare.

Besides a medication synchronization study, HLC also supports changes that would better align incentives for Part D plan providers. CMS recently announced an Enhanced MTM Model demonstration for FFS Part D plans. While we are greatly encouraged by the model’s goals and desire to create more flexibility for plans to target high-risk beneficiaries and provide appropriate level and intensity of services (allows PDPs to stratify services by beneficiary risk; allows different levels and types of MTM services), we are concerned that aspects of the model’s timing and design could hamper progress. (The attached NDHI chart describes our concerns in greater detail.) Additionally, since the new model only applies to plans operating in FFS, we support expanding the model to include MA Prescription Drug (MA-PD) plans.

- *Study on Obesity Drugs*

HLC members have been very active in supporting solutions to obesity. Along with surgery, intensive behavioral therapy (IBT) and newly FDA-approved drugs represent the full range of obesity treatments available. Obesity, now classified as a disease by the AMA, offers a great example of an area where Medicare can shift to prioritize prevention rather than high-cost treatments as the condition worsens. Currently, Medicare covers IBT when provided in a primary care office and bariatric surgery (though fewer than 1 percent of beneficiaries have used the IBT benefit and surgery is only approved for those meeting certain criteria) but does not cover prescription medicines approved to treat obesity, nor the evidence based, low cost community setting IBT services. By covering such pharmaceutical therapies and evidence based community IBT services, Medicare would shift the emphasis away from more dramatic surgery options and refocus on incremental weight loss as a way to stave off the complications and comorbidities of obesity (obesity also triggers a host of other chronic diseases including cardiovascular disease, diabetes, and cancer).

While further study on this issue is critical, HLC members believe that we have enough evidence to show that Medicare Part D coverage of drugs used for weight loss would be beneficial to patients and would decrease health costs by reducing the incidence of obesity and its associated costs. Already, some MA prescription drug plans are permitted to cover the drugs as a supplemental benefit, and private insurers are also covering them. HLC urges the working group to take these learnings into account and allow obesity drugs to be reimbursable by FFS.

HLC appreciates the opportunity to provide input and we look forward to working with you on further developing the proposed policy solutions. If you have any questions, please feel free to contact Teresa de Vries at tdevries@hlc.org or 202-449-3436.

Sincerely,

Mary R. Grealy
President

Attachments: NDHI Care Planning Principles
NDHI Enhanced MTM Model Improvement Chart

NDHI NATIONAL DIALOGUE FOR Healthcare Innovation

HEALTHCARE LEADERSHIP COUNCIL

The Medicare Modernization Act (MMA), which created the Part D program, requires that every Part D plan offer a medication therapy management (MTM) program as a quality improvement feature. However, misaligned incentives inhibit the program from achieving significant benefits. In September 2015, CMS announced its intent to form a Part D Enhanced MTM Model to test changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions.[1]

Below, we examine the new model and areas for improvement.

POSITIVE FEATURES	AREAS FOR IMPROVEMENT
GENERAL	
• **Emphasis on regulatory flexibility** will allow targeting of high-risk beneficiaries and provide appropriate level and intensity of services (allows PDPs to stratify services by beneficiary risk; allows different levels and types of MTM services). • **Waivers** will allow various providers to offer interventions of a type that are not usually furnished in traditional MTM programs	• Timing of the model delays beneficial change. The model will result in a potential delay of seven to 10 years from today before the model's benefits can be extended to all beneficiaries since the model does not start until 2017, runs for five years, and will be evaluated. • The design does not address the value of offering these benefits to all Part D members (including MA-PD plans) to achieve better alignment of PDP sponsor and government financial interests and optimize therapeutic outcomes. • Restriction of the model over the five year demonstration creates unfair competitive disadvantage for plan sponsors outside the designated regions. Additionally, all PDP plans under a single contract should be able to participate, rather than be forced to split the contract (creating administrative burden for CMS and plans as well as denying the benefits of the enhanced model to some patients served by the contract).

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[1] All quotes in this document are from Centers for Medicare & Medicaid Services. CMS Part D Enhanced Medication Therapy Management Model Fact Sheet, September 28, 2015.

SPECIFIC	
Payment Incentives - "Prospective payment for more extensive MTM interventions that will be "outside" of a plan's annual Part D bid"; and - "A performance payment, in the form of an increased direct premium subsidy, for plans that successfully achieve a certain level of reduction in fee-for-service expenditures and fulfill quality and other data reporting requirements through the [Enhanced] model."	- CMS should invest in research to determine whether these payment incentives will offset participating plan sponsors' increased resources in the Enhanced MTM model.
Quality Measures - "CMS will develop new MTM-related data and metric collection requirements for both monitoring and evaluation purposes."	- CMS should provide participating plans with an opportunity to participate in developing the quality indicators that comprise the uniform set of MTM data elements. - CMS should rely on measures that have been developed through an intensive, transparent development and evaluation process such as employed by national quality organizations like the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF). - CMS should work with stakeholders to choose measures that address clinical outcomes for the conditions selected by plans for enhanced MTM services to determine any potential effect that these services have on overall quality of care. - CMS should employ a public comment process that allows a full range of stakeholders to provide input into the final measure set, performance standards (e.g., for purposes of determining performance-based payments), and evaluation methods. - CMS should address the expected differences in Star Ratings between Part D regions CMS has selected to participate in the demonstration and those that are prohibited from participating so as not to penalize those non-selected regions. - CMS should consider the different requirements of plans with high levels of low-income subsidy (LIS) enrollment (e.g., any application of financial incentives to plan payments must be appropriately adjusted for plans serving high concentrations of LIS members who may be more

	difficult to reach out to and serve—especially as this could impact LIS benchmarks also). • CMS should also consider how to fairly measure quality for plans serving many LIS eligible enrollees as they develop quality metrics for monitoring and evaluation of the model.
Emphasis on learning activities and plans to promulgate lessons	• CMS should be more explicit about how plans' proprietary information can be appropriately protected. • Lessons learned should be shared with plans outside of the model's geographic limitations. • CMS should take the lead in robust education of providers and pharmacies on the enhanced MTM model test, particularly as it compares to the standard MTM program. Additionally, increased plan flexibility to customize their communications about the model could create confusion for many physicians and members about how this model test relates to the traditional MTM benefit.
Stakeholder Collaboration	• CMS should reconsider its stance regarding manufacturer and health plan collaborations to allow for appropriate interactions that will result in improved medication adherence.

National Dialogue for Healthcare Innovation
Workgroup on Patient Engagement and Adherence

Comprehensive Care Planning Principles: Diabetes

Draft as of 11/30/2015

1. **Background**

Definitions and Policy Context

The Centers for Medicare & Medicaid Services (CMS) offers a basic definition of a care plan: *"A written plan for your care. It tells what services you will get to reach and keep your best physical, mental, and social well being."*[1] CMS also provides an operational definition of a care plan that is more detailed and relevant for addressing the complexities facing patients who live with chronic illnesses: *"It typically includes but is not limited to the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community and social services ordered, direction and coordination of the services of agencies and specialists unconnected to the practice, identification of the individuals responsible for each intervention, requirements for periodic review, and, when applicable, any revisions."*[2] Accordingly, the concept of comprehensive care planning is patient-centered, participatory, and nested within the broader concept of care coordination for people living with chronic illnesses.[3]

The issue of comprehensive care planning is receiving considerable attention among policymakers. The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014,[4] which mandates common patient assessment data and quality measure reporting requirements for post-acute care (PAC) providers, also establishes new discharge requirements for general acute-care, critical access hospitals, and post-acute providers that are intended to facilitate the flow of patient information to the next healthcare setting. Beginning in late 2016, CMS will require long-term care facilities to develop a care plan for each resident within 48 hours of admission.[5] CMS also proposes to require long-term care facilities to document in a beneficiary's care plan their goals for admission, assess the potential for future discharge, and include discharge planning in the comprehensive care plan for the beneficiary. The agency also proposes to add to the post-discharge plan of care a summary of arrangements for a beneficiary's follow-up care and post-discharge services, and the discharge summary must include a reconciliation of a beneficiary's current medications with those that the beneficiary was taking before entering the facility. Additionally, the Care Planning Act of 2015 (S. 1549) is pending legislation that would help severely ill patients (e.g., patients with late-stage diabetes) improve care coordination through patient-centered care planning – via the establishment of "planning services" as a Medicare benefit. Separately, the Government Accountability Office recently released a report noting that under the Patient Protection and Affordable Care Act, there remain concerns that low-income individuals transitioning from Medicaid to exchange coverage may experience coverage gaps, due to the complex nature of coordinating policies and procedures.[6] Furthermore, the U.S. Senate Committee on Finance announced in May 2015 the formation of a Chronic Care Working Group that aims to improve care coordination and ensure high quality care for people living with chronic illnesses; notably, the committee will place a strong emphasis on care coordination.[7]

The need for comprehensive care planning is salient given the current spotlight on patient non-adherence, a major public health concern that spans the continuum of care. The lack of adherence to a prescribed treatment regimen is shown to lead to poorer patient outcomes, including unnecessary disease progression, reduced quality of life, and even premature death. It also creates a significant societal burden, especially in terms of increasing healthcare costs from hospitalizations and invasive procedures to address complications that may have been prevented with continuous intervention. Patient therapeutic compliance is also associated with disease characteristics. Non-compliance is usually not a major issue in acute illnesses or illnesses of short duration. In contrast, patients who are suffering from chronic diseases, especially multiple chronic diseases, are more likely to be non-compliant. The issue of patient adherence has been extensively researched, but the rates of non-adherence have not improved much in the past three decades.

Patient non-adherence can be arrayed by the type of intervention (i.e., non-adherence related to medication, lifestyle, or exercise guidance from health providers), and the reasons for patient non-adherence are myriad.[8] For example, a 2009 systematic review by RAND[9] found four major types of barriers to medication adherence:

- cost-sharing
- regimen complexity
- medication beliefs
- depression (in patients with diabetes)[10]

(However, it is important to note that much of this research predates the passage of the Affordable Care Act (ACA), which has improved coverage to many individuals who were previously uninsured or underinsured.)

In response to concerns about patient adherence, CMS recently announced the Medicare Part D Enhanced Medication Therapy Management (MTM) Model,[11] which will place an emphasis on "right sizing" MTM and testing innovative regulatory flexibility and payment incentives to target high-risk beneficiaries and provide them with the appropriate level and intensity of services. Maximizing the potential for coverage of therapies and care management and assuring that all payers, providers, and patients recognize the value of patient adherence is key to the long term solution to this complex issue.

National Dialogue for Healthcare Innovation

In light of these challenges, the Healthcare Leadership Council (HLC) established the National Dialogue for Healthcare Innovation (NDHI), to bring together leaders from industry, government, academia, patient organizations, and all sectors of healthcare to discuss and develop consensus approaches to challenges affecting healthcare innovation. The resulting Workgroup on patient engagement and adherence, comprised of NDHI summit participants, HLC members and other diverse organizations from across the healthcare spectrum, brings a perspective and ability to develop comprehensive recommendations that will be beneficial to the patient.

The Need to Focus on Diabetes

The NDHI Patient Engagement and Adherence Workgroup has developed a set of policy principles on comprehensive care planning for patients living with chronic diseases, using diabetes mellitus as a case example. These principles will inform future efforts to provide legislators and policymakers with evidence-based recommendations for addressing the complex needs of people with diabetes – as well as other chronic diseases. Diabetes is an important test case for comprehensive care planning because of its complexity as well as prevalence in the U.S.

Although diabetes is a well-understood disease, individual patients may encounter myriad different obstacles that would prevent them from reaching optimal health. These barriers range from socioeconomic factors or lack of diabetes management education to the competing demands of family responsibilities and dynamics.[12] Cost of care may also be a barrier to good adherence.

The American Diabetes Association (ADA) cites compelling national statistics in its *Standards of Medical Care in Diabetes—2015* report[13] that underscore the need for effective disease management interventions: "[B]etween 33 and 49% of patients [with diabetes] still do not meet targets for glycemic, blood pressure, or cholesterol control, and only 14% meet targets for all three measures and nonsmoking status." Furthermore, diabetes, along with congestive heart failure (CHF) and hypertension, represent three of the top five most prevalent conditions among Medicare beneficiaries. These conditions share many of the same common, modifiable risk factors and comorbidities, including obesity and physical inactivity.

Finally, diabetes presents opportunities to intervene at multiple stages of the disease continuum. Those at high risk for diabetes, even if they are asymptomatic, should be screened consistent with screening guidelines. (The U.S. Preventive recommends screening as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese[14]) so that the disease does not progress unchecked before diagnosis. Even those diagnosed with prediabetes, a condition where blood sugar is higher than normal but not high enough to be diagnosed as diabetes[15], can take steps to delay or prevent progression to Type 2 diabetes.

Diabetes Care Challenges

In spite of the tremendous toll of diabetes, numerous challenges for reimbursement of diabetes-related care hampers efforts to improve patient health.

- Currently in fee-for-service Medicare, CMS provides little or no reimbursement for remote care, care coordination, or coaching (e.g., phone visits, follow-up text messages, online) for the care and management of diabetes.
- Certified Diabetes Educators (CDEs) are not statutorily recognized providers of Diabetes Self-Management Training (DSMT) services, including DSMT by telehealth, under Medicare Part B. Additionally, Diabetes case managers and educators receive differential reimbursement and medical nutrition therapy (MNT) and DSMT are not reimbursable on the same day.
- The new care coordination Healthcare Common Procedure Coding System (HCPCS) G-code has not been interpreted to include remote care coordination or coaching. Beyond basic evaluation and management services, few other avenues exist to compensate diabetes care providers for the intensive time and effort necessary to provide comprehensive management and support to patients with diabetes. This patchwork of regulation and reimbursement creates unnecessary gaps in patient care and makes healthcare more expensive overall.
- For patients with prediabetes, Medicare does not reimburse for participation in National Diabetes Prevention Programs (DPP, a lifestyle change program that can help prevent or delay the onset of type 2 diabetes) or MNT for people at high risk for developing diabetes.

In addition to undermining provider support, the current reimbursement structure makes it difficult for patients with diabetes to monitor the disease themselves. Medicare does not cover the tools and devices that some individuals need to most effectively monitor their diabetes:

- Medicare does not recognize continuous glucose monitoring (CGM) as a covered benefit. In numerous clinical trials, CGM systems have demonstrated improvement in overall glucose control and reductions in dangerous episodes of hypoglycemia when compared to self-monitoring of blood glucose (SMBG). Since CGM technology is covered widely outside of Medicare, beneficiaries entering Medicare may be forced to give up the diabetes blood glucose monitoring system that they had become accustomed to using with another payer.

- The 2013 competitive bidding program limits choices and access to certain types of diabetes testing supplies, such as blood glucose testing strips, purchased through mail order. If beneficiaries have difficulty finding replacements for familiar products, they may be inappropriately influenced to switch test systems. Product switching can have negative health and economic consequences.[16]

Additional challenges include patient adherence for individuals with hypoglycemia, or abnormally low blood glucose levels. Hypoglycemia is the largest single barrier to achieving glycemic control in Type 1 and Type 2 diabetes[17] and is a significant cause of emergency department visits and hospitalizations, which increases the cost of treatment. Consideration of education and alternate therapies for individuals who experience hypoglycemia may help to alleviate the incidence of hypoglycemia.

Another care management challenge to consider in effective diabetes management are cases of clinical inertia – inadequate intensification of therapy by the provider. For example, newly diagnosed patients often stay on the oral medication Metformin alone for about 14 months without additional agents (e.g., insulin) being added, even though they have not met their A1C goal.

Greater alignment between reimbursement structures and appropriate care steps could also lead to better outcomes for both patients and payers. At the healthcare system level, physicians of patients with multiple physicians are not incentivized to work in as a team, which creates challenges for persons with diabetes receiving coordinated, consistent care across numerous encounters. A 2014 RAND study of nearly 300,000 Medicare recipients[18] found that individuals with better continuity of care were less likely to be hospitalized, less likely to visit hospital emergency departments, had lower rates of complications, and had lower overall costs for their episodes of care.

Diabetes management also faces hurdles in the area of reporting and quality. There is a lack of uniform quality metrics across government programs, coupled with limited diabetes quality measures and alignment across Medicare Part A, B, and D. Payment is not currently tied to meeting appropriate standards of care for all services delivered. These gaps do not incentivize comprehensive diabetes care and make it harder for quality to be assessed and for providers and payers to monitor and respond to data.

Finally, quality diabetes care is often impeded by cost—both to the system and to patients. Every effort should be made to design diabetes care protocols that address this barrier. For example, the provision of additional tools for the patient or the provider or the promulgation of value-based benefit design could help address this issue. Additionally, it is crucial to recognize that the enormous prevalence of diabetes has significant consequences for health system stability as a whole, and efforts must be made to make investments in quality care that focuses on halting or slowing disease progression and the onset of complications.

2. Comprehensive Care Planning Principles

Below, we describe three Care Planning Principles for diabetes, along with key components/practices that should be included in comprehensive care plans and rationale for government reimbursement of these activities. These components can also inform the promulgation of quality measures related to comprehensive care plans for diabetes. These principles support NDHI's twin objectives of enhancing value in healthcare by using innovative therapies, policies, and practices to support improved patient adherence that maximizes quality outcomes.

These principles closely align with the ADA's *Standards of Medical Care in Diabetes—2015,* [19] which provide 4 core recommendations for improving diabetes care, overall:

1. A patient-centered communication style that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care should be used.
2. Treatment decisions should be timely and founded on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and comorbidities.
3. Care should be aligned with components of the Chronic Care Model (CCM) to ensure productive interactions between a prepared proactive practice team and an informed activated patient.
4. When feasible, care systems should support team-based care, community involvement, patient registries, and decision support tools to meet patient needs.[20]

Principle 1: Comprehensive care planning must address the population's multiple co-morbidities and complex care needs.

Comprehensive, patient-centered care planning must address a key underlying health system issue: the fragmentation of the health delivery system for people with diabetes. The notion of "team-based care" is one that should be championed as part of care planning.

Component 1.1: Care plans should incorporate evidence-based care coordination strategies (defined by the Agency for Healthcare Research and Quality's (AHRQ's) as "deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care"[21]) that address underlying patient comorbidities (e.g., depression). The ADA suggests that addressing missed treatment goals may require evaluation of barriers such as diabetes-related distress or depression [22] and the American Association of Clinical Endocrinologists and American College of Endocrinology's evidence-based clinical practice guidelines for diabetes makes the following recommendation for patients with diabetes and depression: "Patients with depression or [diabetes]-related distress should be referred to mental health professionals who are integrated into the [diabetes] care team."[23] For example, Katon and colleagues conducted a trial of "collaborative care" in 14 clinics in the state of Washington, in which nurses provided "guideline-based, patient-centered management of depression and chronic disease." The researchers found significant 12-month improvements along a number of measures related to both diabetes and depression (e.g., glycated hemoglobin, patient satisfaction, perceived quality of life) due to the intervention.[24]

Comprehensive care plans, by definition, should address the full range of health problems of a particular patient – i.e., not limited to diabetes. For example, diabetes care plans should explicitly address comorbidities such as cardiovascular disease. The American Heart Association recognizes a strong correlation between cardiovascular disease (CVD) and diabetes. Heart diseases and stroke are the number one causes of death and disability among people with type 2 diabetes and adults with diabetes are two to four times more likely to have heart disease or a stroke than adults without diabetes.[25] In this regard, the ADA notes the need for "a comprehensive plan to reduce cardiovascular risk by addressing blood pressure and lipid control, smoking cessation, weight management, and healthy lifestyle changes that include adequate physical activity" for patients with diabetes. [26]

Component 1.2: Comprehensive care planning should include the use of care coordinators to address the multitude of daily issues facing persons with diabetes. For example, the use of care coordination programs may have potential for managing care transitions and obviating hospital readmissions. Care planning for people living with diabetes may include interdisciplinary teams that can meet the holistic needs of individuals and engage community resources outside the hospital sector.

Care coordinators can be deployed to provide a variety of services, including: assessing treatment adherence, coordinating with providers about patient treatment needs, ensuring that patients have transportation, language translation, and other support services needed to access care, and providing health education. An increasingly multidisciplinary approach to the care of these patients may be one answer for improving patient clinical outcomes and healthcare resource utilization. Community health workers or other non-licensed health providers may also be considered a vital part of the care team if they are providing critical care coordination services.

Component 1.3: Comprehensive care planning should be supported by improved communication and data sharing among providers on the interdisciplinary diabetes care team. For example, the National Diabetes Education Program cites the importance of timely information-sharing via the use of health information systems by care teams, which comprise "the primary care provider, endocrinologist, nurse, diabetes educator, dietitian, mental health provider, exercise physiologist, other team members and specialists, as well as hospital-based providers."[27] The contributions of non-licensed, community-based health providers should also be integrated by the care team into electronic medical record systems so that records maintain confidentiality but also reflect the entirety of patient treatment.

One strategy for achieving communication and data sharing is the increased use of telehealth. While the scientific literature is still emerging on the full benefits of telehealth applications, promising initiatives have been described. For example, a recent randomized clinical trial of a telehealth remote monitoring intervention, in which patients remotely sent their paired glucose tests (i.e., before and after a meal or physical activity) via tablet and subsequently received feedback from certified diabetes educators, led to improvements in A1C levels.[28] Also, the DiaTel randomized, controlled trial of active care management supplemented by home telemonitoring intervention, demonstrated long-term (> 6 months) reductions in A1C levels in a population of veterans.[29]

The use of patient-centered health information technologies for diabetes is one way to ensure communication between patients and providers in care planning and empower patients to express their values, needs, and preferences about their care. Patient adherence can often be improved either through personalized care coordination or through simpler systems of reminders and educational materials. Greater data connectivity can also be used to identify gaps in diabetes care for other important treatment indicators, such as blood glucose monitoring.

For example, remote patient monitoring (RPM) technology enables monitoring of patients outside of conventional clinical settings (e.g., in the home), which may increase access to care and decrease healthcare delivery costs. Incorporating RPM in chronic disease management can significantly improve an individual's quality of life. It allows patients to maintain independence, prevent complications, and minimize personal costs. RPM is used to monitor a variety of chronic illnesses, including diabetes, and transmit alerts to both patient and physician.

Principle 2: Chronic Disease programs must address chronic disease across the entire continuum of care.

Component 2.1: Care planning should promote screening and identification of risk factors for patients all along the disease spectrum. Risk factor identification, screening, and interventions have been successful in identifying and preventing chronic diseases and their associated morbidity and mortality in older adults. Greater impact in this area will require extensive collaboration among stakeholders (providers, health plans, pharmacists, and patients) in order to identify high-risk individuals.

Better effort needs to be made to identify patients with chronic diseases such as diabetes. The 2014 draft U.S. Preventive Services Task Force (USPSTF) factor-based screening guidelines for diabetes would have helped address the fact that many people living with Type 2 diabetes currently are not diagnosed with the disease. Patients with prediabetes, a condition where blood sugar is higher than normal but not high enough to be diagnosed as diabetes, affects more than 1 out of 3 American adults, but 9 of 10 of them do not know they have it.[30] While the final guideline, released October 27, 2015, backtracked from the 2014 draft, it still opened the door for screening for prediabetes.

In patients diagnosed with prediabetes or diabetes, care plans should focus on early intervention to prevent disease progression and complications. Health plans or other providers use data from claims, enrollment, and pharmacies to look for patterns of non-adherence or identify at-risk members. The use of in-home risk assessment also supports early identification of at-risk members, including those with and without diagnosed conditions.

Component 2.2: Comprehensive care planning must focus on care transitions for patients with diabetes. One of the IMPACT Act's stated reasons for collecting standardized data from long-term care hospitals (LTCHs), skilled nursing facilities (SNFs), home health agencies (HHAs) and inpatient rehabilitation facilities (IRFs), is to "improve hospital and PAC [post-acute care] discharge planning." And as the ADA notes in its 2015 *Standards*, "Diabetes discharge planning should start at hospital admission, and clear diabetes management instructions should be provided at discharge." [31]

Numerous ongoing projects are testing evidence-based models for patient transitions from hospitals into their communities. For example, the Patient-Centered Outcomes Research Institute (PCORI) is funding the $15 million Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health In Care Transitions by Evaluating the Value of Evidence), which will "develop recommendations on best practices for the design, implementation and large-scale national spread of highly effective, patient-centered care transition programs."[32] The identification of evidence-based strategies for transitions, including patient-engagement activities, post-discharge, will be crucial for comprehensive care planning for patients with diabetes.

Furthermore, AHRQ's *Care Transitions from Hospital to Home: IDEAL Discharge Planning Implementation Handbook*[33] describes best practices in the management of heart failure, heart attack, and pneumonia, among four high-performing US hospitals (with respect to readmissions). This information could be useful for developing care transition strategies *for diabetes*.

- "A focus on improving clinical quality and patient care with the belief that reductions in readmissions will naturally occur as a result of these improvement efforts.
- Attention to discharge planning from the first day of patients' stay, typically within 8 hours of admission. This includes staff assessment of patients' risk factors, needs, available resources, knowledge of disease, and family support.
- Care coordination after discharge. Two hospitals scheduled follow up appointments for most of their patients prior to discharge. Because of limited resources, the two other hospitals made

follow up appointments on an ad hoc basis for the neediest patients. All hospitals coordinated with home health agencies and connected patients to community resources.

- Empowering patients through educational activities throughout the stay to help patients understand their conditions; manage their diet, activities, medications, and care regimens; and know when to seek care."[34]

AHRQ also provides specific guidance on sound practices in discharge planning: (a) medication reconciliation (e.g., "The patient's medications must be cross-checked to ensure that no chronic medications were stopped and to ensure the safety of new prescriptions"); and (b) structured discharge communication ("Appointment-keeping behavior is enhanced when the inpatient team schedules outpatient medical follow up prior to discharge. Ideally, the inpatient care providers or case managers/discharge planners will schedule follow-up visit(s) with the appropriate professionals, including primary care provider, endocrinologist, and diabetes educator").[35]

Component 2.3: Care planning should also include end-of-life planning and discussions. Such conversations go beyond a narrow focus on resuscitation and address the broad array of concerns shared by most patients and families. These include fears about dying, understanding prognosis, achieving important end-of-life goals, and attending to physical needs. Good communication can facilitate the development of a comprehensive treatment plan that is medically sound and concordant with the patient's wishes and values.[36]

Principle 3: Comprehensive care planning must be cognizant of issues related to the individual and community-level context.

As noted above, missed treatment goals may have myriad contributing causes. Complex care planning must be aware of and seek to address issues related to the individual patient and their context in which they live.

Component 3.1: Care plans must empower and equip patients with the tools they need to play an active role in managing their diabetes. To best help patients when they return home from the clinical setting, it will be essential for care plans to mobilize and incorporate outpatient resources that help support patient engagement and adherence.

Various studies have been conducted to test outpatient strategies to improve medication adherence for patients with diabetes. For example, the Joslin Diabetes Center developed the Diabetes Outpatient Intensive Treatment (DOIT) program, an interactive, 3.5 day-group education and skills training experience that was supplemented with daily medication management. The program led to significant improvements in A1C levels.[37] Furthermore, tailored "health coaching" interventions have also been shown to improve medication adherence among patients with diabetes.[38] Additionally, a community pharmacy-based medication therapy management (MTM) program for patients who with both hypertension and diabetes was found to improve blood pressure control.[39] Finally, the American Pharmacists Association has coined the concept of diabetes "patient credentialing" as part of disease self-management interventions to describe "people who have a certain diagnosis and have achieved certain levels of competency in understanding and managing their disease."[40]

DSMT programs are another important tool. For Type 2 diabetes, the 2015 AHRQ Evidence Report on behavioral interventions for diabetes notes that intensive in-person DSMT programs (11 or more hours of contact time) are most effective at achieving glycemic control, and that targeting interventions for particular populations (i.e., minority groups) may also be beneficial: "our analyses showed limited benefit in glycemic control from DSME programs offering ≤10 hours of contact with delivery personnel and suggested that in-person delivery of behavioral programs is more beneficial than communicating the information with incorporation of technology. Behavioral programs seem to benefit individuals having suboptimal or poor glycemic control more than those with good control. Tailoring programs to ethnic minorities appears to be beneficial."[41] Currently, DSMT participation rates are extremely low (7 percent among those with private insurance and 4 percent among those with Medicare coverage[42]), so increased communication among patients and providers about the benefit is needed, as well as greater reimbursement as noted above.

Registered dieticians also play a role in providing patients with the tools needed to manage their disease. Nutrition therapy is an integral component of diabetes prevention, management, and self-management education, and the ADA recommends all individuals with diabetes should receive individualized medical nutrition therapy, preferably provided by a registered dietitian nutritionist (RDN).[43]

This guidance is consistent with the final recommendation of the USPSTF regarding abnormal blood glucose: "Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity."[44]

This type of education has also been shown to improve quality of life for patients. In adults with type 2 diabetes, one study of quality of life assessment reported that self-perception of health status improved and participants receiving MNT from RDNs felt very knowledgeable and motivated after seeing a dietitian. In another study of adults with type 2 diabetes receiving case management from RDNs, 12-month quality of life scores were significantly better than adults receiving usual care. Emotional stress was also decreased in adults with type 2 diabetes. In persons with type 1 diabetes, three studies reported significant improvements in quality of life (satisfaction with treatment and psychological well-being) despite increases in insulin injections or diet requirements.[45]

The use of community health workers (CHWs) to implement diabetes-focused programs – as well as for obesity management, more generally – have been described in the literature. For example, the Mexican American Trial of Community Health Workers (a randomized, controlled trial in which CHWs delivered diabetes self-management training via home visits over 2 years) led to improvements in A1C levels at both the end of Year 1 as well as Year 2 of the intervention. Regarding obesity management as a whole, a 2014 *JAMA* systematic review found evidence for the effectiveness of intensive behavioral weight loss counseling led by trained interventionists, such as medical assistants and registered dieticians.[46] Furthermore, trials testing the Weight Watchers program have found promising results with respect to weight loss outcomes.[47]

Additionally, Aging and Disability Resource Centers (ADRCs) are one example of a community resource that may provide an opportunity for elderly people living with diabetes to utilize existing community resources. (ADRCs have 5 core functions: "1) information, referral and awareness, 2) options counseling, advice and assistance, 3) streamlined eligibility determination for public programs, 4) person-centered transitions, and 5) quality assurance and continuous improvement. ADRCs perform these functions by integrating, coordinating, and strengthening different pieces of the existing long term supports and services systems, including Area Agencies on Aging, Centers for Independent Living, state and local Medicaid offices, and other community-based organizations."[48])

As the health system seeks to mobilize and incorporate community-based health and support, it may be helpful to draw on the experience of Medicare Advantage (MA) plans. Currently, the only tool health plans have to offer flexibility to the individual are medical management tools that must be offered to an entire population regardless of need (e.g., waiving or eliminating copays on certain medications for one population, providing additional transportation to individuals with more frequent medical appointments or waiving the copay on a type of specialist visit based on an individual's health needs). MA plans should be given flexibility to permit providers to develop individualized care plans that tailor tools to support patient needs. Further, some services plans want to provide do not fall within medical necessity. Examples of such services are: homemaker services, home-delivered meals, personal care services (assistance with bathing and dressing), transportation escort services, inpatient custodial level care, in-home caregiver relief, adult day care services, and non-Medicare-covered medical and safety equipment (e.g., the purchase of a refrigerator to store insulin, an air conditioner in geographies with severe summer temperatures or railings to help prevent falls).

Online and community-based and health providers such as Weight Watchers, Y-USA, and Omada Health that provide CDC-certified diabetes prevention programs offering DPP are also examples of organizations that care plans should look to for assistance in helping patients maintain adherence to treatment plans. Community-based programs such as these are especially important for patients in traditional underserved and minority communities or communities with a high level of mistrust of the traditional medical system.

<u>*Component 3.2:*</u> Diabetes care plans should use health literacy assessments as a tool to inform appropriate interventions for individual patients. A study in *JAMA* on health literacy and diabetes[49] found that patients with inadequate health literacy were less likely than patients with adequate health literacy to achieve tight glycemic control, were more likely to have poor glycemic control, and report having diabetic retinopathy. By using data to identify which patients are most at risk of becoming non-adherent, physicians can best determine which patient engagement strategies to utilize. This also reduces the level of outreach to low-risk patients (those most likely to adhere) and ultimately allows for more targeted deployment of resources and time to the most at-risk patients.

Furthermore, care plans should adopt best-evidence practices in reaching low-literacy patients. As an article in the *American Journal of Health Behavior* on health education for low-literacy audiences noted, "Materials should be focused on offering practical strategies for behavior change, the 'need to do', rather than focused on teaching facts, the 'need to know.'"[50]

<u>*Component 3.3:*</u> Diabetes care plans should incorporate best practices in person-centered, culturally-appropriate guidance for patients with diabetes to address specific cultural beliefs about health (e.g., in some cultures one does not seek health care until symptoms have already developed). To the extent that these beliefs modify health-seeking behaviors, care plans need to adopt strategies described in the literature, such as the use of culturally-salient metaphors for describing diabetes as a disease in terms that certain community members will identify with.[51]

Guidance from the American Association of Diabetes Educators and the National Standards for Diabetes Self-Management Education and Support may be particularly useful guidelines in this regard:

"[T]he prudent diabetes educator provides important information, care, and support to persons affected by diabetes in a manner that:

- Acknowledges that cultural perceptions of health can be unique for each individual.
- Considers the context of learning experiences already present when developing collaborative efforts with the patient to identify barriers to diabetes care success.
- Conveys accurate information in a fashion that is understandable to the learner. Proactively addresses limitations to self-management plan adherence and designs/brokers culturally appropriate goals.
- Utilizes educational materials and resources appropriate for culture, age, literacy level, and learning readiness.
- Includes resources that address access limitations to diabetes-care needs and considers the milieu in which the care plan is to be executed.
- Incorporates sensitivity and respect when educating all people irrespective of ethnicity, race, age, and socioeconomic status."[52]

3. Conclusions

Comprehensive care planning for diabetes requires a holistic, patient-centered approach that spans the continuum of care. These three principles and their components underscore the vision of NDHI's Patient Engagement and Adherence Workgroup to ensure patient adherence and maximizing quality outcomes for diabetes, and may serve as a template for action for other chronic diseases.

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